A Report to the Senate Business, Professions and Economic Development Committee

California State Board of Pharmacy Sunset Review Report 2011 Volume 2

2011

CALIFORNIA STATE
BOARD OF PHARMACY

ATTACHMENTS

- Attachment A: Board Member Procedure Manual
- Attachment B: Board Organizational Chart
- Attachment C: Major Studies
- Attachment D: Organizational Charts
- Attachment E: Records Retention Schedule

CONTENTS

Board's Administrative Manual

Board's Organizational Chart

Major Studies and Reports

Final Report: Addressing Drug and Device Recalls in Hospitals
Emergency Response Policy Statement
Fee Audit 2009
Legislative Program Overview
Prescription Drug: Labeling Requirements (January 2010)
Report on the Requirement that Candidates Failing the (CPJE) Four Times
Disciplinary Guidelines
Strategic Plan for the California State Board of Pharmacy 2006-2011
Health Notes Alternative Medicines
Health Notes Drug Therapy Considerations in Older Adults
The Script
E-Prescribing of Controlled Substances – Guidelines for Pharmacies and Prescribers

Organization Charts

Records Retention Schedule

Attachment A:

Board Member Procedure Manual

California Board of Pharmacy
Board Member Procedure Manual

State of California Department of Consumer Affairs

CALIFORNIA STATE

BOARD OF PHARMACY

Chapter 1

INTRODUCTION

Overview

The California State Board of Pharmacy (board) was created by the California Legislature in 1891 to protect the public by regulating the practice of pharmacy. Section 4000.1 of the California Business and Professions Code specifically establishes that:

> *Protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.*

The board is one of the boards, bureaus, commissions, and committees within the Department of Consumer Affairs (DCA), part of the State and Consumer Services Agency under the aegis of the Governor. The department is responsible for consumer protection and representation through the regulation of licensed professionals and the provision of consumer services. While the DCA provides administrative oversight and support services, the board has policy autonomy and sets its own policies, procedures, and regulations.

The board is presently comprised of 13 members; six are public members, and seven are pharmacists, as required by law. The seven pharmacist members and four public members are appointed by the Governor. One public member is appointed by the Assembly Speaker and one is appointed by the Senate Rules Committee. Board members may serve up to two four-year terms.

According to California law, at least five of the seven pharmacist members of the board must be pharmacists who are actively engaged in the practice of pharmacy. There must be at least one pharmacist representative from each of the following practice settings: an acute care hospital, an independent community pharmacy, a chain community pharmacy, and a long-term health care or skilled nursing facility. The pharmacist appointees shall also include a pharmacist who is a member of a labor union that represents pharmacists. A "chain community pharmacy" means a chain of 75 or more stores in California under the same ownership, and an "independent community pharmacy" means a pharmacy owned by a person or entity who owns no more than four pharmacies in California. *California Business and Professions Code section 4001(c).*

Board members fill non-salaried positions but are paid $100 per day for each meeting day (or 8-hour day spent performing board business) and are reimbursed travel expenses.

The board's operations are guided by its strategic plan, which is revised each year with the active partnership of all board members, staff, and interested stakeholders.

This procedure manual is provided to board members as a ready reference of important laws, regulations, DCA policies, and board policies in order to guide the actions of the board members and ensure board effectiveness and efficiency. The executive officer will coordinate an orientation session with each new board member upon his or her appointment to assist the new member in learning processes and

procedures.

Any questions board members may have at anytime can be addressed to the executive officer.

Abbreviations Used in This Manual

B&P	Business and Professions Code
Board	California State Board of Pharmacy
DCA	Department of Consumer Affairs
EO	Executive Officer
SAM	State Administrative Manual

Chapter 2

BOARD MEETING PROCEDURES

Frequency of Meetings

(B&P Code Section 4002(b))

The board is required by law to meet at least once every four months and may meet more often as it determines necessary. The board's strategic plan also directs at least four meetings annually.

Board Member Attendance at Board Meetings

(Board Policy)

Board members shall attend each meeting of the board. If a member is unable to attend, he or she must contact the board president or the executive officer and ask to be excused from the meeting for a specific reason. Minutes will reflect when a member has been excused or is absent. Two consecutive non-excused absences may result in a request to the appointing authority that the member be replaced.

Board Member Participation

(B & P Code Sections 106 and 106.5)

The Governor has the power to remove from office at any time any member of any board appointed by him/her for continued neglect of duties required by law or for incompetence, or unprofessional or dishonorable conduct. The Governor may also remove from office a board member who directly or indirectly discloses examination questions to an applicant for examination for licensure.

Public Attendance at Board Meetings

(Government Code Section 11120 et seq.)

Board meetings are subject to the provisions of the Bagley-Keene Open Meeting Act. This act governs meetings of the state regulatory boards and meetings of committees of those boards where the committee consists of more than two members. It specifies meeting notice and agenda requirements and prohibits discussing or taking action on matters not included on the agenda. A videotape and written materials on the Open Meeting Act are available from the board, and all members are encouraged to review these materials.

Appendix A contains detailed information about the Open Meeting Act that has been prepared by the department's Legal Office.

Appendix B contains information about when the board may meet in closed session.

Attendance at general conferences which involve a discussion of broad issues and which are attended by a broad spectrum of participants are not covered by open meeting laws so long as members of the board do not discuss among themselves matters which are, or potentially may be, before the board. On the other hand, a

workshop that is focused specifically on board issues and which involves more than two board members must meet the requirements of the Open Meetings Act.

Communications between or among more than two board members may be considered "meetings" if those communications occur in a serial fashion through a series of telephone calls or other communications (such as e-mail) by which more than two of the board members are involved and board business is discussed (e.g., polling of board members). Such communications are prohibited.

Any general discussion of exams or disciplinary procedures shall be held in public. The board may meet in closed session to discuss examinations where a public discussion would compromise the integrity of the examination to deliberate on disciplinary cases and to discuss pending litigation.

An annual evaluation of the executive officer is held in closed session.

If the agenda contains matters that are appropriate for closed session, the agenda must cite the particular statutory section and subdivision authorizing the closed session.

Quorum

(B&P Code Section 4002(b) and Board Policy)

Seven members of the board constitute a quorum for the transaction of business. The majority of a quorum is necessary to act on behalf of the board.

The board uses the following criteria in counting votes on a given motion or decision (this includes motions during board meetings and mail votes on disciplinary matters).

The board must have a quorum of members present to take an action.

- There must be at least seven members voting for the board to take an action or position an item.
- A motion passes if a majority of those voting votes for the measure.
- Abstentions count as votes for purposes of establishing a quorum, but do not count as votes for or against the measure. Abstentions simply mean that the abstaining board member will go along with the majority decision of the board.
- *For example, if seven members are present, and four members abstain from voting, then:*

  a vote of 2 Aye, 1 Nay and 4 Abstain would mean that the motion passes (the majority vote is 2 versus 1, with 4 agreeing to go along with the majority of those voting).
- The board president may determine to vote or not vote on any matter before the board.

Should a board member recuse him or herself from voting on a matter, that member is no longer counted for purposes of achieving a quorum. If this results in a loss of a quorum, the person may participate under the “rule of necessity”, however he or she should not participate in the discussion and abstain from voting. If the reason for the recusal is controversial or substantial (i.e., the member was a witness in the case), the board should wait until another meeting to vote on the matter. This may necessitate a special meeting.

Mail Ballots

(Government Code Section 11500)

The board must approve any decision or stipulation before the formal discipline becomes final and the penalty can take effect.

The Board uses an e-mail voting system. Instructions for this system are available from the executive officer. Proposed stipulations and decisions are e-mailed to each board member for his or her vote. For stipulations, a cover memorandum from board staff and sometimes the board's attorney (a deputy attorney general) accompanies the mail ballot. A two-week deadline generally is given for the mail ballots for stipulations and proposed decisions to be completed and returned to the board's office.

After the deadline of 15 days and after seven votes from board members have been received, a decision has been reached. If majority of the votes are to adopt a decision, the signature pages are sent to the board president, who signs the written decision document.

If two votes are cast before the deadline to hold a case for discussion, the case is set aside and not processed (even if seven votes have been cast on the decision). Instead the case is scheduled for discussion during closed session at the next board meeting. Under board policy when a member wishes to hold a case, the reason for the hold must be provided on the mail ballot. This allows staff the opportunity to prepare the information being requested.

When a ballot is received after the deadline, the vote is retained in the file but is not counted.

Holding Disciplinary Cases for Discussion at Board Meetings

(Board Policy)

When voting on mail ballots for proposed disciplinary decisions or stipulations, a board member may wish to discuss a particular aspect of the decision or stipulation before voting. If this is the case, the ballot should be marked "hold for discussion." For a case to be held for discussion before the board's vote on the matter (this discussion will occur in closed session), two board members must mark the mail ballot "hold for discussion."

If the matter is held for discussion, staff counsel will preside over the closed session to assure compliance with the Administrative Procedure Act and Open Meeting Act.

If the board member is comfortable voting on the matter, but wishes to discuss the policy behind the decision or case, the ballot should be marked "Policy Issue for Discussion. I have voted above. Issue: _____." The EO will respond directly to the member. If still unresolved or if the matter is to be referred to the board, the policy issue will be placed on the agenda for discussion at the next board Enforcement Committee Meeting.

Agenda Items

(Board Policy)

Any board member may suggest items for a board meeting agenda to the executive officer or board president, or during the "New Business" discussion scheduled at every board meeting. The EO sets the agenda at the direction and with the approval of the board president.

Generally agenda items for board meetings originate with one of the board's five standing committees (the Enforcement Committee, Licensing Committee, Communication and Public Education Committee, Legislation and Regulation Committee, and the Organizational Development Committee).

The agendas for board meetings are constructed around the activities of each of these committees, and provided as a committee report to the board.

Initial discussions are typically scheduled at the committee meetings.

Notice of Meetings

(B&P Code Section 4013 and Government Code Section 11120 et seq.)

According to the Open Meetings Act, public meeting notices (including agendas for board meetings) must be sent to persons on the board's mailing list at least 10 calendar days in advance of the meeting. The notice must include a staff person's name, work address and work telephone number who can provide further information prior to the meeting.

All meeting notices for public meetings are also posted on the board's Web site (www.pharmacy.ca.gov) at least 10 calendar days before the meeting. Meeting materials are generally available online 4-7 days before a meeting. These are the same materials provided to board members. The board uses its subscriber alert system (an e-mail notification system) to advise interested parties and board-licensed facilities about meeting dates and release of agendas, meeting materials and minutes.

Record of Meetings

(Board Policy)

Board meeting minutes are a summary, not a transcript, of each board meeting. They are prepared by board staff and submitted for review by board members before the next board meeting. Board meeting minutes are approved at the next scheduled meeting of the board. The purpose of reviewing and approving the minutes at a board meeting is not to approve of actions taken by the board at the previous meeting, but rather to determine whether the minutes as drafted accurately reflect the board's discussion at the previous meeting. When approved, the minutes shall serve as the official record of the meeting.

Tape Recording and Web Casting

(Board Policy)

The public-session portions of a meeting may be tape-recorded if determined

necessary for staff purposes. Tape recordings shall be disposed of following board approval of the minutes. Members of the public may tape record, videotape or otherwise record a meeting unless too disruptive.

Whenever possible, board meetings are to be Web cast, and the Web casting information shall be posted on any agenda and board Web site.

Meeting Rules

(Board Policy)

The board generally uses Robert's Rules of Order as a guide for conducting its meetings, to the extent that this does not conflict with state law (e.g., Bagley-Keene Open Meeting Act). Questions of order are clarified by the board's attorneys.

Board Voting at National Association of Boards of Pharmacy Meetings

(Board Policy)

The board's president shall serve as the official delegate to the annual meeting of the National Association of Boards of Pharmacy. If the president cannot attend the meeting or is absent for a portion of the meeting, the president shall designate an alternate delegate to the meeting to vote on matters before the NABP's sessions.

Chapter 3

COMMITTEE MEETINGS

Committees of the Board

The board's strategic plan establishes five standing committees through which the board establishes its goals and organizes its activities in pursuit of ensuring the public health, safety and welfare, and to assure the provision of quality pharmacist's care. These five committees develop policy related to a board mission-related goal. The committees and their goal areas are:

- Licensing – Ensuring the professional qualifications of licensees. This includes that those entering the practice of pharmacy, as well as those continuing to practice, meet minimum requirements for education, experience and knowledge. The board also ensures that facilities licensed by the board meet minimum standards.
- Enforcement – Protecting the public by exercising oversight on all pharmacy activities. This includes preventing violations and effectively enforcing federal and state pharmacy laws when violations occur.
- Communication and Public Education – Providing relevant information to consumers and licensees. This includes encouraging the public to discuss their medications with their pharmacist; emphasizing the importance of patients complying with their prescription treatment regiments; and helping pharmacists to become better informed on subjects of importance to the public.
- Legislation and Regulation – Advocating legislation and promulgating regulations that advance the vision and mission of the board. These activities ensure better patient care and more effective regulation of the individuals and firms who handle, dispense furnish, ship and store prescription drugs and devices in California.
- Organizational Development – Achieving the board's mission and goals. This is done through strategic planning, budget management and staff development activities.

Each of these committees is comprised of at least two board members and staff who provide technical and administrative input and support. The committees are an important venue for ensuring that staff and board members share information and perspectives in crafting and implementing strategic objectives.

The board's committees allow board members, stakeholders and staff to discuss and conduct problem solving on issues related to the board's strategic goals. They also allow the board to consider options for implementing components for the strategic plan. The committees are charged with coordinating board efforts to reach board goals and achieving positive results on performance measures.

The board president designates one member of each committee as the committee's chairperson. The chairperson coordinates the committee's work and ensures progress toward the board's priorities.

Each committee typically meets once before a quarterly board meeting. The

committees refer policy decisions to the full board during a public meeting for a formal decision and vote. During the committee's discussion, the public is encouraged to provide comments. The board meeting agenda will list action items and discussion items of interest for each committee.

All quarterly meetings of the Enforcement, Licensing and Communication and Public Education Committees are public meetings. This reflects the high interest the public has shown for the agenda items of these committees. The Legislation and Regulation committee generally holds at least two public meetings each year, typically in the spring and fall in order to recommend positions on introduced legislation (in the spring) or to develop legislative or regulatory proposals (in the fall). The Organizational Development Committee typically does not schedule public meetings. Nevertheless, a report of each meeting is provided at each quarterly board meeting. Regardless whether a meeting is public or not, a meeting summary is provided during the committee's report during a board meeting.

During any public committee meeting, comments from the public are strongly sought, and the meetings themselves are frequently public forums on specific issues before a committee. Board members who are not members of a committee may attend a public committee meeting as part of the audience. However, if a quorum of members of the full board are present during a committee meeting, members of the board who are not members of the board committee may attend the committee meeting only as observers.

It is also important to note that any time more than two board members attend a board committee meeting, that committee must have been publicly noticed. The board's legal counsel works with the EO to assure any meeting that fits the requirements for a public meeting is appropriately noticed.

The board also has one standing committee with responsibilities for the California pharmacist licensing examination (the Competency Committee). This committee is described below.

Competency Committee

The board's Competency Committee is responsible for developing and grading the board's pharmacist licensure examination, the California Pharmacist Jurisprudence Examination (known as the CPJE). The committee is comprised of representatives from a cross section of professional practice as well as representatives from each of California's schools of pharmacy.

Membership on this committee is professionally challenging as well as time consuming. The committee meets in two-day meetings held six times annually. There is also a two-day annual goal setting session and occasional subcommittee work. Membership is generally for eight years, and appointment is by the board president.

The Competency Committee is a stand-alone committee that is within the auspices of the board's Licensing Committee. However, meetings of the Competency Committee are not public meetings because these meetings are for examination construction.

Committee Creation and Appointments

(Board Policy)

The president may establish additional committees, whether standing or special, as he or she deems necessary. The composition of the committees and the appointment of the members is determined by the board president in consultation with the vice president, and the EO.

Attendance at Committee Meetings

(Board Policy and Government Code Section 11122.5)

If a board member wishes to attend a meeting of a committee of which he or she is not a member, that board member must obtain permission from the board president or EO to attend. In rare cases the attendance of additional board members may impact the ability of the committee to meet without public notice and the release of an agenda. Therefore, requests to attend a committee meeting should be submitted to the EO at least two weeks in advance.

Board members who are not members of a committee may attend a public committee meeting as part of the audience. However, if a quorum of members of the full board are present during a committee meeting, members of the board who are not members of the board committee may attend the committee meeting only as observers.

Chapter 4

TRAVEL & SALARY POLICIES/PROCEDURES

Travel Approval

(DCA Memorandum 91-26)

Board members shall have board president approval for all travel and salary or per diem reimbursement, except for regularly scheduled board and committee and organization meetings to which a board member is assigned.

The DCA Travel Guide information is attached as Appendix C. Board members will be reimbursed for travel expenses incurred while performing approved board business in accordance with these reimbursement criteria.

Travel Arrangements

(Board Policy)

Board members should either make their own travel arrangements through the board's designated process, or seek assistance for the board's designated travel liaison.

Typically the liaison makes hotel reservations for board members who live outside the area in which a board meeting is scheduled.

State guidelines generally prohibit reimbursement for hotel expenses less than 50 miles from an individual's home address unless preapproval is secured. Board members who wish to request an exemption to stay at a hotel less than 50 miles from their home must contact the EO's secretary to pursue this exemption at least two weeks before the meeting. The exemption must be approved by the DCA's Director's Office before the meeting.

There are also maximum rates for which the board will reimburse hotel (and meal) expenses. Ask the EO or liaison for this amount.

Out-of-State Travel

For approved out-of-state travel, board members will be reimbursed actual lodging expenses, supported by vouchers, and will be reimbursed for meal and supplemental expenses. Out-of-state travel for all persons representing California is controlled and must be pre-approved by the Governor's Office.

Travel Claims

(DCA Memorandum 91-26)

Rules governing reimbursement of travel and meeting expenses for board members are the same as for management level state staff. All expenses must be claimed on the appropriate travel expense claim forms. The board's travel liaison prepares these travel forms from worksheets completed by each board member. It is advisable for board members to submit their travel expense forms immediately after

returning from a trip and not later than two weeks following the trip. It is also necessary to submit original receipts for expenses claimed (except for meal receipts, which are not required for reimbursement).

In order for travel expenses to be reimbursed, board members must follow the procedures contained in DCA memoranda which are periodically disseminated by the director and are provided to board members on at least an annual basis by the EO's secretary.

See Appendix C for departmental policies.

Travel expense worksheet and claim form are attached in Appendix D.

Salary Per Diem

(B&P Code Section 103)

Compensation in the form of salary per diem and reimbursement of travel and other related expenses for board members is regulated by Business and Professions Code Section 103.

In relevant part, this section provides for the payment of salary per diem for board members "for each day actually spent in the discharge of official duties," and provides that the board member "shall be reimbursed for traveling and other expenses necessarily incurred in the performance of official duties."

(Board Policy)
Accordingly, the following general guidelines shall be adhered to in the payment of salary per diem or reimbursement for travel:

- No salary per diem or reimbursement for travel-related expenses shall be paid to board members, except for attendance at official board or assigned committee meetings. Attendance at gatherings, events, hearings, conferences or meetings other than official board or assigned committee meetings in which a substantial official service is performed shall be approved in advance by the board president.

- The term "day actually spent in the discharge of official duties" shall mean such time as is expended from the commencement of a board or committee meeting until that meeting is adjourned. If a member is absent for a portion of a meeting, hours are then reimbursed for time actually spent. Travel time is not included in this component.

- For board-specified work, board members will be compensated for actual time spent performing work authorized by the board president. This may also include, but is not limited to, authorized attendance at other gatherings, events, meetings, hearings, or conferences; and exam item writing. Work also includes preparation time for board or committee meetings and reading mail ballots for disciplinary actions.

- Reimbursable work does not include miscellaneous reading and information gathering, committee work not related to a meeting, preparation time for a presentation and participation at meetings not related to official participation of the board.

Board members may submit their hours for which they seek reimbursement to the EO's assistant on the Board Member Attendance Report. This worksheet may be submitted when desired by the member, but should be submitted at least quarterly. By board policy, board members will be reimbursed for their hours spent at Board Meetings without submitting a claim. However, for reimbursement for all other board-sanctioned activities (including attendance at committee meetings or performing board business), the hours must be submitted on the Board Member Attendance Report. Business and Professions Code section 103 and a Board Member Attendance Report are provided in Appendix E.

At each quarterly meeting of the board, there shall be a report of all reimbursement and travel expenses claimed by each member of the board for the fiscal year.

Chapter 5

OTHER POLICIES/PROCEDURES

Requests for Board Representation or Presentation

If an association or individual requests board participation at an event or meeting, a letter should be submitted to the EO, as to the purpose of the function, and the reason for the request. The board president will approve such requests consistent with the board's strategic plan and if funds are available. Approval to participate will also include the extent of participation (e.g., one time meeting, presentation or continuous participation on a committee). Continued participation as a board representative should be consistent with the board's strategic plan and may need to be approved by the full board.

Prior authorization for any reimbursement must be obtained or expenses will be the responsibility of the participant.

Board members may participate on their own (i.e., as a citizen or professional) but not as an official board representative unless approved by the board president or the board. However, board members should recognize that even when representing themselves as "individuals," their positions might be misconstrued as that of the board.

Resignation of Board Members

(Government Code Section 1750)

In the event that it becomes necessary for a board member to resign, a letter shall be sent to the appropriate appointing authority (Governor, Senate Rules Committee, or Speaker of the Assembly) with the effective date of the resignation. Written notification is required by state law. A copy of this letter shall also be sent to the director of the department, the board president, and the EO.

Officers of the Board

(B&P Code Section 4002(a))

The board shall elect from its members a president, vice president, and treasurer.

Election of Officers

(Board Policy)

The board shall elect the officers at the last meeting of the fiscal year. Officers shall serve terms of one year effective June 1, and may be reelected to consecutive terms.

Officer Vacancies

(Board Policy)

If an office becomes vacant during the year, an election shall be held at the next meeting. If the office of the president becomes vacant, the vice president shall

assume the office of the president until an election is held. Elected officers shall then serve the remainder of the term.

Board Member Addresses

(DCA Policy)

Board member addresses and telephone numbers are confidential and shall not be released to the public without expressed authority by the individual board member.

A roster of board members is maintained for public distribution and is placed on the board's Web site, using the address and telephone numbers of the board.

Written Correspondence and Mailings by Board Members

(Board Policy)

All correspondence, press releases, articles, memoranda or any other communication written by any board member in his or her official capacity must be provided to the EO for reproduction and distribution. The EO will maintain the copy and mail and distribute the written material.

Request for Records Access

(Board Policy)

No board member may access a licensee's or applicant's file without the EO's knowledge and approval of the conditions of access. Records or copies of records shall not be removed from the board's office.

Disciplinary Record Information and Public Disclosure

The board also has a policy regarding public disclosure of disciplinary records, posted on the board's Web site:
http://www.pharmacy.ca.gov/enforcement/disc_info.shtml

The law provides that the following information is public and will appear on a record if applicable to a licensee:

- If a licensee has been disciplined or formally accused of wrongdoing by the board.
- If a licensee is currently on suspension and/or probation with the board.
- If a license has been revoked or voluntarily surrendered.

Board of Pharmacy's public disclosure policy.

Current website information on Board of Pharmacy disciplinary actions only goes as far back as January 1998 following the effective date of the disciplinary penalty (e.g., revocation, surrender, suspension, probation, etc.)

Disciplinary actions rendered by the Board of Pharmacy and penalties imposed become operative on the effective date of the action except in situations where the licensee obtains a court-ordered stay through the appeal process. This may occur after the publication of the information on this website. For updated information on stay orders and appeals, please contact the board at the address below.

To obtain information prior to January 1998 and/or further information on current or past disciplinary actions for a board licensee you may submit a written request to the State Board of Pharmacy, 1625 N. Market Blvd, Suite N219, Sacramento, CA 95834, Attention: Public Records Desk, or you may fax your request to (916) 574-8618. Copies of public documents concerning board disciplinary actions are available for a minimal charge. For additional information, contact the Board at (916) 574-7914.

Communications with Other Organizations/Individuals/Media

(Board Policy)

All communications relating to any board action or policy to any individual, organization, or a representative of the media shall be made only by the president of the board, his or her designee, or the EO. Any board member who is contacted by any of the above should inform the board president or EO of the contact.

Executive Officer (EO)

(B&P Code Section 4003)

The EO is appointed by and serves at the pleasure of the board, and is exempt from civil service. The EO shall exercise the powers and perform the duties delegated by the board and vested in him or her by California pharmacy law. The EO is responsible for the financial operations and integrity of the board, and is the official custodian of records.

Executive Officer's Annual Evaluation

(Board Policy)

At the first meeting of each fiscal year, the EO is evaluated by the board president during a closed session meeting with of board. Board members provide information to the president on the EO's performance in advance of this meeting.

Board Staff

(DCA Reference Manual)

Employees of the board, with the exception of the executive officer, are civil service employees. Their employment, pay, benefits, discipline, termination, and conditions of employment are governed by a myriad of civil service laws and regulations and often by collective bargaining labor agreements. Board members shall not intervene or become involved in specific day-to-day personnel transactions.

Board Administration

(DCA Reference Manual)

Board members should be concerned primarily with formulating decisions on board policies rather than decisions concerning the means for carrying out a specific course of action. It is inappropriate for board members to become involved in the details of program delivery. Strategies for the day-to-day management of programs and staff shall be the responsibility of the executive officer.

Contact with Licensees and Applicants

(Board Policy)

Board members shall not intervene on behalf of applicants and licensees. They should forward all contacts or inquiries to the EO or board staff without direction on how matter should be handled.

Contact with Respondents

(DCA Reference Manual)

Board members should not directly participate in complaint handling and resolution or investigations. To do so would subject the board member to disqualification in any future disciplinary action against the licensee. If a board member is contacted by a respondent or his/her attorney, the board member should immediately refer the individual to the EO or board staff.

Service of Legal Documents

(Board Policy)

If a board member is personally served as a party in any legal proceeding related to his or her capacity as board member, he or she must contact the EO immediately.

Gifts from Licensees or Applicants

(Board Policy)

Gifts of any kind to board members or staff from any licensee or applicant with the board are not permitted.

Additionally, Government Code section 87200 contains specific requirements with respect to gifts. These requirements are among those discussed in the Ethics Course described below.

Conflict of Interest

(Government Code Section 87100)

No board member may make, participate in making or in any way attempt to use his or her official position to influence a governmental decision in which he or she knows or has reason to know he or she has a financial interest. Any board member who has a financial interest, shall disqualify himself/herself from making or attempting to use his/her official position to influence the decision. Any board

member who feels he or she is entering into a situation where there is a potential for a conflict of interest should immediately consult the board president or the EO.

Government Code Section 87100 and related sections are attached as Appendix F.

(Board Policy)

A board member who feels he or she has a potential conflict of interest in a specific case or issue should make his or her position known when the matter is discussed publicly (e.g., during a board meeting). Further the member should reinforce this position by physically leaving the room until the discussion regarding the matter is concluded. Whenever possible, a board member should notify the EO when he or she believes that the member has a conflict of interest. The EO can help refer the board member to appropriate resources for assistance. For example, the Fair Political Practices Commission is another resource.

Within 30 days of taking or leaving office as a board member, and annually before April 1 of each year, every board member must file a conflict of interest statement with the Fair Political Practices Commission filing procedures and handled by the Department of Consumer Affairs. Questions about this process should be directed to the EO.

A sample of situational questions to assess whether you may have a conflict of interest is provided as Appendix G.

Ethics Course

(Government Code Sections 11146-11146.4)

Each board member must complete a course on ethics offered through the department. Upon appointment to the board, a new board member must complete the course within six months. All members must retake the course every two years. Records concerning the attendance of this course must be kept on file for five years. Training information is available on (http://ag.ca.gov/ethics/).

Government Code Sections 11146-11146.4 are provided in Appendix F.

Sexual Harassment Prevention Training

(Government Code Section 12950.1)

Each board member must complete a sexual harassment prevention course offered through the department within six months of assuming office, and retake the course every two years.

The Honoraria Prohibition

(Government Code Section 89503)

As a general rule, members of the board should decline honoraria for speaking at, or otherwise participating in, professional association conferences and meetings. A member of a state board is precluded from accepting an honorarium from any source, if the member would be required to report the receipt of income or gifts from that source on his or her statement of economic interest.

Under the Department of Consumer Affairs Conflict of Interest Code, members of the Board of Pharmacy are required to report income from, among other entities, pharmacy and pharmaceutical professional associations and continuing education providers. Therefore, a board member should decline all offers for honoraria for speaking or appearing before such entities.

There are limited exceptions to the honoraria prohibition. The acceptance of an honorarium is not prohibited under the following circumstances: (1) when a honorarium is returned to the donor (unused) within 30 days; (2) when an honorarium is delivered to the State Controller within thirty days for donation to the General Fund (for which a tax deduction Is not claimed); and (3) when an honorarium is not delivered to the board member, but is donated directly to a bona fide charitable, educational, civic, religious, or similar tax exempt, non-profit organization.

In light of this prohibition, members should report all offers of honoraria to the president so that he or she, in consultation with the EO and staff counsel, may determine whether the potential for conflict of interest exists.

Government Code Section 89503 is provided in Appendix F.

DCA's Board Member Training

(B&P Code Section 453)

Board Member Orientation Course by DCA

The Department of Consumer Affairs provides an orientation session for new board members. The California Business and Professions Code requires that this full day course must be taken within one year of assuming office. The training covers the functions, responsibilities and obligations that come with being a member of a DCA board.

The course is scheduled three times a year, and the EO can advise you about scheduling.

The department also has a Web site for board members:
http://www.dca.ca.gov/pubs/board_members/orientation.htm

Serving as an Expert Witness

During their tenure on the board, members should refrain from acting as pharmacy expert witnesses in civil or criminal court cases. The reasons for this prohibition are twofold.

In the first place, acting as an expert witness for compensation would probably constitute a violation of the Standards of Ethical Conduct for gubernatorial appointees. The first ethical standard precludes a gubernatorial appointee from engaging in activity, which has the appearance of using the prestige of the state for the appointee's private gain or advantage. A professional member of the board would be in high demand as an expert witness in litigation relating to pharmacy,

simply because of his or her status as a board member. Consequently, the member would likely receive more engagements as an expert witness than if he or she were not a member of the board. As such, serving as an expert witness would have the appearance of using the prestige of board-membership for private gain. Parenthetically, although the Governor's ethical standards are addressed to the conduct of gubernatorial appointees, all members of the board should be in compliance.

More importantly, acting as an expert witness would jeopardize a board member's ability to participate in the deliberation and resolution of disciplinary actions before the board. As an expert witness in a civil or criminal action against a pharmacist, a board member would be required to learn all the facts of the case at issue. If the pharmacist who is a party to the civil or criminal comes before the board in a disciplinary action, the board member who served as expert witness would be required to recuse himself or herself because of considerable *ex parte* knowledge of the case.

Request for Grants

All requests for funding/contributions to board projects shall be approved by the board president. Requests for such grants must be made by the EO at the president's direction. If a board member makes an individual request, a copy of the request shall be forwarded to the EO as soon as possible.

The mechanism for receipt, management, and dispersal of funds shall be pre-arranged and approved by the board.

Resources for Board Members

Whenever you have questions as a board member, contact the EO of board president. The DCA has a section of its Web site dedicated to board member resources:
http://www.dca boardmembers.ca.gov/index_shtml

Chapter 6

ENFORCEMENT OVERVIEW

Enforcement Options and Sanctions

Enforcement activities are essential for the board to meet its consumer protection mandate. The enforcement program uses a combination of education, communication and enforcement sanctions to achieve compliance with federal and state pharmacy laws. Where voluntary compliance and education are not enough, the board inspects, mediates, admonishes, cites and fines and pursues formal disciplinary action.

When the board receives a complaint or uncovers a potential violation of the law through its own efforts, the matter is investigated by staff. Investigations in the field are carried out by the board's inspectors, a statewide-dispersed group of pharmacists who are employees of the board. Some consumer complaints are mediated in the board's office by specially trained consumer services staff. These staff are not pharmacists, but their work is reviewed by a pharmacist (a supervising inspector).

During a routine inspection or investigation (which is conducted by a board pharmacist-inspector), if it is believed that a violation of pharmacy law took place, the licensee may be advised of the alleged violation by an "Order of Correction," a written document directing the licensee to comply with pharmacy law within 30 days by submitting a corrective action plan to the inspector. This process simply notifies the licensee of the violations of law that the inspector believes have occurred. This notification may not be the board's final or formal determination regarding the matter depending on the seriousness of the alleged violations. A correction order is not a citation nor is it a disciplinary action.

At this time, the licensee is provided an opportunity to provide a written response to the alleged violation. In the written response, the licensee may address the specifics of the violation, as well as provide any mitigation information that the licensee wishes to have included in any investigation report and/or corrective action plan.

If the "Order of Correction" is for minor violations, and the inspector is satisfied with the pharmacy's compliance, the "Order of Correction" may be the only action taken. If this is the case and the pharmacy doesn't contest the order, then the licensee must maintain in the pharmacy premises a copy of the order of correction and corrective action plan for at least three years from the date the order was issued.

After the inspection or investigation is completed and the inspector makes a determination that the law has been violated, the case is referred to a supervising inspector for review. If the supervising inspector determines that there was no violation or that the violation was so minor that the only action to take would be the issuance of the "Order of Correction," then the case may be closed and the matter goes no further.

If, after review by the supervising inspector, it is determined that action may be warranted, the case is referred to the executive officer or the EO's designees. At this step the matter is reviewed to determine the appropriate course of action. In making

this determination, the following factors may be taken in consideration:

- Gravity of the violation.
- Good or bad faith of the cited person or entity.
- History of previous violations.
- Evidence that the violations were or were not willful.
- Recognition by the licensee of his/her wrongdoing and demonstration of corrective action to prevent recurrence, e.g., new policies and procedures, protocol, hiring of additional staff, etc.
- Extent to which the cited person or entity has cooperated with the board's investigation and other law enforcement or regulatory agencies.
- Extent to which the cited person or entity has mitigated or attempted to mitigate any damage or injury caused by the violation.
- If the violation involves multiple licensees, the relative degree of culpability of each licensee is considered. In the case where a staff pharmacist may have failed to consult, the pharmacist-in-charge and the pharmacy may also be issued a citation and fine, if warranted by the circumstances.
- Any other relevant matters that may be appropriate to consider.

The type of potential actions include:

Further Investigation

A decision may be made that there is insufficient evidence to determine if a violation occurred or if any action is warranted. The case may then be sent to the inspector for further investigation.

Case Closure – No Further Action

If a determination is made that there was no violation, that the violation was so minor as to not merit an action, or that the mitigating circumstances were such that it would be best not to pursue an action, the case may be closed with no further investigation. (The final resolution would be the "Order of Correction.")

Letter of Admonishment

(B&P Code Section 4315)

The executive officer may decide to issue a letter of admonishment. This may occur when the executive officer determines that there was a minor violation, or a violation that mitigating circumstances were such that a letter of admonishment was appropriate. The licensee would be directed to come into compliance within 30 days by submitting a corrective action plan to the executive officer documenting compliance, or the licensee can contest the letter of admonishment to the executive office for an office conference. If an office conference is not requested, compliance with the letter of admonishment does not constitute an admission of the violation noted in the letter of admonishment. The licensee must maintain in the licensed premises a copy of the letter of admonishment and corrective action plan for at least three years from the date the letter was issued. The letter of admonishment is considered a public record for purposes of disclosure.

Citation and Fine
(B&P Code Section 4314)

The executive officer may issue a citation, with or without a fine. The citation will be issued to the licensee and will include a reference to the statute or regulation violated. It will also include a description of the nature and facts of the violation, as well as a notice to the licensee of the appeal rights. It may or may not include an order of abatement either requesting documentation of the licensee's compliance, or directing the licensee to come into compliance and specifying how that must be done.

Disciplinary Action
The executive officer alone may determine that the violation is substantial and warrants discipline of the license. The matter is then referred to the Attorney General's Office, where, if appropriate to do so, an accusation is prepared, which identifies the alleged violations of pharmacy law. Disciplinary penalties include interim suspension orders, license revocation, voluntary license surrender, suspension and probation.

Standards for monitoring probationers or participants in the Pharmacists Recovery Program who have substance abuse problems.

The California State Board of Pharmacy operates a Pharmacists Recovery Program (PRP), which is mandated under provisions in the California Business and Professions Code (4360 et seq). The legislative intent of this program is to

> . . . to rehabilitate pharmacists and intern pharmacists whose competency may be impaired due to abuse of alcohol, drug abuse, or mental illness. The intent of the pharmacists recovery program is to return these pharmacists and intern pharmacists to the practice of pharmacy in a manner that will not endanger the public health and safety.

Only pharmacists and pharmacist interns are eligible for this program, other board licensees are not (pharmacy technicians, designated representatives).

When a pharmacist or pharmacist intern is identified to have a substance abuse problem, the board refers the licensee to the PRP, but continues to investigate the individual and typically formally disciplines the licensee, who may be revoked or placed on probation. If such a pharmacist or intern is placed on probation, he or she is mandated to successfully complete participation in the PRP as a condition of probation. If a pharmacist or pharmacist intern has had his or her license revoked due to a substance abuse problem, upon reinstatement, the individual is placed on a term of probation that includes participation in the PRP.

The standards of probation and the treatment contract terms of the PRP are in part specified by the Uniform Standards developed under section 315 et. seq of the California Business and Professions Code for all health care boards in the Department of Consumer Affairs. These terms have been added to the board's *Disciplinary Guidelines* which are used by the board's enforcement program, board members, deputies attorney general and administrative law judges to establish disciplinary terms when disciplining a licensee.

Pharmacy technicians and designated representative who are identified to have a

substance abuse problem may be revoked or placed on probation. If placed on probation, while not eligible for the close monitoring of the PRP, these licensees still are required to follow designated criteria contained in Uniform Standards developed under section 315 et seq of the California Business and Professions Code as their probation terms.

There are several additional standards that were not added to the *Disciplinary Guidelines* because they are not standards for the probationary terms of licensees, but do instead establish criteria for operational issues for monitoring licensees with substance abuse problems. These standards are detailed in this section of the B*oard Member Procedure Manual* so the board will be knowledgeable about their existence as requirements for probation monitoring programs of those with substance abuse problems.

Uniform Standards Incorporated via Policy:

- Uniform Standard # 6, Type of treatment
  - Sets for the evaluation criteria that must be considered when determining whether inpatient, outpatient, or other type of treatment is necessary.
- Uniform Standard # 8, Positive drug test
  - Requires the board to issue a cease practice order to a licensee's license and notify the licensee, employee and worksite monitor that the licensee may not work.
  - Specifies that after notification, the board should determine if the positive drug test is evidence of prohibited use and sets forth the criteria the board must follow when making such a determination.
  - Specifies that if the board determines that it was not a positive drug test, it shall immediately lift the cease practice order.
- Uniform Standard # 9, Ingestion of a banned substance
  - Specifies that when a board confirms a positive drug test as evidence of use of a prohibited substance, the licensee has committed a major violation.
- Uniform Standard # 10, Consequences for major and minor violations
  - Specifies what constitutes a major violation including: failure to complete a board ordered program or undergo a clinical diagnostic evaluation; treating patients while under the influence of drugs/alcohol, and drug/alcohol related act which would constitute a violation of the state/federal laws, failure to undergo drug testing, confirmed positive drug test, knowingly defrauding or attempting to defraud a drug test.
  - Specifies the consequences for a major violation including: issuing a cease practice order to the licensee; requiring a new clinical evaluation; termination of a contract/agreement; referral for disciplinary action.
  - Specifies what constitutes a minor violation including: untimely receipt of required documentation; unexcused group meeting attendance; failure to contact a monitor when required; any other violations that does not present an immediate threat to the violator or the public.
  - Specifies the consequences for a minor violation including: removal from practice; practice restrictions; required supervision; increased documentation; issuance of a citation and fine or working notice; re-evaluation/testing; other actions as determined by the board.
- Uniform Standard # 11, Return to full time practice

    - Establishes the criteria to return to full time practice, including demonstrated sustained compliance, demonstrated ability to practice safely, negative drug screens for at least six months, two positive worksite monitor reports and compliance with other terms and conditions of the program.
- Uniform Standard # 12, Unrestricted practice
    - Establishes the criteria for a licensee to request unrestricted practice including sustained compliance with a disciplinary order, successful completion of the recovery program, consistent and sustained participation in recovery activities, demonstrated ability to practice safely and continued sobriety of three to five years, as specified.
- Uniform Standard # 13 Private-sector vendor
    - Specifies that the vendor must report any major violation to the board within one business and any minor violation within five business days.
    - Establishes the approval process for providers or contractors that work with the vendor consistent with the uniform standards.
    - Requires the vendor to discontinue the use of providers or contractors that fail to provide effective or timely services as specified.
- Uniform Standard # 14 Confidentiality
    - For any participant in a diversion program whose license in on an inactive status or has practice restrictions, requires the board to disclose the licensee's name and a detailed description of any practice restrictions imposed.
    - Specifies that the disclosure will not include that the restrictions are as a result of the licensee's participation in a diversion program.
- Uniform Standard # 15 Audits of private-sector vendor
    - Requires an external independent audit every three years of a private-sector vendor providing monitoring services.
    - Specifies that the audit must assess the vendor's performance in adhering to the uniform standards and requires the reviewer to provide a report to the board by June 30 of each three year cycle.
    - Requires the board and department to respond to the findings of the audit report.
- Uniform Standard # 16 Measurable criteria for standards
    - Establishing annual reporting to the department and Legislature and details the information that must be provided in the report.
    - Sets forth the criteria to determine if the program protects patients from harm and is effective in assisting licensees in recovering from substance abuse in the long term.

Language from the relevant Uniform Standards is included in Appendix H.

Emergency Response Policy:

When public health disasters or major events disrupt society, public health needs to adapt to quickly permit the care of people in need. To this end, the board has the following emergency response policy:

Advance planning and preparation for disaster and emergency response are important activities for individuals, as well as all Board licensees. The Board has begun working on such preparedness with the federal and state government, and to this end, in October 2006, the Board adopted the following policy statement.

The California State Board of Pharmacy wishes to ensure complete preparation for, and effective response to, any local, state, or national disaster, state of emergency, or other circumstance requiring expedited health system and/or public response. The skills, training, and capacities of board licensees, including wholesalers, pharmacies, pharmacists, intern pharmacists, and pharmacy technicians, will be an invaluable resource to those affected and responding. The Board also wishes to encourage an adequate response to any such circumstance affecting residents of California, by welcoming wholesalers, pharmacies, pharmacists, intern pharmacists, and pharmacy technicians licensed in good standing in other states to assist with health system and/or public response to residents of California.

The Board encourages its licensees to volunteer and become involved in local, state, and national emergency and disaster preparedness efforts. City or county health departments, fire departments, or other first responders can provide information on local opportunities. The Emergency Preparedness Office of the California Department of Health Services is a lead agency overseeing emergency preparedness and response in California, particularly regarding health system response, drug distribution and dispensing, and/or immunization and prophylaxis in the event of an emergency. At the federal level, lead contact agencies include the Department of Health and Human Services, the Centers for Disease Control, and/or the Department of Homeland Security and its Federal Emergency Management Agency (FEMA). Potential volunteers are encouraged to register and get information at *www.medicalvolunteer.ca.gov* (California) and *www.medicalreservecorps.gov* (federal). The Board also continues to be actively involved in such planning efforts, at every level. The Board further encourages its licensees to assist in any way they can in any emergency circumstance or disaster. Under such conditions, the priority must be protection of public health and provision of essential patient care by the most expeditious and efficient means. Where declared emergency conditions exist, the Board recognizes that it may be difficult or impossible for licensees in affected areas to fully comply with regulatory requirements governing pharmacy practice or the distribution or dispensing of lifesaving medications.

In the event of a declared disaster or emergency, the Board expects to utilize its authority under the California Business and Professions Code, including section 4062, subdivision (b) thereof, to encourage and permit emergency provision of care to affected patients and areas, including by waiver of requirements that it may be implausible to meet under these circumstances, such as prescription requirements, record-keeping requirements, labeling requirements, employee ratio requirements, consultation requirements, or other standard pharmacy practices and duties that may interfere with the most efficient response to those affected.

The Board encourages its licensees to assist, and follow directions from, local, state, and national health officials. The Board expects licensees to apply their judgment and training to providing medication to patients in the best interests of the patients, with circumstances on the ground dictating the extent to which regulatory requirements can be met in affected areas. The Board further expects that during such emergency, the highest standard of care possible will be provided, and that once the emergency has dissipated, its licensees will return to practices conforming to state and federal requirements.

Furthermore, during a declared disaster or emergency affecting residents of

California, the Board hopes that persons outside of California will assist the residents of California. To facilitate such assistance, in the event of a declared California disaster or emergency, the Board expects to use its powers under the California Business and Professions Code, including section 900 and section 4062, subdivision (b) thereof, to allow any pharmacists, intern pharmacists, or pharmacy technicians, who are not licensed in California but who are licensed in good standing in another state, including those presently serving military or civilian duty, to provide emergency pharmacy services in California. The Board also expects to allow nonresident pharmacies or wholesalers that are not licensed in California but that are licensed in good standing in another state to ship medications to pharmacies, health professionals or other wholesalers in California.

Finally, the Board also expects to allow use of temporary facilities to facilitate drug distribution during a declared disaster or state of emergency. The Board expects that its licensees will similarly respond outside of the state to disasters or emergencies affecting populations outside California, and will pursue whatever steps may be necessary to encourage that sort of licensee response.

1 Expanded powers in the event of a disaster are also granted to the Governor and/or other chief executives or governing bodies within California by the California Emergency Services Act [Cal. Gov. Code, §§ 8550-8668] and the California Disaster Assistance Act [Cal. Gov. Code, §§ 8680-8690.7], among others. Section 8571 of the Government Code, for instance, permits the Governor to suspend any regulatory statute during a state of war or emergency where strict compliance therewith would prevent, hinder, or delay mitigation.

2 See also the Interstate Civil Defense and Disaster Compact [Cal. Gov. Code, §§ 177-178], the Emergency Management Assistance Compact [Cal. Gov. Code, §§ 179-179.5], and the California Disaster and Civil Defense Master Mutual Aid Agreement [executed 1950], regarding cooperation among the states

Subscriber Alert System:

> The Board of Pharmacy's subscriber alert system is an email notification system used by the board to advise its licensees and other interested parties who are self subscribers about California State Board of Pharmacy policies, publications and activities that impact the board's regulatory jurisdiction or public protection mandate. On occasion, the board will release notices about other matters impacting public health of wide appeal or urgency (such as drug product recalls, notices from other state or federal agencies, emergency declarations). Drug recall notices shall be the top priority for such notices and shall be denoted as a drug recall alert.

Under California law, all sites licensed by the board are required to become subscribers and maintain their current email addresses with this system so that they can receive these board notices. However, the board recognizes the potential to overload licensees and subscribers with less important or unwanted notices, with the ultimate impact that all subscriber alerts sent by the board become viewed with less focus and discernment. As such, the board's executive staff will approve each subscriber alert before release to ensure that the notice advances the board's public protection mandate or relates to the board's regulatory jurisdiction.

APPENDIX A

GUIDE TO THE

BAGLEY-KEENE OPEN MEETING ACT

(Includes Amendments through January 1, 2009)

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BAGLEY-KEENE OPEN MEETING ACT

Table of Contents

Subject	Page(s)
I. Public Policy to Conduct People's Business Openly	**1**
II. Board, Committee, Subcommittee, Task Force Meetings	**2-4**
A. Definition of a "Meeting"	2
B. Exemptions from Definition of Meeting	2
C. Board and Committee Meetings	2-4
III. Types of Meetings; Purpose; Notice; Other Requirements	**4-11**
A. Regularly Scheduled Meetings	4
1. Who May Hold a Regularly Scheduled Meeting	4
2. Purposes for Which the Meeting May be Held	4
3. Notice Requirements for a Regularly Scheduled Meeting	4
a. Board Meetings	4-6
b. Committee, Subcommittee or Task Force Meetings	7
4. Specific Requirements for Regularly-Scheduled Meetings	7
5. Specific Prohibitions on Holding a Regularly-Scheduled Meeting	7-8
B. "Special" Meetings	8-10
1. Who May Hold a Special Meeting	8
2. Purposes for Which a Special Meeting May be Held	8-9
3. Notice Requirements for a Special Meeting	9
4. Specific Requirements During Special Meetings	9-10
5. Specific Prohibitions on Holding a Special Meeting	10
C. "Emergency" Meetings	10-11
1. Who May Hold an Emergency Meeting	10
2. Purposes for Which an Emergency Meeting May be Held	10
3. Notice Requirements for an Emergency Meeting	10
4. Specific Requirements for an Emergency Meeting	10-11
5. Specific Prohibitions on Holding an Emergency Meeting	11
IV. Closed Sessions	**11-17**
A. Purposes for Which Closed Session Can be Held	11
1. Personnel Matters	11-12
2. Examination Matters	12
3. Matters Affecting Individual Privacy	12-13
4. Administrative Disciplinary Matters	13
5. Board of Accountancy Matters	13-14
6. Pending Litigation	14
7. Response to Confidential Final Draft Audit Report	14
8. Threat of Criminal or Terrorist Activity	14
8. Advisory Bodies/Committees May Meet in Closed Session	15
9. Open Session Otherwise Required	15

B. Notice and Reporting Requirements for Closed Sessions 15-17
1. Notice of Closed Session 15-16
2. Reporting After A Closed Session 16
C. Other Procedural Requirements for Closed Sessions 16-17

V. Meeting by Teleconferencing 17-19

VI. Deliberations and Voting 19-20
A. Seriatim Calls to Individual Agency Members Prohibited 19
B. E-Mail Prohibition 19-20
C. Secret Ballot Prohibited 20
D. Voting by Proxy Prohibited 20
E. Voting by Mail on Administrative Disciplinary Matters 20

VII. Miscellaneous Provisions 20-23
A. Conforming Board Member's Conduct 21
B. Providing Open Meeting Act to New Board Members 21
C. Prohibition on Placing Conditions on Public's Attendance 21
1. Sign-in 21
2. Discrimination in Admittance to Meeting Facility 21
3. Access for the Disabled 21
4. Charging a Fee or Requiring a Purchase for Access 21
D. Agency Recording of the Proceedings 21-22
E. Public's Right to Record the Proceedings 22
F. Media Broadcast of the Proceedings 22
G. Taking Agenda Items Out of Order 22
H. Opportunity for Public Comment at Meetings 22-23

VII. Disclosure of Documents 23-24
A. Documents Distributed Prior to the Meeting 23
B. Documents Distributed During the Meeting 23
C. Charging a Fee for Public Documents 23-24

IX. Penalties 24-25

GUIDE TO THE
BAGLEY-KEENE OPEN MEETING ACT
(Includes Amendments through January 1, 2009)

This guide is an update on the provisions of the public meetings law governing state agencies, officially called the Bagley-Keene Open Meeting Act. (Article 9 (commencing with Section 11120), Chapter 1, Part 1, Division 3, Title 2 of the Government Code). The Open Meeting Act closely parallels the Ralph M. Brown Act, which governs meetings of local government agencies. This guide includes all statutory changes through January 1, 2009. Please disregard all earlier memoranda and the previous Guide to the Bagley-Keene Open Meeting Act (distributed December 2007) on this subject.

All statutory references are to the Government Code.

I. PUBLIC POLICY TO CONDUCT PEOPLE'S BUSINESS OPENLY

Section 11120 sets forth the purpose of the law:

> "It is the public policy of this state that public agencies exist to aid in the conduct of the people's business and the proceedings of public agencies be conducted openly so that the public may remain informed.
>
> In enacting this article the Legislature finds and declares that it is the intent of the law that actions of state agencies be taken openly and that their deliberation be conducted openly.
>
> The people of this state do not yield their sovereignty to the agencies which serve them. The people, in delegating authority, do not give their public servants the right to decide what is good for the people to know and what is not good for them to know. The people insist on remaining informed so that they may retain control over the instruments they have created.
>
> This article shall be known and may be cited as the Bagley-Keene Open Meeting Act."

Each board has essentially three duties under the Open Meeting Act. First, to give adequate notice of meetings to be held. Second, to provide an opportunity for public comment. Third, to conduct such meetings in open session, except where a closed session is specifically authorized. We use the terms "agency" and "board" to mean not only boards, but also commissions and any examining committees or boards within the jurisdiction of the Medical Board of California.

II. BOARD, COMMITTEE, SUBCOMMITTEE, TASK FORCE MEETINGS

A. Definition of a "Meeting"

"Meeting" is defined in the Act as including "any congregation of a majority of the members of a state body at the same time and place to hear, discuss, or deliberate upon any item that is within the subject matter jurisdiction of the state body to which it pertains." (§11122.5(a)) The law now prohibits use by a majority of the members of a state body of direct communications, personal intermediaries, or technological devices (such as e-mails) to develop a collective concurrence among the members. (§11122.5(b))

B. Exemptions from Definition of Meeting

The law recognizes that not all gatherings of a majority of members of a state body at a single location constitute a meeting. Current law provides that the provisions of the Act do not apply to the following situations, **provided that** "a majority of the members do not discuss among themselves, other than as part of a scheduled program, business of a specified nature that is within the subject matter jurisdiction of the state body." (§11122.5(c))

- Individual contacts or conversations between a member of a state body and any other person. (§11122.5(c)(1))

- Attendance by a majority of members at a conference or similar gathering open to the public that involves a discussion of issues of general interest to the public or to public agencies of the type represented by the state body. (§11122.5(c)(2))

- Attendance by a majority of members at an open and publicized meeting organized to address a topic of state concern by a person or organization other than the state body. (§11122.5(c)(3))

- Attendance by a majority of members at an open and noticed meeting of another state body or of a legislative body of a local agency. (§11122.5(c)(4))

- Attendance by a majority of members at a purely social or ceremonial occasion. (§11122.5(c)(5))

- Attendance by a majority of members at an open and noticed meeting of a standing committee of that body, provided the members of the body who are not members of the committee attend only as observers. (§11122.5(c)(6))

C. Board and Committee Meetings

There are two basic types of meetings held by agencies in the Department of Consumer Affairs. The first type is a board meeting, where a quorum of the members of the board are present. The second type is a committee meeting consisting of less

than a quorum of the members of the full board. Subcommittee and task force meetings are variations of committee meetings.

Board meetings have historically been required to be noticed and open to the public, except where a closed session is authorized. Committee and subcommittee meetings, where less than a quorum of the board is present, are also required to be noticed and open to the public. The only exception is for a committee that consists of fewer than three persons.

Where a committee of fewer than three persons is to meet, and the meeting is not noticed, other members of the board should not attend the meeting, as such attendance would clearly be perceived as an Open Meeting Act violation. Board staff is not precluded from attending such a meeting.

[Restriction on Attendance at Committee Meetings] Commencing January 1, 2001, the law allows attendance by a majority of members at an open and noticed meeting of a standing committee of the board, provided the members of the board who are not members of the committee attend only as observers. (§11122.5(c)(6)) The Office of the Attorney General has addressed in a formal opinion a provision in the Brown Act relating to the attendance of "observers" at a committee meeting. The Attorney General concluded that "[m]embers of the legislative body of a local public agency may not ask questions or make statements while attending a meeting of a standing committee of the legislative body 'as observers.'" The opinion further concluded that such members of the legislative body may not sit in special chairs on the dais with the committee. (81 Ops.Cal.Atty.Gen. 156)

Thus, under the provisions of section 11122.5(c)(6), and the opinion of the California Attorney General, if a majority of members of the full board are present at a committee meeting, members who are not members of the committee that is meeting may attend that meeting only as observers. The board members who are not committee members may not sit on the dais with the committee, and may not participate in the meeting by making statements or asking questions.

If a board schedules its committee meetings seriatim, and other board members are typically present to ultimately be available for their own committee meeting, your notice of the committee meeting should contain a statement to the effect that "Members of the board who are not members of this committee may be attending the meeting only as observers."

Subcommittees may be appointed to study and report back to a committee or the board on a particular issue or issues. If the subcommittee consists of three or more persons, the same provisions apply to its meetings as apply to meetings of committees.

Board chairpersons may occasionally appoint a task force to study and report on a particular issue. One or two board members typically serve as task force members, along with a number of other non-board members. When this is the case, the same Open Meeting Act rules that apply to committee meetings apply to task force meetings.

Such a formally appointed task force falls under the definition of "state body in Section 11121(c)."

III. TYPES OF MEETINGS; PURPOSE; NOTICE; OTHER REQUIREMENTS

Boards and committees may hold several types of meetings, including a regularly scheduled meeting, a "special" meeting, or an "emergency" meeting under the provisions of section 11125.5. This section of the memorandum addresses who can hold certain types of meetings, the purposes for which the meetings can be held, notice requirements, and any other special requirements or prohibitions.

A. Regularly Scheduled Meetings

1. Who May Hold a Regularly Scheduled Meeting

A board, committee, subcommittee, or task force may hold a regularly scheduled meeting. These are the business meetings that are scheduled throughout the year to conduct the usual and customary business of the board. Such meetings may generally be called by the chairperson, or by a majority of the body. However, you must refer to your particular licensing act, which may contain different provisions as to who may call a meeting.

2. Purposes for Which the Meeting May be Held

These meetings are to conduct the usual and customary business of the board, or the business of a committee, subcommittee or task force as directed by the board. The subject matter of the meetings is essentially dictated by the jurisdiction of the board as found in the board's licensing act. There are no statutory restrictions in the Open Meeting Act on the purposes for which a regularly scheduled meeting may be held.

3. Notice Requirements for a Regularly Scheduled Meeting

a. Board Meetings

An agency is required to give at least 10 calendar days written notice of each board meeting to be held. (§11125(a).) The notice must include the name, address, and telephone number of a person who can provide further information prior to the meeting and must contain the website address where the notice can be accessed. The notice must also be posted on the Internet at least 10 calendar days before the meeting.

In addition to the website posting, effective January 1, 2003, the notice is required to be made available in appropriate alternate formats upon request by any person with a disability.

The notice of each board meeting must include an agenda that is prepared for the meeting. The agenda must include all items of business to be transacted or discussed at the meeting. " ... A brief general description of an item generally need not exceed 20 words. ... No item shall be added to the agenda subsequent to the provision of this notice." (§11125(b)) This provision does not, however, preclude amending an agenda provided the amended notice is distributed and posted on the Internet at least 10 calendar days prior to the meeting. Effective January 1, 2003, the notice must include information that would enable a person with a disability to know how, to whom, and by when a request may be made for any disability-related modification or accommodation, including auxiliary aids or services. We suggest the following as standard language:

> The meeting is accessible to the physically disabled. A person who needs disability-related accommodations or modifications in order to participate in the meeting shall make a request no later than five (5) working days before the meeting to the Board by contacting _____ at (916) _____ or sending a written request to that person at the Board [Address], Sacramento, California, [zip code]. Requests for further information should be directed to [Staff Person's name] at the same address and telephone number.

The definition of "action taken" in Section 11122 is of some aid in determining what the Legislature intended by use of the words "items of business to be transacted."

> "11122. As used in this article 'action taken' means a collective decision made by the members of a state body, a collective commitment or promise by the members of the state body to make a positive or negative decision or an actual vote by the members of a state body when sitting as a body or entity upon a motion, proposal, resolution, order or similar action."

General agenda items such as "New Business," "Old Business," "Executive Officer's Report," "Committee Reports," "President's Report," "Miscellaneous," etc. cannot, without specifying the particular matters thereunder, be used to circumvent this requirement. The Office of the Attorney General has opined that:

> "... the purpose of subdivision (b) [of Government Code Section 11125] is to provide advance information to interested members of the public concerning the state body's anticipated business in order that they may attend the meeting or take whatever other action they deem appropriate under the circumstances.
>
> * * *
>
> "We believe that Section 11125 was and is intended to nullify the need for . . . guesswork or further inquiry on the part of the interested public." (67 Ops.Cal.Atty.Gen. 85, 87)

Items not included on the agenda may not be discussed, even if no action is to be taken by the agency. However, we offer two suggestions so members of the public and board members may raise issues that are not on the agenda.

We strongly encourage boards to include an item on their agendas for "Public Comment on Matters Not on the Agenda." This gives persons who are attending a meeting an opportunity to raise any issues they may have, which may not be on the agenda, but which may be appropriate for future board discussion. Matters raised under this agenda item should be discussed only to the extent necessary to determine whether they should be made an agenda item at a future meeting. (§11125.7(a))

We also strongly encourage boards to include an item on their agenda for "Agenda Items for Future Meetings." This allows all board members an opportunity to request specific agenda items for a meeting. Again, these items should be discussed only to the extent necessary to determine whether they should be included as agenda items for a future meeting.

[CAVEAT: If the regularly scheduled meeting will have a closed session agenda item or items, or be held by teleconference, please refer to the discussion of additional requirements under those headings, below.]

The notice and the agenda must be provided to any person who requests it. A member of the public may request notice for a specific meeting, for all meetings at which a particular subject will be discussed or action taken thereon, or for all meetings of the agency. Mailing lists of persons who desire to be notified of more than one meeting must be maintained pursuant to Section 14911, which provides:

> "14911. Whenever any state agency maintains a mailing list of public officials or other persons to whom publications or other printed matter is sent without charge, the state agency shall correct its mailing list and verify its accuracy at least once each year. This shall be done by addressing an appropriate postcard or letter to each person on the mailing list. The name of any person who does not respond to such letter or postcard, or who indicates that he does not desire to receive such publications or printed matter, shall be removed from the mailing lists. The response of those desiring to be on the mailing list shall be retained by these agencies for one year."

Effective 1/1/98, a sentence was added to subdivision (c) of Section 11125.1 to state that "Nothing in this article shall be construed to require a state body to place any paid advertisement or any other paid notice in any publication." (Stats. 1997, Chapt. 949; SB 95) The Legal Office interprets this provision to supersede any provisions in particular practice acts which require newspaper publication of board or committee meetings. Boards and committees, of course, retain the discretion to publish notices in newspapers if they so chose.

b. Committee, Subcommittee or Task Force Meetings

Each agency is required to give notice of committee, subcommittee or task force ("committee") meetings to be held. However, this requirement does not apply if the committee consists of less than three persons. It is the number of persons on the committee that is determinative, not how many of the persons are board members. Thus, if a committee consisted of two board members and two other interested persons, its meetings would have to meet all the requirements of the Open Meeting Act.

Notice of committee meetings must be provided and posted on the Internet at least 10 calendar days in advance of the meeting. (§11125(a)) The notice "shall include a brief, general description of the business to be transacted or discussed, and no item shall be added subsequent to the provision of the notice." (§11125(c)) The notice must also include the Website address where the notice can be accessed on the Internet. Although the law does not so specify, we would suggest also including in the notice the name, address, and telephone number of a contact person who can provide further information prior to the meeting. As with board meetings, there is no requirement that the notice be published in any newspaper or other periodical. However, the notice must be provided to any person or persons who have requested to be notified of the particular committee's meetings. You may elect to send such notice to those persons on your regular mailing list.

Remember the need to now post your notice on the Internet at least 10 calendar days in advance of the meeting and to make the notice available in appropriate alternate formats upon request by any person with a disability.

Provision is made for certain non-emergency, but sometimes necessary, committee meetings. Where, during the course of a regularly scheduled and properly noticed board meeting, the board desires that a committee presently discuss an item of business on the agenda, the committee may do so provided (a) the specific time and place of the committee meeting is announced during the public meeting of the board, and (b) the committee meeting is conducted within a reasonable time of, and nearby, the meeting of the board. (§11125(c))

4. Specific Requirements for Regularly-Scheduled Meetings

There are no specific requirements, other than those set forth above, for regularly scheduled board, committee, subcommittee or task force meetings.

5. Specific Prohibitions on Holding a Regularly-Scheduled Meeting

There are no statutory prohibitions in the Open Meeting Act on a board, committee, subcommittee or task force conducting a regularly scheduled meeting.

We again remind you that, with respect to committee meetings, members of the board who are not members of the committee that is meeting may only attend the committee meeting as observers. This means these members may not sit on the dais

with the committee, make any statements, or ask any questions during the committee meeting. (81 Ops.Cal.Atty.Gen. 156)

B. "Special" Meetings

SB 95 of 1997 created a new category of meeting, that being a "special" meeting.

1. Who May Hold a Special Meeting

A board, committee, subcommittee or task force may hold a special meeting.

2. Purposes for Which a Special Meeting May be Held

The only purposes for which a special meeting may be held are set forth in section 11125.4, and are drawn from the purposes for which an emergency meeting could be held under the prior law. In essence, the Legislature recharacterized those purposes as constituting "special" circumstances rather than "emergency" circumstances. Section 11125.4 provides in part that:

> "(a) A special meeting may be called at any time by the presiding officer of the state body or by a majority of the members of the state body. A special meeting may only be called for one of the following purposes where compliance with the 10-day notice provisions of Section 11125 would impose a substantial hardship on the state body or where immediate action is required to protect the public interest:
>
> (1) To consider 'pending litigation' as that term is defined in subdivision (e) of Section 11126.
>
> (2) To consider proposed legislation.
>
> (3) To consider issuance of a legal opinion.
>
> (4) To consider disciplinary action involving a state officer or employee.
>
> (5) To consider the purchase, sale, exchange, or lease of real property.
>
> (6) To consider license examinations and applications.
>
> (7) To consider an action on a loan or grant provided pursuant to Division 31 (commencing with Section 50000) of the Health and Safety Code.

(8) To consider its response to a confidential final draft audit report as permitted by Section 11126.2.

(9) To provide for an interim executive officer of a state body upon the death, incapacity, or vacancy in the office of the executive officer.

* * *"

Department of Consumer Affairs licensing boards would most likely hold a special meeting for the purposes set forth in subdivisions (1), (2), (3), (4), and (6).

3. Notice Requirements for a Special Meeting

A special meeting can be called at any time by the presiding officer or a majority of the members of the state body, provided the 10-day notice requirements of section 11125 "would impose a substantial hardship on the state body or where immediate action is required to protect the public interest." (§11125.4(a)) The only purposes for which the meeting can be held are those set forth above.

The normal 10-day advance notice is not required for special meetings. However, notice of the special meeting is required to be provided to each member of the state agency and to persons who have requested notice of the agency's meetings as soon as practicable after the decision to hold the meeting is made. Notice to members, newspapers of general circulation, and radio or television stations must be received at least 48 hours in advance of the meeting. Notice to newspapers, radio and television stations is satisfied by providing notice to all national press wire services. Notices to the general public may be given via appropriate electronic bulletin boards or other appropriate mechanisms. (§11125.4(b)) The notice must also be posted on the Internet at least 48 hours in advance of the meeting.

The notice must specify the time and place of the special meeting and the business to be transacted. In essence, an agenda would be prepared. No business other than that noticed may be transacted. Notice is required even if no action is subsequently taken at the meeting. (§11125.4(b)) The notice must contain the Website address where the notice may be accessed on the Internet.

[CAVEAT: If the special meeting will have a closed session agenda item or items, or be held by teleconference, please refer to the discussion of additional requirements under those headings, below.]

4. Specific Requirements During Special Meetings

At the commencement of a special meeting, the agency must make a finding in open session that providing a 10-day notice of the meeting would pose a substantial hardship on the agency, or that immediate action is required to protect the public interest. The specific facts constituting the hardship or need for immediate action must be articulated. This finding must be adopted by a two-thirds (2/3) vote of the agency members present, or if less than two thirds of the members are present, by a

unanimous vote of the members present. Failure to adopt the finding terminates the meeting. The agency's finding must be made available on the Internet. (§11125.4(c))

5. Specific Prohibitions on Holding a Special Meeting

As discussed above, a special meeting may only be held for the purposes set forth in section 11125.4(b). Other than the limitation on the purposes of the meeting, there are no statutory prohibitions in the Open Meeting Act on a board, committee, subcommittee or task force conducting a special meeting.

C. "Emergency" Meetings

1. Who May Hold an Emergency Meeting

A board, committee, subcommittee or task force may hold an emergency meeting.

2. Purposes for Which an Emergency Meeting May be Held

As noted above, S.B. 95 of 1997 recharacterized a number of "emergency" situations as "special" situations. This resulted in the narrowing of situations for which an emergency meeting may be held. Section 11125.5 provides an emergency meeting may be held only in the case of an "emergency situation," defined as:

> " (1) Work stoppage or other activity that severely impairs public health or safety, or both.
>
> " (2) Crippling disaster that severely impairs public health or safety, or both." (§11125.5(b))

3. Notice Requirements for an Emergency Meeting

An emergency meeting may be held without complying with the 10-day notice requirement in Section 11125 or the 48-hour notice requirement in Section 11125.4. However, newspapers of general circulation, television and radio stations that have requested notice of meetings shall be notified of the emergency by telephone at least one hour before the meeting. If telephone services are not functioning, notice is deemed waived. The notice must be posted on the Internet as soon as practicable after the decision to call an emergency meeting has been made. However, newspapers, television and radio must be notified as soon as possible after the meeting of the fact of the meeting, its purpose, and any action taken. (§11125.5(c))

4. Specific Requirements for an Emergency Meeting

The following are required to be posted in a public place and on the Internet for a minimum of 10 days, as soon as possible after the emergency meeting:

* Minutes of the meeting
* A list of persons notified, or attempted to be notified, of the meeting
* Any action taken at the meeting
* The rollcall vote on action taken (§11125.5(d))

5. Specific Prohibitions on Holding an Emergency Meeting

As discussed above, an emergency meeting may only be held for the purposes set forth in section 11125.5(b).

IV. CLOSED SESSIONS

A. Purposes for Which Closed Session Can be Held

"Closed" sessions were formerly called "executive" sessions. Since all references in the Open Meeting Act have been changed from "executive" session to "closed" session, throughout this memorandum we will refer to such sessions as "closed" sessions.

Section 11123 states that "All meetings of a state body shall be open and public and all persons shall be permitted to attend any meeting of a state body except as otherwise provided in this article."

Section 11126 sets forth those specific items of business which may be transacted in closed session. Only those enumerated items of business may be conducted in closed session. An agency in the Department may convene a closed session pursuant to Section 11126 for the following purposes.

1. Personnel Matters

A board may meet in closed session to " . . . consider the appointment, employment, evaluation of performance, or dismissal of a public employee or to hear complaints or charges brought against such employee by another person unless the employee requests a public hearing." In order to consider such disciplinary action or dismissal the "employee shall be given written notice of his or her right to have a public hearing . . . which notice shall be delivered to the employee personally or by mail at least 24 hours before the meeting." (§11126(a)) If such a notice is not given any action taken during a closed session for the above reason is null and void. Once the public hearing has been held, the agency may convene into closed session to deliberate on the decision to be reached. (§11126(a)(4))

Prior to January 1, 1995, section 11126(a) did not apply to employees who were appointed to their positions, such as executive officers, executive directors, and registrars (referred to as "executive officer" for convenience). For example, any decision or deliberations made in the selection or dismissal of an executive officer

previously had to be conducted in open session. (68 Ops.Cal.Atty.Gen. 34.) However, with the enactment of SB 1316 (Stats. 1994, Chapt. 845) and SB 95 (Stats. 1997, Chapt. 949), a board can now meet in closed session to consider the appointment, employment, evaluation of, or dismissal of its executive officer, unless the executive officer requests a public hearing. (§11126(a)(1), (2)) SB 1316 supersedes the conclusion reached in 68 Ops.Cal.Atty.Gen. 34. As noted above, once the public hearing has been held, the state body may convene in closed session to deliberate on the decision to be reached. (§11126(a)(4))

If the executive officer does not request a public hearing, he or she must be given the opportunity for a hearing in closed session. After the hearing, the executive officer should be excused from the closed session, and the board may then continue in closed session to deliberate on the decision to be reached. (§11126(a)(4))

Section 11126(a) is not to be interpreted to mean that a board is required to handle civil service personnel matters itself. Normally, this function of an agency is administered by its executive officer in conjunction with the Director of Consumer Affairs, who shares authority with respect to civil service personnel.

2. Examination Matters

A board may meet in closed session to "prepare, approve, grade or administer examinations." (§11126(c)(1)) Essentially, this includes any discussion regarding the actual content of examinations, and their reliability and validity. If an agency is perusing examination samples in order to choose one over the others, this may be done in closed session. On the other hand, if an agency is discussing, for example, the general logistics of administering an examination, then this would not be proper subject matter for a closed session. A basic rule is that if a meeting concerns the grading, specific content, validity of an examination, or examination security, then it can and should be conducted in closed session.

Also, an agency may hear appeals from examinees or re-review examinations in closed session as this would be included in the "grading" of the examination.

3. Matters Affecting Individual Privacy

A committee, consisting of less than a quorum of the full board, may meet in closed session to:

> " . . . discuss matters which the [committee] has found would constitute an unwarranted invasion of the privacy of an individual licensee or applicant if discussed in an open meeting, . . . Those matters may include review of an applicant's qualifications for licensure and an inquiry specifically related to the state body's enforcement program concerning an individual licensee or applicant where the inquiry occurs prior to the filing of a civil, criminal, or administrative disciplinary action against the licensee or applicant by the state body." (§11126(c)(2))

Thus, review by a committee (or subcommittee of an examining committee) of an applicant's qualifications for licensure could properly be done in a closed session. Also, for example, an enforcement committee could convene in closed session to discuss an inquiry related to a particular licensee or licensees prior to any action being filed.

CAVEAT: This closed session provision does not authorize such a review by the full board. Nor does it generally authorize a committee of a board to review complaints, investigation reports, or other information to determine whether disciplinary or other action should be filed against a licensee.

To ensure that board members render an impartial and fair decision in considering an Administrative Law Judge's proposed decision, board members are precluded from involving themselves in the investigation or prosecution phase of an action. (§11430.10 *et seq.*) The board's role is that of judge in the case. If a particular board member has any significant involvement in the investigative or prosecution phases, he or she must disqualify himself/herself from participation in the board's action relative to the proposed decision, and not attempt to influence any other board member regarding the decision. Legal counsel should be consulted before any enforcement actions are discussed with individual licensees, as such discussions may impact participation by the member in a final decision on a case (§11430.60), and may require disclosures under the provisions of the state's Administrative Procedure Act. (§11430.50)

Even though these committee meetings may consist entirely of subject matter proper for closed session they are required to be noticed as discussed above.

4. Administrative Disciplinary Matters

A board may meet in closed session to deliberate on a decision in an administrative disciplinary proceeding under the Administrative Procedure Act. (§11400, *et seq.*; §11126(c)(3)) In the closed session, the board may decide whether to adopt a Proposed Decision, review a transcript of a hearing and render a decision of its own, deliberate upon evidence heard by the agency itself, or consider a stipulation.

This section does not authorize an agency to convene into closed session for the purpose of assigning cases, *i.e.* deciding whether a case should be heard by a hearing officer alone or by the agency itself with a hearing officer. This section does not authorize an agency to convene into closed session to review investigation files or complaints. Members of boards that have the discretion to hear cases should not review pending complaints or investigation files for the reasons given above.

5. Board of Accountancy Matters

The administrative committee established by the State Board of Accountancy pursuant to Business and Professions Code Section 5020 may convene in a closed session to "consider disciplinary action against an individual accountant prior to the

filing of an accusation." (§11126(f)(3)) And the examining committee established by that board pursuant to Business and Professions Code Section 5023 may convene in closed session to "interview an individual applicant or accountant regarding the applicant's qualifications."

As noted above, such administrative and examining committee meetings are required to be noticed as previously discussed in this memorandum.

6. Pending Litigation

A board may meet in closed session to confer with or receive advice from its legal counsel regarding pending litigation when discussion in open session concerning those matters would prejudice the position of the state body in the litigation. (§11126(e)(1)) Again, please note the very specific notice requirements discussed below when a closed session is to be held to discuss "pending litigation". Litigation means an adjudicatory proceeding before a court, administrative body, hearing officer or arbitrator. Litigation is considered to be pending if, (1) it has been initiated formally (e.g. a complaint, claim or petition has been filed) or (2) based on existing facts and circumstances and on the advice of its legal counsel, the state body believes there is significant exposure to litigation against it, or it is meeting to decide whether a closed session is authorized because of significant exposure to litigation or (3) based on existing facts and circumstances, the state body has decided or is deciding whether to initiate litigation. (§11126(e)(2))

The agency's legal counsel must submit a memorandum which complies with the requirements of Section 11126(e)(2)(C)(ii) prior to the closed session if possible, but no later than one week after the closed session. This document is confidential until the pending litigation has been finally adjudicated or otherwise settled. (§6254.25)

7. Response to Confidential Final Draft Audit Report

Section 11126.2 (added effective January 1, 2005) permits an agency to meet in closed session to discuss its response to a confidential final draft audit report from the Bureau of State Audits. However, once that audit report becomes final and is released to the public, the agency may only discuss it in open session.

8. Threat of Criminal or Terrorist Activity

Effective January 1, 2006, AB 277 (Chap. 288, Stats. 2005) authorizes an agency at a regular or special meeting to meet in closed session to consider "matters posing a threat or potential threat of criminal or terrorist activity against the personnel, property, buildings, facilities, or equipment, including electronic data, owned, leased, or controlled by the state body," where disclosure of those considerations could compromise or impede the safety or security of the described subjects. The law (Section 11126(c)(18)) requires the agency to authorize the closed session by a two-thirds vote of the members present at the meeting.

9. Advisory Bodies/Committees May Meet in Closed Session

To the extent a licensing board, which is defined as a "state body" in the Open Meeting Act, is authorized to meet in closed session, then committees, subcommittees, or other bodies advisory to the licensing board, which are also defined as "state bodies," may meet in closed session for the same purposes as the licensing board. (§11126((f), (4)-(6))

10. Open Session Otherwise Required

Any other business transacted by an agency must be in open session. Only for the above-mentioned reasons may a board within the Department of Consumer Affairs meet in closed session. (§11132) A board may not meet in closed session for the purpose of electing officers or to discuss the proposal or adoption of rules and regulations. Further, a board may not convene in closed session to discuss testimony received during a hearing on proposed rules and regulations. Finally, an agency may not meet in closed session because it wants to have a frank and open discussion among only members on a matter of controversy. In order for an agency to meet in closed session, the closed session must be specifically authorized by statute.

B. Notice and Reporting Requirements for Closed Sessions

1. Notice of Closed Session

When a closed session will constitute part or all of a meeting, it is important to note Government Code Section 11126.3, which requires that:

> "(a) Prior to holding any closed session, the state body shall disclose, in an open meeting, the general nature of the item or items to be discussed in the closed session. The disclosure may take the form of a reference to the item or items as they are listed by number or letter on the agenda. [A provision applicable to the Public Utilities Commission is not included herein.] If the session is closed pursuant to subparagraph (A) of paragraph (2) of subdivision (e) of Section 11126 [litigation has already commenced], the state body shall state the title of, or otherwise specifically identify, the litigation to be discussed unless the body states that to do so would jeopardize the body's ability to effectuate service of process upon one or more unserved parties, or that to do so would jeopardize its ability to conclude existing settlement negotiations to its advantage."

Thus, if the meeting will consist in part or in its entirety of a closed session, you must include on the notice of the meeting the above-described information. Pay particular attention to these very specific requirements if the closed session is to

discuss pending litigation. Please note that to obtain legal advice in closed session concerning pending litigation, the notice must cite subdivision (e) of Section 11126 and your attorney must prepare a memorandum stating the specific reasons and legal authority for the closed session. Subdivisions of Government Code Section 11126, discussed under "Closed Sessions" above, will generally be the statutory authority cited.

If a closed session agenda to discuss pending litigation has been properly published, and an additional pending litigation issue subsequently arises, the state agency may discuss the new matter in closed session provided that postponement of the discussion would prevent the state agency from complying with any statutory, court-ordered, or other legally-imposed deadline. The state agency must publicly announce the title of, or otherwise identify, the litigation unless to do so would jeopardize the ability to effectuate service of process, or to do so would jeopardize the agency's ability to conclude existing settlement negotiations to its advantage. (§11126.3(d))

If you intend to have a closed session during your meeting, you should first contact your Legal Division attorney to ensure that a closed session is authorized and properly noticed.

2. Reporting After a Closed Session

Section 11126.3(f), requires a state body to convene in open session after a closed session and to report as required in Section 11125.2 , which states that:

> " Any state body shall report publicly at a subsequent public meeting any action taken, and any rollcall vote thereon, to appoint, employ, or dismiss a public employee arising out of any closed session of the state body."

C. Other Procedural Requirements for Closed Sessions

There are certain additional requirements that must be met when closed sessions are to be held.

1. All closed sessions must be held during a regular or special meeting (§11128); they may not be scheduled independently of a noticed meeting of the board or committee. Where, for example, a board or committee meeting is scheduled to discuss only matters appropriate for a closed session, the meeting should be opened as a public meeting with an announcement immediately following that the agency will convene into closed session.

2. As discussed under "Notice Required," above, prior to holding the closed session the agency must announce the general reason(s) for the closed session and the specific statutory or other legal authority under which the session is held. (§11126.3 (a)) With respect to litigation that has already been initiated, it must announce the title

of or otherwise identify the litigation. (§11126.3(a)) Other specific notice requirements, discussed above, also apply to notices regarding pending litigation. In the closed session, only matters covered in the statement may be discussed. (§11126.3(b))

3. The agency is required to designate a staff person to attend the closed session and to record in a minute book a record of topics discussed and decisions made. (§11126.1)

4. The minute book referenced in (3) is available only to members of the agency, or if a violation of the Open Meeting Act is alleged, to a court of general jurisdiction. (§11126.1)

5. Information received and discussions held in closed session are **confidential** and must not be disclosed to outside parties by members or staff who attended the closed session. A recent opinion of the Office of the California Attorney General concluded that:

> " A local school board member may not publicly disclose information that has been received and discussed in closed session concerning pending litigation unless the information is authorized by law to be disclosed." (80 Ops.Cal.Atty.Gen. 231)

That opinion also cited a previous opinion, in which the Attorney General stated that "We have ... routinely observed that it would be *improper* for information received during a closed session to be publicly disclosed." (76 Ops.Cal.Atty.Gen. 289, 290-291; Emphasis in the original.)

V. MEETING BY TELECONFERENCING

Prior to January 1, 1995, the Bagley-Keene Open Meeting Act contained no provision for conducting meetings where the participating members were not physically present in one location.

Effective 1/1/95, subdivision (b) was added to Government Code section 11123 to authorize meetings by teleconference. (Stats. 1994, Chapt. 1153; AB 3467) That subdivision has been amended several times, most recently by AB 192 of 2001, and it currently provides:

> "(a) All meetings of a state body shall be open and public and all persons shall be permitted to attend any meeting of a state body except as otherwise provided in this article.
>
> "(b) (1) This article does not prohibit a state body from holding an open or closed meeting by teleconference for the benefit of the public and state body. The meeting or proceeding held by teleconference shall

otherwise comply with all applicable requirements or laws relating to a specific type of meeting or proceeding, including the following:

(A) The teleconferencing meeting shall comply with all requirements of this article applicable to other meetings.

(B) The portion of the teleconferenced meeting that is required to be open to the public shall be audible to the public at the location specified in the notice of the meeting.

(C) If the state body elects to conduct a meeting or proceeding by teleconference, it shall post agendas at all teleconference locations and conduct teleconference meetings in a manner that protects the rights of any party or member of the public appearing before the state body. Each teleconference location shall be identified in the notice and agenda of the meeting or proceeding, and each teleconference location shall be accessible to the public. The agenda shall provide an opportunity for members of the public to address the state body directly pursuant to Section 11125.7 at each teleconference location.

(D) All votes taken during a teleconferenced meeting shall be by rollcall.

(E) The portion of the teleconferenced meeting that is closed to the public may not include the consideration of any agenda item being heard pursuant to Section 11125.5.

(F) At least one member of the state body shall be physically present at the location specified in the notice of the meeting.

(2) For the purposes of this subdivision, 'teleconference' means a meeting of a state body, the members of which are at different locations, connected by electronic means, through either audio or both audio and video. This section does not prohibit a state body from providing members of the public with additional locations in which the public may observe or address the state body by electronic means, through either audio or both audio and video."

A method is thus available whereby meetings may be conducted by audio or video teleconferencing provided the criteria set forth in the statute have been met. Note the restriction in subdivision (b)(1)(E) that prohibits a closed session emergency meeting. Emergency meetings in open session may be conducted by teleconference.

We emphasize that the law now requires every teleconference meeting location to be identified in the notice and agenda and to be open to the public. Most importantly, the members of the agency must attend the meeting at a public location. Members are no longer able to attend the meeting via teleconference from their offices, homes, or other convenient location unless those locations are identified in the notice

and agenda, and the public is permitted to attend at those locations. Nothing prohibits additional locations, where only the public is connected to the teleconference meeting. (§11123(b)(2))

VI. DELIBERATIONS AND VOTING

Keep in mind the Open Meeting Act declaration of legislative intent that actions of state agencies be taken openly and that their deliberation be conducted openly. (§11120) In this regard, there are a number of provisions in the Open Meeting Act which address deliberations and voting.

A. Seriatim Calls to Individual Agency Members Prohibited

Except as authorized by the above-discussed teleconferencing statutes, telephone conference calls may not be used to avoid the requirements of the Open Meeting Act. A conference call including members of a board, committee, subcommittee or task force sufficient to constitute a majority of that state body is prohibited, except pursuant to an authorized teleconference meeting.

In a case involving the Ralph M. Brown Act, the court concluded that a series of one-to-one telephone calls between members of a local body, where the purpose of the calls was to obtain a collective commitment on an issue, constituted a violation of the Act. (*Stockton Newspapers, Inc. v. Members of the Redevelopment Agency of the City of Stockton* (1985) 171 Cal.App.3d 95) The Brown Act is the local agency counterpart to the Bagley-Keene Open Meeting Act, and decisions rendered on its provisions are frequently followed in Open Meeting Act cases.

Citing the *Stockton Newspapers, Inc.* case, the court *in Sutter Bay Associates v. County of Sutter* held that to prevent evasion of the Brown Act, a series of private meetings (known as serial meetings) by which a majority of the members of the legislative body commit themselves to a decision concerning public business or engage in collective deliberation on public business would violate the open meeting requirement. ((1997) 58 Cal.App.4th 860, 877, 68 Cal.Rptr.2d 492, 502)

B. E-Mail Prohibition

AB 192 of 2001 added subdivision (b) to section 11122.5 to provide:

> "Except as authorized pursuant to Section 11123, any use of direct communication, personal intermediaries, or technological devices that is employed by a majority of the members of the state body to develop a collective concurrence as to action to be taken on an item by the members of the state body is prohibited."

The enactment of subdivision (b) of section 11122.5, expands upon and confirms a recent opinion of the Attorney General prohibiting the use of e-mail

to reach a collective decision outside a regularly scheduled meeting. In 84 Ops.Cal.Atty.Gen. 30, the Attorney General concluded that:

> "A majority of the board members of a local public agency may not e-mail each other to develop a collective concurrence as to action to be taken by the board without violating the Ralph M. Brown Act even if the e-mails are also sent to the secretary and chairperson of the agency, the e-mails are posted on the agency's Internet website, and a printed version of each e-mail is reported at the next public meeting of the board."

As noted above, interpretations of the Brown Act, which governs local public agencies, are often cited as authority in interpreting similar provisions of the Bagley-Keene Open Meeting Act.

Members of a board must refrain from calling or otherwise contacting other members on a one-to-one basis, or conducting serial meetings, in order to arrive at a collective decision outside the meeting on a matter pending before the board.

C. Secret Ballot Prohibited

An agency may not vote by secret ballot in a public meeting nor vote in closed session on any matter where discussion, deliberations, or action taken is required to be in an open meeting. (68 Ops.Cal.Atty.Gen. 65, 69)

For example, the election of board officers may not be conducted by secret ballot or in closed session.

D. Voting by Proxy Prohibited

Voting by proxy is not authorized. (68 Ops.Cal.Atty.Gen. 65, 70)

E. Voting by Mail on Administrative Disciplinary Matters

As a general rule, all voting on items of business to be transacted must be done at a public meeting. However, the Administrative Procedure Act authorizes mail voting on all questions arising under that act. (Govt. Code §11526.) Thus, board members may vote by mail on proposed decisions, stipulated decisions, and other matters in connection with a formal disciplinary case. No other votes may be cast by mail. (68 Ops.Cal.Atty.Gen. 65, 69)

VII. MISCELLANEOUS PROVISIONS

There are several provisions governing public meetings which do not fit under any of the above headings, but of which you should be aware.

A. Conforming Board Member's Conduct

Any person who has been appointed as a member of a state body, who has not yet assumed the duties of the office, must conform his or her conduct to the provisions of the Open Meeting Act. (§11125.95

B. Providing Open Meeting Act to New Board Members

A copy of the Bagley-Keene Open Meeting Act must be provided to each agency member upon his or her appointment to office. Each agency should insure that a copy is given to each new member. (§11121.9.)

C. Prohibition on Placing Conditions on Public's Attendance

1. Sign-in

No person can be required to register or sign-in or fulfill any other condition in order to attend a public meeting of an agency. While a person who wishes to make public comment may be asked to identify himself or herself for the board's record or minutes, a commenter cannot be compelled to do so or prevented from speaking because the commenter refuses to identify himself or herself.

If an attendance list, register, questionnaire, or other similar document is posted at or near the entrance to the room where the meeting is to be held, or is circulated to persons present during the meeting, "it shall state clearly that the signing, registering, or completion of the document is voluntary, and that all persons may attend the meeting regardless of whether a person signs, registers, or completes the document." (§11124)

2. Discrimination in Admittance to Meeting Facility

A meeting may not be held in any facility that prohibits the admittance of any persons on the basis of race, religious creed, color, national origin, ancestry, or sex. (§11131)

3. Access for the Disabled

All meetings must be accessible to the disabled. (§11131)

4. Charging a Fee or Requiring a Purchase for Access

The Open Meeting Act prohibits holding a meeting in any location where the public is required to pay a fee or make a purchase to attend. (§11131)

D. Agency Recording of the Proceedings

A tape or film record of an open and public meeting made by the agency must be made available for public inspection under the California Public Records Act, but may

be erased or destroyed 30 days after the taping or recording. An inspection must be provided without charge on an audio or video tape player made available by the state agency. (§11124.1(b))

E. Public's Right to Record the Proceedings

Persons attending a public meeting have a right to record the proceedings with an audio or video tape recorder or still or motion picture camera, in the absence of a reasonable finding by the agency that the recording could not continue without noise, illumination, or obstruction of view that constitutes, or would constitute, a persistent disruption of the proceedings. (§11124.1(a))

F. Media Broadcast of the Proceedings

A state body may not prohibit or otherwise restrict the broadcast of a public meeting in the absence of a reasonable finding that the broadcast cannot be accomplished without noise, illumination, or obstruction of view that would constitute a persistent disruption of the proceedings. (§11124.1(c))

G. Taking Agenda Items Out of Order

Items listed on the agenda may be taken up out of order, provided the purpose of moving the agenda items is not to frustrate public or other input on the item. It is a good practice to note on either the top or the bottom of your agenda that "All times indicated and the order of business are approximate and subject to change," to alert members of the public this is a possibility.

If your agency schedules a multiple day meeting and may move items scheduled for a subsequent day to an earlier day, you should provide notice of this possibility on your agenda. Suggested language is that "Items scheduled for a particular day may be moved to an earlier day to facilitate the board's business." Again, the purpose may not be to frustrate public or other input.

H. Opportunity for Public Comment at Meetings

Section 11125.7 addresses the subject of public comment at board meetings. With specified exceptions, that section requires state agencies to provide an opportunity for members of the public to directly address the state agency on each agenda item before or during the agency's discussion or consideration of the item. This opportunity for comment need not be made available if:

1. The agenda item has previously been considered at a public meeting by a committee comprised exclusively of board members, where members of the public were provided an opportunity to address the item. However, if the item has been substantially changed since the committee meeting, a new opportunity to address the agency would be required at the full board meeting.

2. The agenda item is one that may properly be considered in closed session, which would include deliberation and action on disciplinary proceedings under the Administrative Procedure Act. (§11125.7)

If a board wishes to establish a standing rule that discussion of agenda items will be given a specified amount of time, or that public comment will be limited to a certain amount of time, the board may do that by adopting an administrative regulation. (§11125.7(b))

The law specifically provides that a state agency may not prohibit public criticism of its policies, programs, or services, or of the acts or omissions of the agency. (§11125.7(c))

VIII. DISCLOSURE OF DOCUMENTS

A. Documents Distributed Prior to the Meeting

When writings which are public records are distributed to all, or a majority of all, of the members of a board or committee for discussion or consideration at a public meeting, the writings must be made available for public inspection. Generally, the records must be made available for inspection at the time of distribution to agency members. (§11125.1(a)) Records exempt from disclosure under Sections 6253.5, 6254 or 6254.7 of the Public Records Act need not be disclosed even though the subject matter of the records may be considered or discussed at the meeting. This includes records which are drafts, notes or memoranda which will not be retained by the agency, records of pending litigation and claims against the state, personnel, medical or similar files, complaint and investigation files, except for Accusations and Proposed Decisions, and any records or data relating to examinations.

B. Documents Distributed During the Meeting

When public records pertaining to an agenda item are prepared by the state body or a member of the state body, and distributed to state body members during a meeting, the documents must be made available for public inspection at the meeting. If records are prepared by some other person, and distributed to members of the state body during a meeting, the documents must be made available for public inspection after the meeting. (§11125.1(b)) Records exempt from public disclosure under specified statutes are not required to be publicly disclosed. (§11125.1(a), (b))

C. Charging a Fee for Public Documents

Under section 11126.7, an agency may not charge a fee for a notice, including the agenda, of a meeting, and may only charge those fees specifically authorized for public documents that are considered at the meeting

At its discretion, an agency may charge a fee to cover reproduction costs for providing the documents required to be made available, as discussed in paragraph (B), immediately above. If an agency charges a fee, it is limited to the direct costs of duplication authorized in Section 6257 for the reproduction of public records. (§11125.1(c))

Effective January 1, 2003, documents distributed prior to or during a meeting that are public records must be made available, upon request by a person with a disability, in appropriate alternative formats. No extra charge can be imposed for putting those documents into an alternative format.

IX. PENALTIES

Under previous law, any interested person could commence court action (mandamus, injunction, declaratory relief) to stop or prevent violations or threatened violations of the Open Meeting Act. SB 95, effective 1/1/98, added the Attorney General and the district attorney to the list of those who may commence such action. Court costs and reasonable attorney's fees may be awarded to a successful plaintiff to be paid from the funds of the agency. (§11130.5)

SB 95 also expanded the law to authorize the Attorney General, a district attorney, or any interested person to seek court action "to determine whether any rule or action by the state body to penalize or otherwise discourage the expression of one or more of its members is valid or invalid under the laws of this state or of the United States, ..." (§11130(a)) This appears to be a rather unique provision, and its implications are unknown at this time.

SB 95 further expanded the law to authorize the Attorney General, a district attorney, or any interested person to seek a court action to compel a state agency to tape record its closed sessions. Upon a judgment of a violation of Section 11126, a court could so compel an agency. Discovery procedures for the tape recordings are also set forth. (§11130(b), and (c))

Section 11130.3 authorizes a person to institute a court action to obtain a judicial determination that an action taken in violation of the notice provisions or the provisions governing closed sessions of the Act is null and void. Court costs and reasonable attorney's fees may also be awarded to a successful plaintiff under this section. This section reinforces the need for a specific, informative agenda as required by Section 11125.

In *Regents of the University of California v. Superior Court (Molloy)*. the California Supreme Court held the remedies under the Bagley-Keene Open Meeting Act applied only to present and future violations, and that the 30-day statute of limitations for bringing an action against an agency for violations of the Act could not be extended. ((1999) 20 Cal.4th 509, 85 Cal.Rptr.2d 257)

AB 1234 amended the Open Meeting Act effective January 1, 2000, to provide that the remedies extend to past actions of an agency, and extends the statute of limitations for brining an action from 30 days to 90 days. (§§11130(c) and 11130.3(a), respectively) The bill states its intent is to expressly supersede the holding in the *Regents v. Superior Court (Molloy)* case.

Section 11130.7 of the Act provides:

> "Each member of a state body who attends a meeting of such body in violation of any provision of this article, and where the member intends to deprive the public of information to which the member knows or has reason to know the public is entitled, is guilty of a misdemeanor." (Emphasis added.)

The Legal Division trusts this guide will be of assistance in answering those questions which frequently arise concerning meetings of your agency. If you have any questions, please contact your assigned Legal Division attorney.

BAGLEY-KEENE OPEN MEETING ACT - 2009

11120. Public policy; legislative finding and declaration; citation of article

It is the public policy of this state that public agencies exist to aid in the conduct of the people's business and the proceedings of public agencies be conducted openly so that the public may remain informed.

In enacting this article the Legislature finds and declares that it is the intent of the law that actions of state agencies be taken openly and that their deliberation be conducted openly.

The people of this state do not yield their sovereignty to the agencies which serve them. The people, in delegating authority, do not give their public servants the right to decide what is good for the people to know and what is not good for them to know. The people insist on remaining informed so that they may retain control over the instruments they have created.

This article shall be known and may be cited as the Bagley-Keene Open Meeting Act.

(Added by Stats.1967, c. 1656, p. 4026, § 122. Amended by Stats.1980, c. 1284, p. 4333, § 4; Stats. 1981, c. 968, p. 3683, § 4.)

11121. State body defined

As used in this article, "state body" means each of the following:

(a) Every state board, or commission, or similar multimember body of the state that is created by statute or required by law to conduct official meetings and every commission created by executive order.

(b) A board, commission, committee, or similar multimember body that exercises any authority of a state body delegated to it by that state body.

(c) An advisory board, advisory commission, advisory committee, advisory subcommittee, or similar multimember advisory body of a state body, if created by formal action of the state body or of any member of the state body, and if the advisory body so created consists of three or more persons.

(d) A board, commission, committee, or similar multimember body on which a member of a body that is a state body pursuant to this section serves in his or her official capacity as a representative of that state body and that is supported, in whole or in part, by funds provided by the state body, whether the multimember body is organized and operated by the state body or by a private corporation.

(Added by Stats.1967, c. 1656, p. 4026, § 122. Amended by Stats.1980, c. 515, § 1; Stats.1981, c. 968, p. 3683, § 5; Stats.1984, c. 193, § 38. Amended by Stats.1996, c. 1023 (S.B.1497), § 88, eff. Sept. 29, 1996; Stats.1996, c. 1064 (A.B.3351), § 783.1, operative July 1, 1997; Stats.2001, c. 243 (A.B.192), § 1; Amended Stats. 2003 ch 62 § 117 (SB 600)).

11121.1. State body; exclusions

As used in this article, "state body" does not include any of the following:

(a) State agencies provided for in Article VI of the California Constitution.

(b) Districts or other local agencies whose meetings are required to be open to the public pursuant to the Ralph M. Brown Act (Chapter 9 (commencing with Section 54950) of Part 1 of Division 2 of Title 5).

(c) State agencies provided for in Article IV of the California Constitution whose meetings are required to be open to the public pursuant to the Grunsky-Burton Open Meeting Act (Article 2.2 (commencing with Section 9027) of Chapter 1.5 of Part 1 of Division 2 of Title 2).

(d) State agencies when they are conducting proceedings pursuant to Section 3596.

(e) State agencies provided for in Section 109260 of the Health and Safety Code, except as provided in Section 109390 of the Health and Safety Code.

(f) The Credit Union Advisory Committee established pursuant to Section 14380 of the Financial Code.

(Added by Stats.2001, c. 243 (A.B.192), § 2. Amended by Stats. 2008, c. 344 (S.B. 1145), § 2, eff. Sept. 26, 2008.)

11121.2. Repealed by Stats. 2001, c. 243 (A.B.192), § 3

The repealed section, added by Stats.1981, c. 968, p. 3684, § 5.2, related to multimember body with authority from state body.

11121.7. Repealed by Stats. 2001, c. 243 (A.B.192), § 4

The repealed section, added by Stats.1980, c. 1284, p. 4333, § 5, amended by Stats.1981, c. 968, p. 3685, § 6, related to representatives of the state body.

11121.8. Repealed by Stats. 2001, c. 243 (A.B.192), § 5

The repealed section, added by Stats.1981, c. 968, p. 3684, § 7, related to advisory bodies.

11121.9. Provision of copy of article to members of state body

Each state body shall provide a copy of this article to each member of the state body upon his or her appointment to membership or assumption of office.

(Added by Stats.1980, c. 1284, p. 4334, § 6. Amended by Stats.1981, c. 714, p. 2659, § 175; Stats.1981, c. 968, p. 3685, § 7.1.)

11121.95. Appointees or elected officials not yet in office; conformity of conduct to article requirements

Any person appointed or elected to serve as a member of a state body who has not yet assumed the duties of office shall conform his or her conduct to the requirements of this article and shall be treated for purposes of this article as if he or she has already assumed office.

(Added by Stats.1997, c. 949 (S.B.95), § 1.)

11122. Action taken

As used in this article "action taken" means a collective decision made by the members of a state body, a collective commitment or promise by the members of the state body to make a positive or negative decision or an actual vote by the members of a state body when sitting as a body or entity upon a motion, proposal, resolution, order or similar action.

(Added by Stats.1967, c. 1656, p. 4026, § 122. Amended by Stats.1981, c. 968, p. 3685, § 7.3.)

11122.5. Meeting defined; collective concurrence prohibited; exceptions

(a) As used in this article, "meeting" includes any congregation of a majority of the members of a state body at the same time and place to hear, discuss, or deliberate upon any item that is within the subject matter jurisdiction of the state body to which it pertains.

(b) Except as authorized pursuant to Section 11123, any use of direct communication, personal intermediaries, or technological devices that is employed by a majority of the members of the state body to develop a collective concurrence as to action to be taken on an item by the members of the state body is prohibited.

(c) The prohibitions of this article do not apply to any of the following:

(1) Individual contacts or conversations between a member of a state body and any other person.

(2) The attendance of a majority of the members of a state body at a conference or similar gathering open to the public that involves a discussion of issues of general interest to the public or to public agencies of the type represented by the state body, provided that a majority of the members do not discuss among themselves, other than as part of the scheduled program, business of a specified nature that is within the subject matter jurisdiction of the state body. This paragraph is not intended to allow members of the public free admission to a conference or similar gathering at which the organizers have required other participants or registrants to pay fees or charges as a condition of attendance.

(3) The attendance of a majority

of the members of a state body at an open and publicized meeting organized to address a topic of state concern by a person or organization other than the state body, provided that a majority of the members do not discuss among themselves, other than as part of the scheduled program, business of a specific nature that is within the subject matter jurisdiction of the state body.

(4) The attendance of a majority of the members of a state body at an open and noticed meeting of another state body or of a legislative body of a local agency as defined by Section 54951, provided that a majority of the members do not discuss among themselves, other than as part of the scheduled meeting, business of a specific nature that is within the subject matter jurisdiction of the other state body.

(5) The attendance of a majority of the members of a state body at a purely social or ceremonial occasion, provided that a majority of the members do not discuss among themselves business of a specific nature that is within the subject matter jurisdiction of the state body.

(6) The attendance of a majority of the members of a state body at an open and noticed meeting of a standing committee of that body, provided that the members of the state body who are not members of the standing committee attend only as observers.

(Added by Stats.2001, c. 243 (A.B.192), § 6.)

11123. Meetings; attendance; teleconference option

(a) All meetings of a state body shall be open and public and all persons shall be permitted to attend any meeting of a state body except as otherwise provided in this article.

(b)(1) This article does not prohibit a state body from holding an open or closed meeting by teleconference for the benefit of the public and state body. The meeting or proceeding held by teleconference shall otherwise comply with all applicable requirements or laws relating to a specific type of meeting or proceeding, including the following:

(A) The teleconferencing meeting shall comply with all requirements of this article applicable to other meetings.

(B) The portion of the teleconferenced meeting that is required to be open to the public shall be audible to the public at the location specified in the notice of the meeting.

(C) If the state body elects to conduct a meeting or proceeding by teleconference, it shall post agendas at all teleconference locations and conduct teleconference meetings in a manner that protects the rights of any party or member of the public appearing before the state body. Each teleconference location shall be identified in the notice and agenda of the meeting or proceeding, and each teleconference location shall be accessible to the

public. The agenda shall provide an opportunity for members of the public to address the state body directly pursuant to Section 11125.7 at each teleconference location.

(D) All votes taken during a teleconferenced meeting shall be by rollcall.

(E) The portion of the teleconferenced meeting that is closed to the public may not include the consideration of any agenda item being heard pursuant to Section 11125.5.

(F) At least one member of the state body shall be physically present at the location specified in the notice of the meeting.

(2) For the purposes of this subdivision, "teleconference" means a meeting of a state body, the members of which are at different locations, connected by electronic means, through either audio or both audio and video. This section does not prohibit a state body from providing members of the public with additional locations in which the public may observe or address the state body by electronic means, through either audio or both audio and video.

(Added by Stats.1967, c. 1656, p. 4026, § 122. Amended by Stats.1981, c. 968, p. 3685, § 7.5. Amended by Stats.1994, c. 1153 (A.B.3467), § 1; Stats.1997, c. 52 (A.B.1097), § 1; Stats.2001, c. 243 (A.B.192), § 7.)

11123.1. State body meetings to meet protections and prohibitions of the Americans with Disabilities Act

All meetings of a state body that are open and public shall meet the protections and prohibitions contained in Section 202 of the Americans with Disabilities Act of 1990 (42 U.S.C. Sec. 12132), and the federal rules and regulations adopted in implementation thereof.

(Added by Stats. 2002, c. 300 (A.B. 3035), § 1.)

11124. Conditions to attendance

No person shall be required, as a condition to attendance at a meeting of a state body, to register his or her name, to provide other information, to complete a questionnaire, or otherwise to fulfill any condition precedent to his or her attendance.

If an attendance list, register, questionnaire, or other similar document is posted at or near the entrance to the room where the meeting is to be held, or is circulated to persons present during the meeting, it shall state clearly that the signing, registering, or completion of the document is voluntary, and that all persons may attend the meeting regardless of whether a person signs, registers, or completes the document.

(Added by Stats.1967, c. 1656, p. 4026, § 122. Amended by Stats.1981, c. 968, p. 3685, § 8.)

11124.1. Tape or film recording of proceedings; inspection of state's recording; broadcast restrictions

(a) Any person attending an open and public meeting of the state body shall have the right to record the proceedings with an audio or video tape recorder or a still or motion picture camera in the absence of a reasonable finding by the state body that the recording cannot continue without noise, illumination, or obstruction of view that constitutes, or would constitute, a persistent disruption of the proceedings.

(b) Any tape or film record of an open and public meeting made for whatever purpose by or at the direction of the state body shall be subject to inspection pursuant to the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1), but may be erased or destroyed 30 days after the taping or recording. Any inspection of an audio or video tape recording shall be provided without charge on an audio or video tape player made available by the state body.

(c) No state body shall prohibit or otherwise restrict the broadcast of its open and public meetings in the absence of a reasonable finding that the broadcast cannot be accomplished without noise, illumination, or obstruction of view that would constitute a persistent disruption of the proceedings.

(Added by Stats.1980, c. 1284, p. 4334, § 7. Amended by Stats.1981, c. 968, p. 3685, § 9. Amended by Stats.1997, c. 949 (S.B.95), § 2.)

11125. Notice of meeting

(a) The state body shall provide notice of its meeting to any person who requests that notice in writing. Notice shall be given and also made available on the Internet at least 10 days in advance of the meeting, and shall include the name, address, and telephone number of any person who can provide further information prior to the meeting, but need not include a list of witnesses expected to appear at the meeting. The written notice shall additionally include the address of the Internet site where notices required by this article are made available.

(b) The notice of a meeting of a body that is a state body shall include a specific agenda for the meeting, containing a brief description of the items of business to be transacted or discussed in either open or closed session. A brief general description of an item generally need not exceed 20 words. A description of an item to be transacted or discussed in closed session shall include a citation of the specific statutory authority under which a closed session is being held. No item shall be added to the agenda subsequent to the provision of this notice, unless otherwise permitted by this article.

(c) Notice of a meeting of a state body that complies with this section

shall also constitute notice of a meeting of an advisory body of that state body, provided that the business to be discussed by the advisory body is covered by the notice of the meeting of the state body, provided that the specific time and place of the advisory body's meeting is announced during the open and public state body's meeting, and provided that the advisory body's meeting is conducted within a reasonable time of, and nearby, the meeting of the state body.

(d) A person may request, and shall be provided, notice pursuant to subdivision (a) for all meetings of a state body or for a specific meeting or meetings. In addition, at the state body's discretion, a person may request, and may be provided, notice of only those meetings of a state body at which a particular subject or subjects specified in the request will be discussed.

(e) A request for notice of more than one meeting of a state body shall be subject to the provisions of Section 14911.

(f) The notice shall be made available in appropriate alternative formats, as required by Section 202 of the Americans with Disabilities Act of 1990 (42 U.S.C. Sec. 12132), and the federal rules and regulations adopted in implementation thereof, upon request, by any person with a disability. The notice shall include information regarding how, to whom, and by when a request for any disability-related modification or accommodation, including auxiliary aids or services may be made by a person with a disability who requires these aids or services in order to participate in the public meeting.

(Added by Stats.1967, c. 1656, p. 4026, § 122. Amended by Stats.1973, c. 1126, p. 2291, § 1; Stats.1975, c. 708, p. 1695, § 1; Stats.1979, c. 284, § 1, eff. July 24, 1979; Stats.1981, c. 968, p. 3685, § 10. Amended by Stats.1997, c. 949 (S.B.95), § 3; Stats.1999, c. 393 (A.B.1234), § 1; Stats.2001, c. 243 (A.B.192), § 8; Stats. 2002, c. 300 (A.B. 3035), § 2.)

11125.1. Agendas and other writings distributed for discussion or consideration at public meetings; public records; Franchise Tax Board; inspection; availability on the Internet; closed sessions

(a) Notwithstanding Section 6255 or any other provisions of law, agendas of public meetings and other writings, when distributed to all, or a majority of all, of the members of a state body by any person in connection with a matter subject to discussion or consideration at a public meeting of the body, are disclosable public records under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1), and shall be made available upon request without delay. However, this section shall not include any writing exempt from public disclosure under Section 6253.5, 6254, or 6254.7 of this code, or Section 489.1 or 583 of the Public Utilities Code.

(b) Writings that are public

records under subdivision (a) and that are distributed to members of the state body prior to or during a meeting, pertaining to any item to be considered during the meeting, shall be made available for public inspection at the meeting if prepared by the state body or a member of the state body, or after the meeting if prepared by some other person. These writings shall be made available in appropriate alternative formats, as required by Section 202 of the American with Disabilities Act of 1990 (42 U.S.C. Sec. 12132), and the federal rules and regulations adopted in implementation thereof, upon request by a person with a disability.

(c) In the case of the Franchise Tax Board, prior to that state body taking final action on any item, writings pertaining to that item that are public records under subdivision (a) that are prepared and distributed to members of the state body by the Franchise Tax Board staff or individual members prior to or during a meeting shall be:

(1) Made available for public inspection at that meeting.

(2) Distributed to all persons who request notice in writing pursuant to subdivision (a) of Section 11125.

(3) Made available on the Internet.

(d) Prior to the State Board of Equalization taking final action on any item that does not involve a named tax or fee payer, writings pertaining to that item that are public records under subdivision (a) that are prepared and distributed by board staff or individual members to members of the state body prior to or during a meeting shall be:

(1) Made available for public inspection at that meeting.

(2) Distributed to all persons who request or have requested copies of these writings.

(3) Made available on the Internet.

(e) Nothing in this section shall be construed to prevent a state body from charging a fee or deposit for a copy of a public record pursuant to Section 6253, except that no surcharge shall be imposed on persons with disabilities in violation of Section 202 of the Americans with Disabilities Act of 1990 (42 U.S.C. Sec. 12132), and the federal rules and regulations adopted in implementation thereof. The writings described in subdivision (b) are subject to the requirements of the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1), and shall not be construed to limit or delay the public's right to inspect any record required to be disclosed by that act, or to limit the public's right to inspect any record covered by that act. This section shall not be construed to be applicable to any writings solely because they are properly discussed in a closed session of a state body. Nothing in this article shall be construed to require a state

body to place any paid advertisement or any other paid notice in any publication.

(f) "Writing" for purposes of this section means " writing" as defined under Section 6252.

(Added by Stats.1975, c. 959, p. 2238, § 4. Amended by Stats.1980, c. 1284, p. 4334, § 8; Stats.1981, c. 968, p. 3686, § 10.1. Amended by Stats.1997, c. 949 (S.B.95), § 4; Stats.2001, c. 670 (S.B.445), § 1; Stats. 2002, c. 300 (A.B. 3035), § 3.5.); Stats. 2005, c. 188 (A.B. 780), § 1.)

11125.2. Appointment, employment or dismissal of public employees; closed sessions; public report

Any state body shall report publicly at a subsequent public meeting any action taken, and any rollcall vote thereon, to appoint, employ, or dismiss a public employee arising out of any closed session of the state body.

(Added by Stats.1980, c. 1284, p. 4335, § 9. Amended by Stats.1981, c. 968, p. 3687, § 10.3.)

11125.3. Action on items of business not appearing on agenda; notice

(a) Notwithstanding Section 11125, a state body may take action on items of business not appearing on the posted agenda under any of the conditions stated below:

(1) Upon a determination by a majority vote of the state body that an emergency situation exists, as defined in Section 11125.5.

(2) Upon a determination by a two-thirds vote of the state body, or, if less than two-thirds of the members are present, a unanimous vote of those members present, that there exists a need to take immediate action and that the need for action came to the attention of the state body subsequent to the agenda being posted as specified in Section 11125.

(b) Notice of the additional item to be considered shall be provided to each member of the state body and to all parties that have requested notice of its meetings as soon as is practicable after a determination of the need to consider the item is made, but shall be delivered in a manner that allows it to be received by the members and by newspapers of general circulation and radio or television stations at least 48 hours before the time of the meeting specified in the notice. Notice shall be made available to newspapers of general circulation and radio or television stations by providing that notice to all national press wire services. Notice shall also be made available on the Internet as soon as is practicable after the decision to consider additional items at a meeting has been made.

(Added by Stats.1994, c. 1153 (A.B.3467), § 2. Amended by Stats.2001, c. 243 (A.B.192), § 9.)

11125.4. Special meetings; authorized purposes; notice; required finding of hardship or need to protect public interest

(a) A special meeting may be called at any time by the presiding officer of the state body or by a majority of the members of the state body. A special meeting may only be called for one of the following purposes where compliance with the 10-day notice provisions of Section 11125 would impose a substantial hardship on the state body or where immediate action is required to protect the public interest:

(1) To consider "pending litigation" as that term is defined in subdivision (e) of Section 11126.

(2) To consider proposed legislation.

(3) To consider issuance of a legal opinion.

(4) To consider disciplinary action involving a state officer or employee.

(5) To consider the purchase, sale, exchange, or lease of real property.

(6) To consider license examinations and applications.

(7) To consider an action on a loan or grant provided pursuant to Division 31 (commencing with Section 50000) of the Health and Safety Code.

(8) To consider its response to a confidential final draft audit report as permitted by Section 11126.2.

(9) To provide for an interim executive officer of a state body upon the death, incapacity, or vacancy in the office of the executive officer.

(b) When a special meeting is called pursuant to one of the purposes specified in subdivision (a), the state body shall provide notice of the special meeting to each member of the state body and to all parties that have requested notice of its meetings as soon as is practicable after the decision to call a special meeting has been made, but shall deliver the notice in a manner that allows it to be received by the members and by newspapers of general circulation and radio or television stations at least 48 hours before the time of the special meeting specified in the notice. Notice shall be made available to newspapers of general circulation and radio or television stations by providing that notice to all national press wire services. Notice shall also be made available on the Internet within the time periods required by this section. The notice shall specify the time and place of the special meeting and the business to be transacted. The written notice shall additionally specify the address of the Internet Web site where notices required by this article are made available. No other business shall be considered at a special meeting by the state body. The written notice may be dispensed with as to any member who

at or prior to the time the meeting convenes files with the clerk or secretary of the state body a written waiver of notice. The waiver may be given by telegram, facsimile transmission, or similar means. The written notice may also be dispensed with as to any member who is actually present at the meeting at the time it convenes. Notice shall be required pursuant to this section regardless of whether any action is taken at the special meeting.

(c) At the commencement of any special meeting, the state body must make a finding in open session that the delay necessitated by providing notice 10 days prior to a meeting as required by Section 11125 would cause a substantial hardship on the body or that immediate action is required to protect the public interest. The finding shall set forth the specific facts that constitute the hardship to the body or the impending harm to the public interest. The finding shall be adopted by a two-thirds vote of the body, or, if less than two-thirds of the members are present, a unanimous vote of those members present. The finding shall be made available on the Internet. Failure to adopt the finding terminates the meeting.

(Added by Stats.1997, c. 949 (S.B.95), § 5. Amended by Stats.1999, c. 393 (A.B.1234), § 2; Stats.2004, c. 576 (A.B.1827), § 1.); Stats. 2007, c. 92 (S.B. 519), § 1.)

11125.5. Emergency meetings

(a) In the case of an emergency situation involving matters upon which prompt action is necessary due to the disruption or threatened disruption of public facilities, a state body may hold an emergency meeting without complying with the 10-day notice requirement of Section 11125 or the 48-hour notice requirement of Section 11125.4.

(b) For purposes of this section, "emergency situation" means any of the following, as determined by a majority of the members of the state body during a meeting prior to the emergency meeting, or at the beginning of the emergency meeting:

(1) Work stoppage or other activity that severely impairs public health or safety, or both.

(2) Crippling disaster that severely impairs public health or safety, or both.

(c) However, newspapers of general circulation and radio or television stations that have requested notice of meetings pursuant to Section 11125 shall be notified by the presiding officer of the state body, or a designee thereof, one hour prior to the emergency meeting by telephone. Notice shall also be made available on the Internet as soon as is practicable after the decision to call the emergency meeting has been made. If telephone services are not functioning, the notice requirements of

this section shall be deemed waived, and the presiding officer of the state body, or a designee thereof, shall notify those newspapers, radio stations, or television stations of the fact of the holding of the emergency meeting, the purpose of the meeting, and any action taken at the meeting as soon after the meeting as possible.

(d) The minutes of a meeting called pursuant to this section, a list of persons who the presiding officer of the state body, or a designee thereof, notified or attempted to notify, a copy of the rollcall vote, and any action taken at the meeting shall be posted for a minimum of 10 days in a public place, and also made available on the Internet for a minimum of 10 days, as soon after the meeting as possible.

(Amended by Stats.1992, c. 1312 (A.B.2912), § 11, eff. Sept. 30, 1992; Stats.1997, c. 949 (S.B.95), § 6; Stats.1999, c. 393 (A.B.1234), § 3.)

11125.6. Fish and Game Commission; emergency meetings; appeals of fishery closures or restrictions

(a) An emergency meeting may be called at any time by the president of the Fish and Game Commission or by a majority of the members of the commission to consider an appeal of a closure of or restriction in a fishery adopted pursuant to Section 7710 of the Fish and Game Code. In the case of an emergency situation involving matters upon which prompt action is necessary due to the disruption or threatened disruption of an established fishery, the commission may hold an emergency meeting without complying with the 10-day notice requirement of Section 11125 or the 48-hour notice requirement of Section 11125.4 if the delay necessitated by providing the 10-day notice of a public meeting required by Section 11125 or the 48-hour notice required by Section 11125.4 would significantly adversely impact the economic benefits of a fishery to the participants in the fishery and to the people of the state or significantly adversely impact the sustainability of a fishery managed by the state.

(b) At the commencement of an emergency meeting called pursuant to this section, the commission shall make a finding in open session that the delay necessitated by providing notice 10 days prior to a meeting as required by Section 11125 or 48 hours prior to a meeting as required by Section 11125.4 would significantly adversely impact the economic benefits of a fishery to the participants in the fishery and to the people of the state or significantly adversely impact the sustainability of a fishery managed by the state. The finding shall set forth the specific facts that constitute the impact to the economic benefits of the fishery or the sustainability of the fishery. The finding shall be adopted by a vote of at least four members of the commission, or, if less than four of the members are present, a unanimous vote of those members present. Failure to adopt the finding shall terminate the meeting.

(c) Newspapers of general circulation and radio or television stations that have requested notice of meetings pursuant to Section 11125 shall be notified by the presiding officer of the commission, or a designee thereof, one hour prior to the emergency meeting by telephone.

(d) The minutes of an emergency meeting called pursuant to this section, a list of persons who the president of the commission, or a designee thereof, notified or attempted to notify, a copy of the rollcall vote, and any action taken at the meeting shall be posted for a minimum of 10 days in a public place as soon after the meeting as possible.

(Added by Stats.1998, c. 1052 (A.B.1241), S 21.)

11125.7. Agenda item discussion before state body; opportunity for public address; regulation by state body; freedom of expression; application of provisions

(a) Except as otherwise provided in this section, the state body shall provide an opportunity for members of the public to directly address the state body on each agenda item before or during the state body's discussion or consideration of the item. This section is not applicable if the agenda item has already been considered by a committee composed exclusively of members of the state body at a public meeting where interested members of the public were afforded the opportunity to address the committee on the item, before or during the committee's consideration of the item, unless the item has been substantially changed since the committee heard the item, as determined by the state body. Every notice for a special meeting at which action is proposed to be taken on an item shall provide an opportunity for members of the public to directly address the state body concerning that item prior to action on the item. In addition, the notice requirement of Section 11125 shall not preclude the acceptance of testimony at meetings, other than emergency meetings, from members of the public, provided, however, that no action is taken by the state body at the same meeting on matters brought before the body by members of the public.

(b) The state body may adopt reasonable regulations to ensure that the intent of subdivision (a) is carried out, including, but not limited to, regulations limiting the total amount of time allocated for public comment on particular issues and for each individual speaker.

(c) The state body shall not prohibit public criticism of the policies, programs, or services of the state body, or of the acts or omissions of the state body. Nothing in this subdivision shall confer any privilege or protection for expression beyond that otherwise provided by law.

(d) This section is not applicable to closed sessions held pursuant to Section 11126.

(e) This section is not applicable to decisions regarding proceedings held pursuant to Chapter 5 (commencing with Section 11500), relating to administrative adjudication, or to the conduct of those proceedings.

(f) This section is not applicable to hearings conducted by the California Victim Compensation and Government Claims board pursuant to Sections 13963 and 13963.1.

(g) This section is not applicable to agenda items that involve decisions of the Public Utilities Commission regarding adjudicatory hearings held pursuant to Chapter 9 (commencing with Section 1701) of Part 1 of Division 1 of the Public Utilities Code. For all other agenda items, the commission shall provide members of the public, other than those who have already participated in the proceedings underlying the agenda item, an opportunity to directly address the commission before or during the commission's consideration of the item.

(Added by Stats.1993, c. 1289 (S.B.367), § 2. Amended by Stats.1995, c. 938 (S.B.523), § 13, operative July 1, 1997; Stats.1997, c. 949 (S.B.95), § 7.); Stats. 2006, c. 538 (S.B. 1852), § 248.)

11125.8. Hearings to consider crimes against minors or crimes of sexual assault or domestic violence; identification of applicant; disclosure of nature of hearing

(a) Notwithstanding Section 11131.5, in any hearing that the State California Victim Compensation and Government Claims Board conducts pursuant to Section 13963.1 and that the applicant or applicant's representative does not request be open to the public, no notice, agenda, announcement, or report required under this article need identify the applicant.

(b) In any hearing that the board conducts pursuant to Section 13963.1 and that the applicant or applicant's representative does not request be open to the public, the board shall disclose that the hearing is being held pursuant to Section 13963.1. That disclosure shall be deemed to satisfy the requirements of subdivision (a) of Section 11126.3.

(Added by Stats.1997, c. 949 (S.B.95), § 9.; Stats. 2006, c. 538 (S.B. 1852, § 249.)

11125.9. Regional water quality control boards; compliance with notification guidelines

Regional water quality control boards shall comply with the notification guidelines in Section 11125 and, in addition, shall do both of the following:

(a) Notify, in writing, all clerks of the city councils and county boards of

supervisors within the regional board's jurisdiction of any and all board hearings at least 10 days prior to the hearing. Notification shall include an agenda for the meeting with contents as described in subdivision (b) of Section 11125 as well as the name, address, and telephone number of any person who can provide further information prior to the meeting, but need not include a list of witnesses expected to appear at the meeting. Each clerk, upon receipt of the notification of a board hearing, shall distribute the notice to all members of the respective city council or board of supervisors within the regional board's jurisdiction.

(b) Notify, in writing, all newspapers with a circulation rate of at least 10,000 within the regional board's jurisdiction of any and all board hearings, at least 10 days prior to the hearing. Notification shall include an agenda for the meeting with contents as described in subdivision (b) of Section 11125 as well as the name, address, and telephone number of any person who can provide further information prior to the meeting, but need not include a list of witnesses expected to appear at the meeting.

(Added by Stats.1997, c. 301 (A.B.116), § 1.)

11126. Closed sessions

(a)(1) Nothing in this article shall be construed to prevent a state body from holding closed sessions during a regular or special meeting to consider the appointment, employment, evaluation of performance, or dismissal of a public employee or to hear complaints or charges brought against that employee by another person or employee unless the employee requests a public hearing.

(2) As a condition to holding a closed session on the complaints or charges to consider disciplinary action or to consider dismissal, the employee shall be given written notice of his or her right to have a public hearing, rather than a closed session, and that notice shall be delivered to the employee personally or by mail at least 24 hours before the time for holding a regular or special meeting. If notice is not given, any disciplinary or other action taken against any employee at the closed session shall be null and void.

(3) The state body also may exclude from any public or closed session, during the examination of a witness, any or all other witnesses in the matter being investigated by the state body.

(4) Following the public hearing or closed session, the body may deliberate on the decision to be reached in a closed session.

(b) For the purposes of this section, "employee" does not include any person who is elected to, or appointed to a public office by, any state body. However, officers of the California State University who receive compensation for their services, other than per diem and ordinary and

necessary expenses, shall, when engaged in that capacity, be considered employees. Furthermore, for purposes of this section, the term employee includes a person exempt from civil service pursuant to subdivision (e) of Section 4 of Article VII of the California Constitution.

(c) Nothing in this article shall be construed to do any of the following:

(1) Prevent state bodies that administer the licensing of persons engaging in businesses or professions from holding closed sessions to prepare, approve, grade, or administer examinations.

(2) Prevent an advisory body of a state body that administers the licensing of persons engaged in businesses or professions from conducting a closed session to discuss matters that the advisory body has found would constitute an unwarranted invasion of the privacy of an individual licensee or applicant if discussed in an open meeting, provided the advisory body does not include a quorum of the members of the state body it advises. Those matters may include review of an applicant's qualifications for licensure and an inquiry specifically related to the state body's enforcement program concerning an individual licensee or applicant where the inquiry occurs prior to the filing of a civil, criminal, or administrative disciplinary action against the licensee or applicant by the state body.

(3) Prohibit a state body from holding a closed session to deliberate on a decision to be reached in a proceeding required to be conducted pursuant to Chapter 5 (commencing with Section 11500) or similar provisions of law.

(4) Grant a right to enter any correctional institution or the grounds of a correctional institution where that right is not otherwise granted by law, nor shall anything in this article be construed to prevent a state body from holding a closed session when considering and acting upon the determination of a term, parole, or release of any individual or other disposition of an individual case, or if public disclosure of the subjects under discussion or consideration is expressly prohibited by statute.

(5) Prevent any closed session to consider the conferring of honorary degrees, or gifts, donations, and bequests that the donor or proposed donor has requested in writing to be kept confidential.

(6) Prevent the Alcoholic Beverage Control Appeals Board from holding a closed session for the purpose of holding a deliberative conference as provided in Section 11125.

(7)(A) Prevent a state body from holding closed sessions with its negotiator prior to the purchase, sale, exchange, or lease of real property by or for the state body to give instructions to its negotiator regarding the price and

terms of payment for the purchase, sale, exchange, or lease.

(B) However, prior to the closed session, the state body shall hold an open and public session in which it identifies the real property or real properties that the negotiations may concern and the person or persons with whom its negotiator may negotiate.

(C) For purposes of this paragraph, the negotiator may be a member of the state body.

(D) For purposes of this paragraph, "lease" includes renewal or renegotiation of a lease.

(E) Nothing in this paragraph shall preclude a state body from holding a closed session for discussions regarding eminent domain proceedings pursuant to subdivision (e).

(8) Prevent the California Postsecondary Education Commission from holding closed sessions to consider matters pertaining to the appointment or termination of the Director of the California Postsecondary Education Commission.

(9) Prevent the Council for Private Postsecondary and Vocational Education from holding closed sessions to consider matters pertaining to the appointment or termination of the Executive Director of the Council for Private Postsecondary and Vocational Education.

(10) Prevent the Franchise Tax Board from holding closed sessions for the purpose of discussion of confidential tax returns or information the public disclosure of which is prohibited by law, or from considering matters pertaining to the appointment or removal of the Executive Officer of the Franchise Tax Board.

(11) Require the Franchise Tax Board to notice or disclose any confidential tax information considered in closed sessions, or documents executed in connection therewith, the public disclosure of which is prohibited pursuant to Article 2 (commencing with Section 19542) of Chapter 7 of Part 10.2 of the Revenue and Taxation Code.

(12) Prevent the Corrections Standards Authority from holding closed sessions when considering reports of crime conditions under Section 6027 of the Penal Code.

(13) Prevent the State Air Resources Board from holding closed sessions when considering the proprietary specifications and performance data of manufacturers.

(14) Prevent the State Board of Education or the Superintendent of Public Instruction, or any committee advising the board or the superintendent, from holding closed sessions on those portions of its review of assessment instruments pursuant to Chapter 5 (commencing with Section 60600) of, or pursuant to Chapter 9

(commencing with Section 60850) of, Part 33 of the Education Code during which actual test content is reviewed and discussed. The purpose of this provision is to maintain the confidentiality of the assessments under review.

(15) Prevent the California Integrated Waste Management Board or its auxiliary committees from holding closed sessions for the purpose of discussing confidential tax returns, discussing trade secrets or confidential or proprietary information in its possession, or discussing other data, the public disclosure of which is prohibited by law.

(16) Prevent a state body that invests retirement, pension, or endowment funds from holding closed sessions when considering investment decisions. For purposes of consideration of shareholder voting on corporate stocks held by the state body, closed sessions for the purposes of voting may be held only with respect to election of corporate directors, election of independent auditors, and other financial issues that could have a material effect on the net income of the corporation. For the purpose of real property investment decisions that may be considered in a closed session pursuant to this paragraph, a state body shall also be exempt from the provisions of paragraph (7) relating to the identification of real properties prior to the closed session.

(17) Prevent a state body, or boards, commissions, administrative officers, or other representatives that may properly be designated by law or by a state body, from holding closed sessions with its representatives in discharging its responsibilities under Chapter 10 (commencing with Section 3500), Chapter 10.3 (commencing with Section 3512), Chapter 10.5 (commencing with Section 3525), or Chapter 10.7 (commencing with Section 3540) of Division 4 of Title 1 as the sessions relate to salaries, salary schedules, or compensation paid in the form of fringe benefits. For the purposes enumerated in the preceding sentence, a state body may also meet with a state conciliator who has intervened in the proceedings.

(18)(A) Prevent a state body from holding closed sessions to consider matters posing a threat or potential threat of criminal or terrorist activity against the personnel, property, buildings, facilities, or equipment, including electronic data, owned, leased, or controlled by the state body, where disclosure of these considerations could compromise or impede the safety or security of the personnel, property, buildings, facilities, or equipment, including electronic data, owned, leased, or controlled by the state body.

(B) Notwithstanding any other provision of law, a state body, at any regular or special meeting, may meet in a closed session pursuant to subparagraph (A) upon a two-thirds vote of the members present at the meeting.

(C) After meeting in closed session pursuant to subparagraph (A), the state body shall reconvene in open session prior to adjournment and report that a closed session was held pursuant to subparagraph (A), the general nature of the matters considered, and whether any action was taken in closed session.

(D) After meeting in closed session pursuant to subparagraph (A), the state body shall submit to the Legislative Analyst written notification stating that it held this closed session, the general reason or reasons for the closed session, the general nature of the matters considered, and whether any action was taken in closed session. The Legislative Analyst shall retain for no less than four years any written notification received from a state body pursuant to this subparagraph.

(d)(1) Notwithstanding any other provision of law, any meeting of the Public Utilities Commission at which the rates of entities under the commission's jurisdiction are changed shall be open and public.

(2) Nothing in this article shall be construed to prevent the Public Utilities Commission from holding closed sessions to deliberate on the institution of proceedings, or disciplinary actions against any person or entity under the jurisdiction of the commission.

(e)(1) Nothing in this article shall be construed to prevent a state body, based on the advice of its legal counsel, from holding a closed session to confer with, or receive advice from, its legal counsel regarding pending litigation when discussion in open session concerning those matters would prejudice the position of the state body in the litigation.

(2) For purposes of this article, all expressions of the lawyer-client privilege other than those provided in this subdivision are hereby abrogated. This subdivision is the exclusive expression of the lawyer-client privilege for purposes of conducting closed session meetings pursuant to this article. For purposes of this subdivision, litigation shall be considered pending when any of the following circumstances exist:

(A) An adjudicatory proceeding before a court, an administrative body exercising its adjudicatory authority, a hearing officer, or an arbitrator, to which the state body is a party, has been initiated formally.

(B)(i) A point has been reached where, in the opinion of the state body on the advice of its legal counsel, based on existing facts and circumstances, there is a significant exposure to litigation against the state body.

(ii) Based on existing facts and circumstances, the state body is meeting only to decide whether a closed session is authorized pursuant to clause (i).

(C)(i) Based on existing facts and circumstances, the state body has

decided to initiate or is deciding whether to initiate litigation.

(ii) The legal counsel of the state body shall prepare and submit to it a memorandum stating the specific reasons and legal authority for the closed session. If the closed session is pursuant to paragraph (1), the memorandum shall include the title of the litigation. If the closed session is pursuant to subparagraph (A) or (B), the memorandum shall include the existing facts and circumstances on which it is based. The legal counsel shall submit the memorandum to the state body prior to the closed session, if feasible, and in any case no later than one week after the closed session. The memorandum shall be exempt from disclosure pursuant to Section 6254.25.

(iii) For purposes of this subdivision, "litigation" includes any adjudicatory proceeding, including eminent domain, before a court, administrative body exercising its adjudicatory authority, hearing officer, or arbitrator.

(iv) Disclosure of a memorandum required under this subdivision shall not be deemed as a waiver of the lawyer-client privilege, as provided for under Article 3 (commencing with Section 950) of Chapter 4 of Division 8 of the Evidence Code.

(f) In addition to subdivisions (a), (b), and (c), nothing in this article shall be construed to do any of the following:

(1) Prevent a state body operating under a joint powers agreement for insurance pooling from holding a closed session to discuss a claim for the payment of tort liability or public liability losses incurred by the state body or any member agency under the joint powers agreement.

(2) Prevent the examining committee established by the State Board of Forestry and Fire Protection, pursuant to Section 763 of the Public Resources Code, from conducting a closed session to consider disciplinary action against an individual professional forester prior to the filing of an accusation against the forester pursuant to Section 11503.

(3) Prevent an administrative committee established by the California Board of Accountancy pursuant to Section 5020 of the Business and Professions Code from conducting a closed session to consider disciplinary action against an individual accountant prior to the filing of an accusation against the accountant pursuant to Section 11503. Nothing in this article shall be construed to prevent an examining committee established by the California Board of Accountancy pursuant to Section 5023 of the Business and Professions Code from conducting a closed hearing to interview an individual applicant or accountant regarding the applicant's qualifications.

(4) Prevent a state body, as defined in subdivision (b) of Section 11121, from conducting a closed

session to consider any matter that properly could be considered in closed session by the state body whose authority it exercises.

(5) Prevent a state body, as defined in subdivision (d) of Section 11121, from conducting a closed session to consider any matter that properly could be considered in a closed session by the body defined as a state body pursuant to subdivision (a) or (b) of Section 11121.

(6) Prevent a state body, as defined in subdivision (c) of Section 11121, from conducting a closed session to consider any matter that properly could be considered in a closed session by the state body it advises.

(7) Prevent the State Board of Equalization from holding closed sessions for either of the following:

(A) When considering matters pertaining to the appointment or removal of the Executive Secretary of the State Board of Equalization.

(B) For the purpose of hearing confidential taxpayer appeals or data, the public disclosure of which is prohibited by law.

(8) Require the State Board of Equalization to disclose any action taken in closed session or documents executed in connection with that action, the public disclosure of which is prohibited by law pursuant to Sections 15619 and 15641 of this code and Sections 833, 7056, 8255, 9255, 11655, 30455, 32455, 38705, 38706, 43651, 45982, 46751, 50159, 55381, and 60609 of the Revenue and Taxation Code.

(9) Prevent the California Earthquake Prediction Evaluation Council, or other body appointed to advise the Director of the Office of Emergency Services or the Governor concerning matters relating to volcanic or earthquake predictions, from holding closed sessions when considering the evaluation of possible predictions.

(g) This article does not prevent either of the following:

(1) The Teachers' Retirement Board or the Board of Administration of the Public Employees' Retirement System from holding closed sessions when considering matters pertaining to the recruitment, appointment, employment, or removal of the chief executive officer or when considering matters pertaining to the recruitment or removal of the Chief Investment Officer of the State Teachers' Retirement System or the Public Employees' Retirement System.

(2) The Commission on Teacher Credentialing from holding closed sessions when considering matters relating to the recruitment, appointment, or removal of its executive director.

(h) This article does not prevent the Board of Administration of the Public Employees' Retirement System from

holding closed sessions when considering matters relating to the development of rates and competitive strategy for plans offered pursuant to Chapter 15 (commencing with Section 21660) of Part 3 of Division 5 of Title 2.

(i) This article does not prevent the Managed Risk Medical Insurance Board from holding closed sessions when considering matters related to the development of rates and contracting strategy for entities contracting or seeking to contract with the board pursuant to Part 6.2 (commencing with Section 12693), Part 6.3 (commencing with Section 12695), Part 6.4 (commencing with Section 12699.50), or Part 6.5 (commencing with Section 12700) of Division 2 of the Insurance Code.

(j) Nothing in this article shall be construed to prevent the board of the State Compensation Insurance Fund from holding closed sessions in the following:

(1) When considering matters related to claims pursuant to Chapter 1 (commencing with Section 3200) of Division 4 of the Labor Code, to the extent that confidential medical information or other individually identifiable information would be disclosed.

(2) To the extent that matters related to audits and investigations that have not been completed would be disclosed.

(3) To the extent that an internal audit containing proprietary information would be disclosed.

(4) To the extent that the session would address the development of rates, contracting strategy, underwriting, or competitive strategy, pursuant to the powers granted to the board in Chapter 4 (commencing with Section 11770) of Part 3 of Division 2 of the Insurance Code, when discussion in open session concerning those matters would prejudice the position of the State Compensation Insurance Fund.

(k) The State Compensation Insurance Fund shall comply with the procedures specified in Section 11125.4 of the Government Code with respect to any closed session or meeting authorized by subdivision (j), and in addition shall provide an opportunity for a member of the public to be heard on the issue of the appropriateness of closing the meeting or session.

(Amended by Stats.1992, c. 1050 (A.B.2987), § 17; Stats.1994, c. 26 (A.B.1807), § 230, eff. March 30, 1994; Stats.1994, c. 422 (A.B.2589), § 15.5, eff. Sept. 7, 1994; Stats.1994, c. 845 (S.B.1316), § 1; Stats.1995, c. 975 (A.B.265), § 3; Stats.1996, c. 1041 (A.B.3358), § 2; Stats.1997, c. 949 (S.B.95), § 8; Stats.1998, c. 210 (S.B.2008), § 1; Stats.1998, c. 972 (S.B.989), § 1; Stats.1999, c. 735 (S.B.366), § 9, eff. Oct. 10, 1999; Stats.2000, c. 1002 (S.B.1998), § 1; Stats.2000, c. 1055 (A.B.2889), § 30, eff. Sept. 30, 2000; Stats.2001, c. 21 (S.B.54), § 1, eff. June 25, 2001; Stats.2001, c. 243 (A.B.192), § 10.; Stats. 2002, c. 664 (A.B. 3034), § 93.7; Stats. 2002, c. 1113 (A.B. 2072), § 1.); Stats. 2005, c. 288 (A.B. 277), § 1.); Stats. 2007, c. 577 (A.B. 1750), § 4, eff. Oct. 13, 2007;

Stats. 2008, c. 179 (S.B. 1498), § 91; Stats. 2008, c. 344 (S.B. 1145), § 3, eff. Sept. 26, 2008.)

11126.1. Record of topics discussed and decisions made at closed sessions; availability

The state body shall designate a clerk or other officer or employee of the state body, who shall then attend each closed session of the state body and keep and enter in a minute book a record of topics discussed and decisions made at the meeting. The minute book made pursuant to this section is not a public record subject to inspection pursuant to the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1), and shall be kept confidential. The minute book shall be available to members of the state body or, if a violation of this chapter is alleged to have occurred at a closed session, to a court of general jurisdiction. Such minute book may, but need not, consist of a recording of the closed session.

(Added by Stats.1980, c. 1284, p. 4340, § 12. Amended by Stats.1981, c. 968, p. 3691, § 13.)

11126.2. Closed session; response to confidential final draft audit report; public release of report

(a) Nothing in this article shall be construed to prohibit a state body that has received a confidential final draft audit report from the Bureau of State Audits from holding closed sessions to discuss its response to that report.

(b) After the public release of an audit report by the Bureau of State Audits, if a state body meets to discuss the audit report, it shall do so in an open session unless exempted from that requirement by some other provision of law.

(Added by Stats.2004, c. 576 (A.B.1827), § 2.)

11126.3. Disclosure of nature of items to be discussed in closed session; scope of session; notice of meeting; announcement of pending litigation; unnecessary disclosures; disclosures at open session following closed session

(a) Prior to holding any closed session, the state body shall disclose, in an open meeting, the general nature of the item or items to be discussed in the closed session. The disclosure may take the form of a reference to the item or items as they are listed by number or letter on the agenda. If the session is closed pursuant to paragraph (2) of subdivision (d) of Section 11126, the state body shall state the title of, or otherwise specifically identify, the proceeding or disciplinary action contemplated. However, should the body determine that to do so would jeopardize the body's ability to effectuate service of process upon one or more unserved parties if the proceeding or disciplinary action is commenced or that to do so would fail to protect the private economic and business reputation of the person or entity if the proceeding or disciplinary

action is not commenced, then the state body shall notice that there will be a closed session and describe in general terms the purpose of that session. If the session is closed pursuant to subparagraph (A) of paragraph (2) of subdivision (e) of Section 11126, the state body shall state the title of, or otherwise specifically identify, the litigation to be discussed unless the body states that to do so would jeopardize the body's ability to effectuate service of process upon one or more unserved parties, or that to do so would jeopardize its ability to conclude existing settlement negotiations to its advantage.

(b) In the closed session, the state body may consider only those matters covered in its disclosure.

(c) The disclosure shall be made as part of the notice provided for the meeting pursuant to Section 11125 or pursuant to subdivision (a) of Section 92032 of the Education Code and of any order or notice required by Section 11129.

(d) If, after the agenda has been published in compliance with this article, any pending litigation (under subdivision (e) of Section 11126) matters arise, the postponement of which will prevent the state body from complying with any statutory, court-ordered, or other legally imposed deadline, the state body may proceed to discuss those matters in closed session and shall publicly announce in the meeting the title of, or otherwise specifically identify, the litigation to be discussed, unless the body states that to do so would jeopardize the body's ability to effectuate service of process upon one or more unserved parties, or that to do so would jeopardize its ability to conclude existing settlement negotiations to its advantage. Such an announcement shall be deemed to comply fully with the requirements of this section.

(e) Nothing in this section shall require or authorize a disclosure of names or other information that would constitute an invasion of privacy or otherwise unnecessarily divulge the particular facts concerning the closed session or the disclosure of which is prohibited by state or federal law.

(f) After any closed session, the state body shall reconvene into open session prior to adjournment and shall make any reports, provide any documentation, and make any other disclosures required by Section 11125.2 of action taken in the closed session.

(g) The announcements required to be made in open session pursuant to this section may be made at the location announced in the agenda for the closed session, as long as the public is allowed to be present at that location for the purpose of hearing the announcement.

(Added by Stats.1980, c. 1284, p. 4341, § 13. Amended by Stats.1981, c. 968, p. 3692, § 14; Stats.1987, c. 1320, § 3. Amended by Stats.1997, c. 949 (S.B.95), § 10; Stats.1998, c. 210 (S.B.2008), § 2; Stats.2001, c. 243 (A.B.192), § 11.)

11126.4. Closed sessions of Gambling Control Commission; information prohibited from being disclosed by law or tribal-state gaming compact; limitations; public notice

(a) Nothing in this article shall be construed to prevent the California Gambling Control Commission from holding a closed session when discussing matters involving trade secrets, nonpublic financial data, confidential or proprietary information, and other date and information, the public disclosure of which is prohibited by law or a tribal-state gaming compact.

(b) Discussion in closed session authorized by this section shall be limited to the confidential data and information related to the agendized item and shall not include discussion of any other information or matter.

(c) Before going into closed session the commission shall publicly announce the type of data or information to be discussed in closed session, which shall be recorded upon the commission minutes.

(d) Action taken on agenda items discussed pursuant to this section shall be taken in open session.

(Added by Stats. 2005, c. 274 (S.B. 919), § 1.)

11126.5. Disorderly conduct of general public during meeting; clearing of room

In the event that any meeting is willfully interrupted by a group or groups of persons so as to render the orderly conduct of such meeting unfeasible and order cannot be restored by the removal of individuals who are willfully interrupting the meeting the state body conducting the meeting may order the meeting room cleared and continue in session. Nothing in this section shall prohibit the state body from establishing a procedure for readmitting an individual or individuals not responsible for willfully disturbing the orderly conduct of the meeting. Notwithstanding any other provision of law, only matters appearing on the agenda may be considered in such a session. Representatives of the press or other news media, except those participating in the disturbance, shall be allowed to attend any session held pursuant to this section.

(Added by Stats.1970, c. 1610, p. 3385, § 1. Amended by Stats.1981, c. 968, p. 3692, § 15.)

11126.7. Fees

No fees may be charged by a state body for providing a notice required by Section 11125 or for carrying out any provision of this article, except as specifically authorized pursuant to this article.

(Added by Stats.1980, c. 1284, p. 4341, § 14. Amended by Stats.1981, c. 968, p. 3692, § 16.)

11127. Application of article

Each provision of this article shall apply to every state body unless the body is specifically excepted from that provision by law or is covered by any other conflicting provision of law.

(Added by Stats.1967, c. 1656, p. 4026, § 122. Amended by Stats.1981, c. 968, p. 3692, § 17.)

11128. Time of closed session

Each closed session of a state body shall be held only during a regular or special meeting of the body.

(Added by Stats.1967, c. 1656, p. 4026, § 122. Amended by Stats.1980, c. 1284, p. 4341, § 15; Stats.1981, c. 968, p. 3692, § 18.)

11128.5. Adjournment; declaration; notice; hour for reconvened meeting

The state body may adjourn any regular, adjourned regular, special, or adjourned special meeting to a time and place specified in the order of adjournment. Less than a quorum may so adjourn from time to time. If all members are absent from any regular or adjourned regular meeting, the clerk or secretary of the state body may declare the meeting adjourned to a stated time and place and he or she shall cause a written notice of the adjournment to be given in the same manner as provided in Section 11125.4 for special meetings, unless that notice is waived as provided for special meetings. A copy of the order or notice of adjournment shall be conspicuously posted on or near the door of the place where the regular, adjourned regular, special, or adjourned special meeting was held within 24 hours after the time of the adjournment. When a regular or adjourned regular meeting is adjourned as provided in this section, the resulting adjourned regular meeting is a regular meeting for all purposes. When an order of adjournment of any meeting fails to state the hour at which the adjourned meeting is to be held, it shall be held at the hour specified for regular meetings by law or regulation.

(Added by Stats.1997, c. 949 (S.B.95), § 11.)

11129. Continuance; posting notice

Any hearing being held, or noticed or ordered to be held by a state body at any meeting may by order or notice of continuance be continued or recontinued to any subsequent meeting of the state body in the same manner and to the same extent set forth in Section 11128.5 for the adjournment of meetings. A copy of the order or notice of continuance shall be conspicuously posted on or near the door of the place where the hearing was held within 24 hours after the time of the continuance; provided, that if the hearing is continued to a time less than 24 hours after the time specified in the order or notice of hearing, a copy of the order or notice of continuance of hearing shall be

posted immediately following the meeting at which the order or declaration of continuance was adopted or made.

(Added by Stats.1967, c. 1656, p. 4026, § 122. Amended by Stats.1981, c. 968, p. 3692, § 19. Amended by Stats.1997, c. 949 (S.B.95), § 12.)

11130. Actions to prevent violations or determine applicability of article; validity of rules discouraging expression; taping of closed sessions; discovery procedures for tapes

(a) The Attorney General, the district attorney, or any interested person may commence an action by mandamus, injunction, or declaratory relief for the purpose of stopping or preventing violations or threatened violations of this article or to determine the applicability of this article to past actions or threatened future action by members of the state body or to determine whether any rule or action by the state body to penalize or otherwise discourage the expression of one or more of its members is valid or invalid under the laws of this state or of the United States, or to compel the state body to tape record its closed sessions as hereinafter provided.

(b) The court in its discretion may, upon a judgment of a violation of Section 11126, order the state body to tape record its closed sessions and preserve the tape recordings for the period and under the terms of security and confidentiality the court deems appropriate.

(c)(1) Each recording so kept shall be immediately labeled with the date of the closed session recorded and the title of the clerk or other officer who shall be custodian of the recording.

(2) The tapes shall be subject to the following discovery procedures:

(A) In any case in which discovery or disclosure of the tape is sought by the Attorney General, the district attorney, or the plaintiff in a civil action pursuant to this section or Section 11130.3 alleging that a violation of this article has occurred in a closed session that has been recorded pursuant to this section, the party seeking discovery or disclosure shall file a written notice of motion with the appropriate court with notice to the governmental agency that has custody and control of the tape recording. The notice shall be given pursuant to subdivision (b) of Section 1005 of the Code of Civil Procedure.

(B) The notice shall include, in addition to the items required by Section 1010 of the Code of Civil Procedure, all of the following:

(i) Identification of the proceeding in which discovery or disclosure is sought, the party seeking discovery or disclosure, the date and time of the meeting recorded, and the governmental agency that has custody and control of the recording.

(ii) An affidavit that contains specific facts indicating that a violation of the act occurred in the closed session.

(3) If the court, following a review of the motion, finds that there is good cause to believe that a violation has occurred, the court may review, in camera, the recording of that portion of the closed session alleged to have violated the act.

(4) If, following the in-camera review, the court concludes that disclosure of a portion of the recording would be likely to materially assist in the resolution of the litigation alleging violation of this article, the court shall, in its discretion, make a certified transcript of the portion of the recording a public exhibit in the proceeding.
(5) Nothing in this section shall permit discovery of communications that are protected by the attorney-client privilege.

(Amended by Stats.1997, c. 949 (S.B.95), § 13; Stats.1999, c. 393 (A.B.1234), § 4.)

11130.3. Judicial determination action by state body in violation of §§ 11123 or 11125 null and void; action by interested person; grounds

(a) Any interested person may commence an action by mandamus, injunction, or declaratory relief for the purpose of obtaining a judicial determination that an action taken by a state body in violation of Section 11123 or 11125 is null and void under this section. Any action seeking such a judicial determination shall be commenced within 90 days from the date the action was taken. Nothing in this section shall be construed to prevent a state body from curing or correcting an action challenged pursuant to this section.

(b) An action shall not be determined to be null and void if any of the following conditions exist:

(1) The action taken was in connection with the sale or issuance of notes, bonds, or other evidences of indebtedness or any contract, instrument, or agreement related thereto.

(2) The action taken gave rise to a contractual obligation upon which a party has, in good faith, detrimentally relied.

(3) The action taken was in substantial compliance with Sections 11123 and 11125.

(4) The action taken was in connection with the collection of any tax.

(Amended by Stats.1999, c. 393 (A.B.1234), § 5.)

11130.5. Court costs and attorney fees

A court may award court costs and reasonable attorney's fees to the plaintiff in an action brought pursuant to Section 11130 or 11130.3 where it is

found that a state body has violated the provisions of this article. The costs and fees shall be paid by the state body and shall not become a personal liability of any public officer or employee thereof.

A court may award court costs and reasonable attorney's fees to a defendant in any action brought pursuant to Section 11130 or 11130.3 where the defendant has prevailed in a final determination of the action and the court finds that the action was clearly frivolous and totally lacking in merit.

(Added by Stats.1975, c. 959, p. 2240, § 6. Amended by Stats.1981, c. 968, p. 3693, § 21; Stats.1985, c. 936, § 2.)

11130.7. Violations; misdemeanor

Each member of a state body who attends a meeting of that body in violation of any provision of this article, and where the member intends to deprive the public of information to which the member knows or has reason to know the public is entitled under this article, is guilty of a misdemeanor.

(Added by Stats.1980, c. 1284, p. 4341, § 16. Amended by Stats.1981, c. 968, p. 3693, § 22. Amended by Stats.1997, c. 949 (S.B. 95), § 14.)

11131. Use of facility allowing discrimination; state agency

No state agency shall conduct any meeting, conference, or other function in any facility that prohibits the admittance of any person, or persons, on the basis of ancestry, or any characteristic listed or defined in Section 11135 or that is inaccessible to disabled persons, or where members of the public may not be present without making a payment or purchase. As used in this section, "state agency" means and includes every state body, office, officer, department, division, bureau, board, council, commission, or other state agency.

(Added by Stats.1970, c. 383, p. 798, § 1. Amended by Stats.1981, c. 968, p. 3693, § 23. Amended by Stats.1997, c. 949 (S.B.95), § 15.; Stats. 2007, c. 568 (A.B. 14), § 32.)

11131.5. Identity of victims or alleged victims of crimes, tortious sexual conduct, or child abuse; public disclosure

No notice, agenda, announcement, or report required under this article need identify any victim or alleged victim of crime, tortious sexual conduct, or child abuse unless the identity of the person has been publicly disclosed.

(Added by Stats.1997, c. 949 (S.B.95), § 16.)

11132. Closed session by state body prohibited

Except as expressly authorized by this article, no closed session may be held by any state body.

(Added by Stats.1987, c. 1320, § 4.)

APPENDIX B

STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

STATE AND CONSUMER SERVICES AGENCY • ARNOLD SCHWARZENEGGER, GOVERNOR
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MEMORANDUM

DATE	December 17, 2010
TO	**ALL EXECUTIVE OFFICERS**
FROM	**DOREATHEA JOHNSON** **Deputy Director** **Legal Affairs Division** **Department of Consumer Affairs**
SUBJECT	**Closed Session Protocols**

Each board has essentially three duties under the Open Meeting Act.

1. To give adequate notice of meetings to be held.

2. To provide an opportunity for public comment.

3. To conduct such meetings in open session, except where a closed session is specifically authorized. The terms "agency" and "board" mean not only boards, but also commissions and any examining committees or boards within the jurisdiction of the Medical Board of California.

CLOSED SESSIONS

Government Code Section 11123 states that "All meetings of a state body shall be open and public and all persons shall be permitted to attend any meeting of a state body, except as otherwise provided in this article."Section 11126 sets forth the specific items of business which may be transacted in closed session. Therefore, absent statutory authorization, business transacted by an agency must be transacted in open session.

A. Purposes for Closed Session

Government Code Section 11126 enumerates those items of business that may be conducted in closed session. Accordingly, an agency within the Department of

Consumer Affairs may convene a closed session, pursuant to Section 11126 for the following purposes:

- **Personnel Matters**
- **Examination Matters**
- **Matters Affecting Individual Privacy**
- **Administrative Disciplinary Matters**
- **Board of Accountancy Matters**
- **Pending Litigation**
- **Response to Confidential Final Draft Audit Report**
- **Threat of Criminal or Terrorist Activity**
- **Advisory Bodies/Committees May Meet in Closed Session**

1. Personnel Matters

A board may meet in closed session to " . . . consider the appointment, employment, evaluation of performance, or dismissal of a public employee; or to hear complaints or charges brought against such employee by another person unless the employee requests a public hearing."

Before considering personnel action in closed session, the employee must be given 24 hour written notice of his or her right to a public hearing. If notice is not given, any disciplinary or other action taken against any employee at the closed session shall be null and void.

As noted above, once the public hearing has been held, the state body may convene in closed session to deliberate on the decision to be reached.

If the employee (e.g., executive officer) did not request a public hearing, he or she must be given the opportunity for a hearing in closed session. After the hearing, the public employee should be excused from the closed session, and the board may then continue in closed session to deliberate on the decision to be reached.

Please note that Section 11126(a) is not to be interpreted to mean that a board is required to handle civil service personnel matters itself. Normally, this function of an agency is administered by its executive officer in conjunction with the Director of Consumer Affairs, who shares authority with respect to civil service personnel.

2. Examination Matters

A board may meet in closed session to "prepare, approve, grade or administer examinations." This includes any discussion regarding the actual content of examinations, and their reliability and validity.

This **does not** include discussion of the general logistics of administering an examination. This is not a proper subject matter for a closed session.

Also, an agency may hear appeals from examinees or re-review examinations in closed session as this would be included in the "grading" of the examination.

3. Matters Affecting Individual Privacy

A committee, *consisting of less than a quorum* of the full board, may meet in closed session to:

> " . . . discuss matters which the [committee] has found would constitute an unwarranted invasion of the privacy of an individual licensee or applicant if discussed in an open meeting, . . . Those matters may include review of an applicant's qualifications for licensure and an inquiry specifically related to the state body's enforcement program concerning an individual licensee or applicant where the inquiry occurs prior to the filing of a civil, criminal, or administrative disciplinary action against the licensee or applicant by the state body."

CAVEAT: *This closed session provision does not authorize such a review by the full board. Nor does it generally authorize a committee of a board to review complaints, investigation reports, or other information to determine whether disciplinary or other action should be filed against a licensee.*

To ensure that board members render an impartial and fair decision in considering an Administrative Law Judge's proposed decision, board members are precluded from involving themselves in the investigation or prosecution phase of an action. (§11430.10 *et seq.*) The board's role is that of judge in the case. If a particular board member has any significant involvement in the investigative or prosecution phases, he or she must disqualify himself/herself from participation in the board's action relative to the proposed decision, and not attempt to influence any other board member regarding the decision. Legal counsel should be consulted before any enforcement actions are discussed with individual licensees, as such discussions may impact participation by the member in a final decision on a case (§11430.60), and may require disclosures under the provisions of the state's Administrative Procedure Act. (§11430.50)

4. Administrative Disciplinary Matters

A board may meet in closed session to deliberate on a decision in an administrative disciplinary proceeding under the Administrative Procedure Act.

A. The board may decide whether to:

(1) adopt a Proposed Decision,

(2) review a transcript of a hearing and render a decision of its own,

(3) deliberate upon evidence heard by the agency itself,

(4) consider a stipulation.

B. The board may not convene into closed sessionto:

(1) assign cases, *i.e.* deciding whether a case should be heard by a hearing officer alone or by the agency itself with a hearing officer.

(2) to review investigation files or complaints.

Members of boards that have the discretion to hear cases should not review pending complaints or investigation files for the reasons given above.

5. Board of Accountancy Matters

Pursuant to Business and Professions Code Section 5020, the administrative committee established by the State Board of Accountancy may convene in a closed session to "consider disciplinary action against an individual accountant prior to the filing of an accusation." (§11126(f)(3)) And the examining committee, established by that board pursuant to Business and Professions Code Section 5023, may convene in closed session to "interview an individual applicant or accountant regarding the applicant's qualifications."

As noted above, such administrative and examining committee meetings are required to be noticed as previously discussed in this memorandum.

6. Pending Litigation

A board may meet in closed session to confer with or receive advice from its legal counsel regarding pending litigation when discussion in open session concerning those matters would prejudice the position of the state body in the litigation.

Please note the very specific notice requirements discussed below when a closed session is to be held to discuss "pending litigation". Litigation means an adjudicatory proceeding before a court, administrative body, hearing officer or arbitrator. Litigation is considered to be pending if, (1) it has been initiated formally (e.g. a complaint, claim or petition has been filed) or (2) based on existing facts and circumstances and on the advice of its legal counsel, the state body believes there is significant exposure to litigation against it, or it is meeting to decide whether a closed session is authorized because of significant exposure to litigation or (3) based on existing facts and circumstances, the state body has decided or is deciding whether to initiate litigation. (§11126(e)(2))

The agency's legal counsel must submit a memorandum which complies with the requirements of Section 11126(e)(2)(C)(ii) prior to the closed session if possible, but no later than one week after the closed session. This document is confidential until the pending litigation has been finally adjudicated or otherwise settled. (§6254.25)

7. Response to Confidential Final Draft Audit Report

Section 11126.2 (added effective January 1, 2005) permits an agency to meet in closed session to discuss its response to a confidential final draft audit report from the Bureau of State Audits. However, once that audit report becomes final and is released to the public, the agency may only discuss it in open session.

8. Threat of Criminal or Terrorist Activity

Effective January 1, 2006, AB 277 (Chap. 288, Stats. 2005) authorizes an agency at a regular or special meeting to meet in closed session to consider "matters posing a threat or potential threat of criminal or terrorist activity against the personnel, property, buildings, facilities, or equipment, including electronic data, owned, leased, or controlled by the state body," where disclosure of those considerations could compromise or impede the safety or security of the described subjects. The law (Section 11126(c)(18)) requires the agency to authorize the closed session by a two-thirds vote of the members present at the meeting.

9. Advisory Bodies/Committees May Meet in Closed Session

To the extent a licensing board, which is defined as a "state body" in the Open Meeting Act, is authorized to meet in closed session, then committees, subcommittees, or other bodies advisory to the licensing board, which are also defined as "state bodies," may meet in closed session for the same purposes as the licensing board. (§11126((f), (4)-(6))

B. Open Session Otherwise Required

Only for the above-mentioned reasons may a board within the Department of Consumer Affairs meet in closed session. (§11132) A board may not meet in closed session for the purpose of electing officers or to discuss the proposal or adoption of rules and regulations. Further, a board may not convene in closed session to discuss testimony received during a hearing on proposed rules and regulations. Finally, an agency may not meet in closed session because it wants to have a frank and open discussion among only members on a matter of controversy.

C. Notice and Reporting Requirements

1. *Notice of Closed Session*

When a closed session will constitute part or all of a meeting, it is important to note Government Code Section 11126.3, which requires that:

> "(a) Prior to holding any closed session, the state body shall disclose, in an open meeting, the general nature of the item or items to be discussed in the closed session. The disclosure may take the form of a reference to the item or items as they are listed by number or letter on the agenda. [A provision applicable to the Public Utilities Commission is not included herein.] If the session is closed pursuant to subparagraph (A) of paragraph (2) of subdivision (e) of Section 11126 [litigation has already commenced], the state body shall state the title of, or otherwise specifically identify, the litigation to be discussed unless the body states that to do so would jeopardize the body's ability to effectuate service of process upon one or more unserved parties, or that to do so would jeopardize its ability to conclude existing settlement negotiations to its advantage."

Thus, if the meeting will consist in part or in its entirety of a closed session, you must include on the notice of the meeting the above-described information. If the closed session is for the purpose of discussing pending litigation, it is important that the above-requirements be adhered to. To obtain legal advice in closed session concerning pending litigation, the notice must cite subdivision (e) of Section 11126 and your attorney must prepare a memorandum stating the specific reasons and legal authority for the closed session.

If a closed session agenda to discuss pending litigation has been properly published, and an additional pending litigation issue subsequently arises, the state agency may discuss the new matter in closed session provided that postponement of the discussion would prevent the state agency from complying with any statutory, court-

ordered, or other legally-imposed deadline. The state agency must publicly announce the title of, or otherwise identify, the litigation unless to do so would jeopardize the ability to effectuate service of process, or to do so would jeopardize the agency's ability to conclude existing settlement negotiations to its advantage. (§11126.3(d))

If you intend to have a closed session during your meeting, **contact your Legal Division attorney to ensure that a closed session is authorized and properly noticed.**

2. *Reporting After a Closed Session*

Section 11126.3(f), requires a state body to convene in open session after a closed session and to report as required in Section 11125.2, which states that:

> " Any state body shall report publicly at a subsequent public meeting any action taken, and any rollcall vote thereon, to appoint, employ, or dismiss a public employee arising out of any closed session of the state body."

D. Other Procedural Requirements for Closed Sessions

There are certain additional requirements that must be met when closed sessions are convened.

1. *Closed sessions must be held during a duly noticed regular or special meeting* (§11128).

Closed sessions may not be scheduled independently of a noticed meeting of the board or committee. For example, where a board or committee meeting is scheduled to discuss only matters appropriate for a closed session, the meeting should be opened as a public meeting with an announcement immediately following that the agency will convene into closed session.

2. *The general reasons for and the legal authority for the closed session must be announced prior to holding the closed session.*

As discussed under "Notice Required," above, prior to holding the closed session the agency must announce the general reason(s) for the closed session and the specific statutory or other legal authority under which the session is held. (§11126.3 (a)) With respect to litigation that has already been initiated, it must announce the title of or otherwise identify the litigation. (§11126.3(a)) Other specific notice requirements, discussed above, also apply to notices regarding pending litigation. In the closed session, only matters covered in the statement may be discussed. (§11126.3(b))

3. *Required agency staff person's attendance in closed session.*
The agency is required to designate a staff person to attend the closed session and to record in a minute book a record of topics discussed and decisions made. (§11126.1)

4. *Restriction on additional closed session attendees.*
As a general rule, closed sessions may involve only the membership of the membership of the body in question plus any additional support staff which may be required (e.g., attorney required to provide legal advice; supervisor may be required in connection with disciplinary proceeding; labor negotiator required for consultation.) Persons without an official role in the meeting should not be present. (*Cf.* 83 Ops.Cal.Atty.Gen 221, 222.) In this case, the "trusted staff members who are generally permitted to remain" in closed session, should not be in attendance during the closed session if they have no official role during the deliberations involved in the closed session. Their presence compromises the closed session deliberations of the board.

5. *Confidentiality of the minute book.*
The minute book referenced in (3) is available only to members of the agency, or if a violation of the Open Meeting Act is alleged, to a court of general jurisdiction. (§11126.1)

6. *The discussion and information received in closed session is confidential.*
Information received and discussions held in closed session are **confidential** and must not be disclosed to outside parties by members or staff who attended the closed session. A recent opinion of the Office of the California Attorney General concluded that:

> " A local school board member may not publicly disclose information that has been received and discussed in closed session concerning pending litigation unless the information is authorized by law to be disclosed." (80 Ops.Cal.Atty.Gen. 231)

That opinion also cited a previous opinion, in which the Attorney General stated that "We have ... routinely observed that it would be *improper* for information received during a closed session to be publicly disclosed." (76 Ops.Cal.Atty.Gen. 289, 290-291; Emphasis in the original.)

E. MEETING BY TELECONFERENCING

Effective 1/1/95, subdivision (b) was added to Government Code section 11123 to authorize meetings by teleconference. (Stats. 1994, Chapt. 1153; AB 3467) This section provides the following in pertinent part:

"(a) All meetings of a state body shall be open and public and all persons shall be permitted to attend any meeting of a state body except as otherwise provided in this article.

"(b) (1) A state body may hold an open or closed meeting by teleconference for the benefit of the public and state body. The meeting or proceeding held by teleconference shall otherwise comply with all applicable requirements or laws relating to a specific type of meeting or proceeding, including the following:

(A) The teleconferencing meeting shall comply with all requirements of this article applicable to other meetings.

(B) The portion of the teleconferenced meeting that is required to be open to the public shall be audible to the public at the location specified in the notice of the meeting.

(C) If the state body elects to conduct a meeting or proceeding by teleconference, it shall post agendas at all teleconference locations and conduct teleconference meetings in a manner that protects the rights of any party or member of the public appearing before the state body. Each teleconference location shall be identified in the notice and agenda of the meeting or proceeding, and each teleconference location shall be accessible to the public. The agenda shall provide an opportunity for members of the public to address the state body directly pursuant to Section 11125.7 at each teleconference location.

(D) All votes taken during a teleconferenced meeting shall be by rollcall.

(E) The portion of the teleconferenced meeting that is closed to the public may not include the consideration of any agenda item being heard pursuant to Section 11125.5.

(F) At least one member of the state body shall be physically present at the location specified in the notice of the meeting.

(2) For the purposes of this subdivision, 'teleconference' means a meeting of a state body, the members of which are at different locations, connected by electronic means, through either audio or both audio and video. This section does not prohibit a state body from providing members of the public with additional locations in which the public may

observe or address the state body by electronic means, through either audio or both audio and video."

A method is thus available whereby meetings may be conducted by audio or video teleconferencing provided the criteria set forth in the statute have been met. Note the restriction in subdivision (b)(1)(E) that prohibits a closed session emergency meeting. Emergency meetings in open session may be conducted by teleconference.

We emphasize that the law now requires every teleconference meeting location to be identified in the notice and agenda and be open to the public. Most importantly, the members of the agency must attend the meeting at a public location. Members are no longer able to attend the meeting via teleconference from their offices, homes, or other convenient location unless those locations are identified in the notice and agenda, and the public is permitted to attend at those locations. Nothing prohibits additional locations, where only the public is connected to the teleconference meeting. (§11123(b)(2))

STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

STATE AND CONSUMER SERVICES AGENCY • ARNOLD SCHWARZENEGGER, GOVERNOR
DIVISION OF LEGAL AFFAIRS
1625 N. Market Blvd., Suite S 309, Sacramento, CA 95834
P (916) 574-8220 F (916) 574-8623 |

MEMORANDUM

DATE: **October 7, 2010**

TO: **Executive Officers**
Board Presidents/Chairs

FROM: **DOREATHEA JOHNSON**
Deputy Director
Legal Affairs

SUBJECT: **Board Meeting Protocols**

Three Duties for Board Meetings

1. Give adequate notice of meetings that will be held and agenda items.
2. Conduct meetings in open session.
3. Provide the public an opportunity to comment.

First Duty
Adequate Notice of Meetings and Agenda Items

1. Timely – Law requires 10 days notice to those on a mailing list and posting notice and agenda on your website.
2. Specific Notice – Detailed, itemized agenda, identifying all items of business to be conducted at the meeting.
   - Items not on agenda cannot be discussed nor can they be acted on.
   - Can't discuss items under the heading of "New or Old Business" unless they are specifically identified.
   - Test for Specific Notice --Is an item specific enough for a member of the public to reasonably ascertain the nature of the business to occur at the meeting?

Second Duty
Conduct Meetings

Open Session

General rule: Meetings must be conducted in Open Session and all discussion and actions must take place in the public, unless specifically authorized by law to go into closed session, with regard to that item of business.

Vote in public.– Votes must be publically taken. Secret votes or votes by proxy are not permitted.

Closed Session

Business statutorily authorized to be conducted in closed session:

- Disciplinary matters;
- Preparing, approving or grading examinations;
- Pending litigation;
- Matters affecting personal privacy;
- Executive officer appointment, employment or dismissal.

Once in closed session, you can only discuss those matters that were identified as closed session on your agenda.

Third Duty
Public Comment At The Meeting

General Rule

Must allow public comment on each open session agenda item.

Suggested script to be read at the beginning of the meeting:

The Board Chair will allow public comment on agenda items, as those items are taken up by the Board, during the meeting. Under the Open Meetings Act, the Board may not take any action on items raised by public comment that are not on the Agenda, other than to decide whether to schedule that item for a future meeting.

If any person desires to address the Board, it will be appreciated if he or she will stand or come forward and give his or her name, and if he or she represents an organization, the name of such organization, so that we will have a record of all those who appear. Please note that a person wishing to provide comment is not

required to identify him or herself when making public comment, but it is appreciated.

In order to allow the Board sufficient time to conduct its scheduled business, public comment will be limited to ___ minutes. Please make your comments focused and relevant to the duties of the Board. It is not necessary to repeat statements or views of a previous speaker, it is sufficient to state that you agree. Written statements should be summarized and submitted to the Board. They should not be read.

If as chairperson/president, I forget to ask for public comment on an agenda item, it is not because I intend to limit comment but just because I forgot. So in that situation, please raise your hand and I will recognize you.

Suggested script to be used for each item on the agenda:

1. Call the Agenda Item
2. Committee Presents the agenda item
3. Ask for a motion
4. Ask for a second, unless the motion is made by the committee (second is not needed)
5. Ask for board discussion.
6. Ask if there is public comment. [You may reverse the order of these 2.]
7. Ask if there is further board discussion
8. Repeat the Motion
9. Take the vote

Suggested script for public comment on items not on the agenda:

The board values input from the public as part of its consumer protection mission. It invites and welcomes public comment during this section of the agenda. However, board members cannot engage in dialogue with those who testify during this section of the agenda due to constraints imposed on the board and its members by law. The law prohibits the board from substantively discussing or voting on any matter brought up during public comment. A member of the public who would like the board to discuss a general topic not related to a specific case involving one of its licensees can ask the board to consider placing the issue on the board's agenda for a future meeting.

If you have an application or disciplinary charges pending before the board, we ask that you not discuss the details of your case or pending complaint since the board members will be the "judges" and by law are not permitted to receive evidence or information that is not part of the administrative record in the case.

Disruptive persons:

The public has the right to express its disapproval, and may sometimes make emotional presentations. It is the board's duty and obligation to allow that public comment. Since the purpose of the meeting is for the agency to conduct its business, commenters shouldn't be permitted to thwart that purpose and may be

removed from the meeting if disruptive behavior continues after a request that it stop.

Suggested script to use when there is a disruptive person:

Under the Open Meetings Act (Government Code Section 11126.5), if you continue in this manner, I will ask you to leave the meeting and if you do not leave the meeting, you will be removed. Accordingly, I am asking you to discontinue your disruptive conduct so that all participants can be heard in an orderly fashion.

Miscellaneous

Wording of Motions

- Motions must be clearly worded.
- The test: Could a reasonable person reading the motion understand what the board meant to accomplish?
- Chair should restate the motion before the discussion and just before the vote is taken

Improper Disclosure of Information

- Improper for information received during closed session to be publicly disclosed without authorization of the body as a whole.

Role of the Attorney

The attorney's role during board meetings is to advise the agency of its obligations and authority under the law when it appears that the agency may be deviating from it, e.g. Open Meetings Act, quorum requirements, practice acts, regulations. In some cases, it may be necessary for the attorney to assist the agency in identifying an issue, framing a motion that accurately reflects the agency's deliberations and intent or seeking clarification from a speaker or board member.

When a problem is identified, the attorney is expected to assist the board in developing a lawful alternative method of accomplishing the board's goal.

It is not the attorney's responsibility or role to chair the meetings or direct the discussion. And the attorney should refrain from doing so even if requested to take on that role.

APPENDIX C

Board and Committee Member Travel Guide

Reimbursement rates, methods of travel, and the documentation required for reimbursement are explained in the following guidelines for Board and Committee Members who are required to travel on official state business.

Time Reporting

A 24-hour clock or military time should be used on all Travel Expense Claims (TEC), Std. form 262. For example:

12:01 AM	0001	3:00 PM	1500
5:30 AM	0530	5:30 PM	1730
7:21 AM	0721	10:00 PM	2200
11:00 AM	1100	12:30 PM	1230

Accountability/Claim Requirements

Each item of travel expense claimed in the amount of $25 or more requires an original receipt. Parking expenses require an original receipt if over $10. Original receipts for airline tickets and car rentals must be attached. Meals, incidentals and lodging are to be listed in the appropriate column on Travel Expense Claim (TEC). Although staff may complete the TEC for you, do not sign blank claim forms. The use of correction tape is unacceptable on TEC's. Line through corrections and initial changes.

In-State Reimbursement Rates

You will be reimbursed for actual costs up to the maximum reimbursement for each meal, incidental, and lodging expense incurred while on travel status.

Meals and Incidentals	Reimbursement
Breakfast	Up to $ 6.00
Lunch	Up to 10.00
Dinner	Up to 18.00
Incidental	Up to 6.00

Lodging	Reimbursement
Actual lodging cost with substantiating itemized receipt up to maximum of.....	$84 plus taxes on the entire cost of the lodging rate.
Los Angeles and San Francisco Counties....	$110 plus taxes on the entire cost of the lodging rate.

ALL NON-COMMERCIAL TRAVEL REIMBURSEMENT IS ABOLISHED. Employees who stay with friends or relatives, or who do not produce a receipt for commercial lodging, will be eligible to claim meals only.

You may not claim lodging within 50 miles of your primary residence. You must be on travel status to claim reimbursement.

24-hours of Travel or More

On the first day of travel of 24 hours or more:

Timeframe	Meal Reimbursement
Begins before or at 6:00 a.m.	Breakfast
Begins before or at 11:00 a.m.	Lunch
Begins before or at 5:00 p.m.	Dinner

On the last fractional day of travel of more than 24 hours:

Timeframe	Meal Reimbursement
Ends at or after 8 a.m.	Breakfast
Ends at or after 2 p.m.	Lunch
Ends at or after 7 p.m.	Dinner

One Day Travel *(Less than 24 hours/Over 100 miles round trip)*

Timeframe	Meal Reimbursement
Begins at or before 6 a.m. and ends at or after 9 a.m.	Breakfast
Please refer to Note below	Lunch
Begins at or before 4 p.m. and ends at or after 7 p.m.	Dinner
If required and pre-approved, with receipt	Lodging

NOTE: Board and Committee members are entitled to lunch ONLY when attending Board of Committee meetings (does not need to be over 100 miles).

Incidental Reimbursement

Includes expenses for personal items, personal telephone calls, personal porter fees, etc. Reimbursement is allowed only for a FULL 24 hours of travel. For example, if you leave at 1900 and return at 1850 the following day, you DO NOT qualify for the incidental reimbursement.

Commercial Care Rental Information

Board and Committee members cannot use contract rates for personal business.

Reservations should be made at least 24 hours in advance. To guarantee the contract rate when making reservations directly with the car rental agency, the Board or Committee member must identify that he or she is a State government employee and show their General Services (GSA) card when picking up the rental car. (i.e., Vendor must give contract rate to employee with GSA card.)

Car rental reservations can also be made through your travel agency. To guarantee contract rate, General Services card must still be shown when picking up the rental car.

Board and Committee members using larger and/or luxury class vehicles without substantiation of the need will be required to pay the additional costs for the rental.

NOTE: Loss Damage Waiver (LDW) is included in the daily rate when renting a vehicle from a contract company. However, insurance for collision (collision damage waiver) and medical insurance (personal accident insurance) obtained when renting a commercial automobile are not reimbursable by the State.

It is not acceptable to extend retail agreements for personal use and pay the difference for those days the vehicle was used on personal business. If you wish to extend the rental of a vehicle for personal business, make arrangements with the contract vendor to have the rental agreement for state business closed out at the end of your state business. Have a new rental agreement drawn up for your personal business.

Airline Travel

Be prepared to provide the following information when making reservations through the travel agency:

- Your name/name of traveler
- The board/committee name
- General Services Account number
- Departure date
- Origin and destination cities
- Preferred departure and arrival time
- Date, time, and place for ticket delivery
- Special requests (i.e., seating, meals, hotel, non-smoking room, rental car, ticketless)

PREMIUMS OR PROMOTIONAL PRIZES, SUCH AS SAVINGS BONDS AND FREQUENT FLYER COUPONS ARE THE PROPERTY OF THE STATE AND MUST BE SURRENDERED.

Return any unused airline tickets to the board office for credit refund.

If your American Express Corporate card is lost or stolen, you must call 1-800-528-2122 or 1-800-92203404 to file a report. You must also report the loss to the board office.

APPENDIX D

BOARD OF PHARMACY
TRAVEL EXPENSE REPORT

NAME_____

LICENSE PLATE#_____

PURPOSE OF TRIP_____

LOCATION WHERE EXPENSES WERE INCURRED_____

TRAVEL

MONTH/YEAR	DAY	DAY	DAY	DAY	DAY
HOUR TRIP BEGAN					
HOUR TRIP ENDED					
MEALS: BREAKFAST (MAX $6.00)					
LUNCH (MAX $10.00)					
DINNER (MAX $18.00)					
INCIDENTALS ($6.00 PER DAY)					
LODGING					
TRANSPORTATION:					
TYPE USED (PERSONAL CAR, RENTAL CAR, ETC.)					
MILEAGE ($0.55)					
TOLLS					
PARKING					
TAXI					
BUSINESS EXPENSE					

Note: Receipts are required for the following: Lodging, Air Transportation, Rental Car, Taxi, Business Expense, and Parking (if charge exceeds $10.00). Please submit these receipts with your travel clam work sheet. Please keep meal receipts for your records.

* A = Air; PC = Private Car; RC = Rental Car

STATE OF CALIFORNIA – PERSONNEL ADMINISTRATION

TRAVEL EXPENSE CLAIM

STD. 262 (REV. 6-93c)

*See Instructions and *Privacy Statement On Reverse Side*

Page _____ of _____ Pages

CLAIMANT'S NAME		SSN or EMPLOYEE NUMBER*	DEPARTMENT
POSITION	CB/ID No.	DIVISION or BUREAU	INDEX NUMBER
RESIDENCE ADDRESS *		HEADQUARTERS ADDRESS	TELEPHONE NUMBER
CITY STATE ZIP CODE		CITY STATE ZIP CODE	

(1) MONTH/YEAR (2) DATE	TIME	(3) LOCATION WHERE EXPENSES WERE INCURRED	(4) LODGING	(5) MEALS BREAK-FAST	LUNCH	O.T., L/T, N/C, RELO, OR DINNER	(6) INCIDEN-TALS	(7) TRANSPORTATION (A) COST OF TRANS.	(B) TYPE USED	(C) CARFARE, TOLLS, PARKING	(D) PRIVATE CAR USE MILES	AMOUNT	(8) BUSINESS EXPENSE	(9) TOTAL EXPENSES FOR DAY
														0.00
														0.00
														0.00
														0.00
														0.00
														0.00
														0.00
														0.00
														0.00
														0.00
														0.00
														0.00
														0.00
(10)		SUBTOTALS	0.00	0.00	0.00	0.00	0.00	0.00		0.00	0	0.00	0.00	0.00
COLUMN CODE (ACCT'G USE ONLY)														
		CLAIM TOTAL												0.00

(11) PURPOSE OF TRIP, REMARKS AND DETAILS (Attach receipts/vouchers when required)

(12) NORMAL WORK HOURS

(13) PRIVATE VEHICLE LICENSE NUMBER

(14) MILEAGE RATE CLAIMED

AGENCY ACCOUNTING OFFICE USE ONLY

PAID BY REVOLVING FUND CHECK NUMBER

(15) I HEREBY CERTIFY That the above is a true statement of the travel expenses incurred by me in accordance with DPA rules in the service of the State of California. If a privately owned vehicle was used, and if mileage rates exceed the minimum rate, I certify that the cost of operating the vehicle was equal to or greater than the rate claimed, and that I have met the requirements as prescribed by SAM Sections 0750, 0751, 0752, 0753 and 0754 pertaining to vehicle safety and seat belt usage.

CLAIMANT'S SIGNATURE	DATE	(16) SIGNATURE OF OFFICER APPROVING TRAVEL AND PAYMENT	DATE

(17) SPECIAL EXPENSE AUTHORIZATION - SIGNATURE and TITLE *(See Item 17 on reverse)* DATE

STATE OF CALIFORNIA – PERSONNEL ADMINISTRATION

TRAVEL EXPENSE CLAIM

STD. 262 (REV. 6-93c)

INSTRUCTIONS

ense accounts are to be submitted at least once a month and not more often than twice a month, except where the amount claimed is less than $10, the claim need not be submitted until it exceeds $10 or June 30, whichever occurs first. Requests for reimbursement of out-of-state travel expenses must be claimed separately. Requests for reimbursement of travel expenses which are incurred in different fiscal years must be claimed separately. A brief statement, one line if possible, of the purpose or objective, of the trip must be entered on the line immediately below the last entry for each trip. If the claim is for several trips for the same purpose or objective, one statement will suffice for those trips. Vouchers which are required in support of various expenses must be arranged in chronological order and attached to the claim. Each voucher must show the date, cost, and nature of the expense.

MULTIPLE PAGES–If your claim is more than one page, indicate page number and total number of pages. DO NOT total each page. Use subtotals and enter the total amount of the claim on the last page of the claim in the space for "TOTALS" and "CLAIM TOTAL."

COLUMN ENTRIES

(1) MONTH/YEAR–Enter numerical designation of month and last two digits of the year in which the first expenses shown on the form were incurred.

(2) DATE/TIME–Enter date and time of departure on the appropriate line using twenty-four-hour clock (example: 1700 = 5:00 p.m.). Show time of departure on date of departure, show time of return on the date of return. If departure and return are on the same date, enter departure time above and return time below on the same line. Where the first date shown is a continuation of trip, enter "Continuing" above that date, and where a trip is continuing beyond the last date shown, write "Continuing" after the last date.

(3) LOCATIONS WHERE EXPENSES WERE INCURRED–Enter the name of the city, town, or location where expenses were incurred. Abbreviations may be used.

(4) LODGING–Enter the actual cost of the lodging not to exceed the maximum amount authorized by current Department of Personnel Administration (DPA) regulations, bargaining agreements and detailed in the State Administrative Manual (SAM) Sections 0721 to 0724. A receipt is required for any expenditure of $25 or more.

(5) MEALS–Enter the actual cost of each meal not to exceed the maximum amount for each meal as authorized by current DPA regulations, bargaining agreements and detailed in SAM Sections 0761 to 0763. Dinner column is to be used to claim dinner on regular travel, overtime meals, and long term, noncommercial and relocation daily meal expenses.

OVERTIME MEAL AND BUSINESS RELATED MEAL–Enter the actual cost of the meal not to exceed the maximum amount authorized by current DPA regulations, and bargaining agreements. Refer to DPA Management Memos for receipt requirements.

(6) INCIDENTALS–Enter the total actual cost of incidentals not to exceed the maximum amount authorized by current DPA regulations and agreements.

(7) TRANSPORTATION–Purchase the least expensive round-trip or special rate ticket available. Otherwise the difference will be deducted from the claim. If you travel between the same points without using round-trip tickets, an explanation should be given.

(A) COST OF TRANSPORTATION–Enter the cost of cash purchase of transportation. Show how transportation was obtained if fare was not purchased for cash. Use "CC" for credit card and "C" for cash. If transportation was paid by the State, enter method of payment only. Use "SCC" for State credit card, "TO" for ticket order or "BSA" for billed to State agency. Attach all passenger coupons and ticket order stubs including the unused portion of tickets, other credit documents or premiums, where credits or refunds are due to the State.

(B) TYPE OF TRANSPORTATION USED–Enter method of transportation used. Use "R" for railway, "B" for bus, airporter, light rail, or BART, "A" for scheduled commercial airline, "RA" for rental aircraft, "DA" for department-owned aircraft, "PA" for privately owned aircraft, "PC" for privately owned car, truck or other privately owned vehicles, "SV" for specially equipped vehicle for the handicapped, "SC" for State vehicles, "RC" for rental vehicles, "T" for taxi, and "BI" for bicycle. Supervisors shall not authorize the use of motorcycles on official State business, and no reimbursement will be allowed for motorcycles.

(C) CAR FARE, TOLLS, AND PARKING–Enter carfare, bridge tolls, and parking charges; attach a voucher for any parking charge in excess of $6.00 for any one continuous period of parking.

(D) PRIVATE CAR USE–Enter number of miles traveled and amount due for mileage for the use of privately owned automobiles as authorized by current agreements, regulations, and detailed in SAM Section 0754.

(8) BUSINESS EXPENSE–Claims for phone calls must include the place and party called. If charge exceeds $2.50, support by vouchers or other evidence. Emergency purchases of equipment, clothing or supplies, travel expenses of inmates, wards, or patients of institutions, and all other charges in excess of $1.00 require receipts and an explanation.

(9) ENTER TOTAL EXPENSES FOR DAY

(10) ENTER SUBTOTALS OR TOTALS

(11) PURPOSE OF TRIP, REMARKS OR DETAILS–Explain need for travel and any unusual expenses. Enter detail or explanation of items in other columns, if necessary. Vouchers must be provided for any miscellaneous item of expense.

(12) NORMAL WORK HOURS–Enter your beginning and ending normal work hours using twenty-four-hour clock (example: 0800 = 8:00 a.m.).

(13) PRIVATE VEHICLE LICENSE NUMBER–Enter license number of the privately owned vehicle used on official State business. To claim reimbursement, you must have met the requirements as prescribed by SAM Sections 0751, 0752 and 0753 pertaining to operator requirements, vehicle safety, seat belt usage and authorization.

(14) MILEAGE RATE CLAIMED–Enter the rate of reimbursement being claimed for private vehicle use.

(15) CLAIMANT'S CERTIFICATION AND SIGNATURE–Your signature certifies that expenses claimed were actually incurred and that the cost of operating is at or above the rate claimed.

(16) SIGNATURE OF OFFICER APPROVING PAYMENT–Certifies and authorizes travel; approves expenses as incurred on State business.

(17) SIGNATURE OF AUTHORITY FOR SPECIAL EXPENSES–When a claim for conference or convention expense under Section 599.635 of the DPA regulations and detailed in SAM Section 0724 is included, or when reimbursement of a business expense exceeds $25.00 or when reimbursement for Bar dues or license fees is included, the signature of the approving officer is required, either on a separate document attached to this claim or by signature in this block.

* PRIVACY STATEMENT

The Information Practices Act of 1977 (Civil Code Section 1798.17) and the Federal Privacy Act (Public Law 93-579) require that the following notice be provided when collecting personal information from individuals.

AGENCY NAME: Appointing powers and the State Controller's Office (SCO).

UNITS RESPONSIBLE FOR MAINTENANCE: The accounting office within each appointing power and the Audits Division, SCO, 3301 C Street, Room 404, Sacramento, CA 95816.

AUTHORITY: The reimbursement of travel expenses is governed by Government Code Sections 19815.4(d), 19816, and 19820. These sections allow the Department of Personnel Administration (DPA) to establish rules and regulations which define the amount, time, and place that expenses and allowances may be paid to representatives of the State while on State business.

PURPOSE: The information you furnish will allow the above-named agencies to reimburse you for expenses you incur while on official State business.

OTHER INFORMATION: While your social security account number (SSAN) and home address are voluntary information under Civil Code Section 1798.17, the absence of this information may cause payment of your claim to be delayed or rejected. You should contact your department's Accounting Office to determine the necessity for this information.

APPENDIX E

BUSINESS AND PROFESSIONS CODE

SECTION 103

Each member of a board, commission, or committee created in the various chapters of Division 2 (commencing with Section 500) and Division 3 (commencing with Section 5000), and in Chapter 2 (commencing with Section 18600) and Chapter 3 (commencing with Section 19000) of Division 8, shall receive the moneys specified in this section when authorized by the respective provisions.

Each such member shall receive a per diem of one hundred dollars ($100) for each day actually spent in the discharge of official duties, and shall be reimbursed for traveling and other expenses necessarily incurred in the performance of official duties.

The payments in each instance shall be made only from the fund from which the expenses of the agency are paid and shall be subject to the availability of money.

Notwithstanding any other provision of law, no public officer or employee shall receive per diem salary compensation for serving on those boards, commissions, committees, or the Consumer Advisory Council on any day when the officer or employee also received compensation for his or her regular public employment.

Attendance Report

Board Member: _____ **Month:** _____

In the areas below, please report the **actual** time you spent attending meetings or performing board business.

MEETINGS ATTENDED	DATE	HOURS IN MEETINGS (do not include meal and/or travel times)	
		From:	To:
1.			
2.			
3.			
4.			
5.			

MAIL BALLOTS/TRANSCRIPTS REVIEWED	DATE	HOURS	MINUTES
1.			
2.			
3.			
4.			
5. Review of Transcript -- Case #			

PRE-MEETING PREPARATION *(please list meeting)*	DATE	HOURS	MINUTES
1.			
2.			
3.			
4.			
5. Reviewing Board Packet			

You will be paid in eight-hour increments at the end of each month; any portion of hours remaining will be carried over into the next month.

To the best of my knowledge and belief, the information stated above is accurate.

Signature: _____ **Date:** _____

APPENDIX F

GOVERNMENT CODE SECTION 87100-87105

87100. No public official at any level of state or local government shall make, participate in making or in any way attempt to use his official position to influence a governmental decision in which he knows or has reason to know he has a financial interest.

GOVERNMENT CODE SECTION 11146-11146.4

11146. For purposes of this article, the following terms have the following meanings:

(a) "State agency" has the same meaning as set forth in Section 82049, but does not include the Legislature.

(b) "Filer" means each member, officer, or designated employee of a state agency who is required to file a statement of economic interests under either Article 2 (commencing with Section 87200) or Article 3 (commencing with Section 87300) of Chapter 7 of Title 9 because of the position he or she holds with the agency.

11146.1. Each state agency shall offer at least semiannually to each of its filers an orientation course on the relevant ethics statutes and regulations that govern the official conduct of state officials.

11146.2. Each state agency shall maintain records indicating the specific attendees, each attendee's job title, and dates of their attendance for each orientation course offered pursuant to Section 11146.1 for a period of not less than five years after each course is given. These records shall be public records subject to inspection and copying consistent with subdivision (a) of Section 81008 and otherwise subject to the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1).

11146.3. Except as set forth in Section 11146.4, each filer shall attend the orientation course required in Section 11146.1, as follows:

(a) For a filer who holds a position with the agency on January 1, 2003, not later than December 31, 2003 and, thereafter, at least once during each consecutive period of two calendar years commencing on January 1, 2005.

(b) For a person who becomes a filer with the agency after January 1, 2003, within six months after he or she becomes a filer and at least once during each consecutive period of two calendar years commencing on the first odd-numbered year thereafter.

11146.4. (a) The requirements of Section 11146.3 shall not apply to filers with a state agency who have taken an equivalent ethics orientation course through another state agency or the Legislature within the time periods set forth in subdivision (a) or (b) of Section 11146.3, as applicable.

(b) State agencies may jointly conduct and filers from more than one state agency may jointly attend an orientation course required by Section 11146.1, as long as the course content is relevant to the official duties of the attending filers.

(c) Before conducting each orientation course required by Section

11146.1, state agencies shall consult with the Fair Political Practices Commission and the Attorney General regarding appropriate course content.

GOVERNMENT CODE SECTION 89503

89503. (a) No elected state officer, elected officer of a local government agency, or other individual specified in Section 87200 shall accept gifts from any single source in any calendar year with a total value of more than two hundred fifty dollars ($250).

(b) (1) No candidate for elective state office, for judicial office, or for elective office in a local government agency shall accept gifts from any single source in any calendar year with a total value of more than two hundred fifty dollars ($250). A person shall be deemed a candidate for purposes of this subdivision when the person has filed a statement of organization as a committee for election to a state or local office, a declaration of intent, or a declaration of candidacy, whichever occurs first. A person shall not be deemed a candidate for purposes of this subdivision after he or she is sworn into the elective office, or, if the person lost the election, after the person has terminated his or her campaign statement filing obligations for that office pursuant to Section 84214 or after certification of the election results, whichever is earlier.

(2) Paragraph (1) shall not apply to any person who is a candidate as described in paragraph (1) for judicial office on or before December 31, 1996.

(c) No member of a state board or commission or designated employee of a state or local government agency shall accept gifts from any single source in any calendar year with a total value of more than two hundred fifty dollars ($250) if the member or employee would be required to report the receipt of income or gifts from that source on his or her statement of economic interests.

(d) This section shall not apply to a person in his or her capacity as judge. This section shall not apply to a person in his or her capacity as a part-time member of the governing board of any public institution of higher education unless that position is an elective office.

(e) This section shall not prohibit or limit the following:

(1) Payments, advances, or reimbursements for travel and related lodging and subsistence permitted by Section 89506.

(2) Wedding gifts and gifts exchanged between individuals on birthdays, holidays, and other similar occasions, provided that the gifts exchanged are not substantially disproportionate in value.

(f) Beginning on January 1, 1993, the commission shall adjust the gift limitation in this section on January 1 of each odd-numbered year to reflect changes in the Consumer Price Index, rounded to the nearest ten dollars ($10).

(g) The limitations in this section are in addition to the limitations on gifts in Section 86203.

APPENDIX G

ETHICAL DECISION MAKING

Handout #2

Questions	Mandatory Disqualification	Need Further Discussion
Have you served as • investigator • prosecutor, or • advocate before or during the adjudicative proceeding?	**Yes**	
Are you biased or prejudiced for or against the person? or Do you have an interest (including a financial interest) in the proceeding?	**Yes** **Yes**	
Have you • engaged in a prohibited ex parte communication before or during adjudicative proceeding (may result in disqualification)? OR • complained to you about investigation currently in progress and said how great he or she is √ "Ex parte" communication: direct or indirect communication with you by one of the parties or its representative without notice and opportunity for all parties to participate in the communication (e.g. applicant or licensee (or someone acting on that person's behalf)		**Yes** **Yes**
Do you or your spouse or a close family member (such as an uncle or cousin) have personal knowledge of disputed evidentiary facts concerning the proceeding?		**Yes**
Do you doubt your capacity to be impartial?		**Yes**
Do you, for any reason, believe that your recusal would further the interests of justice?		**Yes**

APPENDIX H

#6 SENATE BILL 1441 REQUIREMENT

Standards used in determining whether inpatient, outpatient, or other type of treatment is necessary.

#6 Uniform Standard

In determining whether inpatient, outpatient, or other type of treatment is necessary, the board shall consider the following criteria:

- recommendation of the clinical diagnostic evaluation pursuant to Uniform Standard #1;
- license type;
- licensee's history;
- documented length of sobriety/time that has elapsed since substance abuse;
- scope and pattern of substance use;
- licensee's treatment history;
- licensee's medical history and current medical condition;
- nature, duration, and severity of substance abuse, and
- threat to himself/herself or the public.

#8 SENATE BILL 1441 REQUIREMENT

Procedures to be followed when a licensee tests positive for a banned substance.

#8 Uniform Standard

When a licensee tests positive for a banned substance:

1. The board shall order the licensee to cease practice;

2. The board shall contact the licensee and instruct the licensee to leave work; and

3. The board shall notify the licensee's employer, if any, and worksite monitor, if any, that the licensee may not work.

Thereafter, the board should determine whether the positive drug test is in fact evidence of prohibited use. If so, proceed to Standard #9. If not, the board shall immediately lift the cease practice order.

In determining whether the positive test is evidence of prohibited use, the board should, as applicable:

1. Consult the specimen collector and the laboratory;

2. Communicate with the licensee and/or any physician who is treating the licensee; and

3. Communicate with any treatment provider, including group facilitator/s.

#9 SENATE BILL 1441 REQUIREMENT

Procedures to be followed when a licensee is confirmed to have ingested a banned substance.

#9 Uniform Standard

When a board confirms that a positive drug test is evidence of use of a prohibited substance, the licensee has committed a major violation, as defined in Uniform Standard #10 and the board shall impose the consequences set forth in Uniform Standard #10.

#10 SENATE BILL 1441 REQUIREMENT

Specific consequences for major and minor violations. In particular, the committee shall consider the use of a "deferred prosecution" stipulation described in Section 1000 of the Penal Code, in which the licensee admits to self-abuse of drugs or alcohol and surrenders his or her license. That agreement is deferred by the agency until or unless licensee commits a major violation, in which case it is revived and license is surrendered.

#10 Uniform Standard

Major Violations include, but are not limited to:

1. Failure to complete a board-ordered program;

2. Failure to undergo a required clinical diagnostic evaluation;

3. Multiple minor violations;

4. Treating patients while under the influence of drugs/alcohol;

5. Any drug/alcohol related act which would constitute a violation of the practice act or state/federal laws;

6. Failure to obtain biological testing for substance abuse;

7. Testing positive and confirmation for substance abuse pursuant to Uniform Standard #9;

8. Knowingly using, making, altering or possessing any object or product in such a way as to defraud a drug test designed to detect the presence of alcohol or a controlled substance.

Consequences for a major violation include, but are not limited to:

1. Licensee will be ordered to cease practice.

    a) the licensee must undergo a new clinical diagnostic evaluation, and

    b) the licensee must test negative for at least a month of continuous drug testing before being allowed to go back to work.

2. Termination of a contract/agreement.

3. Referral for disciplinary action, such as suspension, revocation, or other action as determined by the board.

Minor Violations include, but are not limited to:

1. Untimely receipt of required documentation;
2. Unexcused non-attendance at group meetings;
3. Failure to contact a monitor when required;
4. Any other violations that do not present an immediate threat to the violator or to the public.

Consequences for minor violations include, but are not limited to**:**

1. Removal from practice;
2. Practice limitations;
3. Required supervision;
4. Increased documentation;
5. Issuance of citation and fine or a warning notice;
6. Required re-evaluation/testing;
7. Other action as determined by the board.

#11 SENATE BILL 1441 REQUIREMENT

Criteria that a licensee must meet in order to petition for return to practice on a full time basis.

#11 Uniform Standard

"Petition" as used in this standard is an informal request as opposed to a "Petition for Modification" under the Administrative Procedure Act.

The licensee shall meet the following criteria before submitting a request (petition) to return to full time practice:

1. Demonstrated sustained compliance with current recovery program.

2. Demonstrated the ability to practice safely as evidenced by current work site reports, evaluations, and any other information relating to the licensee's substance abuse.

3. Negative drug screening reports for at least six (6) months, two (2) positive worksite monitor reports, and complete compliance with other terms and conditions of the program.

#12 SENATE BILL 1441 REQUIREMENT

Criteria that a licensee must meet in order to petition for reinstatement of a full and unrestricted license.

#12 Uniform Standard

"Petition for Reinstatement" as used in this standard is an informal request (petition) as opposed to a "Petition for Reinstatement" under the Administrative Procedure Act.

The licensee must meet the following criteria to request (petition) for a full and unrestricted license.

1. Demonstrated sustained compliance with the terms of the disciplinary order, if applicable.

2. Demonstrated successful completion of recovery program, if required.

3. Demonstrated a consistent and sustained participation in activities that promote and support their recovery including, but not limited to, ongoing support meetings, therapy, counseling, relapse prevention plan, and community activities.

4. Demonstrated that he or she is able to practice safely.

5. Continuous sobriety for three (3) to five (5) years.

#13 SENATE BILL 1441 REQUIREMENT

If a board uses a private-sector vendor that provides diversion services, (1) standards for immediate reporting by the vendor to the board of any and all noncompliance with process for providers or contractors that provide diversion services, including, but not limited to, specimen collectors, group meeting facilitators, and worksite monitors; (3) standards requiring the vendor to disapprove and discontinue the use of providers or contractors that fail to provide effective or timely diversion services; and (4) standards for a licensee's termination from the program and referral to enforcement.

#13 Uniform Standard

1. A vendor must report to the board any major violation, as defined in Uniform Standard #10, within one (1) business day. A vendor must report to the board any minor violation, as defined in Uniform Standard #10, within five (5) business days.

2. A vendor's approval process for providers or contractors that provide diversion services, including, but not limited to, specimen collectors, group meeting facilitators, and worksite monitors is as follows:

   (a) Specimen Collectors:

   (1) The provider or subcontractor shall possess all the materials, equipment, and technical expertise necessary in order to test every licensee for which he or she is responsible on any day of the week.

   (2) The provider or subcontractor shall be able to scientifically test for urine, blood, and hair specimens for the detection of alcohol, illegal, and controlled substances.

   (3) The provider or subcontractor must provide collection sites that are located in areas throughout California.

   (4) The provider or subcontractor must have an automated 24-hour toll-free telephone system and/or a secure on-line computer database that allows the participant to check in daily for drug testing.

   (5) The provider or subcontractor must have or be subcontracted with operating collection sites that are engaged in the business of collecting urine, blood, and hair follicle specimens for the testing of drugs and alcohol within the State of California.

   (6) The provider or subcontractor must have a secure, HIPAA compliant, website or computer system to allow staff access to drug test results and compliance reporting information that is available 24 hours a day.

(7) The provider or subcontractor shall employ or contract with toxicologists that are licensed physicians and have knowledge of substance abuse disorders and the appropriate medical training to interpret and evaluate laboratory drug test results, medical histories, and any other information relevant to biomedical information.

(8) A toxicology screen will not be considered negative if a positive result is obtained while practicing, even if the practitioner holds a valid prescription for the substance.

(9) Must undergo training as specified in Uniform Standard #4 (6).

(b) Group Meeting Facilitators:

A group meeting facilitator for any support group meeting:

(1) must have a minimum of three (3) years experience in the treatment and rehabilitation of substance abuse;

(2) must be licensed or certified by the state or other nationally certified organization;

(3) must not have a financial relationship, personal relationship, or business relationship with the licensee within the last year;

(4) shall report any unexcused absence within 24 hours to the board, and,

(5) shall provide to the board a signed document showing the licensee's name, the group name, the date and location of the meeting, the licensee's attendance, and the licensee's level of participation and progress.

(c) Work Site Monitors:

The worksite monitor must meet the following qualifications:

(1) Shall not have financial, personal, or familial relationship with the licensee, or other relationship that could reasonably be expected to compromise the ability of the monitor to render impartial and unbiased reports to the board. If it is impractical for anyone but the licensee's employer to serve as the worksite monitor, this requirement may be waived by the board; however, under no circumstances shall a licensee's worksite monitor be an employee of the licensee.

(2) The monitor's licensure scope of practice shall include the scope of practice of the licensee that is being monitored, be another health care professional if no

monitor with like practice is available, or, as approved by the board, be a person in a position of authority who is capable of monitoring the licensee at work.

(3) Shall have an active unrestricted license, with no disciplinary action within the last five (5) years.

(4) Shall sign an affirmation that he or she has reviewed the terms and conditions of the licensee's disciplinary order and/or contract and agrees to monitor the licensee as set forth by the board.

2. The worksite monitor must adhere to the following required methods of monitoring the licensee:

   a) Have face-to-face contact with the licensee in the work environment on a frequent basis as determined by the board, at least once per week.

   b) Interview other staff in the office regarding the licensee's behavior, if applicable.

   c) Review the licensee's work attendance.

3. Any suspected substance abuse must be verbally reported to the contractor, the board, and the licensee's employer within one (1) business day of occurrence. If occurrence is not during the board's normal business hours the verbal report must be within one (1) hour of the next business day. A written report shall be submitted to the board within 48 hours of occurrence.

4. The worksite monitor shall complete and submit a written report monthly or as directed by the board. The report shall include:

   - the licensee's name;
   - license number;
   - worksite monitor's name and signature;
   - worksite monitor's license number;
   - worksite location(s);
   - dates licensee had face-to-face contact with monitor;
   - staff interviewed, if applicable;
   - attendance report;
   - any change in behavior and/or personal habits;

- any indicators that can lead to suspected substance abuse.

(d) Treatment Providers

Treatment facility staff and services must have:

(1) Licensure and/or accreditation by appropriate regulatory agencies;

(2) Sufficient resources available to adequately evaluate the physical and mental needs of the client, provide for safe detoxification, and manage any medical emergency;

(3) Professional staff who are competent and experienced members of the clinical staff;

(4) Treatment planning involving a multidisciplinary approach and specific aftercare plans;

(5) Means to provide treatment/progress documentation to the provider.

(e) General Vendor Requirements

The vendor shall disapprove and discontinue the use of providers or contractors that fail to provide effective or timely diversion services as follows:

(1) The vendor is fully responsible for the acts and omissions of its subcontractors and of persons either directly or indirectly employed by any of them. No subcontract shall relieve the vendor of its responsibilities and obligations. All state policies, guidelines, and requirements apply to all subcontractors.

(2) If a subcontractor fails to provide effective or timely services as listed above, but not limited to any other subcontracted services, the vendor will terminate services of said contractor within 30 business days of notification of failure to provide adequate services.

(3) The vendor shall notify the appropriate board within five (5) business days of termination of said subcontractor.

#14 SENATE BILL 1441 REQUIREMENT

If a board uses a private-sector vendor that provides diversion services, the extent to which licensee participation in that program shall be kept confidential from the public.

#14 Uniform Standard

The board shall disclose the following information to the public for licensees who are participating in a board monitoring/diversion program regardless of whether the licensee is a self-referral or a board referral. However, the disclosure shall not contain information that the restrictions are a result of the licensee's participation in a diversion program.

- Licensee's name;
- Whether the licensee's practice is restricted, or the license is on inactive status;
- A detailed description of any restriction imposed.

#15 SENATE BILL 1441 REQUIREMENT

If a board uses a private-sector vendor that provides diversion services, a schedule for external independent audits of the vendor's performance in adhering to the standards adopted by the committee.

#15 Uniform Standard

1. If a board uses a private-sector vendor to provide monitoring services for its licensees, an external independent audit must be conducted at least once every three (3) years by a qualified, independent reviewer or review team from outside the department with no real or apparent conflict of interest with the vendor providing the monitoring services. In addition, the reviewer shall not be a part of or under the control of the board. The independent reviewer or review team must consist of individuals who are competent in the professional practice of internal auditing and assessment processes and qualified to perform audits of monitoring programs.

2. The audit must assess the vendor's performance in adhering to the uniform standards established by the board. The reviewer must provide a report of their findings to the board by June 30 of each three (3) year cycle. The report shall identify any material inadequacies, deficiencies, irregularities, or other non-compliance with the terms of the vendor's monitoring services that would interfere with the board's mandate of public protection.

3. The board and the department shall respond to the findings in the audit report.

#16 SENATE BILL 1441 Requirement

Measurable criteria and standards to determine whether each board's method of dealing with substance-abusing licensees protects patients from harm and is effective in assisting its licensees in recovering from substance abuse in the long term.

#16 Uniform Standard

Each board shall report the following information on a yearly basis to the Department of Consumer Affairs and the Legislature as it relates to licensees with substance abuse problems who are either in a board probation and/or diversion program.

- Number of intakes into a diversion program
- Number of probationers whose conduct was related to a substance abuse problem
- Number of referrals for treatment programs
- Number of relapses (break in sobriety)
- Number of cease practice orders/license in-activations
- Number of suspensions
- Number terminated from program for noncompliance
- Number of successful completions based on uniform standards
- Number of major violations; nature of violation and action taken
- Number of licensees who successfully returned to practice
- Number of patients harmed while in diversion

The above information shall be further broken down for each licensing category, specific substance abuse problem (i.e. cocaine, alcohol, Demerol etc.), whether the licensee is in a diversion program and/or probation program.

If the data indicates that licensees in specific licensing categories or with specific substance abuse problems have either a higher or lower probability of success, that information shall be taken into account when determining the success of a program. It may also be used to determine the risk factor when a board is determining whether a license should be revoked or placed on probation.

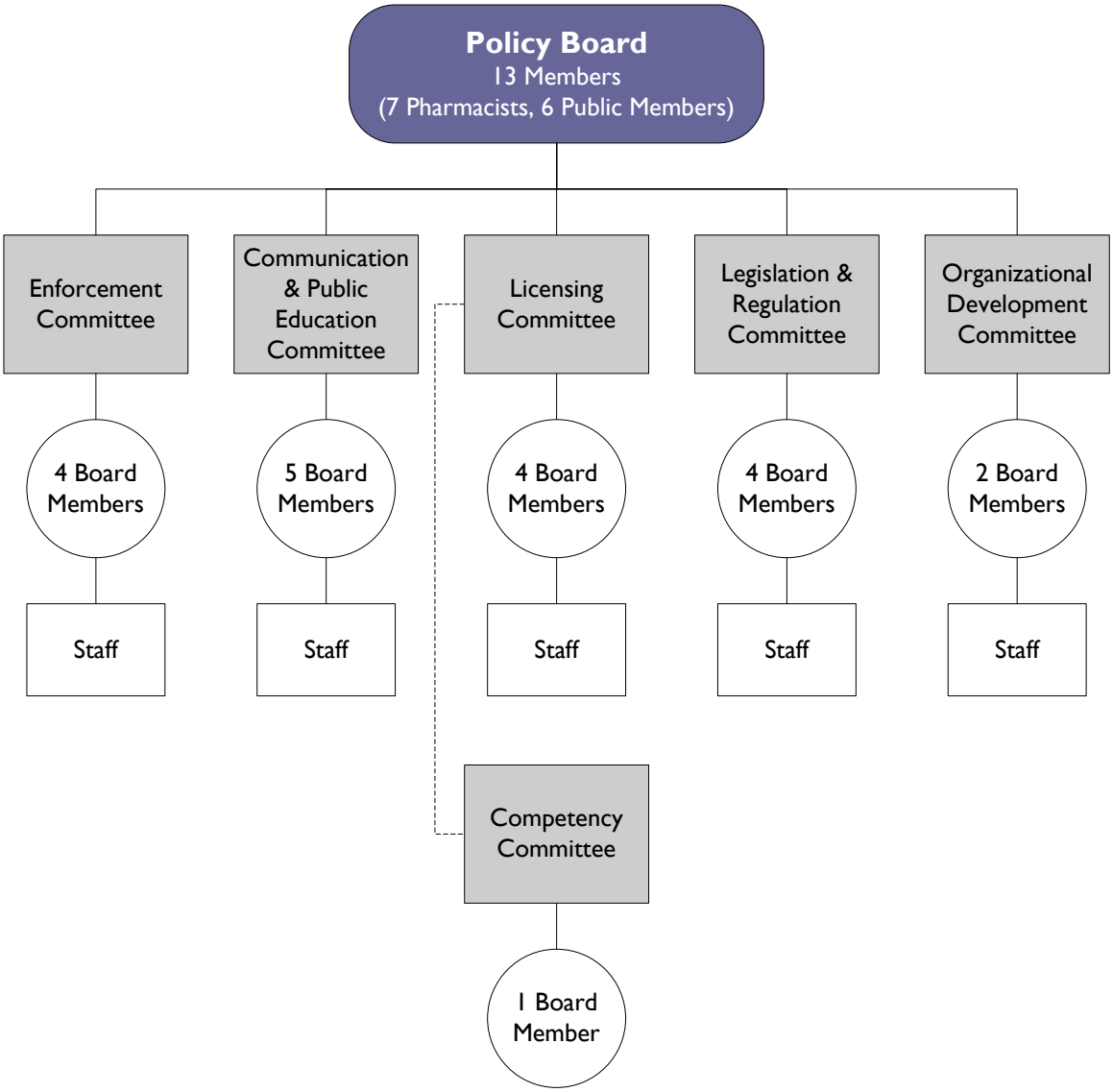
The board shall use the following criteria to determine if its program protects patients from harm and is effective in assisting its licensees in recovering from substance abuse in the long term.

- At least 100 percent of licensees who either entered a diversion program or whose license was placed on probation as a result of a substance abuse problem successfully completed either the program or the probation, or had their license to practice revoked or surrendered on a timely basis based on noncompliance of those programs.

- At least 75 percent of licensees who successfully completed a diversion program or probation did not have any substantiated complaints related to substance abuse for at least five (5) years after completion.

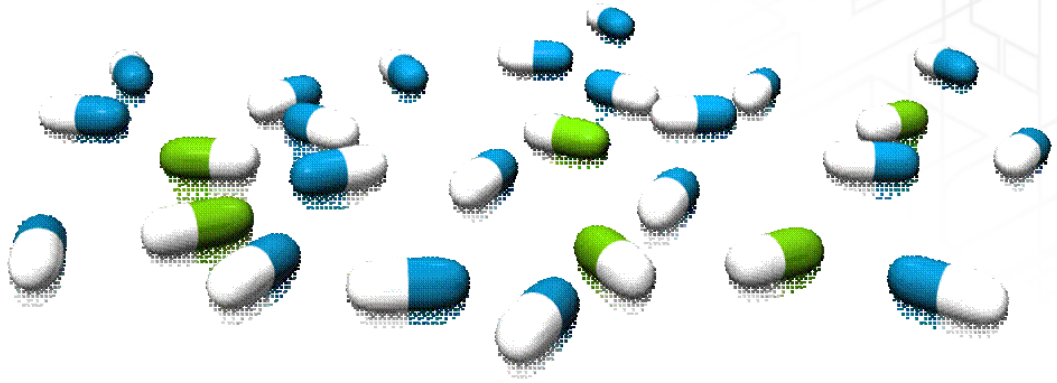
Attachment B:

Board Organizational Chart


Policy Board
13 Members
(7 Pharmacists, 6 Public Members)
Enforcement Committee
Communication & Public Education Committee
Licensing Committee
Legislation & Regulation Committee
Organizational Development Committee
4 Board Members
5 Board Members
4 Board Members
4 Board Members
2 Board Members
Staff
Staff
Staff
Staff
Staff
Competency Committee
1 Board Member

Attachment C:

Final Report: Addressing Drug and Device Recalls in Hospitals



Addressing Drug and Device Recalls in Hospitals

Developed by participants at the meetings of the California State Board of Pharmacy's Subcommittee to Evaluate Drug Distribution in Hospitals

January 2010

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Note:

This is a guidance document (not law, statute or regulation) for recalls in hospitals, and represents a list of possible actions to take to remove recalled drugs from all patient care areas in hospitals.

These practices can be summarized as:

1. Pre-position the facility to receive notice of recalls from multiple sources,
2. Identify if the facility has the product,
3. If so, quickly remove the product from all patient care areas,
4. Identify, assess, notify and treat patients who may have received the product,
5. Identify alternative products to maintain therapy,
6. Return the quarantined product,
7. Document and evaluate the process.

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Actions for Recalls

A product recall includes any notice from a drug manufacturer, wholesaler and/or FDA to return a drug product or medical device due to suspected contamination or defect. For ease of discussion throughout this discussion, "drug product" also includes medical device.

Pre-Recall Planning

The pharmacy department has direct authority and ultimate responsibility for implementation of the facility's recall policy and procedures. To achieve this, the hospital's administration needs to provide full support to the pharmacy department in executing the duties described below.

The pharmacy department should develop and implement written policies and procedures for the effective and efficient removal of recalled products from all patient care areas (inpatient and outpatient) and storage areas. However, policy and procedure development must be multidisciplinary in approach. At a minimum, representatives from nursing, medicine, pharmacy services and administration should be involved. The focus should encompass all patient care areas, including outpatient services.

1. Components of Written Procedures for Recalls:
   - Develop a duties or detail list with all steps needed to be taken during a recall so that any staff member can effectively carry out the steps. The procedures should identify the specific roles and responsibilities of all personnel involved in the recall process in sufficient detail to ensure maximum compliance. For many hospitals, a dedicated and trained recall team that knows all the policies, procedures and pertinent regulations will provide best support to the hospital in responding consistently in handling recalls. In other hospitals, fewer staff may be involved.
   - Ensure knowledge of drug recall procedures by developing facility-wide systems and providing periodic training at least annually. Ensure that:
     - Staff understand federal and state regulations governing drug product or medical device recalls.
     - Communication occurs about all pertinent recall information and a notice of the recall is distributed to all impacted areas and appropriate staff in a timely manner.
     - Various communication avenues throughout the organization are used to spread notices of recalls (email, fax inter-campus, interoffice mail, hospital newsletter – some of these methods are too slow but can serve as reminders).
     - Flyers are posted about recalls; for example, post flyers saying "bad heparin" with the lot numbers recalled.
     - There is a centrally located repository of recall notices that is readily retrievable.

2. Know All Drug Storage Areas in Hospitals:
   - Maintain control over drug storage everywhere in the hospital. Identify all locations where drugs are kept throughout the hospital: prohibit storage outside these areas.

- Allow no drugs in the hospital that were not purchased through the pharmacy. There should be no allowance for drugs to be brought in for patient use without the express knowledge and approval of the pharmacy department.
- Medical devices should be inventoried and controlled in a manner that facilitates their rapid location by the manufacturer, model product or serial number.
- Minimize the number of and maximize the quality and authority of the individuals carrying out monthly inspections. Ensure that someone is authorized to do what is necessary to secure the drug supply throughout the facility. During monthly inspections, check for recently recalled drugs to double check they have been removed from the hospital's supplies.

3. Once a Recall Has Been Initiated:
   - Establish a centralized method to receive, interpret and disseminate information about recalls, especially Class 1 recalls.
   - Assess the actual or potential clinical significance of the recall on patient care, and identify alternative drug therapy for recalled drugs or devices.
   - Specify who is responsible for checking specified drug storage areas and obtain a signoff by the individual conducting the check.
   - Establish timelines for completion of each task.
   - Establish a method to ensure all drug storage areas are checked, and then perform an audit. For example, after recall notices are faxed to all pharmacies, require all responses confirming that all recalled drugs have been removed be returned within 72 hours. After the faxes are received, consider double checking via audit of the drug storage locations.
   - Ensure that recalled drugs and devices are stored by the pharmacy in an area clearly designated as a quarantine area until disposed of as directed in the recall notice.

4. Additional Steps:
   - Monitor subsequent product shipments to ensure recalled products are not shipped into the facility.
   - Establish a system by which patients who may have been affected by the recalled product are identified and the patients' primary physician is notified and provided with recall information.
   - Establish a system to monitor implementation on a regular basis to provide insight into opportunities for process improvement.

5. Quality Assurance and Process Improvement:
   - Implement monthly reporting of recall activities. Such reports should include:
     - The number of recalls received by the organization.
     - The number of recalls requiring action by the organization.
     - The length of time from receipt of the recall notice until closure is attained.
     - The number of patients affected or potentially affected, including any adverse outcomes.
     - The location and quantity of recalled product returned.

- Identification of any problems encountered with the recall process.

- Share these reports with staff to review and identify opportunities for process improvement.

6. Activities with Drug Wholesalers to Improve Recalls:
   - Have a wholesaler representative dedicated to the hospital or hospital group. Alternatively, designate one person as the hospital's liaison with the wholesaler. This person can run reports and identify recalled drugs purchased by the hospital.
   - Collaborate and communicate with the wholesaler on drug shipments and recalls, including shipments after a recall is announced.

7. Technology-Based Solutions:
   - Stock drugs in automated dispensing cabinets (Pyxis, Omnicell) to easily and quickly do an electronic lockout for recalls.
   - Implement an adverse drug reaction system that allows better tracking of what occurred in relation to a recalled drug was administered to patients. Outcome: better communication with patients.
   - Obtain an electronic receipt of recall notices from multiple sources.

IMPROVEMENTS FOR THE RECALL SYSTEM:

1. Notification System for Recalls Needs Improvement:
   - Have a more effective recall notification system that originates in one place, listing what the issue is, what should be done, what steps should be taken, etc. Having one notice from one source with all the relevant information would minimize confusion.
   - Encourage the FDA to develop a standardized format for recalls, including listing the reason for the recall, so adherence is easier to achieve.
   - Recall notices should state whether the recall is a Class I, II or III recall. Also, notices should have clear instructions about what actions to take.
   - Encourage wholesalers to communicate recalled lot numbers to purchasers of their products.
   - Recalled products repackaged under another name or brand by a different distributor should be recalled by all names, and a separate recall notice should be listed for the distributor.

2. Establish Tracking of Drugs Throughout the Hospital:
   - Institute bar coding to better track drugs throughout the facility. Hospitals need to prioritize bar coding technology.
   - Electronic tracing or notification (e.g., secure email) of recalls would be helpful.
   - Institute RFID or bar codes and advocate to have standardized methodology in the way the information is sequenced. This should apply to the entire lifecycle of the product, so a recalled product can be identified in the hospital. E-pedigree requirements would enable better execution of a recall within a hospital.

3. Methods of Obtaining Recall Information:

- Redundant notification systems should be established to ensure the facility receives recall notices. Facilities are encouraged to subscribe to more than one method available for product recalls. Sole reliance on recall notification via the US Postal Service is not acceptable.
- Recall notices can arrive at hospitals via fax, certified letter, standard mail, emails from manufacturers, wholesalers, or notices with invoices for other drugs. Listserves of the FDA (http://www.fda.gov/Safety/MedWatch/default.htm, the California Board of Pharmacy and other entities can provide recall information.
- Closely working with the hospital's drug wholesalers will improve notice and distribution of recall information.

4. Administrative Policies

- Require that drugs be stored in specific locations and institute consequences when drugs are stored out of these areas. Increase the authority of the pharmacist-in-charge to better control where and how drugs are stored.
- Expand policies to increase responsibility of other department heads during a recall. All health care providers that are touching the drug are accountable.
- Bring together management, California Hospital Association, Medical Board, Nursing Board and Board of Pharmacy. Other health care providers should be cited and fined for their failure to follow the facility's recall procedures.

5. "Geographic" Concerns:

- Ensure there is a system to identify all outpatient clinics and other departments that are on the facility's license. This will help clarify what a pharmacist-in-charge is responsible for.
- Establish guidelines for an authorized medication storage area.
- Outside medications from vendors or contractors should not be allowed in the hospital.

Attachment C:

Emergency Response Policy Statement

Board of Pharmacy
Disaster Response Policy Statement
October 2006

Advance planning and preparation for disaster and emergency response are important activities for individuals, as well as all Board licensees. The Board has begun working on such preparedness with the federal and state government, and to this end, in October 2006, the Board adopted the following policy statement.

The California State Board of Pharmacy wishes to ensure complete preparation for, and effective response to, any local, state, or national disaster, state of emergency, or other circumstance requiring expedited health system and/or public response. The skills, training, and capacities of board licensees, including wholesalers, pharmacies, pharmacists, intern pharmacists, and pharmacy technicians, will be an invaluable resource to those affected and responding. The Board also wishes to encourage an adequate response to any such circumstance affecting residents of California, by welcoming wholesalers, pharmacies, pharmacists, intern pharmacists, and pharmacy technicians licensed in good standing in other states to assist with health system and/or public response to residents of California.

The Board encourages its licensees to volunteer and become involved in local, state, and national emergency and disaster preparedness efforts. City or county health departments, fire departments, or other first responders can provide information on local opportunities. The Emergency Preparedness Office of the California Department of Health Services is a lead agency overseeing emergency preparedness and response in California, particularly regarding health system response, drug distribution and dispensing, and/or immunization and prophylaxis in the event of an emergency. At the federal level, lead contact agencies include the Department of Health and Human Services, the Centers for Disease Control, and/or the Department of Homeland Security and its Federal Emergency Management Agency (FEMA). Potential volunteers are encouraged to register and get information at *www.medicalvolunteer.ca.gov* (California) and *www.medicalreservecorps.gov* (federal).

The Board also continues to be actively involved in such planning efforts, at every level. The Board further encourages its licensees to assist in any way they can in any emergency circumstance or disaster. Under such conditions, the priority must be protection of public health and provision of essential patient care by the most expeditious and efficient means. Where declared emergency conditions exist, the Board recognizes that it may be difficult or impossible for licensees in affected areas to fully comply with regulatory requirements governing pharmacy practice or the distribution or dispensing of lifesaving medications.

In the event of a declared disaster or emergency, the Board expects to utilize its authority under the California Business and Professions Code, including section 4062, subdivision (b) thereof, to encourage and permit emergency provision of care to affected patients and areas, including by waiver of requirements that it may be implausible to meet under these

circumstances, such as prescription requirements, record-keeping requirements, labeling requirements, employee ratio requirements, consultation requirements, or other standard pharmacy practices and duties that may interfere with the most efficient response to those affected.

The Board encourages its licensees to assist, and follow directions from, local, state, and national health officials. The Board expects licensees to apply their judgment and training to providing medication to patients in the best interests of the patients, with circumstances on the ground dictating the extent to which regulatory requirements can be met in affected areas. The Board further expects that during such emergency, the highest standard of care possible will be provided, and that once the emergency has dissipated, its licensees will return to practices conforming to state and federal requirements.

Furthermore, during a declared disaster or emergency affecting residents of California, the Board hopes that persons outside of California will assist the residents of California. To facilitate such assistance, in the event of a declared California disaster or emergency, the Board expects to use its powers under the California Business and Professions Code, including section 900 and section 4062, subdivision (b) thereof, to allow any pharmacists, intern pharmacists, or pharmacy technicians, who are not licensed in California but who are licensed in good standing in another state, including those presently serving military or civilian duty, to provide emergency pharmacy services in California. The Board also expects to allow nonresident pharmacies or wholesalers that are not licensed in California but that are licensed in good standing in another state to ship medications to pharmacies, health professionals or other wholesalers in California.

Finally, the Board also expects to allow use of temporary facilities to facilitate drug distribution during a declared disaster or state of emergency. The Board expects that its licensees will similarly respond outside of the state to disasters or emergencies affecting populations outside California, and will pursue whatever steps may be necessary to encourage that sort of licensee response.

1Expanded powers in the event of a disaster are also granted to the Governor and/or other chief executives or governing bodies within California by the California Emergency Services Act [Cal. Gov. Code, §§ 8550-8668] and the California Disaster Assistance Act [Cal. Gov. Code, §§ 8680-8690.7], among others. Section 8571 of the Government Code, for instance, permits the Governor to suspend any regulatory statute during a state of war or emergency where strict compliance therewith would prevent, hinder, or delay mitigation.

2See also the Interstate Civil Defense and Disaster Compact [Cal. Gov. Code, §§ 177-178], the Emergency Management Assistance Compact [Cal. Gov. Code, §§ 179-179.5], and the California Disaster and Civil Defense Master Mutual Aid Agreement [executed 1950], regarding cooperation among the states.

Attachment C:

Fee Audit 2009

California Board of Pharmacy

Independent Review of the Board's Fee Structure

December 2008

SJOBERG EVASHENK CONSULTING, INC

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Table of Contents

EXECUTIVE SUMMARY AND INTRODUCTION 1

RESULTS IN BRIEF 3

SCOPE AND METHODOLOGY 4

COST ALLOCATION ANALYSIS RESULTS 5

APPENDICES 24

California Board of Pharmacy
Independent Review of the Board's Fee Structure

Executive Summary and Introduction

The California Department of Consumer Affairs, Board of Pharmacy (Board) contracted with Sjoberg Evashenk Consulting, Inc. (SEC), to conduct an independent audit of the Board's fee structure, considering the following objectives:

- Performing an analysis of the Board's fee structure to determine if fee levels are appropriate for the recovery of the actual cost of conducting its programs;
- Assessing and revealing any levels of subsidy, surplus, or cross subsidies existing between licensure groups, such as individuals and facilities;
- Projecting fees and revenues and related costs for the next five years; and
- Assessing activity and workload data for each staff person to determine an hourly cost or cost per unit for the various Board activities and services.

Currently within the Department of Consumer Affairs, the Board was established in 1891 to protect consumers by licensing and regulating all aspects of the practice of pharmacy in California, including pharmacists, pharmacy practice, and prescription drugs and devices. The Board also regulates drug wholesalers, specialized facilities, and other practitioners such as pharmacist interns and technicians. The Board's activities are financed through its ability to collect fees related to application and license-processing services it provides to the following 14 major categories:

- Pharmacist
- Pharmacy Technician
- Pharmacist Intern
- Designated Representative - VET Exemption
- Designated Representative - WLS Exemption
- Pharmacy (including hospitals and correctional facilities)
- Non-Resident Pharmacy
- Clinic
- Wholesaler
- Hypodermic Needle and Syringe
- Non-Resident Wholesaler
- Sterile Compounding
- Non-Resident Sterile Compounding
- Veterinary Food Drug Retailer

There are also additional miscellaneous fees associated with transferring intern hours, verifying licenses, regrading pharmacist licensure exams, changing permits (addresses and reissuance), changing the pharmacist or designated representative in charge, and issuing duplicate, replacement, or retired pharmacist licenses.

As of July 2008, the Board's licensee population was just over 108,000. This is an increase of about 65 percent since 1998 without a significant change in staffing.

Table 1: License Growth—1998 to 2008

License Type	1998	2008	% Change
Pharmacist	29,261	36,077	23%
Pharmacist Intern	2,550	4,591	80%
Pharmacy Technician	23,931	54,790	129%
Designated Representative (WLS & VET)	2,138	2,887	35%
Pharmacy (including hospitals and licensed correctional facilities)	5,934	6,647	12%
Non-Resident Pharmacy	135	345	156%
Clinics (including drug rooms)	445	1,151	159%
Wholesalers	461	489	6%
Non-Resident Wholesalers	271	528	95%
Hypodermic	368	304	-17%
Sterile Compounding	N/A	225	N/A
Non-Resident Sterile Compounding	N/A	53	N/A
Veterinarian Food Drug Retailer	N/A	23	N/A
Totals	**65,494**	**108,110**	**65%**

The California Business and Professions code allows the Board to charge fees to cover the cost of providing licensing and compliance services—limiting the Board to charging fees that are not beyond a certain statutory maximum. Prior to January 2008, the Board had not implemented a fee increase in nearly 20 years[1], although it has experienced increases in the cost of providing services, particularly related to employee salaries and benefits. The Board historically has experienced difficulty hiring and retaining inspectors, as those positions require individuals with Pharmacy degrees. To address this difficulty, the Board recently began providing this class of employees with monthly recruitment and retention bonuses, which have significantly increased the Board's expenditures and thus, its cost of providing services.

[1] With the exception of a brief period between 1995 and 1999 where fees were temporarily increased and subsequently reduced.

In January 2008, the Board increased all categories of fees to the statutory maximums as expenditures had surpassed its revenue collections for several years. Operating with expenditures exceeding revenues had the effect of reducing the Board's fund balance as well as its ability to meet the 12-months of expenditures reserve required by statute.

Additionally, several future initiatives by the Board may further increase its costs in the future, including:

- Regular Site Inspections and Audits—Currently, due to resource limitations, the Board's site inspection activities are in reaction to complaints; the Board stated a desire to become proactive with routine and regular inspections of all site facilities.
- Criminal Conviction Unit—The Board is establishing this unit to address the high volume of rap sheets and arrest notifications received annually; responsibilities will include reviewing the rap sheets to determine the category of conviction and whether it is substantially related to the licensee's duties, qualifications, and functions, the seriousness of the offense, and the imminent threat, if any, to the public's health and safety.
- Drug Tack-Back— Current law does not allow for environmental-friendly, or "green," options for disposing of unwanted medicine; the Board is coordinating with other state agencies, local governments, drug manufacturers, and pharmacies to develop sustainable and efficient policies to manage pharmaceutical wastes and the disposal of devices.
- Drug Recall Monitoring—A series of recent recalls and subsequent inspections and investigations have prompted the Board to take action in identifying problems with the recall system; the Board is working with the California Department of Public Health, the California Society of Health-System Pharmacists, the California Hospital Association, and the FDA to identify potential problems and develop California-specific solutions.

However, the costs associated with these planned initiatives were not included in the future projections related to this study as the costs associated with implementing these programs are not yet determined.

Results in Brief

We performed an expenditure-allocation analysis to determine the cost of the services provided by the Board to compare against the fees charged for providing those services. While cost allocation results do not necessarily set the ideal price point to charge for providing and being reimbursed for the services, the information is one key consideration in identifying consumption of resources and establishing reasonable justification for ultimate fees for those services. Other key considerations involve workload changes, economic volatility, and client climate.

Based on the cost allocation process that we employed to arrive at the unit cost for each of the fees charged by the Board, we were able to estimate the Board's future fee revenue

and reserve position. As a result, our analysis reveals that the Board's current fee structure is insufficient to maintain the legislatively mandated 12-month reserve requirement (beginning in Fiscal Year 2008-2009) and the Board's position will continue to deteriorate until it eventually exhausts all reserves. As such, we created four scenarios to adjust the Board's fee structure; each scenario projection improves the Board's reserve position. The major difference in the scenarios pertains to which fees (some or all) are adjusted and the method to which they are adjusted:

- Increasing only the fees that are below their associated unit cost,
- Full cost recovery of every fee, and
- Two across the board fee hikes—high (20%) and low (15%).

This information is intended to provide the Board with data to assist its decision-making processes and to improve its reserve position.

Scope and Methodology

The objectives of this rate study audit were to provide the California Board of Pharmacy with analyses of the Board's fee structure to determine whether existing fee levels are appropriate for the recovery of the actual cost of conducting its many programs. To meet the audit objectives, we performed the following procedures:

- Interviewed Board officials to gain an understanding of the Board's overall environment as it relates to processing and licensing applicants;
- Reviewed Board-developed process flow diagrams, workload data projections and statistics, and timed task information.
- Obtained and analyzed projected-to-actual revenue and expenditure and workload data;
- Developed cost allocation methodology, utilizing workload and timed task data prepared by the Board;
- Identified fees charged by the Board and determined annual amount of revenues collected;
- Calculated the cost of providing the services, including determining the hourly unit cost for activities and services for each staff person;
- Compared the amount of fees charged for services to the cost of providing the services and determined if the current fee levels are appropriate for recovering of the cost of providing the services;
- Identified surpluses and subsidies that exist between licensure groups;
- Reviewed Board fiscal records showing actual expenditures;
- Projected fees, revenues, and expenditures for the next five years (through 2013); and
- Ascertained whether the fee amounts currently charged are sufficient so that the Board's reserve fund complies with legislative requirements.

Board's Current Fee Structure is Insufficient to Maintain Mandated Reserve Requirements

At the beginning of 2008, many of the Board's fees were increased to legislative maximums because the Board's expenditures were outpacing receipts and draining the Board's reserves. The January 2008 fee increase was the first increase in nearly 20 years (with the exception of a temporary increase in 1995 that lasted four years). According to Business and Profession Code 4400 (p), the Board shall maintain a reserve[2] equal to one-year of operating expenditures to cushion against unexpected revenue shortfalls. However, our analysis reveals that the Board's current fee structure is insufficient to maintain the legislatively mandated 12-month reserve requirement and will continue to deteriorate until the Board eventually exhausts all reserves.

To understand why the Board's expenditures are outpacing receipts, we performed a detailed cost-allocation analysis, analyzed the Board's reserve position under the current fee structure, and estimated future receipts based on workload projections. Then, we created four scenarios to adjust the Board's current fee structure; each scenario projects an increase in revenue and an improvement in reserve position:

- Increasing only the fees that are below their associated unit cost,
- Full cost recovery of every fee, and
- Two across the board fee hikes—high (20%) and low (15%).

Each of the four scenarios utilize the same projections related to interest, cite and fine and cost recovery revenue, and expenditures. The only key component in projecting the Board's reserve position that is adjusted in the four scenarios relates to the Board's fee revenues.

In the following discussion, we first present the Board's current reserve position and then present the four scenarios described above.

Analysis of Board's Reserve Position Under Current Fee Structure

Based on our cost allocation process (Refer to the detailed methodology discussion beginning on page 15), we arrived at the unit cost for each of the fees charged by the Board. Based upon those unit costs and workload trends, we can estimate the Board's future fee revenue. To estimate the Board's reserve position, we developed estimates related to the following key components:

- Fee Revenue (applications, licenses, etc)
- Interest Revenue
- Cite and Fine, Cost Recovery, Miscellaneous Revenue
- Expenditures

[2] Total revenues less expenditures including carry-overs from previous periods.

Fee Revenue

To estimate future fee revenue, we first developed workload trends based on fiscal-years 2005/2006 to 2007/2008 actual workload data[3], which shows that during that time period workload increased by an overall average of more than 4 percent annually with variances amongst individual license categories. Refer to Table 2 for actual workload data for Fiscal Years 2005/2006 through 2007/2008.

Table 2: Actual Workload Data—2005/2006 through 2007/2008

License Category	FY 2005-2006	FY 2006-2007	FY 2007-2008	Average % Change
Pharmacist	18,549	18,808	19,259	1.90%
Pharmacist Technician	26,624	30,025	30,949	7.93%
Pharmacy Intern	1,510	1,614	1,733	7.12%
Designated Representative—VET	50	73	61	14.64%
Designated Representative—WLS	3,243	3,025	3,130	-1.63%
Pharmacy (including hospitals and licensed correctional facilities)[4]	6,921	6,359	6,531	-2.71%
Non-Resident Pharmacy	280	312	324	7.61%
Clinics (including drug rooms)	896	959	1,020	6.69%
Wholesalers	525	508	495	-2.93%
Non-Resident Wholesalers	478	494	528	5.11%
Hypodermic	309	300	284	-4.05%
Sterile Compounding	212	214	215	0.80%
Non-Resident Sterile Compounding	46	55	67	20.69%
Veterinarian Food Drug Retailer	18	23	23	13.89%
Transfer of Intern Hours/License Verification	828	795	898	4.49%
Re-grade of Pharmacist Licensure Exam	40	28	12	-43.57%
Change of Permit - Re-issuance	532	496	589	5.99%
Change of Permit - Trade style/Address	101	105	284	87.22%
Change of Pharmacist in Charge	1,340	1,572	1,419	3.79%
Change of Designated Representative in Charge	57	62	82	20.51%
Duplicate/Replacement License	615	568	679	5.98%
Retired Pharmacist	24	36	13	-6.94%
Totals	**63,198**	**66,430**	**68,595**	**4.19%**

[3] Workload data derived from CAL Stars reports includes number of applications renewed and processed.
[4] Includes one-time change of ownership related to a chain pharmacy buy-out.

While the Board does not escalate workload when developing their projections of future revenue, our projections of future workload utilized fiscal year 2007/2008 workload data as the baseline and applied a percentage increase for future years using the 2005/2006 to 2007/2008 actual workload trends; however, to be conservative, the projected percentage increases were reduced by half with an overall annual workload estimated increase of slightly more than 2 percent. To arrive at estimate revenue totals, each category's workload trends were multiplied against the current fees charged for providing services. On Table 3, we provide detailed revenue projections under the current fee structure and in Appendix A, we provide detailed revenue projections for each fee under the current fee structure.

Interest Revenue

While the Board includes estimates of interest revenue in its projections, it does not escalate the interest estimates; rather it projects a flat $127,000 in Fiscal Year 2008/2009 and beyond. Because 2007/2008 actual interest revenues of nearly $490,000 were unusually high due to interest received related to a General Fund loan that has since been repaid to the Board, we did not use this figure as the baseline in our projections. Instead, we used the Board's $127,000 projection and simply escalated this amount by almost 2 percent through 2013 to keep consistent with projections of workload increases and cite and fine, cost recovery projections. Refer to Table 3 for a summary of the interest revenue projections for the next five years.

Cite and Fine, Cost Recovery, and Miscellaneous Revenue

Although the Board typically does not include Cite and Fine or Cost Recovery income in their projections of future revenue, our projections include this additional non-fee revenue as it accounted for more than 11 percent of total income in Fiscal Year 2007/2008. To provide a conservative estimate of this revenue, our projections cut in half the 2007/2008 Cite and Fine and Cost Recovery income, and project this revenue by little more than 2 percent through 2013 to remain consistent with projections of workload increases. Refer to Table 3 for a summary of the Cite and Fine and Cost Recover income projections for the next five years.

Expenditures

Expenditure trends based on 2005/2006 to 2007/2008 actual data revealed the Board's costs have increased by an overall average of more than 10 percent annually—$7.6 million in 2005/2006 to $9.1 million in 2007/2008. However, certain expenditures during Fiscal Year 2007/2008 (such as recruitment and retention bonuses for Inspectors) were one-time adjustments. As such, we discounted the non-recurring items resulting in approximately $8.1 million in recurring expenditures in 2007/2008, which we used as the baseline for our projections. The adjusted average increase is slightly more than 3 percent and our projections of future expenditures through 2013 increase expenditures by approximately the same percentage. Refer to Table 3 for a summary of expenditure projections for the next five years.

Reserve Position

According to Business and Profession Code 4400 (p), the Board is required to maintain a reserve equal to one-year of operating expenditures to cushion against unexpected revenue shortfalls. At the end of Fiscal-Year 2007/2008, the Board met this requirement as it had 13.7 months of expenditures in reserve. However, using our projections of revenue and expenditures and as illustrated in Table 3, we were able to conclude that the Board's reserve position will begin to deteriorate next year and continue to erode each year thereafter. As a result, the projected months of expenditures in reserve will also fall and the Board is estimated to have only 6.7 months of expenditure reserves by 2013. Refer to Table 3 for a summary of the Board's reserve position projections through 2013 under the current fee structure.

Table 3: Board's 2007/2008 Actual Financial Condition and 2008/2009 through 2012/13 Financial Condition Projections under the Current Fee Structure

	FY 2007/2008[5]	FY 2008/2009	FY 2009/2010	FY 2010/2011	FY 2011/2012	FY 2012/2013
Beginning Fund Balance reserve	$11,015,150	$10,782,385	$9,149,309	$8,375,243	$8,457,399	$7,387,809
Fee Revenue	$7,409,661	$8,210,997	$8,347,911	$8,490,715	$8,634,502	$8,769,688
Interest	$487,970	$127,000	$129,730	$132,519	$135,368	$138,279
Cite and Fine, cost recovery, misc.	$1,004,966	$445,831	$455,416	$465,207	$475,209	$485,426
GF loan	$0	$(1,000,000)	$0	$1,000,000	$0	$0
Expenditures	$9,135,362	$9,416,904	$9,707,123	$10,006,287	$10,314,670	$10,632,558
Ending fund balance reserves	$10,782,385	$9,149,309	$8,375,243	$8,457,399	$7,387,809	$6,148,644
Expenditure projections (for following year)	$9,416,904	$9,707,123	$10,006,287	$10,314,670	$10,632,558	$10,960,242
Expenditures per month	$784,742	$808,926	$833,857	$859,555	$886,046	$913,353
Months of reserve projected	**13.7**	**11.3**	**10.0**	**9.8**	**8.3**	**6.7**

[5] 2007/2008 are actual figures Per CAL-Stars Fiscal Records.

Projections Utilizing Increases to Fees Currently Subsidized

In this scenario, future reserve projections are based on individual analysis of each license group and only the current fees charged that are below the unit cost of providing the services are increased. Further, each fee increase is assigned an escalator based on its percentage share of responsibility for the overall revenue shortfall. For example, the Pharmacy Technician category represents a larger percentage of the overall shortfall and thus a larger percentage increase is applied to that category. However, the fees are not raised to their full unit cost and continue to be subsidized by other fees—but to a lesser degree. See Table 4 for a list of the fees with unit costs higher than current fees charged and the corresponding upward adjustment of those fees. Refer to Appendix B for a detailed comparison of 2007-2008 revenue and expenses for each fee, including the subsidies or surpluses for each fee category.

Table 4: Upward Adjustment of Fees with Unit Costs Higher than Current Fees

	Difference between revenue and expenditures (Subsidies)	% of subsidy	2007/ 2008 Unit Costs	Jan 2008 Fees	Increase based on % of subsidy[6]	Unit Cost Plus Increase Rounded Up	Evened Out to a maximum of $5	Total Adjustment (maximum 100% increase)
Pharmacist Licensure Exam Application	$84,688	2.63%	$219	$185	$14.60	$200	$0	$200
Pharmacy Technician Original License	$552,398	17.16%	$123	$50	$25.74	$76	$4	$80
Pharmacy Technician Renewal	$2,219,827	68.96%	$153	$50	$103.44	$154	N/A	$100
Pharmacy Technician Delinquent Fee	$78,396	2.44%	$67	$25	$1.83	$27	$3	$30[7]
Pharmacist Intern Permit	$143,516	4.46%	$151	$75	$10.03	$86	$4	$90
Designated Representative - VET Original Application	$204	0.01%	$141	$100	$0.02	$101	$4	$105
Designated Representative – VET Delinquent Fee	$37	0.00%	$92	$55	$0.00	$56	$4	$60[7]
Designated Representative - WLS Original Application	$21,105	0.66%	$155	$140	$2.75	$143	$2	$145
Hypodermic Needle and Syringe Original Permit	$2,955	0.09%	$339	$125	$0.34	$126	$4	$130
Sterile Compounding Original Permit	$5,236	0.16%	$653	$600	$2.92	$603	$2	$605
Veterinary Food-Animal Drug Retailer Permit	$944	0.03%	$872	$400	$0.35	$401	$4	$405
Transfer of Intern Hours/License Verification	$63,005	1.96%	$85	$20	$1.17	$22	$3	$25
Regrade of Pharmacist Licensure Exam	$1,685	0.05%	$220	$85	$0.13	$86	$4	$90
Change of Permit Tradestyle/Address	$12,786	0.40%	$75	$30	$0.36	$31	$4	$35
Duplicate/Replacement License	$31,144	0.97%	$76	$30	$0.87	$31	$ 4	$35
Retired Pharmacist	$1,069	0.03%	$112	$30	$0.03	$31	$4	$35
	$3,218,993	**100%**						

[6] Each fee is adjusted by increasing each current fee by its % of subsidy and multiplying the result by a factor of 3.

[7] Any changes to delinquency fees must adhere to Section 163.5 of the Business and Professions Code authorizes specifies that delinquency fees shall be 50% of the renewal fee—thus, adjustments may be needed to any finalized fee changes.

Also, under this scenario no current fees are reduced, even if the unit cost of providing the service is below the amount charged. Given that certain activity subsidizes other types of processing activity, the Board should determine whether they wish to lower certain renewal fees. However, doing so will require other fee increases.

Following the scenario to increase those fees not fully supporting the associated activity would result in increased fee revenue from $8,347,911 under the current fee structure to $9,087,398 in 2009/2010 and from $8,490,715 to $10,024,306 in 2010/2011. Refer to Table 5 for a summary of the Board's reserve position projections through 2013 under this scenario.

Table 5: Board's 2007/2008 Actual Financial Condition and 2008/2009 through 2012/2013 Financial Condition Projections Utilizing Increases to Fees Currently Subsidized

	FY 2007/2008[8]	FY 2008/2009[9]	FY 2009/2010[10]	FY 2010/2011	FY 2011/2012	FY 2012/2013
Beginning Fund Balance reserve	$11,015,150	$10,782,385	$9,149,309	$9,114,730	$10,730,477	$11,248,356
Fee Revenue	$7,409,661	$8,210,997	$9,087,398	$10,024,306	$10,221,971	$10,406,801
Interest	$487,970	$127,000	$129,730	$132,519	$135,368	$138,279
Cite and Fine, cost recovery, misc.	$1,004,966	$445,831	$455,416	$465,207	$475,209	$485,426
GF loan	$0	$(1,000,000)	$0	$1,000,000	$0	$0
Expenditures	$9,135,362	$9,416,904	$9,707,123	$10,006,287	$10,314,670	$10,632,558
Ending fund balance reserves	$10,782,385	$9,149,309	$9,114,730	$10,730,477	$11,248,356	$11,646,306
Expenditure projections (for following year)	$9,416,904	$9,707,123	$10,006,287	$10,314,670	$10,632,558	$10,960,242
Expenditures per month	$784,742	$808,926	$833,857	$859,555	$886,046	$913,353
Months of reserve projected	**13.7**	**11.3**	**10.9**	**12.5**	**12.7**	**12.8**

[8] 2007/2008 are actual figures Per CAL-Stars Fiscal Records.
[9] 2008/2009 Projections are under the current fee structure as an increase would not likely go into effect until mid Fiscal Year 2009/2010.
[10] 2008/2009 Projections are under the current fee structure for half the year as an increase would not likely go into effect until Fiscal Year 2009/2010.

Projections Utilizing Full Cost Recovery

A second approach to shore up the Board's future reserve position is based on full recovery of the unit cost of each fee category. To most accurately reflect the cost of services, under this scenario, some fees were significantly reduced as the current fee charged far exceeds the unit cost of providing the service while other fees were significantly increased as the current fee charged is far below the unit cost of providing the service. There is no subsidy of one fee by another under this scenario. The Board may want to consider this information when requesting changes to the statutory maximum for each fee—even if the Board chooses not to raise the fees to that maximum in the near term and continues to subsidize certain fees, such as Pharmacy Technician fees.

Increasing the fees following the full-recovery approach would increase fee revenue from $8,347,911 under the current fee structure to $9,027,475 in 2009/2010 and from $8,490,715 to $10,006,195 in 2010/2011. Refer to Table 6 for a summary of the Board's reserve position projections through 2013 under the full cost recovery structure. Refer to Appendix D for a detailed listing of revenue projections for each fee under this scenario.

Table 6: Board's 2007/2008 Actual Financial Condition and 2008/2009 through 2012/13 Financial Condition Projections under a Full Cost Recovery Structure

	FY 2007/2008[11]	FY 2008/2009[12]	FY 2009/2010[13]	FY 2010/2011	FY 2011/2012	FY 2012/2013
Beginning Fund Balance reserve	$11,015,150	$10,782,385	$9,149,309	$9,054,849	$10,652,577	$11,263,156
Fee Revenue	$7,409,661	$8,210,997	$9,027,518	$10,006,287	$10,314,670	$10,632,558
Interest	$487,970	$127,000	$129,730	$132,519	$135,368	$138,279
Cite and Fine, cost recovery, misc.	$1,004,966	$445,831	$455,416	$465,207	$475,209	$485,426
GF loan	$0	$(1,000,000)	$0	$1,000,000	$0	$0
Expenditures	$9,135,362	$9,416,904	$9,707,123	$10,006,287	$10,314,670	$10,632,558
Ending fund balance reserves	$10,782,385	$9,149,309	$9,054,849	$10,652,577	$11,263,156	$11,886,862
Expenditure projections (for following year)	$9,416,904	$9,707,123	$10,006,287	$10,314,670	$10,632,558	$10,960,242
Expenditures per month	$784,742	$808,926	$833,857	$859,555	$886,046	$913,353
Months of reserve projected	**13.7**	**11.3**	**10.9**	**12.4**	**12.7**	**13.0**

[11] 2007/2008 are actual figures Per CAL-Stars Fiscal Records.
[12] 2008/2009 Projections are under the current fee structure as an increase would not likely go into effect until mid Fiscal Year 2009/2010.
[13] 2008/2009 Projections are under the current fee structure for half the year as an increase would not likely go into effect until Fiscal Year 2009/2010.

Projections Utilizing Across the Board % Increase (Low and High)

Finally, a third option utilizes two scenarios of "across the board" increases for all fee categories. Future reserve projections greatly improve under across the board percent increases, raising all fees by the same percentage. We present two scenarios: a low across the board increase at 15 percent and a high across the board increase at 20 percent.

- Across the Board Low—Increasing the fees using this scenario will increase fee revenue from $8,347,911 under the current fee structure to $8,968,511 in 2009/2010 and from $8,490,715 under the current fee structure to $9,753,454 in 2010/2011.
- Across the Board High—Increasing the fees using this scenario will increase fee revenue from $8,347,911 under the current fee structure to $9,177,033 in 2009/2010 and from $8,490,715 under the current fee structure to $10,177,517 in 2010/2011.

Refer to Tables 7 and 8, for a summary of the Board's reserve position projections through 2013 under an across the board increase low (15%) and high (20%). Also, refer to Appendices E and F for a detailed listing of each fee increase under these scenarios.

Table 7: Board's 2007/2008 Actual Financial Condition and 2008/2009 through 2012/13 Financial Condition Projections under an Across the Board Increase—Low (15%)

	FY 2007/2008[14]	FY 2008/2009[15]	FY 2009/2010[16]	FY 2010/2011	FY 2011/2012	FY 2012/2013
Beginning Fund Balance reserve	$11,015,150	$10,782,385	$9,149,309	$8,995,903	$10,340,798	$10,555,516
Fee Revenue	$7,409,661	$8,210,997	$8,968,571	$9,753,454	$9,918,810	$10,074,273
Interest	$487,970	$127,000	$129,730	$132,519	$135,368	$138,279
Cite and Fine, cost recovery, misc.	$1,004,966	$445,831	$455,416	$465,207	$475,209	$485,426
GF loan	$0	$(1,000,000)	$0	$1,000,000	$0	$0
Expenditures	$9,135,362	$9,416,904	$9,707,123	$10,006,287	$10,314,670	$10,632,558
Ending fund balance reserves	$10,782,385	$9,149,309	$8,995,903	$10,340,798	$10,555,516	$10,620,937
Expenditure projections (for following year)	$9,416,904	$9,707,123	$10,006,287	$10,314,670	$10,632,558	$10,960,242
Expenditures per month	$784,742	$808,926	$833,857	$859,555	$886,046	$913,353
Months of reserve projected	**13.7**	**11.3**	**10.8**	**12.0**	**11.9**	**11.6**

[14] 2007/2008 are actual figures Per CAL-Stars Fiscal Records.
[15] 2008/2009 Projections are under the current fee structure as an increase would not likely go into effect until mid Fiscal Year 2009/2010.
[16] 2008/2009 Projections are under the current fee structure for half the year as an increase would not likely go into effect until Fiscal Year 2009/2010.

Table 8: Board's 2007/2008 Actual Financial Condition and 2008/2009 through 2012/2013 Financial Condition Projections under an Across the Board Increase—High (20%)

	FY 2007/2008[17]	FY 2008/2009[18]	FY 2009/2010[19]	FY 2010/2011	FY 2011/2012	FY 2012/2013
Beginning Fund Balance reserve	$11,015,150	$10,782,385	$9,149,309	$9,204,365	$10,973,323	$11,619,294
Fee Revenue	$7,409,661	$8,210,997	$9,177,033	$10,177,517	$10,350,062	$10,512,285
Interest	$487,970	$127,000	$129,730	$132,519	$135,368	$138,279
Cite and Fine, cost recovery, misc.	$1,004,966	$445,831	$455,416	$465,207	$475,209	$485,426
GF loan	$0	$(1,000,000)	$0	$1,000,000	$0	$0
Expenditures	$9,135,362	$9,416,904	$9,707,123	$10,006,287	$10,314,670	$10,632,558
Ending fund balance reserves	$10,782,385	$9,149,309	$9,204,365	$10,973,323	$11,619,294	$12,122,727
Expenditure projections (for following year)	$9,416,904	$9,707,123	$10,006,287	$10,314,670	$10,632,558	$10,960,242
Expenditures per month	$784,742	$808,926	$833,857	$859,555	$886,046	$913,353
Months of reserve projected	**13.7**	**11.3**	**11.0**	**12.8**	**13.1**	**13.3**

[17] 2007/2008 are actual figures Per CAL-Stars Fiscal Records.
[18] 2008/2009 Projections are under the current fee structure as an increase would not likely go into effect until mid Fiscal Year 2009/2010.
[19] 2008/2009 Projections are under the current fee structure for half the year as an increase would not likely go into effect until Fiscal Year 2009/2010.

Cost Allocation Analysis Methodology

We performed an expenditure-allocation analysis to determine the cost of the various services provided by the Board to compare against the related fees charged for providing those services. While cost allocation results do not necessarily set the ideal price point to charge for providing and being reimbursed for the services, the information is one key consideration in identifying uses of resources and establishing reasonable justification for ultimate fees for those services. Included in our cost allocation analysis are the following types of costs:

- Direct costs, such as Attorney General and DCA data processing charges that generally relate only to licensing activities.
- Indirect or "common costs" such as salaries, benefits, facilities, office equipment, and training etc. relate to all activities performed by Board employees, including application processing, administration, investigations, etc. These cost elements are included in arriving at the unit cost of the Board's fees and in calculating fully-loaded billing rates for Board employees.

Pass-through costs related to fingerprint reports are reimbursed in full through separate fees charged to and paid by applicants. The fees collected are given directly to the Department of Justice that, in turn, incurs the cost of fingerprint analysis. As such, pass-through costs were eliminated from the cost allocation analysis.

Table 9, reflects the Board's expenditures grouped by cost type.

Table 9: Board Expenditures—Fiscal Year 2007/2008

Expenditure Category	FY 2007/08
Direct Costs	
General Data Processing	$60,599
Printing	$94,866
Postage	$88,901
DCA Data Processing	$373,668
Consulting	$505,610
Licensure Enforcement (OAG Billings)	$1,135,423
Examinations	$157,438
Total Direct Costs	**$2,416,505**
Indirect Costs	
Insurance	$1,892
Vehicle Operations	$72,605
Cell Phones	$31,899
Travel Expense[20]	$243,708
Personnel & Benefits	$4,843,175
DCA Facilities Operations	$263,903
Training	$12,468
General Expense	$173,827
Other Communications	$20,050
Office Equipment Expense	$113,193
DCA Central Admin Pro-Rata	$334,043
DCA Indirect Distribution Costs	$523,517
Total Indirect Costs	**$6,634,280**
Total 2007/08 Expenditures[21]	**$9,050,785**

[20] Includes Board member travel costs.

[21] Total 2007/2008 Expenditures do not include Pass-through Costs – Fingerprint reports for $84,577.

Allocation of Direct or "Purchase" Costs

To begin the allocation process related to the approximate $2.4 million in direct costs, we initially formed a high-level distribution across each of the Board's 14 major license categories based on each category's number of licenses and permits as of July 2008.

Table 10: High Level Allocation of Fiscal Year 2007/2008 Direct Costs

License Category	Number of Licenses as of July 2008	Category Percentage	High Level Allocation of Direct Costs
Pharmacist	36,077	33.37%	$806,403
Pharmacist Intern	4,591	4.25%	$102,619
Pharmacy Technician	54,790	50.68%	$1,224,681
Designated Representative—WLS	60	0.06%	$1,341
Designated Representative—VET	2,827	2.61%	$63,190
Pharmacy (including hospitals and licensed correctional facilities)	6,647	6.15%	$148,576
Non-Resident Pharmacy	345	0.32%	$7,712
Clinics (including drug rooms)	1,151	1.06%	$25,727
Wholesalers	489	0.45%	$10,930
Non-Resident Wholesalers	528	0.49%	$11,802
Hypodermic	304	0.28%	$6,795
Sterile Compounding	225	0.21%	$5,029
Non-Resident Sterile Compounding	53	0.05%	$1,185
Veterinarian Food Drug Retailer	23	0.02%	$514
Total	**108,110**	**100%**	**$2,416,505**

We further allocated the direct costs to the individual fees within each of the 14 major license categories based on each fee's percentage of the category's total workload—see example related to Pharmacists fees in Table 11.

Table 11: Detailed Allocation of Direct Costs to Fees within the Pharmacist Category

Pharmacist	07/08 work-load	% of work-load	Allocation within Group	Less 15% DCA Data Processing[22]	Less 7% Exams[18]	Sub-Total Allocation within Group	Reallocation of DCA Billings	Reallocation of Examinations	Total Allocation of Direct Costs
Pharmacist Licensure Exam Application	1,918	10%	$80,310	$12,418	$5,232	$62,659	N/A	$157,438	$220,097
Pharmacist Original License	1,351	7%	$56,568	$8,747	$3,685	$44,136	N/A	N/A	$44,136
Pharmacist Renewal	15,677	81%	$656,420	$101,503	$42,766	$512,150	$122,255	N/A	$634,404
Pharmacist Delinquent Fee	313	2%	$13,106	$2,027	$854	$10,225	$2,441	N/A	$12,666
Totals	**19,259**	**100%**	**$806,403**	**$124,695**	**$52,538**	**$629,170**	**$124,695**	**$157,438**	**$911,303**

Refer to Appendix G for a detailed listing of the amount of direct costs allocated to each of the Board's fees within these 14 major categories.

Allocation of Indirect or "Common" Costs

To begin allocating the $6.6 million in indirect costs, we performed a high level allocation by assigning portions of the indirect costs across major employee groups, including Executive, Supervising Inspectors, Inspectors, Enforcement, Licensing Programs & Exams, Customer Support & Public Education, and Organizational Development & Support according to the amount of the indirect cost the employee group consumes. For example, vehicle and insurance costs were only allocated to the inspector group, as they are the only employees that incur those costs. Additionally, facility costs were not allocated to the inspectors as they work from home. Refer to Appendix H for a detailed description of the allocation basis. In Table 12, costs at a high level are allocated across major employee groups.

[22] DCA data processing and examinations were subtracted from each fee category and reallocated only to the fees they are associated—DCA data processing (approx 15% of direct costs) relate to only renewal and delinquency fees and Examinations (approx 7% of direct costs) relate to only the Pharmacy Licensure Exam Application fee.

Table 12: High Level Allocation of Indirect Costs Across Major Employee Groups

High Level Allocation of Indirect Expenses	Executive	Supervising Inspectors	Field Inspectors	Enforcement Programs	Licensing Programs & Exams	Customer Support and Public Education	Org Dev & Support	Totals
Insurance	N/A	$328	$1,564	N/A	N/A	N/A	N/A	$1,892
Vehicle Operations	N/A	$12,600	$60,005	N/A	N/A	N/A	N/A	$72,605
Cell Phones	$2,547	$5,094	$24,259	N/A	N/A	N/A	N/A	$31,899
Travel Expense	$19,458	$38,915	$185,335	N/A	N/A	N/A	N/A	$243,708[23]
Personnel & Benefits	$191,691	$588,906	$2,703,087	$539,760	$386,250	$275,336	$158,146	$4,843,175
DCA Facilities Operations	$15,609	$31,217	N/A	$78,043	$61,108	$43,431	$34,495	$263,903
Training	$472	$943	$4,493	$2,358	$1,847	$1,312	$1,042	$12,468
General Expense	$6,576	$13,153	$62,639	$32,881	$25,746	$18,298	$14,534	$173,827
Other Communications	$759	$1,517	$7,225	$3,793	$2,970	$2,111	$1,676	$20,050
Office Equipment Expense	$4,282	$8,565	$40,789	$21,412	$16,765	$11,916	$9,464	$113,193
DCA Central Admin Pro-Rata	$12,638	$25,275	$120,373	$63,188	$49,476	$35,164	$27,929	$334,043
DCA Indirect Distribution Costs	$19,806	$39,612	$188,650	$99,029	$77,540	$55,110	$43,771	$523,517
Totals	**$273,836**	**$766,125**	**$3,398,419**	**$840,464**	**$621,702**	**$444,678**	**$291,057**	**$6,634,280**

Next, using the indirect cost totals assigned to each employee group from the table above, we split each group's assigned cost amongst the employees within the group based on each individual's percentage of salary to total salary costs for the group. Each individual's assigned portion of indirect cost was divided by their total hours available to work during a typical year (1 FTE = 1,778 hours) to arrive at each employee's fully loaded hourly billing rate. In Table 6, we provide an example of the Supervising Investigator group's detailed assigned indirect cost.

[23] Includes Board member travel costs.

Table 13: Indirect Costs Assigned to the Supervising Inspector Employee Group

Supervising Inspector Employee Group FTE	2007/2008 Budgeted Salaries	% of Total Salaries	2007/2008 Indirect Costs	Total BOP Employee Hours Available	2007/2008 Hourly Billing Rate/ Fully Loaded Process Cost
1	$141,528	24.95%	$191,119	1,778	$107.49
1	$146,244	25.78%	$197,488	1,778	$111.07
1	$133,316	23.50%	$180,030	1,778	$101.25
1	$146,244	25.78%	$197,488	1,778	$111.07
4	**$567,332**	**100.00%**	**$766,125**	**7,112**	**$107.72**

As illustrated in Table 13, the Supervising Investigator employee group has total budgeted salary costs of $567,332 for fiscal year 2007/2008 and each of the four Supervising Investigators represent between 23.5 percent and 25.8 percent of the total salary costs budgeted for the group. We assigned portions of the group's $766,125 indirect costs using the percentage of total salaries, which resulted in indirect costs assigned to individual Supervising Inspectors ranging from about $180,000 to $197,500 with hourly billing rates averaging $107.72. Refer to Appendix I for a listing of all positions hourly billing rates.

Next, we divided the $6.6 million in overall indirect costs into two major categories—License Processing Timed Task Hours and Non-Specific Hours:

- License Processing Timed Task Hours: Board employees completed timed task sheets indicating the number of processing hours per year each task they perform requires. The cost to have the employees perform the tasks was calculated by multiplying the employees' billing rate against the number of required hours. These costs were assigned directly to the associated fee.
- Non-Specific Hours: Non-specific hours relate to the portion of total hours available for an employee to work during a given year that are not reflected on the timed task sheets previously described. These hours typically are not related specifically to license processing and include activities such as investigations, meetings, training, etc. The cost to have the employees perform these tasks was also calculated by multiplying the employees' billing rate against the number of required hours. As the hours are not related directly to a specific license category or type, the hours were allocated across all license categories and fee types and assigned based on each category's percentage of total annual workload.

Additionally, from the non-specific hours, we segregated enforcement-related hours into a separate group, as the majority of these activities are associated only with license renewal fees. As such, we allocated enforcement-related hours to renewal fees based on

each category's number of licenses and permits in July 2008. A small amount of the enforcement related hours (15%) were allocated across all categories and license types based on total annual workload to account for administrative related functions (meetings, training, etc).

In Table 14, we provide the summary allocation of indirect costs related to License Processing Timed Task Hours and Non-Specific Hours.

Table 14: Summary Allocation of $6.6 million Indirect Costs Related to License Processing Timed Task Hours and Non-Specific Hours

Indirect Cost Categories	Hours	Allocated Cost	Cost Assignment Basis
License Processing Timed Task Hours	15,383	$653,601	Direct to fee
Non-Specific Hours:			
All Non-Specific Hours Except Enforcement	22,086	$1,104,587	Workload
Non-Specific Hours Related to Enforcement Activities	56,525	$4,876,092	# of license and permits
Total Indirect Hours/Costs	**93,994**	**$6,634,280**	

Overall Summary Allocation

The next phase of the allocation process was to add the direct and indirect costs assigned to each license category together to arrive at the total cost associated with each fee within all license categories. The analysis reveals that the costs related to certain license fees are significantly higher than the revenue generated for providing the service and vice versa. For example, all three of the fee types within the Pharmacy Technician license category result in costs of providing the services far outweighing the associated fees. This imbalance results in annual revenue shortfalls totaling more than $2.8 million; thus, the Board is forced to subsidize the costs associated with the Pharmacy Technician license category from several other license categories, such as the Pharmacy. This circumstance for Pharmacy Technician and Pharmacy is illustrated in Tables 15 and 16. Also, refer to Appendix B for detailed comparison of 2007/2008 cost allocation and 2007/2008 revenue for all license categories.

Table 15: Pharmacy Technician Comparison of 2007/08 Allocated Costs and Revenue

Pharmacy Technician	Indirect Allocation	Direct Allocation	Total Cost Allocation 2007/2008	Revenue 2007/2008	Surplus/(Subsidy)	Percent
Pharmacy Technician Original License	$696,202	$232,110	$928,312	$375,914	$(552,398)	(33.66)%
Pharmacy Technician Renewal	$2,457,940	$840,012	$3,297,952	$1,078,125	$(2,219,827)	(135.26)%
Pharmacy Technician Delinquent Fee	$52,324	$72,770	$125,094	$46,698	$(78,396)	(4.78)%
Totals	**$3,206,466**	**$1,144,892**	**$4,351,358**	**$1,500,737**	**($2,850,621)**	

Table 16: Pharmacy Comparison of 2007/2008 Allocated Costs and Revenue

Pharmacy (includes hospital and LCF)	Indirect Allocation	Direct Allocation	Total Cost Allocation 2007/2008	Revenue 2007/2008	Surplus/(Subsidy)	Percent
Pharmacy Original Permit	$86,259	$4,704	$90,963	$134,426	$43,463	2.65%
Pharmacy Permit Renewal	$300,834	$131,195	$432,030	$1,364,355	$932,325	56.81%
Pharmacy Delinquent Fee	$2,275	$902	$3,177	$4,400	$1,223	0.07%
Totals	**$389,368**	**$136,801**	**$526,170**	**$1,503,181**	**$977,011**	

To arrive at the unit cost for each fee, we divided the fee's cost by the associated workload. As expected, based on the surpluses and subsidies discussed earlier, the unit costs related to certain license fees are significantly higher than the fees charged for providing the services resulting in subsidies from other categories. Similar to the previous examples, each of the three fee types within the Pharmacy Technician license category have unit costs that are significantly higher than the fees charged for those services; thus, the Board is forced to subsidize the costs associated with the Pharmacy Technician license category via other multiple license categories, such as the Pharmacy,

Wholesaler, and Clinic categories. Refer to the Pharmacy Technician and Pharmacy examples in Table 17 and refer to Appendix B for all license categories.

Table 17: Pharmacy Technician and Pharmacy Comparison of Unit Costs and Current Fees

Pharmacy Technician	2007/2008 Total Cost Allocation	2007/2008 Workload	2007/2008 Unit Costs	Current Fees[24]	Difference
Pharmacy Technician Original License	$928,312	7,518	$123	$50	($73)
Pharmacy Technician Renewal	$3,297,952	21,563	$153	$50	($103)
Pharmacy Technician Delinquent Fee	$125,094	1,868	$67	$25	($42)
Pharmacy [25]					
Pharmacy Original Permit	$90,963	265	$343	$400	$57
Pharmacy Permit Renewal	$432,030	6,106	$71	$250	$179
Pharmacy Delinquent Fee	$3,177	42	$76	$125	$49

[24] Fees as of the increase implemented in January 2008.
[25] Pharmacy Includes Hospital and License Correctional Facilities.

Appendix A: Current Fee Structure Revenue Projections

	08 Current Fees	08/09 Workload projections based on actual trends	09/10 Workload projections based on actual trends	10/11 Workload projections based on actual trends	11/12 Workload projections based on actual trends	12/13 Workload projections based on actual trends	08/09 projection revenue from actual workload trend based on current fees	09/10 projection revenue from actual workload trend based on current fees	10/11 projection revenue from actual workload trend based on current fees	11/12 projection revenue from actual workload trend based on current fees	12/13 projection revenue from actual workload trend based on current fees
Individual Licensing Services											
Pharmacist											
Pharmacist Licensure Exam Application	$ 185	1961	2003	2044	2085	2121	$ 362,729.71	$ 370,468.81	$ 378,201.20	$ 385,656.44	$ 392,364.25
Pharmacist Original License	$ 150	1373	1394	1416	1436	1454	$ 205,951.15	$ 209,166.29	$ 212,360.63	$ 215,423.59	$ 218,165.18
Pharmacist Renewal	$ 150	15802	15922	16041	16154	16254	$ 2,370,242.75	$ 2,388,299.04	$ 2,406,097.36	$ 2,423,032.16	$ 2,438,079.79
Pharmacist Deliquent Fee	$ 75	309	305	302	299	296	$ 23,183.02	$ 22,906.68	$ 22,639.58	$ 22,390.25	$ 22,172.68
Pharmacy Technician											
Pharmacy Technician Original License	$ 50	7744	7968	8193	8411	8609	$ 387,215.42	$ 398,385.78	$ 409,628.55	$ 420,546.38	$ 430,436.51
Pharmacy Technician Renewal	$ 50	22445	23326	24221	25098	25901	$ 1,122,273.35	$ 1,166,288.74	$ 1,211,036.02	$ 1,254,918.79	$ 1,295,041.93
Pharmacy Technician Deliquent Fee	$ 25	1956	2045	2136	2225	2307	$ 48,909.28	$ 51,126.66	$ 53,394.18	$ 55,630.71	$ 57,686.78
Pharmacist Intern											
Pharmacist Intern Orignal Permit	$ 75	1792	1851	1910	1968	2021	$ 134,418.30	$ 138,822.02	$ 143,271.15	$ 147,607.78	$ 151,550.03
Designated Represenative - VET Exemption											
Designated Representative - VET Original Application	$ 100	5	5	5	5	5	$ 503.12	$ 506.12	$ 509.08	$ 511.89	$ 514.38
Designated Representative - VET Original Certificate	$ 150	5	6	7	8	9	$ 719.59	$ 857.03	$ 1,017.17	$ 1,196.67	$ 1,383.01
Designated Representative - VET Renewal	$ 110	55	59	63	68	72	$ 6,043.47	$ 6,490.98	$ 6,961.18	$ 7,437.42	$ 7,886.38
Designated Representative – VET Deliquent Fee	$ 55	2	3	5	9	14	$ 97.24	$ 168.81	$ 290.35	$ 487.79	$ 780.46
Designated Represenative - WLS Exemption											
Designated Representative - WLS Original Application	$ 140	408	377	350	326	306	$ 57,061.18	$ 52,802.76	$ 48,947.81	$ 45,572.83	$ 42,800.23
Designated Representative - WLS Original Certificate	$ 110	396	364	336	312	292	$ 43,506.15	$ 40,073.02	$ 36,979.54	$ 34,283.46	$ 32,078.01
Designated Representative - WLS Renewal	$ 150	2177	2266	2357	2446	2527	$ 326,562.28	$ 339,914.13	$ 353,509.76	$ 366,863.65	$ 379,091.59
Designated Representative – WLS Deliquent Fee	$ 75	178	188	197	207	216	$ 13,374.10	$ 14,081.03	$ 14,809.14	$ 15,532.36	$ 16,201.66

Site Licensing Services											
Pharmacy (includes Hospita & LCF)											
Pharmacy Original Permit	$ 400	262	259	256	253	251	$ 104,707.29	$ 103,483.55	$ 102,300.41	$ 101,195.77	$ 100,231.61
Pharmacy Permit Renewal	$ 250	6156	6204	6251	6296	6336	$ 1,538,910.01	$ 1,550,899.61	$ 1,562,719.96	$ 1,573,968.70	$ 1,583,965.51
Pharmacy Deliquent Fee	$ 125	40	37	35	34	32	$ 4,948.15	$ 4,675.51	$ 4,423.49	$ 4,198.30	$ 4,009.72
Temporary Pharmacy Permit	$ 250	95	77	63	52	44	$ 23,700.74	$ 19,235.66	$ 15,690.56	$ 12,959.46	$ 10,969.12
Non-resident Pharmacy											
Non-Resident Pharmacy Original Permit	$ 400	76	79	82	85	87	$ 30,319.82	$ 31,496.26	$ 32,691.79	$ 33,863.75	$ 34,934.90
Non-Resident Pharmacy Permit Renewal	$ 250	239	246	253	260	267	$ 59,747.40	$ 61,523.32	$ 63,312.29	$ 65,050.99	$ 66,627.27
Non-Resident Pharmacy Deliquent Fee	$ 125	21	23	25	27	29	$ 2,613.41	$ 2,864.83	$ 3,134.44	$ 3,413.04	$ 3,680.70
Clinic											
Clinic Original Permit	$ 400	95	101	108	116	122	$ 37,825.69	$ 40,529.67	$ 43,363.96	$ 46,227.99	$ 48,921.98
Clinic Permit Renewal	$ 250	886	906	925	944	962	$ 221,522.20	$ 226,446.79	$ 231,371.42	$ 236,123.61	$ 240,402.84
Clinic Deliquent Fee	$ 125	75	86	97	109	121	$ 9,422.61	$ 10,706.08	$ 12,132.67	$ 13,659.54	$ 15,176.33
Wholesaler											
Wholesale Drug Original Permit	$ 600	45	40	36	33	30	$ 26,884.14	$ 24,208.25	$ 21,851.08	$ 19,841.63	$ 18,231.64
Wholesale Drug Permit Renewal	$ 600	417	418	420	421	422	$ 249,972.32	$ 250,907.77	$ 251,826.31	$ 252,696.99	$ 253,467.90
Wholesale Drug Deliquent Fee	$ 150	20	18	17	15	14	$ 2,991.08	$ 2,722.75	$ 2,483.80	$ 2,277.93	$ 2,111.34
Temporary Wholesale Permit	$ 550	8	8	8	8	8	$ 4,400.00	$ 4,400.00	$ 4,400.00	$ 4,400.00	$ 4,400.00
Hypodermic Needle and Syringe											
Hypodermic Needle and Syringe Original Permit	$ 125	12	12	12	11	11	$ 1,557.61	$ 1,495.71	$ 1,437.56	$ 1,384.77	$ 1,339.91
Hypodermic Needle and Syringe Permit Renewal	$ 125	246	243	240	237	235	$ 30,722.40	$ 30,341.57	$ 29,973.64	$ 29,630.36	$ 29,330.93
Hypodermic Needle and Syringe Deliquent Fee	$ 63	21	19	18	17	16	$ 1,284.54	$ 1,203.54	$ 1,129.31	$ 1,063.52	$ 1,008.86
Non-Resident Wholesaler											
Non-Resident Wholesaler Original Permit	$ 600	91	86	81	77	74	$ 54,786.77	$ 51,707.59	$ 48,864.64	$ 46,327.26	$ 44,204.65
Non-Resident Wholesaler Permit Renewal	$ 600	401	418	436	454	470	$ 240,364.19	$ 250,953.62	$ 261,769.23	$ 272,424.21	$ 282,208.34
Non-Resident Wholesaler Deliquent Fee	$ 150	49	52	56	60	64	$ 7,296.63	$ 7,862.91	$ 8,459.88	$ 9,066.48	$ 9,640.10
Temporary NonResident Wholesale Permit	$ 550	3	3	3	3	3	$ 1,650.00	$ 1,650.00	$ 1,650.00	$ 1,650.00	$ 1,650.00
Sterile Compounding											
Sterile Compounding Original Permit	$ 600	49	48	47	46	45	$ 29,347.09	$ 28,735.01	$ 28,148.72	$ 27,606.30	$ 27,136.91
Sterile Compounding Permit Renewal	$ 600	167	169	172	174	177	$ 100,001.56	$ 101,561.37	$ 103,111.07	$ 104,597.02	$ 105,927.03
Sterile Compounding Deliquent Fee	$ 150	1	1	1	1	1	$ 132.00	$ 116.82	$ 103.68	$ 92.66	$ 83.97
Temp permit	$ 550	14	14	14	14	14	$ 7,800.00	$ 7,800.00	$ 7,800.00	$ 7,800.00	$ 7,800.00
Non-Res Sterile Compounding											
Sterile Compounding Original Permit	$ 600	25	27	30	32	34	$ 15,054.18	$ 16,365.33	$ 17,759.69	$ 19,188.79	$ 20,551.23
Sterile Compounding Permit Renewal	$ 600	45	49	53	57	61	$ 26,866.96	$ 29,239.67	$ 31,765.78	$ 34,357.66	$ 36,831.22
Sterile Compounding Deliquent Fee	$ 150	3	4	4	5	5	$ 504.00	$ 561.96	$ 625.18	$ 691.61	$ 756.44
Vet Food-Animal Drug Retailer											
Veterinary Food-Animal Drug Retailer Original Permit	$ 400	2	2	2	1	1	$ 736.00	$ 679.57	$ 628.61	$ 584.08	$ 547.57
Veterinary Food-Animal Drug Retailer Permit Renewal	$ 250	21	23	25	26	28	$ 5,373.33	$ 5,757.83	$ 6,160.87	$ 6,568.18	$ 6,951.32

Miscellaneous Services											
Transfer of Intern Hours/License Verification	$ 20	917	936	955	973	990	$ 18,346.66	$ 18,725.19	$ 19,103.13	$ 19,467.28	$ 19,794.71
Regrade of Pharmacist Licensure Exam	$ 85	9	8	6	5	4	$ 806.67	$ 644.99	$ 518.53	$ 422.51	$ 353.47
Change of Permit - Reissuance	$ 100	606	623	639	656	670	$ 60,593.93	$ 62,263.96	$ 63,942.72	$ 65,570.96	$ 67,044.23
Change of Permit - Tradestyle/Address	$ 30	403	565	786	1078	1430	$ 12,086.88	$ 16,936.19	$ 23,583.34	$ 32,325.16	$ 42,897.70
Change of Pharmacist in Charge	$ 100	1445	1470	1495	1519	1541	$ 144,481.65	$ 147,000.75	$ 149,508.05	$ 151,916.44	$ 154,075.73
Change of Exemptee in Charge	$ 100	90	99	108	117	126	$ 9,007.47	$ 9,857.50	$ 10,767.52	$ 11,706.32	$ 12,606.90
Change of Designated Representative in Charge	$ -	0	0	0	0	0	$ -	$ -	$ -	$ -	$ -
Duplicate/Replacement License	$ 30	698	718	737	756	773	$ 20,954.21	$ 21,530.14	$ 22,109.04	$ 22,670.47	$ 23,178.44
Retired Pharmacist	$ 30	13	12	12	11	11	$ 377.00	$ 364.96	$ 353.55	$ 343.12	$ 334.18
totals		**70,373**	**72,185**	**74,091**	**76,040**	**77,914**	**8,210,997**	**8,347,911**	**8,490,715**	**8,634,502**	**8,769,688**

Appendix B: 2007-2008 Revenue and Expenses Comparisons

	07/08 Actual Fee Revenue Per Fiscal Record	Total Allocation of 07/08 expenses	Difference	07/08 Actual Workload	2007-2008 Unit Costs	08 Current Fees
Individual Licensing Services						
Pharmacist						
Pharmacist Licensure Exam Application	$ 335,300	$ 419,988	$ (84,688)	1918	$ 219	$ 185
Pharmacist Original License	$ 170,660	$ 176,639	$ (5,979)	1351	$ 131	$ 150
Pharmacist Renewal	$ 2,072,090	$ 2,183,320	$ (111,231)	15677	$ 139	$ 150
Pharmacist Deliquent Fee	$ 20,400	$ 23,614	$ (3,214)	313	$ 75	$ 75
Pharmacy Technician						
Pharmacy Technician Original License	$ 375,914	$ 928,312	$ (552,398)	7518	$ 123	$ 50
Pharmacy Technician Renewal	$ 1,078,125	$ 3,297,952	$ (2,219,827)	21563	$ 153	$ 50
Pharmacy Technician Deliquent Fee	$ 46,698	$ 125,094	$ (78,396)	1868	$ 67	$ 25
Pharmacist Intern						
Pharmacist Intern Orignal Permit	$ 117,870	$ 261,386	$ (143,516)	1733	$ 151	$ 75
Designated Represenative - VET Exemption						
Designated Representative - VET Original Application	$ 500	$ 704	$ (204)	5	$ 141	$ 100
Designated Representative - VET Original Certificate	$ 600	$ 427	$ 173	4	$ 107	$ 150
Designated Representative - VET Renewal	$ 5,610	$ 5,130	$ 480	51	$ 101	$ 110
Designated Representative – VET Deliquent Fee	$ 55	$ 92	$ (37)	1	$ 92	$ 55
Designated Represenative - WLS Exemption						
Designated Representative - WLS Original Application	$ 47,471	$ 68,576	$ (21,105)	442	$ 155	$ 140
Designated Representative - WLS Original Certificate	$ 49,004	$ 41,346	$ 7,658	431	$ 96	$ 110
Designated Representative - WLS Renewal	$ 279,948	$ 199,800	$ 80,148	2088	$ 96	$ 150
Designated Representative – WLS Deliquent Fee	$ 11,195	$ 9,721	$ 1,474	169	$ 58	$ 75

*Some 2008 current fees above are higher than their corresponding unit costs; however, some of these fees were lower than their unit costs before the January 2008 fee increase. Thus, some unit costs appear lower than their current fees even though the fee category shows a subsidy for the year.

Site Licensing Services						
Pharmacy (includes Hospita & LCF)						
Pharmacy Original Permit	$ 134,426	$ 90,963	$ 43,463	265	$ 343	$ 400
Pharmacy Permit Renewal	$ 1,364,355	$ 432,030	$ 932,325	6106	$ 71	$ 250
Pharmacy Deliquent Fee	$ 4,400	$ 3,177	$ 1,223	42	$ 76	$ 125
Temporary Pharmacy Permit	$ 24,250	$ 14,219	$ 10,031	118	$ 121	$ 250
Non-resident Pharmacy						
Non-Resident Pharmacy Original Permit	$ 26,800	$ 28,798	$ (1,998)	73	$ 395	$ 400
Non-Resident Pharmacy Permit Renewal	$ 50,000	$ 26,685	$ 23,315	232	$ 115	$ 250
Non-Resident Pharmacy Deliquent Fee	$ 1,975	$ 1,510	$ 465	19	$ 79	$ 125
Clinic						
Clinic Original Permit	$ 32,600	$ 19,437	$ 13,163	88	$ 221	$ 400
Clinic Permit Renewal	$ 185,900	$ 80,251	$ 105,649	866	$ 93	$ 250
Clinic Deliquent Fee	$ 7,275	$ 4,282	$ 2,993	66	$ 65	$ 125
Wholesaler						
Wholesale Drug Original Permit	$ 28,800	$ 14,987	$ 13,813	50	$ 300	$ 600
Wholesale Drug Permit Renewal	$ 238,150	$ 37,836	$ 200,314	415	$ 91	$ 600
Wholesale Drug Deliquent Fee	$ 3,300	$ 2,455	$ 845	22	$ 112	$ 150
Temporary Wholesale Permit	$ 4,400	$ 1,360	$ 3,040	8	$ 170	$ 550
Hypodermic Needle and Syringe						
Hypodermic Needle and Syringe Original Permit	$ 1,450	$ 4,405	$ (2,955)	13	$ 339	$ 125
Hypodermic Needle and Syringe Permit Renewal	$ 27,010	$ 19,984	$ 7,026	249	$ 80	$ 125
Hypodermic Needle and Syringe Deliquent Fee	$ 1,280	$ 1,207	$ 73	22	$ 55	$ 63

*Part of the costs associated with temporary wholesaler fees that is not reflected on the table above related to the fact that Board staff must put all other work on hold to accommodate these permits.

Non-Resident Wholesaler						
Non-Resident Wholesaler Original Permit	$ 55,130	$ 28,043	$ 27,087	97	$ 289	$ 600
Non-Resident Wholesaler Permit Renewal	$ 220,850	$ 46,102	$ 174,748	383	$ 120	$ 600
Non-Resident Wholesaler Deliquent Fee	$ 6,750	$ 6,380	$ 370	45	$ 142	$ 150
Temporary NonResident Wholesale Permit	$ 1,650	$ 266	$ 1,384	3	$ 89	$ 550
Sterile Compounding						
Sterile Compounding Original Permit	$ 27,400	$ 32,636	$ (5,236)	50	$ 653	$ 600
Sterile Compounding Permit Renewal	$ 88,600	$ 59,691	$ 28,909	164	$ 364	$ 600
Sterile Compounding Deliquent Fee	$ 150	$ 148	$ 2	1	$ 148	$ 150
Temp permit	$ 7,800	$ 1,251	$ 6,549	14		$ 550
Non-Res Sterile Compounding						
Sterile Compounding Original Permit	$ 12,860	$ 6,091	$ 6,769	23	$ 265	$ 600
Sterile Compounding Permit Renewal	$ 22,000	$ 5,703	$ 16,297	41	$ 139	$ 600
Sterile Compounding Deliquent Fee	$ 450	$ 424	$ 26	3	$ 141	$ 150
Vet Food-Animal Drug Retailer						
Veterinary Food-Animal Drug Retailer Original Permit	$ 800	$ 1,744	$ (944)	2	$ 872	$ 400
Veterinary Food-Animal Drug Retailer Permit Renewal	$ 5,000	$ 2,602	$ 2,398	20	$ 130	$ 250
Veterinary Food-Animal Drug Retailer Deliquent Fee	$ 125	$ 92	$ 33	1	$ 92	$ 125
Temporary Veterinary Food-Animal Drug Permit						$ 250

Miscellaneous Services						
Transfer of Intern Hours/License Verification	$ 13,360	$ 76,365	$ (63,005)	898	$ 85	$ 20
Regrade of Pharmacist Licensure Exam	$ 960	$ 2,645	$ (1,685)	12	$ 220	$ 85
Change of Permit - Reissuance	$ 48,640	$ 54,103	$ (5,463)	589	$ 92	$ 100
Change of Permit - Tradestyle/Address	$ 8,520	$ 21,306	$ (12,786)	284	$ 75	$ 30
Change of Pharmacist in Charge	$ 113,660	$ 118,687	$ (5,027)	1419	$ 84	$ 100
Change of Exemptee in Charge		$ -	$ -			$ 100
Change of Designated Representative in Charge	$ 6,310	$ 7,338	$ (1,028)	82	$ 89	$ 100
Duplicate/Replacement License	$ 20,370	$ 51,514	$ (31,144)	679	$ 76	$ 30
Retired Pharmacist	$ 390	$ 1,459	$ (1,069)	13	$ 112	$ 30
totals	**$ 7,409,661**	**$ 9,050,785**	**$ (1,640,612)**	**68,609**		

Appendix C: Subsidized Fees Increased Revenue Projections

	Fee Adjustments (Increases are Bolded)	08/09 Workload projections based on actual trends	09/10 Workload projections based on actual trends	10/11 Workload projections based on actual trends	11/12 Workload projections based on actual trends	12/13 Workload projections based on actual trends	08/09 projection revenue from actual workload trend based on individual fee analysis	09/10 projection revenue from actual workload trend based on individual fee analysis	10/11 projection revenue from actual workload trend based on individual fee analysis	11/12 projection revenue from actual workload trend based on individual fee analysis	12/13 projection revenue from actual workload trend based on individual fee analysis
Individual Licensing Services											
Pharmacist											
Pharmacist Licensure Exam Application	**$ 200**	1,961	2,003	2,044	2,085	2,121	$ 392,140.23	$ 400,506.82	$ 408,866.16	$ 416,925.88	$ 424,177.57
Pharmacist Original License	$ 150	1,373	1,394	1,416	1,436	1,454	$ 205,951.15	$ 209,166.29	$ 212,360.63	$ 215,423.59	$ 218,165.18
Pharmacist Renewal	$ 150	15,802	15,922	16,041	16,154	16,254	$ 2,370,242.75	$ 2,388,299.04	$ 2,406,097.36	$ 2,423,032.16	$ 2,438,079.79
Pharmacist Deliquent Fee	$ 75	309	305	302	299	296	$ 23,183.02	$ 22,906.68	$ 22,639.58	$ 22,390.25	$ 22,172.68
group total		**19,444**	**19,624**	**19,803**	**19,973**	**20,125**	**$ 2,991,517**	**$ 3,020,879**	**$ 3,049,964**	**$ 3,077,772**	**$ 3,102,595**
Pharmacy Technician											
Pharmacy Technician Original License	**$ 80**	7,744	7,968	8,193	8,411	8,609	$ 619,544.67	$ 637,417.25	$ 655,405.69	$ 672,874.21	$ 688,698.42
Pharmacy Technician Renewal	**$ 100**	22,445	23,326	24,221	25,098	25,901	$ 2,244,546.70	$ 2,332,577.48	$ 2,422,072.04	$ 2,509,837.58	$ 2,590,083.87
Pharmacy Technician Deliquent Fee	**$ 30**	1,956	2,045	2,136	2,225	2,307	$ 58,691.13	$ 61,351.99	$ 64,073.02	$ 66,756.85	$ 69,224.14
group total		**32,146**	**33,339**	**34,549**	**35,735**	**36,817**	**$ 2,922,782**	**$ 3,031,347**	**$ 3,141,551**	**$ 3,249,469**	**$ 3,348,006**
Pharmacist Intern											
Pharmacist Intern Orignal Permit	**$ 90**	1,792	1,851	1,910	1,968	2,021	$ 161,301.95	$ 166,586.43	$ 171,925.38	$ 177,129.33	$ 181,860.04
group total		**1,792**	**1,851**	**1,910**	**1,968**	**2,021**	**$ 161,302**	**$ 166,586**	**$ 171,925**	**$ 177,129**	**$ 181,860**
Designated Represenative - VET Exemption											
Designated Representative - VET Original Application	**$ 105**	5	5	5	5	5	$ 528.27	$ 531.43	$ 534.53	$ 537.48	$ 540.10
Designated Representative - VET Original Certificate	$ 150	5	6	7	8	9	$ 720	$ 857	$ 1,017	$ 1,197	$ 1,383
Designated Representative - VET Renewal	$ 110	55	59	63	68	72	$ 6,043	$ 6,491	$ 6,961	$ 7,437	$ 7,886
Designated Representative – VET Deliquent Fee	**$ 60**	2	3	5	9	14	$ 106	$ 184	$ 317	$ 532	$ 851
group total		**67**	**73**	**80**	**90**	**100**	**$ 7,397**	**$ 8,064**	**$ 8,830**	**$ 9,704**	**$ 10,661**

Designated Represenative - WLS Exemption												
Designated Representative - WLS Original Application	**$ 145**	408	377	350	326	306	$ 59,099	$ 54,689	$ 50,696	$ 47,200	$ 44,329
Designated Representative - WLS Original Certificate	$ 110	396	364	336	312	292	$ 43,506	$ 40,073	$ 36,980	$ 34,283	$ 32,078
Designated Representative - WLS Renewal	$ 150	2,177	2,266	2,357	2,446	2,527	$ 326,562	$ 339,914	$ 353,510	$ 366,864	$ 379,092
Designated Representative – WLS Deliquent Fee	$ 75	178	188	197	207	216	$ 13,374	$ 14,081	$ 14,809	$ 15,532	$ 16,202
group total		**3,158**	**3,195**	**3,240**	**3,290**	**3,341**	**$ 442,542**	**$ 448,757**	**$ 455,994**	**$ 463,880**	**$ 471,700**
Site Licensing Services											
Pharmacy (includes Hospita & LCF)											
Pharmacy Original Permit	$ 400	262	259	256	253	251	$ 104,707	$ 103,484	$ 102,300	$ 101,196	$ 100,232
Pharmacy Permit Renewal	$ 250	6,156	6,204	6,251	6,296	6,336	$ 1,538,910	$ 1,550,900	$ 1,562,720	$ 1,573,969	$ 1,583,966
Pharmacy Deliquent Fee	$ 125	40	37	35	34	32	$ 4,948	$ 4,676	$ 4,423	$ 4,198	$ 4,010
Temporary Pharmacy Permit	$ 250	95	77	63	52	44	$ 23,701	$ 19,236	$ 15,691	$ 12,959	$ 10,969
group total		**6,552**	**6,577**	**6,605**	**6,634**	**6,662**	**$ 1,672,266**	**$ 1,678,294**	**$ 1,685,134**	**$ 1,692,322**	**$ 1,699,176**
Non-resident Pharmacy											
Non-Resident Pharmacy Original Permit	$ 400	76	79	82	85	87	$ 30,320	$ 31,496	$ 32,692	$ 33,864	$ 34,935
Non-Resident Pharmacy Permit Renewal	$ 250	239	246	253	260	267	$ 59,747	$ 61,523	$ 63,312	$ 65,051	$ 66,627
Non-Resident Pharmacy Deliquent Fee	$ 125	21	23	25	27	29	$ 2,613	$ 2,865	$ 3,134	$ 3,413	$ 3,681
group total		**336**	**348**	**360**	**372**	**383**	**$ 92,681**	**$ 95,884**	**$ 99,139**	**$ 102,328**	**$ 105,243**
Clinic											
Clinic Original Permit	$ 400	95	101	108	116	122	$ 37,826	$ 40,530	$ 43,364	$ 46,228	$ 48,922
Clinic Permit Renewal	$ 250	886	906	925	944	962	$ 221,522	$ 226,447	$ 231,371	$ 236,124	$ 240,403
Clinic Deliquent Fee	$ 125	75	86	97	109	121	$ 9,423	$ 10,706	$ 12,133	$ 13,660	$ 15,176
group total		**1,056**	**1,093**	**1,131**	**1,169**	**1,205**	**$ 268,770**	**$ 277,683**	**$ 286,868**	**$ 296,011**	**$ 304,501**

Wholesaler											
Wholesale Drug Original Permit	$ 600	45	40	36	33	30	$ 26,884	$ 24,208	$ 21,851	$ 19,842	$ 18,232
Wholesale Drug Permit Renewal	$ 600	417	418	420	421	422	$ 249,972	$ 250,908	$ 251,826	$ 252,697	$ 253,468
Wholesale Drug Deliquent Fee	$ 150	20	18	17	15	14	$ 2,991	$ 2,723	$ 2,484	$ 2,278	$ 2,111
Temporary Wholesale Permit	$ 550	8	8	8	8	8	$ 4,400	$ 4,400	$ 4,400	$ 4,400	$ 4,400
group total		**489**	**485**	**481**	**477**	**475**	**$ 284,248**	**$ 282,239**	**$ 280,561**	**$ 279,217**	**$ 278,211**
Hypodermic Needle and Syringe											
Hypodermic Needle and Syringe Original Permit	**$ 130**	12	12	12	11	11	$ 1,620	$ 1,556	$ 1,495	$ 1,440	$ 1,394
Hypodermic Needle and Syringe Permit Renewal	$ 125	246	243	240	237	235	$ 30,722	$ 30,342	$ 29,974	$ 29,630	$ 29,331
Hypodermic Needle and Syringe Deliquent Fee	$ 63	21	19	18	17	16	$ 1,285	$ 1,204	$ 1,129	$ 1,064	$ 1,009
group total		**279**	**274**	**269**	**265**	**262**	**$ 33,627**	**$ 33,101**	**$ 32,598**	**$ 32,134**	**$ 31,733**
Non-Resident Wholesaler											
Non-Resident Wholesaler Original Permit	$ 600	91	86	81	77	74	$ 54,787	$ 51,708	$ 48,865	$ 46,327	$ 44,205
Non-Resident Wholesaler Permit Renewal	$ 600	401	418	436	454	470	$ 240,364	$ 250,954	$ 261,769	$ 272,424	$ 282,208
Non-Resident Wholesaler Deliquent Fee	$ 150	49	52	56	60	64	$ 7,297	$ 7,863	$ 8,460	$ 9,066	$ 9,640
Temporary NonResident Wholesale Permit	$ 550	3	3	3	3	3	$ 1,650	$ 1,650	$ 1,650	$ 1,650	$ 1,650
group total		**544**	**560**	**577**	**595**	**611**	**$ 304,098**	**$ 312,174**	**$ 320,744**	**$ 329,468**	**$ 337,703**
Sterile Compounding											
Sterile Compounding Original Permit	**$ 605**	49	48	47	46	45	$ 29,592	$ 28,974	$ 28,383	$ 27,836	$ 27,363
Sterile Compounding Permit Renewal	$ 600	167	169	172	174	177	$ 100,002	$ 101,561	$ 103,111	$ 104,597	$ 105,927
Sterile Compounding Deliquent Fee	$ 150	1	1	1	1	1	$ 132	$ 117	$ 104	$ 93	$ 84
Temp permit	$ 550	14	14	14	14	14	$ -	$ -	$ -	$ -	$ -
group total		**230**	**232**	**233**	**235**	**236**	**$ 129,725**	**$ 130,653**	**$ 131,598**	**$ 132,526**	**$ 133,374**

Non-Res Sterile Compounding											
Sterile Compounding Original Permit	$ 600	25	27	30	32	34	$ 15,054	$ 16,365	$ 17,760	$ 19,189	$ 20,551
Sterile Compounding Permit Renewal	$ 600	45	49	53	57	61	$ 26,867	$ 29,240	$ 31,766	$ 34,358	$ 36,831
Sterile Compounding Deliquent Fee	$ 150	3	4	4	5	5	$ 504	$ 562	$ 625	$ 692	$ 756
group total		**73**	**80**	**87**	**94**	**101**	**$ 42,425**	**$ 46,167**	**$ 50,151**	**$ 54,238**	**$ 58,139**
Vet Food-Animal Drug Retailer											
Veterinary Food-Animal Drug Retailer Original Permit	**$ 405**	2	2	2	1	1	$ 745	$ 688	$ 636	$ 591	$ 554
Veterinary Food-Animal Drug Retailer Permit Renewal	$ 250	21	23	25	26	28	$ 5,373	$ 5,758	$ 6,161	$ 6,568	$ 6,951
Veterinary Food-Animal Drug Retailer Deliquent Fee	$ 125	1	1	1	1	1	$ 110	$ 97	$ 86	$ 77	$ 70
Temporary Veterinary Food-Animal Drug Permit		-	-	-	-	-					
group total		**24**	**26**	**27**	**28**	**30**	**$ 6,229**	**$ 6,543**	**$ 6,884**	**$ 7,237**	**$ 7,576**
Miscellaneous Services											
Transfer of Intern Hours/License Verification	**$ 25**	917	936	955	973	990	$ 22,933	$ 23,406	$ 23,879	$ 24,334	$ 24,743
Regrade of Pharmacist Licensure Exam	**$ 90**	9	8	6	5	4	$ 854	$ 683	$ 549	$ 447	$ 374
Change of Permit - Reissuance	$ 100	606	623	639	656	670	$ 60,594	$ 62,264	$ 63,943	$ 65,571	$ 67,044
Change of Permit - Tradestyle/Address	**$ 35**	403	565	786	1,078	1,430	$ 14,101	$ 19,759	$ 27,514	$ 37,713	$ 50,047
Change of Pharmacist in Charge	$ 100	1,445	1,470	1,495	1,519	1,541	$ 144,482	$ 147,001	$ 149,508	$ 151,916	$ 154,076
Change of Designated Representative in Charge	$ 100	90	99	108	117	126	$ 9,007	$ 9,857	$ 10,768	$ 11,706	$ 12,607
Duplicate/Replacement License	**$ 35**	698	718	737	756	773	$ 24,447	$ 25,119	$ 25,794	$ 26,449	$ 27,042
Retired Pharmacist	**$ 35**	13	12	12	11	11	$ 440	$ 426	$ 412	$ 400	$ 390
group total		**4,182**	**4,429**	**4,738**	**5,115**	**5,545**	**$ 276,858**	**$ 288,515**	**$ 302,366**	**$ 318,537**	**$ 336,323**
totals		**70,373**	**72,184**	**74,091**	**76,040**	**77,914**	**$ 9,636,467**	**$ 9,826,885**	**$ 10,024,307**	**$ 10,221,971**	**$ 10,406,802**

Appendix D: Full Cost Recovery Revenue Projections

	2007-2008 Unit Costs	08/09 Workload projections based on actual trends	09/10 Workload projections based on actual trends	10/11 Workload projections based on actual trends	11/12 Workload projections based on actual trends	12/13 Workload projections based on actual trends	08/09 projection revenue from actual workload trend based on unit costs - Full Recovery	09/10 projection revenue from actual workload trend based on unit costs - Full Recovery	10/11 projection revenue from actual workload trend based on unit costs - Full Recovery	11/12 projection revenue from actual workload trend based on unit costs - Full Recovery	12/13 projection revenue from actual workload trend based on unit costs - Full Recovery
Individual Licensing Services											
Pharmacist											
Pharmacist Licensure Exam Application	$ 219	1,961	2,003	2,044	2,085	2,121	$ 435,739	$ 447,488	$ 459,188	$ 470,871	$ 482,694
Pharmacist Original License	$ 131	1,373	1,394	1,416	1,436	1,454	$ 182,193	$ 186,056	$ 189,874	$ 193,695	$ 197,647
Pharmacist Renewal	$ 139	15,802	15,922	16,041	16,154	16,254	$ 2,233,487	$ 2,262,902	$ 2,291,544	$ 2,320,641	$ 2,352,760
Pharmacist Deliquent Fee	$ 75	309	305	302	299	296	$ 23,668	$ 23,515	$ 23,361	$ 23,234	$ 23,182
Pharmacy Technician											
Pharmacy Technician Original License	$ 123	7,744	7,968	8,193	8,411	8,609	$ 970,514	$ 1,004,013	$ 1,037,681	$ 1,071,325	$ 1,104,835
Pharmacy Technician Renewal	$ 153	22,445	23,326	24,221	25,098	25,901	$ 3,484,103	$ 3,640,700	$ 3,799,916	$ 3,959,735	$ 4,117,328
Pharmacy Technician Deliquent Fee	$ 67	1,956	2,045	2,136	2,225	2,307	$ 132,965	$ 139,760	$ 146,712	$ 153,716	$ 160,607
Pharmacist Intern											
Pharmacist Intern Orignal Permit	$ 151	1,792	1,851	1,910	1,968	2,021	$ 274,352	$ 284,901	$ 295,552	$ 306,209	$ 316,771
Designated Represenative - VET Exemption											
Designated Representative - VET Original Application	$ 141	5	5	5	5	5	$ 719	$ 727	$ 735	$ 744	$ 753
Designated Representative - VET Original Certificate	$ 107	5	6	7	8	9	$ 520	$ 623	$ 743	$ 879	$ 1,023
Designated Representative - VET Renewal	$ 101	55	59	63	68	72	$ 5,609	$ 6,057	$ 6,529	$ 7,015	$ 7,495
Designated Representative – VET Deliquent Fee	$ 92	2	3	5	9	14	$ 166	$ 289	$ 499	$ 844	$ 1,360

*Unit costs under this scenario slightly increase each year as expenditure projections increase.

Designated Represenative - WLS Exemption												
Designated Representative - WLS Original Application	$ 155	408	377	350	326	306	$ 64,178	$ 59,716	$ 55,642	$ 52,097	$ 49,299	
Designated Representative - WLS Original Certificate	$ 96	396	364	336	312	292	$ 38,507	$ 35,664	$ 33,081	$ 30,842	$ 29,076	
Designated Representative - WLS Renewal	$ 96	2,177	2,266	2,357	2,446	2,527	$ 211,430	$ 221,287	$ 231,327	$ 241,415	$ 251,353	
Designated Representative – WLS Deliquent Fee	$ 58	178	188	197	207	216	$ 10,410	$ 11,021	$ 11,650	$ 12,288	$ 12,915	
Site Licensing Services												
Pharmacy (includes Hospita & LCF)												
Pharmacy Original Permit	$ 343	262	259	256	253	251	$ 91,193	$ 90,624	$ 90,051	$ 89,579	$ 89,398	
Pharmacy Permit Renewal	$ 71	6,156	6,204	6,251	6,296	6,336	$ 442,035	$ 447,934	$ 453,680	$ 459,513	$ 465,939	
Pharmacy Deliquent Fee	$ 76	40	37	35	34	32	$ 3,039	$ 2,888	$ 2,746	$ 2,621	$ 2,522	
Temporary Pharmacy Permit	$ 121	95	77	63	52	44	$ 11,594	$ 9,462	$ 7,758	$ 6,444	$ 5,495	
Non-resident Pharmacy												
Non-Resident Pharmacy Original Permit	$ 395	76	79	82	85	87	$ 30,411	$ 31,765	$ 33,141	$ 34,522	$ 35,884	
Non-Resident Pharmacy Permit Renewal	$ 115	239	246	253	260	267	$ 27,923	$ 28,911	$ 29,906	$ 30,900	$ 31,888	
Non-Resident Pharmacy Deliquent Fee	$ 79	21	23	25	27	29	$ 1,686	$ 1,859	$ 2,044	$ 2,238	$ 2,432	
Clinic												
Clinic Original Permit	$ 221	95	101	108	116	122	$ 21,198	$ 22,839	$ 24,562	$ 26,332	$ 28,077	
Clinic Permit Renewal	$ 93	886	906	925	944	962	$ 83,337	$ 85,659	$ 87,974	$ 90,285	$ 92,619	
Clinic Deliquent Fee	$ 65	75	86	97	109	121	$ 4,964	$ 5,671	$ 6,460	$ 7,313	$ 8,187	

Wholesaler											
Wholesale Drug Original Permit	$ 300	45	40	36	33	30	$ 13,630	$ 12,341	$ 11,197	$ 10,225	$ 9,466
Wholesale Drug Permit Renewal	$ 91	417	418	420	421	422	$ 38,550	$ 38,907	$ 39,252	$ 39,609	$ 40,031
Wholesale Drug Deliquent Fee	$ 112	20	18	17	15	14	$ 2,258	$ 2,067	$ 1,895	$ 1,748	$ 1,632
Temporary Wholesale Permit	$ 170	8	8	8	8	8	$ 1,380	$ 1,387	$ 1,395	$ 1,402	$ 1,413
Hypodermic Needle and Syringe											
Hypodermic Needle and Syringe Original Permit	$ 339	12	12	12	11	11	$ 4,285	$ 4,138	$ 3,997	$ 3,872	$ 3,775
Hypodermic Needle and Syringe Permit Renewal	$ 80	246	243	240	237	235	$ 20,019	$ 19,880	$ 19,741	$ 19,624	$ 19,573
Hypodermic Needle and Syringe Deliquent Fee	$ 55	21	19	18	17	16	$ 1,144	$ 1,078	$ 1,017	$ 963	$ 920
Non-Resident Wholesaler											
Non-Resident Wholesaler Original Permit	$ 289	91	86	81	77	74	$ 26,792	$ 25,425	$ 24,151	$ 23,026	$ 22,138
Non-Resident Wholesaler Permit Renewal	$ 120	401	418	436	454	470	$ 48,940	$ 51,378	$ 53,869	$ 56,377	$ 58,845
Non-Resident Wholesaler Deliquent Fee	$ 142	49	52	56	60	64	$ 6,999	$ 7,584	$ 8,202	$ 8,839	$ 9,470
Temporary NonResident Wholesale Permit	$ 89	3	3	3	3	3	$ 270	$ 271	$ 272	$ 274	$ 276
Sterile Compounding											
Sterile Compounding Original Permit	$ 653	49	48	47	46	45	$ 32,401	$ 31,901	$ 31,411	$ 30,979	$ 30,683
Sterile Compounding Permit Renewal	$ 364	167	169	172	174	177	$ 61,567	$ 62,872	$ 64,161	$ 65,452	$ 66,787
Sterile Compounding Deliquent Fee	$ 148	1	1	1	1	1	$ 133	$ 118	$ 105	$ 95	$ 86
Temp permit		14	14	14	14	14					

Non-Res Sterile Compounding											
Sterile Compounding Original Permit	$ 265	25	27	30	32	34	$ 6,743	$ 7,371	$ 8,040	$ 8,736	$ 9,427
Sterile Compounding Permit Renewal	$ 139	45	49	53	57	61	$ 6,321	$ 6,917	$ 7,554	$ 8,216	$ 8,874
Sterile Compounding Deliquent Fee	$ 141	3	4	4	5	5	$ 482	$ 540	$ 604	$ 672	$ 740
Vet Food-Animal Drug Retailer											
Veterinary Food-Animal Drug Retailer Original Permit	$ 872	2	2	2	1	1	$ 1,628	$ 1,511	$ 1,405	$ 1,313	$ 1,240
Veterinary Food-Animal Drug Retailer Permit Renewal	$ 130	21	23	25	26	28	$ 2,838	$ 3,058	$ 3,289	$ 3,526	$ 3,760
Veterinary Food-Animal Drug Retailer Deliquent Fee	$ 92	1	1	1	1	1	$ 82	$ 73	$ 65	$ 59	$ 54
Temporary Veterinary Food-Animal Drug Permit											
Miscellaneous Services											
Transfer of Intern Hours/License Verification	$ 85	917	936	955	973	990	$ 79,172	$ 81,251	$ 83,319	$ 85,384	$ 87,479
Regrade of Pharmacist Licensure Exam	$ 220	9	8	6	5	4	$ 2,123	$ 1,707	$ 1,379	$ 1,130	$ 953
Change of Permit - Reissuance	$ 92	606	623	639	656	670	$ 56,489	$ 58,365	$ 60,249	$ 62,130	$ 64,008
Change of Permit - Tradestyle/Address	$ 75	403	565	786	1,078	1,430	$ 30,676	$ 43,220	$ 60,494	$ 83,384	$ 111,495
Change of Pharmacist in Charge	$ 84	1,445	1,470	1,495	1,519	1,541	$ 122,648	$ 125,474	$ 128,273	$ 131,072	$ 133,943
Change of Designated Representative in Charge	$ 89	90	99	108	117	126	$ 8,181	$ 9,002	$ 9,884	$ 10,806	$ 11,726
Duplicate/Replacement License	$ 76	698	718	737	756	773	$ 53,781	$ 55,564	$ 57,353	$ 59,140	$ 60,923
Retired Pharmacist	$ 112	13	12	12	11	11	$ 1,431	$ 1,393	$ 1,357	$ 1,324	$ 1,299
totals		**70,373**	**72,185**	**74,091**	**76,040**	**77,914**	**$ 9,416,904**	**$ 9,707,124**	**$ 10,006,287**	**$ 10,314,671**	**$ 10,632,558**

Appendix E: Across the Board Low Revenue Projections

	08 Current Fees	Fee Audit Adjusted Fees (low range)	08/09 Workload projections based on actual trends	09/10 Workload projections based on actual trends	10/11 Workload projections based on actual trends	11/12 Workload projections based on actual trends	12/13 Workload projections based on actual trends	08/09 projection revenue from actual workload trend based on low range fees - across the board	09/10 projection revenue from actual workload trend based on low range fees- across the board	10/11 projection revenue from actual workload trend based on low range fees- across the board	11/12 projection revenue from actual workload trend based on low range fees- across the board	12/13 projection revenue from actual workload trend based on low range fees- across the board
Individual Licensing Services		1.15										
Pharmacist												
Pharmacist Licensure Exam Application	$ 185	$ 213	1961	2003	2044	2085	2121	$ 417,139	$ 426,039	$ 434,931	$ 443,505	$ 451,219
Pharmacist Original License	$ 150	$ 173	1373	1394	1416	1436	1454	$ 236,844	$ 240,541	$ 244,215	$ 247,737	$ 250,890
Pharmacist Renewal	$ 150	$ 173	15802	15922	16041	16154	16254	$ 2,725,779	$ 2,746,544	$ 2,767,012	$ 2,786,487	$ 2,803,792
Pharmacist Deliquent Fee	$ 75	$ 86	309	305	302	299	296	$ 26,660	$ 26,343	$ 26,036	$ 25,749	$ 25,499
Pharmacy Technician												
Pharmacy Technician Original License	$ 50	$ 58	7744	7968	8193	8411	8609	$ 445,298	$ 458,144	$ 471,073	$ 483,628	$ 495,002
Pharmacy Technician Renewal	$ 50	$ 58	22445	23326	24221	25098	25901	$ 1,290,614	$ 1,341,232	$ 1,392,691	$ 1,443,157	$ 1,489,298
Pharmacy Technician Deliquent Fee	$ 25	$ 29	1956	2045	2136	2225	2307	$ 56,246	$ 58,796	$ 61,403	$ 63,975	$ 66,340
Pharmacist Intern												
Pharmacist Intern Orignal Permit	$ 75	$ 86	1792	1851	1910	1968	2021	$ 154,581	$ 159,645	$ 164,762	$ 169,749	$ 174,283
Designated Represenative - VET Exemption												
Designated Representative - VET Original Application	$ 100	$ 115	5	5	5	5	5	$ 579	$ 582	$ 585	$ 589	$ 592
Designated Representative - VET Original Certificate	$ 150	$ 173	5	6	7	8	9	$ 828	$ 986	$ 1,170	$ 1,376	$ 1,590
Designated Representative - VET Renewal	$ 110	$ 127	55	59	63	68	72	$ 6,950	$ 7,465	$ 8,005	$ 8,553	$ 9,069
Designated Representative – VET Deliquent Fee	$ 55	$ 63	2	3	5	9	14	$ 112	$ 194	$ 334	$ 561	$ 898
Designated Represenative - WLS Exemption												
Designated Representative - WLS Original Application	$ 140	$ 161	408	377	350	326	306	$ 65,620	$ 60,723	$ 56,290	$ 52,409	$ 49,220
Designated Representative - WLS Original Certificate	$ 110	$ 127	396	364	336	312	292	$ 50,032	$ 46,084	$ 42,526	$ 39,426	$ 36,890
Designated Representative - WLS Renewal	$ 150	$ 173	2177	2266	2357	2446	2527	$ 375,547	$ 390,901	$ 406,536	$ 421,893	$ 435,955
Designated Representative – WLS Deliquent Fee	$ 75	$ 86	178	188	197	207	216	$ 15,380	$ 16,193	$ 17,031	$ 17,862	$ 18,632

Site Licensing Services												
Pharmacy (includes Hospita & LCF)												
Pharmacy Original Permit	$ 400	$ **460**	262	259	256	253	251	$ 120,413	$ 119,006	$ 117,645	$ 116,375	$ 115,266
Pharmacy Permit Renewal	$ 250	$ **288**	6156	6204	6251	6296	6336	$ 1,769,747	$ 1,783,535	$ 1,797,128	$ 1,810,064	$ 1,821,560
Pharmacy Deliquent Fee	$ 125	$ **144**	40	37	35	34	32	$ 5,690	$ 5,377	$ 5,087	$ 4,828	$ 4,611
Temporary Pharmacy Permit	$ 250	$ **288**	95	77	63	52	44	$ 27,256	$ 22,121	$ 18,044	$ 14,903	$ 12,614
	$ -											
Non-resident Pharmacy	$ -											
Non-Resident Pharmacy Original Permit	$ 400	$ **460**	76	79	82	85	87	$ 34,868	$ 36,221	$ 37,596	$ 38,943	$ 40,175
Non-Resident Pharmacy Permit Renewal	$ 250	$ **288**	239	246	253	260	267	$ 68,710	$ 70,752	$ 72,809	$ 74,809	$ 76,621
Non-Resident Pharmacy Deliquent Fee	$ 125	$ **144**	21	23	25	27	29	$ 3,005	$ 3,295	$ 3,605	$ 3,925	$ 4,233
Clinic												
Clinic Original Permit	$ 400	$ **460**	95	101	108	116	122	$ 43,500	$ 46,609	$ 49,869	$ 53,162	$ 56,260
Clinic Permit Renewal	$ 250	$ **288**	886	906	925	944	962	$ 254,751	$ 260,414	$ 266,077	$ 271,542	$ 276,463
Clinic Deliquent Fee	$ 125	$ **144**	75	86	97	109	121	$ 10,836	$ 12,312	$ 13,953	$ 15,708	$ 17,453
Wholesaler												
Wholesale Drug Original Permit	$ 600	$ **690**	45	40	36	33	30	$ 30,917	$ 27,839	$ 25,129	$ 22,818	$ 20,966
Wholesale Drug Permit Renewal	$ 600	$ **690**	417	418	420	421	422	$ 287,468	$ 288,544	$ 289,600	$ 290,602	$ 291,488
Wholesale Drug Deliquent Fee	$ 150	$ **173**	20	18	17	15	14	$ 3,440	$ 3,131	$ 2,856	$ 2,620	$ 2,428
Temporary Wholesale Permit	$ 550	$ **633**	8	8	8	8	8	$ 5,060	$ 5,060	$ 5,060	$ 5,060	$ 5,060
Hypodermic Needle and Syringe												
Hypodermic Needle and Syringe Original Permit	$ 125	$ **144**	12	12	12	11	11	$ 1,791	$ 1,720	$ 1,653	$ 1,592	$ 1,541
Hypodermic Needle and Syringe Permit Renewal	$ 125	$ **144**	246	243	240	237	235	$ 35,331	$ 34,893	$ 34,470	$ 34,075	$ 33,731
Hypodermic Needle and Syringe Deliquent Fee	$ 63	$ **72**	21	19	18	17	16	$ 1,477	$ 1,384	$ 1,299	$ 1,223	$ 1,160

Non-Resident Wholesaler												
Non-Resident Wholesaler Original Permit	$ 600	**$ 690**	91	86	81	77	74	$ 63,005	$ 59,464	$ 56,194	$ 53,276	$ 50,835
Non-Resident Wholesaler Permit Renewal	$ 600	**$ 690**	401	418	436	454	470	$ 276,419	$ 288,597	$ 301,035	$ 313,288	$ 324,540
Non-Resident Wholesaler Deliquent Fee	$ 150	**$ 173**	49	52	56	60	64	$ 8,391	$ 9,042	$ 9,729	$ 10,426	$ 11,086
Temporary NonResident Wholesale Permit	$ 550		3	3	3	3	3					
Sterile Compounding	$ -											
Sterile Compounding Original Permit	$ 600	**$ 690**	49	48	47	46	45	$ 33,749	$ 33,045	$ 32,371	$ 31,747	$ 31,207
Sterile Compounding Permit Renewal	$ 600	**$ 690**	167	169	172	174	177	$ 115,002	$ 116,796	$ 118,578	$ 120,287	$ 121,816
Sterile Compounding Deliquent Fee	$ 150	**$ 173**	1	1	1	1	1	$ 152	$ 134	$ 119	$ 107	$ 97
Temp permit	$ 550		14	14	14	14	14					
	$ -											
Non-Res Sterile Compounding	$ -											
Sterile Compounding Original Permit	$ 600	**$ 690**	25	27	30	32	34	$ 17,312	$ 18,820	$ 20,424	$ 22,067	$ 23,634
Sterile Compounding Permit Renewal	$ 600	**$ 690**	45	49	53	57	61	$ 30,897	$ 33,626	$ 36,531	$ 39,511	$ 42,356
Sterile Compounding Deliquent Fee	$ 150	**$ 173**	3	4	4	5	5	$ 580	$ 646	$ 719	$ 795	$ 870
	$ -											
Vet Food-Animal Drug Retailer	$ -											
Veterinary Food-Animal Drug Retailer Original Permit	$ 400	**$ 460**	2	2	2	1	1	$ 846	$ 782	$ 723	$ 672	$ 630
Veterinary Food-Animal Drug Retailer Permit Renewal	$ 250	**$ 288**	21	23	25	26	28	$ 6,179	$ 6,621	$ 7,085	$ 7,553	$ 7,994
Veterinary Food-Animal Drug Retailer Deliquent Fee	$ 125	**$ 144**	1	1	1	1	1	$ 127	$ 112	$ 99	$ 89	$ 80
Temporary Veterinary Food-Animal Drug Permit	$ 250	**$ 288**	0	0	0	0	0					
	$ -											

Miscellaneous Services	$ -											
Transfer of Intern Hours/License Verification	$ 20	$ 23	917	936	955	973	990	$ 21,099	$ 21,534	$ 21,969	$ 22,387	$ 22,764
Regrade of Pharmacist Licensure Exam	$ 85	$ 98	9	8	6	5	4	$ 928	$ 742	$ 596	$ 486	$ 406
Change of Permit - Reissuance	$ 100	$ 115	606	623	639	656	670	$ 69,683	$ 71,604	$ 73,534	$ 75,407	$ 77,101
Change of Permit - Tradestyle/Address	$ 30	$ 35	403	565	786	1078	1430	$ 13,900	$ 19,477	$ 27,121	$ 37,174	$ 49,332
Change of Pharmacist in Charge	$ 100	$ 115	1445	1470	1495	1519	1541	$ 166,154	$ 169,051	$ 171,934	$ 174,704	$ 177,187
Change of Exemptee in Charge	$ 100	$ 115	90	99	108	117	126	$ 10,359	$ 11,336	$ 12,383	$ 13,462	$ 14,498
Change of Designated Representative in Charge	$ -	$ -	0	0	0	0	0					
Duplicate/Replacement License	$ 30	$ 35	698	718	737	756	773	$ 24,097	$ 24,760	$ 25,425	$ 26,071	$ 26,655
Retired Pharmacist	$ 30	$ 35	13	12	12	11	11	$ 434	$ 420	$ 407	$ 395	$ 384
totals			**70,373**	**72,185**	**74,091**	**76,040**	**77,914**	**$ 9,431,779**	**$ 9,589,231**	**$ 9,753,455**	**$ 9,918,810**	**$ 10,074,273**

Appendix F: Across the Board High Revenue Projections

	08 Current Fees	Fee Audit Adjusted Fees (high range)	08/09 Workload projections based on actual trends	09/10 Workload projections based on actual trends	10/11 Workload projections based on actual trends	11/12 Workload projections based on actual trends	12/13 Workload projections based on actual trends	08/09 projection revenue from actual workload trend based on high range fees-across the board	09/10 projection revenue from actual workload trend based on high range fees-across the board	10/11 projection revenue from actual workload trend based on high range fees-across the board	11/12 projection revenue from actual workload trend based on high range fees-across the board	12/13 projection revenue from actual workload trend based on high range fees-across the board
Individual Licensing Services		1.2										
Pharmacist												
Pharmacist Licensure Exam Application	$ 185	**$ 222**	1,961	2,003	2,044	2,085	2,121	$ 435,276	$ 444,563	$ 453,841	$ 462,788	$ 470,837
Pharmacist Original License	$ 150	**$ 180**	1,373	1,394	1,416	1,436	1,454	$ 247,141	$ 251,000	$ 254,833	$ 258,508	$ 261,798
Pharmacist Renewal	$ 150	**$ 180**	15,802	15,922	16,041	16,154	16,254	$ 2,844,291	$ 2,865,959	$ 2,887,317	$ 2,907,639	$ 2,925,696
Pharmacist Deliquent Fee	$ 75	**$ 90**	309	305	302	299	296	$ 27,820	$ 27,488	$ 27,167	$ 26,868	$ 26,607
Pharmacy Technician												
Pharmacy Technician Original License	$ 50	**$ 60**	7,744	7,968	8,193	8,411	8,609	$ 464,658	$ 478,063	$ 491,554	$ 504,656	$ 516,524
Pharmacy Technician Renewal	$ 50	**$ 60**	22,445	23,326	24,221	25,098	25,901	$ 1,346,728	$ 1,399,546	$ 1,453,243	$ 1,505,903	$ 1,554,050
Pharmacy Technician Deliquent Fee	$ 25	**$ 30**	1,956	2,045	2,136	2,225	2,307	$ 58,691	$ 61,352	$ 64,073	$ 66,757	$ 69,224
Pharmacist Intern												
Pharmacist Intern Orignal Permit	$ 75	**$ 90**	1,792	1,851	1,910	1,968	2,021	$ 161,302	$ 166,586	$ 171,925	$ 177,129	$ 181,860
Designated Represenative - VET Exemption												
Designated Representative - VET Original Application	$ 100	**$ 120**	5	5	5	5	5	$ 604	$ 607	$ 611	$ 614	$ 617
Designated Representative - VET Original Certificate	$ 150	**$ 180**	5	6	7	8	9	$ 864	$ 1,028	$ 1,221	$ 1,436	$ 1,660
Designated Representative - VET Renewal	$ 110	**$ 132**	55	59	63	68	72	$ 7,252	$ 7,789	$ 8,353	$ 8,925	$ 9,464
Designated Representative – VET Deliquent Fee	$ 55	**$ 66**	2	3	5	9	14	$ 117	$ 203	$ 348	$ 585	$ 937
Designated Represenative - WLS Exemption												
Designated Representative - WLS Original Application	$ 140	**$ 168**	408	377	350	326	306	$ 68,473	$ 63,363	$ 58,737	$ 54,687	$ 51,360
Designated Representative - WLS Original Certificate	$ 110	**$ 132**	396	364	336	312	292	$ 52,207	$ 48,088	$ 44,375	$ 41,140	$ 38,494
Designated Representative - WLS Renewal	$ 150	**$ 180**	2,177	2,266	2,357	2,446	2,527	$ 391,875	$ 407,897	$ 424,212	$ 440,236	$ 454,910
Designated Representative – WLS Deliquent Fee	$ 75	**$ 90**	178	188	197	207	216	$ 16,049	$ 16,897	$ 17,771	$ 18,639	$ 19,442

Site Licensing Services												
Pharmacy (includes Hospita & LCF)												
Pharmacy Original Permit	$ 400	**$ 480**	262	259	256	253	251	$ 125,649	$ 124,180	$ 122,760	$ 121,435	$ 120,278
Pharmacy Permit Renewal	$ 250	**$ 300**	6,156	6,204	6,251	6,296	6,336	$ 1,846,692	$ 1,861,080	$ 1,875,264	$ 1,888,762	$ 1,900,759
Pharmacy Deliquent Fee	$ 125	**$ 150**	40	37	35	34	32	$ 5,938	$ 5,611	$ 5,308	$ 5,038	$ 4,812
Temporary Pharmacy Permit	$ 250	**$ 300**	95	77	63	52	44	$ 28,441	$ 23,083	$ 18,829	$ 15,551	$ 13,163
Non-resident Pharmacy												
Non-Resident Pharmacy Original Permit	$ 400	**$ 480**	76	79	82	85	87	$ 36,384	$ 37,796	$ 39,230	$ 40,636	$ 41,922
Non-Resident Pharmacy Permit Renewal	$ 250	**$ 300**	239	246	253	260	267	$ 71,697	$ 73,828	$ 75,975	$ 78,061	$ 79,953
Non-Resident Pharmacy Deliquent Fee	$ 125	**$ 150**	21	23	25	27	29	$ 3,136	$ 3,438	$ 3,761	$ 4,096	$ 4,417
Clinic												
Clinic Original Permit	$ 400	**$ 480**	95	101	108	116	122	$ 45,391	$ 48,636	$ 52,037	$ 55,474	$ 58,706
Clinic Permit Renewal	$ 250	**$ 300**	886	906	925	944	962	$ 265,827	$ 271,736	$ 277,646	$ 283,348	$ 288,483
Clinic Deliquent Fee	$ 125	**$ 150**	75	86	97	109	121	$ 11,307	$ 12,847	$ 14,559	$ 16,391	$ 18,212
Wholesaler												
Wholesale Drug Original Permit	$ 600	**$ 720**	45	40	36	33	30	$ 32,261	$ 29,050	$ 26,221	$ 23,810	$ 21,878
Wholesale Drug Permit Renewal	$ 600	**$ 720**	417	418	420	421	422	$ 299,967	$ 301,089	$ 302,192	$ 303,236	$ 304,161
Wholesale Drug Deliquent Fee	$ 150	**$ 180**	20	18	17	15	14	$ 3,589	$ 3,267	$ 2,981	$ 2,734	$ 2,534
Temporary Wholesale Permit	$ 550	**$ 660**	8	8	8	8	8	$ 5,280	$ 5,280	$ 5,280	$ 5,280	$ 5,280
Hypodermic Needle and Syringe												
Hypodermic Needle and Syringe Original Permit	$ 125	**$ 150**	12	12	12	11	11	$ 1,869	$ 1,795	$ 1,725	$ 1,662	$ 1,608
Hypodermic Needle and Syringe Permit Renewal	$ 125	**$ 150**	246	243	240	237	235	$ 36,867	$ 36,410	$ 35,968	$ 35,556	$ 35,197
Hypodermic Needle and Syringe Deliquent Fee	$ 63	**$ 75**	21	19	18	17	16	$ 1,541	$ 1,444	$ 1,355	$ 1,276	$ 1,211

Non-Resident Wholesaler												
Non-Resident Wholesaler Original Permit	$ 600	**$ 720**	91	86	81	77	74	$ 65,744	$ 62,049	$ 58,638	$ 55,593	$ 53,046
Non-Resident Wholesaler Permit Renewal	$ 600	**$ 720**	401	418	436	454	470	$ 288,437	$ 301,144	$ 314,123	$ 326,909	$ 338,650
Non-Resident Wholesaler Deliquent Fee	$ 150	**$ 180**	49	52	56	60	64	$ 8,756	$ 9,435	$ 10,152	$ 10,880	$ 11,568
Temporary NonResident Wholesale Permit	$ 550		3	3	3	3	3					
Sterile Compounding												
Sterile Compounding Original Permit	$ 600	**$ 720**	49	48	47	46	45	$ 35,217	$ 34,482	$ 33,778	$ 33,128	$ 32,564
Sterile Compounding Permit Renewal	$ 600	**$ 720**	167	169	172	174	177	$ 120,002	$ 121,874	$ 123,733	$ 125,516	$ 127,112
Sterile Compounding Deliquent Fee	$ 150	**$ 180**	1	1	1	1	1	$ 158	$ 140	$ 124	$ 111	$ 101
Temp permit	$ 550		14	14	14	14	14					
Non-Res Sterile Compounding												
Sterile Compounding Original Permit	$ 600	**$ 720**	25	27	30	32	34	$ 18,065	$ 19,638	$ 21,312	$ 23,027	$ 24,661
Sterile Compounding Permit Renewal	$ 600	**$ 720**	45	49	53	57	61	$ 32,240	$ 35,088	$ 38,119	$ 41,229	$ 44,197
Sterile Compounding Deliquent Fee	$ 150	**$ 180**	3	4	4	5	5	$ 605	$ 674	$ 750	$ 830	$ 908
Vet Food-Animal Drug Retailer												
Veterinary Food-Animal Drug Retailer Original Permit	$ 400	**$ 480**	2	2	2	1	1	$ 883	$ 815	$ 754	$ 701	$ 657
Veterinary Food-Animal Drug Retailer Permit Renewal	$ 250	**$ 300**	21	23	25	26	28	$ 6,448	$ 6,909	$ 7,393	$ 7,882	$ 8,342
Veterinary Food-Animal Drug Retailer Deliquent Fee	$ 125	**$ 150**	1	1	1	1	1	$ 132	$ 117	$ 104	$ 93	$ 84
Temporary Veterinary Food-Animal Drug Permit	$ 250	**$ 300**										

Miscellaneous Services												
Transfer of Intern Hours/License Verification	$ 20	**$ 24**	917	936	955	973	990	$ 22,016	$ 22,470	$ 22,924	$ 23,361	$ 23,754
Regrade of Pharmacist Licensure Exam	$ 85	**$ 102**	9	8	6	5	4	$ 968	$ 774	$ 622	$ 507	$ 424
Change of Permit - Reissuance	$ 100	**$ 120**	606	623	639	656	670	$ 72,713	$ 74,717	$ 76,731	$ 78,685	$ 80,453
Change of Permit - Tradestyle/Address	$ 30	**$ 36**	403	565	786	1,078	1,430	$ 14,504	$ 20,323	$ 28,300	$ 38,790	$ 51,477
Change of Pharmacist in Charge	$ 100	**$ 120**	1,445	1,470	1,495	1,519	1,541	$ 173,378	$ 176,401	$ 179,410	$ 182,300	$ 184,891
Change of Designated Representative in Charge	$ 100	**$ 120**	90	99	108	117	126	$ 10,809	$ 11,829	$ 12,921	$ 14,048	$ 15,128
Duplicate/Replacement License	$ 30	**$ 36**	698	718	737	756	773	$ 25,145	$ 25,836	$ 26,531	$ 27,205	$ 27,814
Retired Pharmacist	$ 30	**$ 36**	13	12	12	11	11	$ 452	$ 438	$ 424	$ 412	$ 401
totals			**70,373**	**72,185**	**74,091**	**76,040**	**77,914**	**9,841,856**	**10,006,154**	**10,177,518**	**10,350,063**	**10,512,285**

Appendix G: Direct Costs Allocated to Each Fee

	07/08 Total Actual Workload	% workload within category	Licensing Support Allocation	Less 15% DCA Data Processing	Less 7% Exams	Sub-Total Allocation Within Group	Reallocation of DCA Billings	Reallocation of Examinations	Total Allocation of Direct Costs
Individual Licensing Services									
Pharmacist									
Pharmacist Licensure Exam Application	1,918	10%	$ 80,309.54	$ 12,418.39	$ 5,232.26	$ 62,658.89		$ 157,438	$ 220,096.89
Pharmacist Original License	1,351	7%	$ 56,568.40	$ 8,747.26	$ 3,685.49	$ 44,135.64			$ 44,135.64
Pharmacist Renewal	15,677	81%	$ 656,419.50	$ 101,503.19	$ 42,766.46	$ 512,149.85	$ 122,254.53		$ 634,404.37
Pharmacist Deliquent Fee	313	2%	$ 13,105.78	$ 2,026.57	$ 853.86	$ 10,225.36	$ 2,440.88		$ 12,666.24
	19,259	**100%**	**$ 806,403.21**	**$ 124,695.41**	**$ 52,538.07**	**$ 629,169.73**	**$ 124,695.41**	**$ 157,438.00**	**$ 911,303.14**
Pharmacy Technician				$ -	$ -	$ -			$ -
Pharmacy Technician Original License	7,518	24%	$ 297,494.43	$ 46,002.03	$ 19,382.09	$ 232,110.30			$ 232,110.30
Pharmacy Technician Renewal	21,563	70%	$ 853,268.46	$ 131,942.26	$ 55,591.39	$ 665,734.81	$ 174,276.85		$ 840,011.66
Pharmacy Technician Deliquent Fee	1,868	6%	$ 73,918.54	$ 11,430.14	$ 4,815.88	$ 57,672.52	$ 15,097.58		$ 72,770.11
	30,949	**100%**	**$ 1,224,681.43**	**$ 189,374.43**	**$ 79,789.36**	**$ 955,517.63**	**$ 189,374.43**		**$ 1,144,892.06**
Pharmacist Intern									
Pharmacist Intern Orignal Permit	**1,733**	**100%**	**$ 102,619.32**	**$ 15,868.19**	**$ 6,685.76**	**$ 80,065.37**	**$ 15,868.19**		**$ 95,933.55**
Designated Represenative - VET Exemption									
Designated Representative - VET Original Application	5	8%	$ 109.93	$ 17.00	$ 7.16	$ 85.77			$ 85.77
Designated Representative - VET Original Certificate	4	7%	$ 87.94	$ 13.60	$ 5.73	$ 68.61			$ 68.61
Designated Representative - VET Renewal	51	84%	$ 1,121.28	$ 173.39	$ 73.05	$ 874.84	$ 203.39		$ 1,078.23
Designated Representative – VET Deliquent Fee	1	2%	$ 21.99	$ 3.40	$ 1.43	$ 17.15	$ 3.99		$ 21.14
	61	**100%**	**$ 1,341.14**	**$ 207.38**	**$ 87.38**	**$ 1,046.38**	**$ 207.38**		**$ 1,253.76**
Designated Represenative - WLS Exemption				$ -	$ -	$ -			$ -
Designated Representative - WLS Original Application	442	14%	$ 8,923.30	$ 1,379.82	$ 581.36	$ 6,962.11			$ 6,962.11
Designated Representative - WLS Original Certificate	431	14%	$ 8,701.23	$ 1,345.48	$ 566.89	$ 6,788.85			$ 6,788.85
Designated Representative - WLS Renewal	2,088	67%	$ 42,153.52	$ 6,518.26	$ 2,746.35	$ 32,888.90	$ 9,039.51		$ 41,928.41
Designated Representative – WLS Deliquent Fee	169	5%	$ 3,411.85	$ 527.58	$ 222.29	$ 2,661.98	$ 731.65		$ 3,393.63
	3,130	**100%**	**$ 63,189.90**	**$ 9,771.15**	**$ 4,116.89**	**$ 49,301.85**	**$ 9,771.15**		**$ 59,073.00**

Site Licensing Services									
Pharmacy (including Hospital)									
Pharmacy Original Permit	265	4%	$ 6,028.56	$ 932.21	$ 392.77	$ 4,703.59			$ 4,703.59
Pharmacy Chain Permit	0	0%							
Pharmacy Permit Renewal	6,106	93%	$ 138,907.16	$ 21,479.43	$ 9,049.96	$ 108,377.77	$ 22,817.53		$ 131,195.30
Pharmacy Deliquent Fee	42	1%	$ 955.47	$ 147.75	$ 62.25	$ 745.47	$ 156.95		$ 902.42
Temporary Pharmacy Permit	118	2%	$ 2,684.42	$ 415.10	$ 174.89	$ 2,094.43			$ 2,094.43
	6,531	**100%**	**$ 148,575.61**	**$ 22,974.48**	**$ 9,679.87**	**$ 115,921.26**	**$ 22,974.48**		**$ 138,895.74**
Non-resident Pharmacy									
Non-Resident Pharmacy Original Permit	73	23%	$ 1,735.78	$ 268.41	$ 113.09	$ 1,354.29			$ 1,354.29
Non-Resident Pharmacy Permit Renewal	232	72%	$ 5,523.05	$ 854.04	$ 359.83	$ 4,309.18	$ 1,102.11		$ 5,411.29
Non-Resident Pharmacy Deliquent Fee	19	6%	$ 452.71	$ 70.00	$ 29.49	$ 353.21	$ 90.34		$ 443.55
	324	**100%**	**$ 7,711.54**	**$ 1,192.45**	**$ 502.42**	**$ 6,016.67**	**$ 1,192.45**		**$ 7,209.12**
Clinic									
Clinic Original Permit	88	9%	$ 2,219.63	$ 343.22	$ 144.61	$ 1,731.79			$ 1,731.79
Clinic Permit Renewal	866	85%	$ 21,843.13	$ 3,377.64	$ 1,423.10	$ 17,042.39	$ 3,696.56		$ 20,738.94
Clinic Deliquent Fee	66	6%	$ 1,664.72	$ 257.42	$ 108.46	$ 1,298.84	$ 281.72		$ 1,580.57
	1,020	**100%**	**$ 25,727.47**	**$ 3,978.28**	**$ 1,676.17**	**$ 20,073.02**	**$ 3,978.28**		**$ 24,051.30**
Wholesaler									
Wholesale Drug Original Permit	50	10%	$ 1,104.07	$ 170.72	$ 71.93	$ 861.41			$ 861.41
Wholesale Drug Permit Renewal	415	84%	$ 9,163.76	$ 1,417.01	$ 597.03	$ 7,149.72	$ 1,605.08		$ 8,754.80
Wholesale Drug Deliquent Fee	22	4%	$ 485.79	$ 75.12	$ 31.65	$ 379.02	$ 85.09		$ 464.11
Temporary Wholesale Permit	8	2%	$ 176.65	$ 27.32	$ 11.51	$ 137.83			$ 137.83
	495	**100%**	**$ 10,930.26**	**$ 1,690.16**	**$ 712.12**	**$ 8,527.98**	**$ 1,690.16**		**$ 10,218.15**
Hypodermic Needle and Syringe									
Hypodermic Needle and Syringe Original Permit	13	5%	$ 311.04	$ 48.10	$ 20.26	$ 242.68			$ 242.68
Hypodermic Needle and Syringe Permit Renewal	249	88%	$ 5,957.67	$ 921.24	$ 388.15	$ 4,648.28	$ 965.44		$ 5,613.71
Hypodermic Needle and Syringe Deliquent Fee	22	8%	$ 526.38	$ 81.40	$ 34.29	$ 410.69	$ 85.30		$ 495.99
	284	**100%**	**$ 6,795.09**	**$ 1,050.74**	**$ 442.71**	**$ 5,301.65**	**$ 1,050.74**		**$ 6,352.39**

Non-Resident Wholesaler										
Non-Resident Wholesaler Original Permit	97	18%	$ 2,168.17	$ 335.27	$ 141.26	$ 1,691.64				$ 1,691.64
Non-Resident Wholesaler Permit Renewal	383	73%	$ 8,560.92	$ 1,323.79	$ 557.75	$ 6,679.38	$ 1,633.09			$ 8,312.47
Non-Resident Wholesaler Deliquent Fee	45	9%	$ 1,005.85	$ 155.54	$ 65.53	$ 784.78	$ 191.88			$ 976.66
Temporary NonResident Wholesale Permit ????	3	1%	$ 67.06	$ 10.37	$ 4.37	$ 52.32				$ 52.32
	528	**100%**	**$ 11,802.00**	**$ 1,824.96**	**$ 768.91**	**$ 9,208.13**	**$ 1,824.96**			**$ 11,033.09**
Sterile Compounding										
Sterile Compounding Original Permit	50	22%	$ 1,097.22	$ 169.67	$ 71.49	$ 856.07				$ 856.07
Sterile Compounding Permit Renewal	164	72%	$ 3,598.89	$ 556.50	$ 234.47	$ 2,807.91	$ 772.97			$ 3,580.88
Sterile Compounding Deliquent Fee	1	0%	$ 21.94	$ 3.39	$ 1.43	$ 17.12	$ 4.71			$ 21.83
temp permit	14	6%	$ 311.21	$ 48.12	$ 20.28	$ 242.81				$ 242.81
	229	**100%**	**$ 5,029.26**	**$ 777.68**	**$ 327.66**	**$ 3,923.92**	**$ 777.68**			**$ 4,701.60**
Non-Res Sterile Compounding										
Sterile Compounding Original Permit	23	34%	$ 406.68	$ 62.89	$ 26.50	$ 317.30				$ 317.30
Sterile Compounding Permit Renewal	41	61%	$ 724.95	$ 112.10	$ 47.23	$ 565.62	$ 170.70			$ 736.31
Sterile Compounding Deliquent Fee	3	4%	$ 53.04	$ 8.20	$ 3.46	$ 41.39	$ 12.49			$ 53.88
	67	**100%**	**$ 1,184.67**	**$ 183.19**	**$ 77.18**	**$ 924.30**	**$ 183.19**			**$ 1,107.49**
Vet Food-Animal Drug Retailer										
Veterinary Food-Animal Drug Retailer Original Permit	2	9%	$ 44.70	$ 6.91	$ 2.91	$ 34.88				$ 34.88
Veterinary Food-Animal Drug Retailer Permit Renewal	20	87%	$ 447.05	$ 69.13	$ 29.13	$ 348.79	$ 75.71			$ 424.50
Veterinary Food-Animal Drug Retailer Deliquent Fee	1	4%	$ 22.35	$ 3.46	$ 1.46	$ 17.44	$ 3.79			$ 21.23
Temporary Veterinary Food-Animal Drug Permit		0%								
	23	**100%**	**$ 514.10**	**$ 79.50**	**$ 33.49**	**$ 401.11**	**$ 79.50**			**$ 480.61**
				$ -						
Totals	**64,633**		**2,416,505**	**373,668**	**157,438**	**1,885,399**	**$ 373,668**	**$ 157,438**		**2,416,505**

Appendix H: Indirect Cost Allocation Basis and Distribution

Indirect Allocations Basis	Executive	Supervising Inspectors	Field Inspectors	Staff Services Managers/Specialists	Enforcement Programs	Licensing Programs and Exams	Customer Support and Public Education	Org Dev and Support	Totals
2007/2008 Personnel & Benefit %	4%	12%	56%	0%	11%	8%	6%	3%	100%
2007/2008 FTEs	2	4	19.05	0	10	7.83	5.57	4.42	52.87
FTE %	3.8%	7.6%	36.0%	0.0%	18.9%	14.8%	10.5%	8.4%	100.0%
Insurance %	N/A	17.4%	82.6%	N/A	N/A	N/A	N/A	N/A	100.0%
Vehicle Operations %	N/A	17.4%	82.6%	N/A	N/A	N/A	N/A	N/A	100.0%
Cell Phone %	8.0%	16.0%	76.0%	N/A	N/A	N/A	N/A	N/A	100.0%
Travel %	8.0%	16.0%	76.0%	N/A	N/A	N/A	N/A	N/A	100.0%
DCA Facilities Operations %	5.9%	11.8%	N/A	0.0%	29.6%	23.2%	16.5%	13.1%	100.0%

2007/2008 Indirect Expenses Allocated	Executive	Supervising Inspectors	Field Inspectors	Staff Services Managers/Specialists	Enforcement Programs	Licensing Programs & Exams	Customer Support and Public Education	Org Dev & Support	Totals
Insurance (Inspector Autos)	N/A	$ 328	$ 1,564	N/A	N/A	N/A	N/A	N/A	**$ 1,892**
Vehicle Operations	N/A	$ 12,600	$ 60,005	N/A	N/A	N/A	N/A	N/A	**$ 72,605**
Cell Phones	$ 2,547	$ 5,094	$ 24,259	N/A	N/A	N/A	N/A	N/A	**$ 31,899**
Travel Expense	$ 19,458	$ 38,915	$ 185,335	N/A	N/A	N/A	N/A	N/A	**$ 243,708**
Personnel & Benefits	$ 191,691	$ 588,906	$ 2,703,087	$ -	$ 539,760	$ 386,250	$ 275,336	$ 158,146	**$ 4,843,175**
DCA Facilities Operations	$ 15,609	$ 31,217	N/A	$ -	$ 78,043	$ 61,108	$ 43,431	$ 34,495	**$ 263,903**
Training	$ 472	$ 943	$ 4,493	$ -	$ 2,358	$ 1,847	$ 1,312	$ 1,042	**$ 12,468**
General Expense	$ 6,576	$ 13,153	$ 62,639	$ -	$ 32,881	$ 25,746	$ 18,298	$ 14,534	**$ 173,827**
Other Communications	$ 759	$ 1,517	$ 7,225	$ -	$ 3,793	$ 2,970	$ 2,111	$ 1,676	**$ 20,050**
Office Equipment Expense	$ 4,282	$ 8,565	$ 40,789	$ -	$ 21,412	$ 16,765	$ 11,916	$ 9,464	**$ 113,193**
DCA Central Admin Pro-Rata	$ 12,638	$ 25,275	$ 120,373	$ -	$ 63,188	$ 49,476	$ 35,164	$ 27,929	**$ 334,043**
DCA Indirect Distribution Costs	$ 19,806	$ 39,612	$ 188,650	$ -	$ 99,029	$ 77,540	$ 55,110	$ 43,771	**$ 523,517**
Totals	**$ 273,836**	**$ 766,125**	**$ 3,398,419**	**$ -**	**$ 840,464**	**$ 621,702**	**$ 442,678**	**$ 291,057**	**$ 6,634,280**

Appendix I: Hourly Rates of all Board Positions

Employee Group	FTE	2007/2008 Budgeted Salaries	2007/2008 Indirect Costs	Total BOP Employee Hours Available	2007-2008 ee Hourly Billing Rate/ Fully Loaded Process Cost
Executive	**1**	$ 103,608	$ 153,636	1,778	$ 86.41
	1	$ 81,060	$ 120,200	1,778	$ 67.60
Total Executive	**2**	**$ 184,668**	**$ 273,836**	**3,556**	**$ 77.01**
Supervising Inspectors	**1**	$ 141,528	$ 191,119	1,778	$ 107.49
	1	$ 146,244	$ 197,488	1,778	$ 111.07
	1	$ 133,316	$ 180,030	1,778	$ 101.25
	1	$ 146,244	$ 197,488	1,778	$ 111.07
Total Supervising Inspectors	**4**	**$ 567,332**	**$ 766,125**	**7,112**	**$ 107.72**
Field Inspectors					
	1	$ 137,076	$ 178,891	1,778	$ 100.61
	1	$ 137,076	$ 178,891	1,778	$ 100.61
	1	$ 137,076	$ 178,891	1,778	$ 100.61
	1	$ 137,076	$ 178,891	1,778	$ 100.61
	1	$ 137,076	$ 178,891	1,778	$ 100.61
	1	$ 137,076	$ 178,891	1,778	$ 100.61
	1	$ 137,076	$ 178,891	1,778	$ 100.61
	1	$ 137,076	$ 178,891	1,778	$ 100.61
	1	$ 137,076	$ 178,891	1,778	$ 100.61
	0.75	$ 102,807	$ 134,168	1,334	$ 100.61
	0.3	$ 33,885	$ 44,221	533	$ 82.90
	1	$ 137,076	$ 178,891	1,778	$ 100.61
	1	$ 137,076	$ 178,891	1,778	$ 100.61
	1	$ 137,076	$ 178,891	1,778	$ 100.61
	1	$ 137,076	$ 178,891	1,778	$ 100.61
	1	$ 137,076	$ 178,891	1,778	$ 100.61
	1	$ 137,076	$ 178,891	1,778	$ 100.61
	1	$ 137,076	$ 178,891	1,778	$ 100.61
	1	$ 137,076	$ 178,891	1,778	$ 100.61
	1	$ 137,076	$ 178,891	1,778	$ 100.61
	1	$ 137,076	$ 178,891	1,778	$ 100.61
Total Field Inspectors	**19.05**	**$ 2,604,060**	**$ 3,398,419**	**33,871**	**$ 100.33**

*All inspectors (supervising and field) hourly rates average $102

Enforcement Programs	**1**	$ 64,500	$ 104,253	1,778	$ 58.63
	1	$ 58,350	$ 94,312	1,778	$ 53.04
	1	$ 52,800	$ 85,342	1,778	$ 48.00
	1	$ 54,911	$ 88,754	1,778	$ 49.92
	1	$ 47,457	$ 76,706	1,778	$ 43.14
	1	$ 53,352	$ 86,234	1,778	$ 48.50
	1	$ 39,156	$ 63,289	1,778	$ 35.60
	1	$ 36,768	$ 59,429	1,778	$ 33.42
	1	$ 39,168	$ 63,308	1,778	$ 35.61
	1	$ 73,524	$ 118,838	1,778	$ 66.84
Total Enforcement Programs	**10**	**$ 519,986**	**$ 840,464**	**17,780**	**$ 47.27**
Licensing Programs & Exams	**1**	$ 58,824	$ 98,283	1,778	$ 55.28
	1	$ 43,164	$ 72,118	1,778	$ 40.56
	1	$ 39,156	$ 65,422	1,778	$ 36.80
	1	$ 64,176	$ 107,225	1,778	$ 60.31
	1	$ 33,441	$ 55,873	1,778	$ 31.42
	1	$ 33,840	$ 56,540	1,778	$ 31.80
	0.33	$ 12,255	$ 20,476	587	$ 34.90
	0.5	$ 13,720	$ 22,923	889	$ 25.79
	0	$ -	$ -	0	#DIV/0!
	1	$ 73,524	$ 122,843	1,778	$ 69.09
Total Licensing Programs & Exams	**7.83**	**$ 372,100**	**$ 621,702**	**13,922**	**$ 44.66**
Customer Support and Public Education					
	1	$ 66,027	$ 110,193	1,778	$ 61.98
	0.47	$ 27,908	$ 46,576	827	$ 56.33
	1	$ 43,896	$ 73,259	1,778	$ 41.20
	1	$ 46,716	$ 77,965	1,778	$ 43.85
	0.1	$ 3,500	$ 5,841	178	$ 32.85
	1	$ 33,306	$ 55,585	1,778	$ 31.26
	1	$ 43,896	$ 73,259	1,778	$ 41.20
Total Customer Support and Public Education	**5.57**	**$ 265,249**	**$ 442,678**	**$ 9,895**	**$ 44.74**

Org Dev & Support					
	0	$ 119	$ 227	0	
	0.12	$ 5,509	$ 10,525	213	$ 49.33
	1	$ 39,156	$ 74,805	1,778	$ 42.07
	1	$ 34,079	$ 65,105	1,778	$ 36.62
	1	$ 32,232	$ 61,577	1,778	$ 34.63
	1	$ 33,172	$ 63,373	1,778	$ 35.64
	0.3	$ 8,085	$ 15,446	533	$ 28.96
Total Org Dev & Support	**4.42**	**$ 152,352**	**$ 291,057**	**7,859**	**$ 37.04**
Totals	**52.87**	**$ 4,665,747**	**$ 6,634,280**	**93,994**	**$ 70.58**

Attachment C:

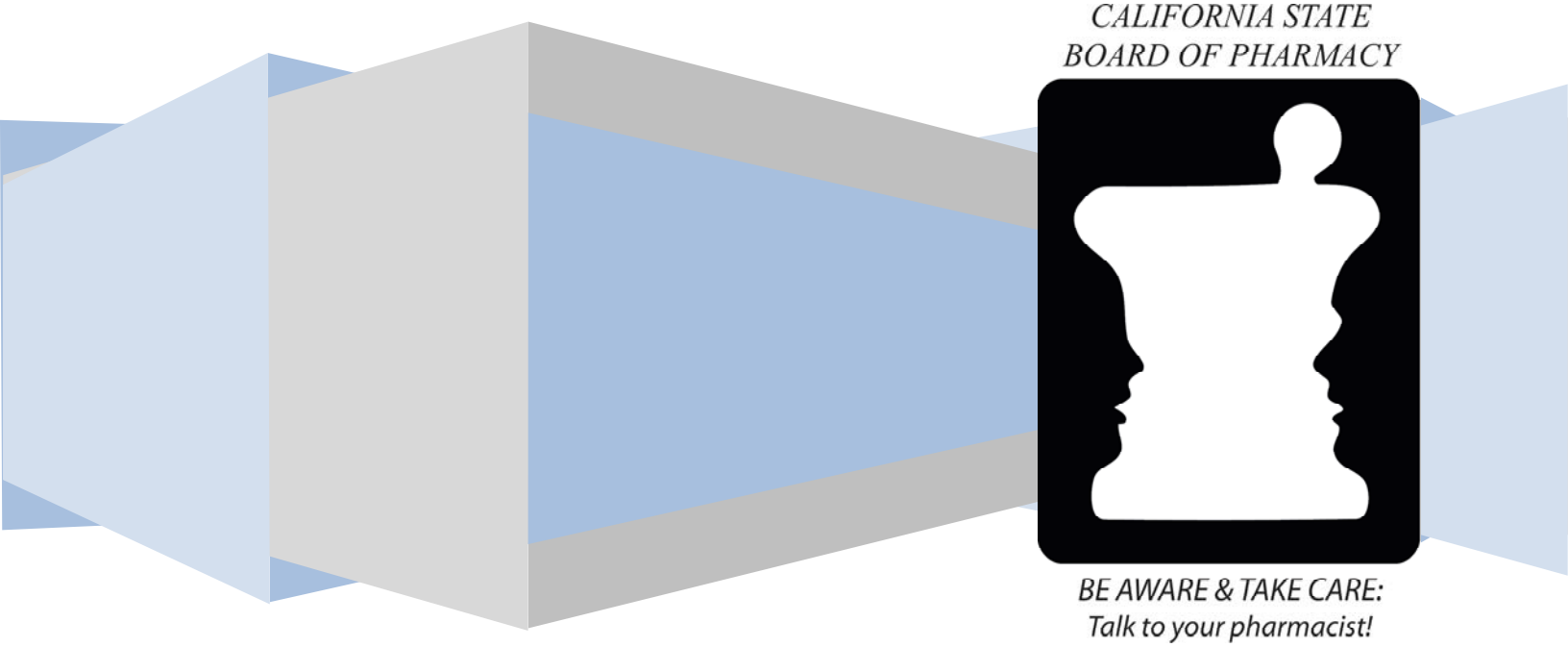
Legislative Program Overview

California State
Board of Pharmacy

Legislative Program Overview

A Report to the Chair of the Assembly Business and Professions Committee

February 2010



1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834

Forward

This report has been written in response to a January 2010 request from the Chair of the Assembly Committee on Business and Professions seeking information about how the California State Board of Pharmacy develops and sponsors legislation. Executive staff of the board prepared this report.

Accordingly for each bill sponsored by the board, information is organized by topic headings, according to parameters set by the Chair in her request:

- Originator of the bill
- Criteria for sponsorship and consideration of consumer protection factors
- Research and approval timeline
- Summary of issues that arose during the Legislative Process

Introduction

The California State Board of Pharmacy is a consumer protection agency charged with enforcement of the state's Pharmacy Law. The board has 13 major regulatory programs that regulate both the individuals and firms that procure, ship, store and dispense prescription drugs and devices to the state's health care providers and patients, both from within and outside California.

The board is comprised of 13 members; seven pharmacists and six public members. Four of the public members and all seven pharmacists are appointed by the Governor, the Assembly and the Senate each appoint one public member. At the time of this report, the board is comprised of four pharmacists and six public members. There are three pharmacist positions vacant.

The board is mandated under California Business and Professions Code section 4001.1 that:

> Protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

The Board of Pharmacy organizes its activities according to a strategic plan, which is reviewed and revised annually. This plan is divided into five strategic areas that are managed by a committee of the board:

- Enforcement
- Licensing
- Communication and Public Education
- Legislation and Regulation
- Organizational Development

Committee members and the chairperson are appointed by the board president on an annual basis.

In this report, the functions and activities of the board and its Legislation and Regulation Committee will be discussed.

The goal of the Legislation and Regulation Committee is to advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy. The board's vision is: "Healthy Californians through quality pharmacist's care."

The board's mission is: "The Board of Pharmacy protects and promotes the health and safety of Californians by pursuing the highest quality of pharmacist's care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation, and enforcement."

Pursuant to this mission and vision, all legislation advocated by the board, whether sponsored or reviewed, must either benefit the public with respect to pharmacist's care or advance the board's ability to license and enforce provisions that support pharmacist's care. In this vein, consumer protection is more than enforcing licensing standards and initiating enforcement actions. It includes devising and implementing prevention strategies for the misuse of dangerous drugs and devices, and eliminating unnecessary barriers to access to vital health care resources. As a regulator of a dynamic profession, it is necessary for the board to maintain vigilance to ensure outdated laws are updated or repealed, and new laws, reflecting new practices or responding to emerging issues, are enacted. Legislation and regulations involving licensing and enforcement activities of the board must be continually evaluated to ensure that minimum standards for competency in the professions are set and maintained.

Each year, the board typically sponsors at least one bill. The origin of legislative proposals comes from:

1. Issues before the board or Administration,
2. Comments addressed to the board from members, stakeholders and the public,
3. Investigations conducted by the board,
4. Health care issues affecting patients and drug distribution,
5. Board staff.

Legislation and promulgation of regulations are necessary to keep Pharmacy Law current. Health care continues to undergo dramatic changes as new technology and new medications compete with costs to drive down the expenses related to health care. Emerging technology that can provide enhanced health care at lower overall expense to the health care system sometimes cannot be used without changes in law. Emerging enforcement matters and health care issues also are the impetus for board-sponsored legislative proposals. Issues in public health or board initiatives frequently necessitate a legislative or regulation response.

But the board also responds to legislative proposals of others, not by sponsoring the proposal but by providing technical assistance to aid implementation or supporting those proposals that advance or opposing those that compromise the board's consumer protection mandate.

As stated in its 2002 Sunset Report: the rapid advance of health care technology (e.g., automation, communications and clinical innovations), workforce issues (e.g., persistent shortages of pharmacists and other health care professionals, geographic and socioeconomic imbalances in the distribution of pharmacies and pharmacists), demographic changes (e.g., aging population, rapidly increasing numbers of consumers from distinct racial, ethnic and linguistic backgrounds), and marketplace issues (e.g., consolidation, growth in chain pharmacies, direct-to-patient advertising of prescription medications, mail order pharmacies, internet pharmacies, rapidly rising drug costs and rapid increases in prescription volumes) increase the complexity of the board's policymaking activities.

Without a legislative program, the board would have significant challenges in moving forward towards its vision of "healthy Californians through quality pharmacist's care." Without seeking or responding to statutory change, the board would be passive and inactive to emerging health care issues. Outdated laws would remain on the books, and innovation and change to improve the public health would be impeded. This is not characteristic of a dynamic consumer protection program, a vigorous public health program or a desirable characteristic for a program regulating those who provide health care on behalf of California's citizens. Pursuing legislative and regulatory changes therefore are necessary components of the board's consumer protection mandate.

The board does its decision making in public, and seeks the participation of the public and other stakeholders in the process. Meeting agendas are placed online and distributed in hard copy form at least 10 days before a meeting. A "subscriber alert" is also emailed to interested parties who have signed up to be notified about board activities through the board's email contact list. Additionally, meeting materials that are provided to board members are also put online at the same time they are distributed to the board, and the availability of the meeting materials is announced via a subscriber alert.

Each year the board holds at least four full public board meetings, where the board acts on matters before it, including legislative and regulation proposals affecting consumers or the board's jurisdiction. In advance of any board meeting, the board usually schedules a committee meeting of the board's strategic committees so an in-depth

discussion of emerging issues is permitted. These meetings are also accessible to the public. Finally, meeting minutes are posted online to allow those who are interested in following board activities to do so without having to attend the meetings in person.

Administration Review of Proposals

The board works closely with the Department of Consumer Affairs to secure its legislative objectives. As an executive branch agency, concerns of the Administration are important to the board. If unaddressed, such concerns could result in an oppose position or a veto if the legislation reaches the Governor. Accordingly, the board notifies the Administration of its annual legislative proposals once determined (usually following the October or the January board meetings). The board also conducts its decision making in public board meetings where the department is present.

For legislation sponsored in 2009, the board made its decisions at the October 2008 board meeting, and within one day of the meeting, notified the State and Consumer Services Agency as well as the legislative staff of the Department of Consumer Affairs about its proposals.

For legislation the board will sponsor in 2010, the board finalized its legislative agenda at the January 2010 board meeting, and notified the Department of Consumer Affairs Legislative Affairs Office the next business day.

Throughout any legislative session, updates to the Administration are provided in response to their inquiries before bills are up in committee hearings as well as in monthly reports to the DCA director. Additionally the board's staff works closely with departmental legislative and budget staff on all legislative matters as the session progresses.

Board-Sponsored Legislation 2009 and 2010

2009

AB 977 (Skinner), Immunizations (two-year bill)

AB 1071 (Emmerson), Board of Pharmacy Fees, Chapter 270, Statutes of 2009

SB 470 (Corbett), Addition of Purpose to Prescription Labels, Chapter 590, Statutes of 2009

SB 819 (Yee/ Senate Business, Professions and Economic Development Committee), Health Care Boards Omnibus Bill, Chapter 308, Statutes of 2009

SB 821 (Senate Business, Professions and Economic Development Committee), Health Care Boards Omnibus Bill, Chapter 307, Statutes of 2009

2010

Unnumbered bill – provisions for the Senate Business, Professions and Economic Development Committee Health Boards Care Omnibus Bill

Unnumbered bill – provisions to enhance the board's enforcement program

No bill planned, provisions approved – Standards for reverse distributors/wholesalers

Specific details about each of these proposals are provided on the following pages.

In Closing

The Board of Pharmacy is pleased to share this report with the Chair of the Assembly Business and Professions Committee.

The Board of Pharmacy's legislative program is one component the board activates to fulfill its consumer protection mandate. Legislative proposals are developed during public meetings, with input from stakeholders. During any legislative session, once legislation is introduced, amendments are made to remove opposition or clarify provisions. This is the legislative process.

The board seeks comments that will enable it to maintain or improve its level of excellence in seeking, providing and improving consumer protection. This is part of the public feedback built into every Board Meeting and Legislation and Regulation Committee Meeting.

Finally, activities performed in pursuing legislation support the board's vision of "healthy Californians through quality pharmacist care," and the board's mission.

2009 Legislation Sponsored by the Board of Pharmacy:

AB 977 (Skinner)

Bill Originator

Dr. Jeff Goad, Professor, University of Southern California

Strategic Plan Reference

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Outcome: Improve the health and safety of Californians.

Overall Legislative Intent

Increase access to life-saving vaccinations.

Consumer Protection Factors

1. Vaccines are a safe, effective, and efficient means to prevent sickness and death from infectious diseases as reported by the United States Department of Health and Human Services (HHS).
2. The federal Centers for Disease Control and Prevention report that 220,000,000 persons should get the influenza vaccination annually; however, fewer than 100,000,000 do.
3. According to Families USA, 12.1 millions Californians are uninsured.
4. Pharmacists represent the third largest health professional group in the United States and are on the frontline of preventative care.
5. Pharmacists are trained to screen, administer, and properly deal with any adverse events that may arise from vaccines.
6. Pharmacists are the most accessible health care provider – they interact with patients without an appointment.
7. Pharmacists have four years of professional training post baccalaureate degree to earn their PharmD degree, and many pursue post-doctorate residencies in addition.
8. Pharmacists have a formal national immunization training program based on the CDC's "Pink Book" guidelines.

9. Since 1995, Pharmacy Law has allowed a pharmacist to administer immunizations pursuant to a protocol with a physician. Since that time, pharmacists have safely initiated and administered thousands of immunizations to Californians. Patients seem comfortable obtaining these immunizations from pharmacists.

10. The proposal establishes additional standardized training, continuing education and reporting requirements.

Background

The CDC reports that vaccine-preventable disease levels are at or near record lows; however, the CDC notes that it cannot take high immunization coverage levels for granted. "To continue to protect American's children and adults, we must obtain maximum immunization coverage in all populations, establish effective partnerships, conduct reliable scientific research, implement immunization systems, and ensure vaccine safety."

Research and Approval Timeline

Assembly Bill 977, as initially introduced, would have allowed specially trained pharmacists to administer specific vaccines to patients. These vaccines are those recommended by the Centers for Disease Control. There are 10 of these that are recommended for adolescents aged 7-18, and 10 vaccines that are recommended for adults.

The origin of the concept was a presentation made to the board's Licensing Committee Meeting in March 2007, where the board heard a presentation by USC School of Pharmacy Professor Jeff Goad. Dr. Goad provided information about the CDC's concerns about immunization rates in some patients given the benefits of vaccines. He described the training of pharmacists in today's schools of pharmacy with respect to immunizations. The board agreed to proceed with legislation to allow specially trained pharmacists to administer immunizations pursuant to CDC protocols, and under specific conditions.

Over the following 18 months, the board developed language, but did not initiate work on finding an author due to other workload priorities and staffing commitments.

The immunization legislative proposal was brought by staff to the board in the fall of 2008, where at the October 2008 Board Meeting, the board approved the language. Approval was based on:

1. Improving access of patients to vaccines, should it result in increased immunization rates, is a public health issue that will improve the overall health of the public.

2. The integration of vaccination training as part of the education of pharmacists and ongoing training programs for licensed pharmacists prepares them to administer vaccines.

3. Immunization clinics, especially for flu, are well received by the public, and the board has never received a complaint from a consumer regarding a pharmacist-administered vaccination.

4. The Advisory Committee for Immunization Practices of the CDC develops the parameters for administration of vaccines in the US.

5. The proposal would in part address the objectives of the California Department of Public Health, voiced directly to the board in various board meetings in preparing health care providers to prepare for emergency response situations due to disasters, pandemics (e.g., H1N1 vaccinations) or terrorism. The board has worked over the years on preparing pharmacies and pharmacists to prepare for such emergency responses in accordance with the CDPH's objectives.

Bill History

This bill was introduced on February 26, 2009 and was amended six times, most recently January 25, 2010. The bill is currently referred to the Senate Health Committee and the Senate Business, Professions and Economic Development Committee.

Summary of Issues

The following summary is that of the board's executive staff and provides their opinions and understanding of what has occurred during the deliberations of the legislative process.

The introduced version of AB 977 met with opposition from the California Medical Association, other physicians' groups and the California Nurses Association that was not resolvable. The board scaled back the proposal before the first policy hearing in the Assembly Business and Professions Committee to include only influenza and pneumococcal vaccines. Why was this approach selected?

- Combined – influenza and pneumonia are the 8th leading cause of death in people of all ages and the 7th leading cause of death in people over the age of 65.

- During most influenza seasons, up to 20 percent of the people in the US may be infected with the influenza virus. Influenza immunization can reduce physicians' visits, lost work days and reduce antibiotic use.

- Over 30 percent of Californians were without health insurance in the spring of 2009.
- One of every 20 people who get pneumococcal pneumonia dies from it.
- This would have aided the California Department of Public Health's plans to identify immunizers to administer H1N1 vaccines to Californians.

Thus, this version of the bill contained the focus of the board's goals in seeking this proposal, although substantially scaled back.

However, the two vaccine version of AB 977 was also strongly opposed, and resolution could not be reached in April 2009 before the legislative deadline for policy committees to pass bills in the house of origin. The bill was amended to direct the California Pharmacists Association to do a study of protocols. This version of the bill never had a hearing, nor did the board take a position on it. The bill became a two-year bill.

In an attempt to resolve opposition from the medical community, another approach considered and discussed with the author's office and other proponents of the bill would have resulted in the state (Medical Board and Board of Pharmacy) developing a general protocol under which pharmacists could administer influenza and pneumococcal vaccines. The development of such a protocol had occurred in the past for pharmacists to provide emergency contraception.

This concept became the origin for the provisions in the January 4, 2010 version of the bill, which was drafted by board staff in November 2009, reviewed by AB 977 supporters, and sent to the author's chief of staff on November 24, 2009. The Medical Board's staff was notified of the proposed amendment, and they indicated that their board might have problems with the two immunizations specified in the bill, but a review by their board would not occur until the end of January.

In December 2009, the author's office worked directly with the California Medical Association on resolving the CMA's still strong opposition to the board's proposed draft amendments (for a joint Medical Board/Pharmacy Board protocol for flu and pneumococcal vaccines). The board was not involved in these discussions. At some point, negotiations between the author's office and the CMA resulted in the CMA drafting amendments that if incorporated in AB 977, would change their position to neutral. These amendments were put into the bill on January 5, during the Assembly Health Committee Hearing, and would appear in print as the January 6 version of AB 977.

On January 4, 2010, the bill was amended to authorize pharmacists to administer flu and pneumococcal vaccines to any person 11 years of age and older pursuant to a standardized protocol developed by Board of Pharmacy and the Medical Board of California. This version also specified training, continuing

education requirements and record keeping for any pharmacist immunizing under its provisions.

Next, the bill was amended again during the Assembly Health Committee on January 5 (published as the January 6 version), with CMA's proposed changes. This scaled back version of the bill would require the Board of Pharmacy and the Medical Board to develop a protocol for administration of flu vaccines by a pharmacist to an adult. The program would be a four-year pilot program and mandate a report to the Legislature one year prior to sunset of the provisions.

Because of conflicting schedules and absences over the holidays, combined with the tight legislative deadlines needed to pass two-year bills in the house of origin in January 2010, the board did not actually see the proposed amendments in a mock-up form until immediately before the Assembly Health hearing. As such, the executive officer indicated during the hearing that the board could support the proposed amendments if existing law remained in section 4052, and the proposed new state protocol was created as a new provision. This was the essence of the CMA amendments.

The bill was passed by the Assembly Health Committee, and referred to the Assembly Business and Professions Committee for hearing on January 12.

On January 11, the board learned from the author's office that the chair of the Assembly Business and Professions Committee wanted additional amendments in AB 977 that would be inserted during the Assembly Business and Professions Committee hearing on January 12 to require the Medical Board solely to develop the protocol. The executive officer indicated that she would not testify because she wanted to see the proposed amendment. However, at the request of the author's office, she agreed to come.

During the Assembly Business and Professions Committee hearing, the bill was passed with an amendment during the hearing. The amendments were not in print prior to the hearing, not made available to the board, and had been negotiated without the board's participation or knowledge.

During the hearing, the author's office, the lobbyist for the California Pharmacists Association and the committee chair agreed on the negotiated amendment that the Medical Board would solely be responsible for developing the protocol. The executive officer stated during the hearing that the board could support the amendment but noted that regulations by the Board of Pharmacy would likely be needed to implement the protocol, which had been required for the emergency contraception protocol done five years earlier. The bill was passed by the committee, and amendments printed on January 13.

On January 13, the board's executive officer was contacted by the Assembly Appropriations consultant, to identify the potential fiscal impact of AB 977, and was alerted that AB 977 was a likely candidate for suspense. After January 14, there was no further update from the Appropriations Committee.

Meanwhile, on January 20 and 21, 2010, the January Board Meeting took place. The board also held a Legislation and Regulation Committee meeting at the end of the day on January 20. As one piece of business, the committee reviewed the January 6 version of the bill.

The board staff who prepare meeting materials for the board inadvertently failed to provide the January 13 version of the bill which likely appeared in print as the packet materials were being compiled.

This oversight was repeated during the Legislation and Regulation Committee report during the January 21 Board Meeting. During the Board Meeting on January 21, the board voted to support the January 6 version of the bill, unaware that AB 977 had been more recently amended. Moreover, because the bill had been targeted for suspense, the board's staff thought the bill would die on the suspense file and focused its attention during the meeting to other pressing regulation issues.

Near the end of the January, the board learned that the bill had been passed by the Assembly Appropriations Committee on January 21 while the Board Meeting was underway. Also at the end of January, via a media inquiry from the *Sacramento Bee* seeking clarification on a controversy that occurred during the floor vote, the board learned that AB 977 had been passed by the Assembly.

The current version of the bill (January 25, 2010), substantially scales back what the board initially proposed in October 2008. More recently, on February 23, the Department of Consumer Affairs took an oppose position on the bill because there has been no problem demonstrated with provisions in existing law regarding physician and pharmacist protocols, nor a shortage of locations for patients to receive flu vaccines.

The next meeting of the board is April 21 and 22, 2010, where the board will consider its position on AB 977.

Support
California Pharmacists Association
California Retailers Association

AB 1071 (Emmerson)

Bill Originator

California State Board of Pharmacy

Strategic Plan Reference

Goal 5: Achieve the board's mission and goals.

Outcome: An effective organization.

Overall Legislative Intent

Ensure the financial solvency of the board.

Consumer Protection Factors

1. Business and Professions Code Section 4001 establishes the California State Board of Pharmacy which is vested with the administration and enforcement of Chapter 9, Division 2 of the Business and Professions Code.
2. The board regulates almost 120,000 licensees.
3. In fiscal year 2008/09, the board received over 16,000 applications, issued almost 12,000 licenses, and renewed over 50,000 licenses.
4. In fiscal year 2008/09, the board initiated over 2,700 investigations, completed over 2,100 investigations, issued 965 citation and fines, referred 136 cases to the Office of the Attorney General, revoked 32 licenses, and formally disciplined an additional 34 licensees. It also collected $1.2 million in citations.

Background

Beginning in 2008, many of the board's fees were increased to their statutory maximum because board-authorized expenditures exceeded annual revenue. This was done via a regulation change pursuant to the Administrative Procedure Act. The statutory maximum fee levels were established in statute in 1987.

A review of the Consumer Price Index reveals that the cost of consumer goods has risen steadily since 1988 by approximately 85 percent; however, board fees have remained unchanged.

The board's licensee population has grown 20 percent over the last five years, yet the size of the board's staff remains relatively constant until July 2009.

Research and Approval Timeline

During each quarterly board meeting, board members are provided with a budget update including a fund condition report. Over the last few years, expenditures have exceeded revenue, resulting in a depletion of the board's fund. In 2008, a DCA fund condition report predicted a fund deficit by 2011/12.

In 2008 the board commissioned an independent fee audit to determine the unit cost to process applications and license renewals. The audit reaffirmed that the board's expenditures were exceeding its revenues resulting in the draining of the contingent fund balance. The audit concluded that the board's current fee structure was insufficient to maintain the legislatively mandated 12-month reserve requirement and noted that the board's fund condition will continue to drop until it eventually exhausts all reserves and a deficit would occur.

During the July 2008 Board Meeting, the board discussed the initiation of an independent fee audit as a precursor to pursuing a statutory change in the board's fees.

In October 2008, the board again publicly discussed the need to pursue a statutory fee increase and noted that a fee audit was underway.

During the January 2009 Board Meeting, the board heard a presentation by the independent auditor on the findings and recommendations of the audit. Also during this meeting, the board voted to increase licensing fees at an amount that would be sufficient to remedy the board's fund condition and fulfill fiduciary requirements for the next five years.

Bill History

The bill was introduced on February 27, 2009. As initially introduced, the bill only addressed the increase in board licensing and renewal fees. The bill was later amended on September 2, 2009 to include provisions to extend the sunset dates for various boards within the Department of Consumer Affairs. The bill was enrolled on September 17, 2009 and chaptered on October 11, 2009.

Summary of Concerns

No concerns were raised and no opposition was on file for this proposal.

SB 470 (Corbett)

Bill Originator

Pharmacy Foundation of California

Strategic Plan Reference

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy

Outcome: Improve the health and safety of Californians.

Goal 4: Provide relevant information to information to consumers and licensees.

Outcome: Improved consumer awareness and licensee knowledge.

Overall Legislative Intent

Reduce medication errors.

Consumer Protection Factors

1. According to the Archives of Internal Medicine Report, in 2004, 34 Americans were being killed each day because of medication errors that occur in their home.
2. The Institute of Medicine projects that at least 1.5 million Americans are sickened, injured or killed each year by medication errors.
3. Recommendation 2 from the SCR 49 Panel (see below) provides, "Require that the intended use of a medication be included on all prescriptions and require that the intended use of medications be included on medication labels/labeling unless disapproved by the prescriber or the patient."
4. Up to one-half of all medications are taken incorrectly or mixed with other medications that cause dangerous reactions that can lead to injury and death.

Background

In 2005, Senator Jackie Speier authored SCR 49 which called for the creation of an expert panel to 1) study the causes of medication errors in the community setting and 2) recommend changes in the health care system that would reduce errors associated with over-the-counter and prescription medications in the outpatient setting. Over the course of one year, the panel met and heard

testimony from members of academia, consumer groups and various health professionals. The result of the panel's work was a comprehensive report summarizing medication errors and the outcomes of such errors as well as recommendations to mitigate errors.

A copy of the SCR 49 report can be found on the board's Web site.

Subsequent to the SCR 49 report, in 2007 Senator Corbett introduced SB 472, creating the California Patient Medication Safety Act of 2007 to standardize the prescription label and make it patient-centered. Specifically, this bill directed the board to develop a standardized patient-centered prescription label for medicine dispensed to California patients after January 1, 2011.

To facilitate implementation of the requirements contained within SB 472, the board held public meetings to elicit input from consumers as well as conducted individual consumer surveys. The board posted its survey document on its web site to allow for electronic submission, published the survey document in a statewide AARP newsletter, mailed the survey to various consumer groups, and attended and disseminated the surveys at various public events and health fairs statewide. Also, in conjunction with the Pharmacy Foundation of California, the board developed and deployed a radio survey of the public about prescription container labels.

A full report of the board's development of the regulation requirements for prescription container labels as directed by SB 472, including survey results, can be found on the board's Web site.

Research and Approval Timeline

During the July 2008 Board Meeting, the board heard a request from Steve Gray, PharmD, representing the Pharmacy Foundation of California. The Foundation requested that the board sponsor legislation to clarify a pharmacist's authorization within Business and Professions Code § 4076(a)(10) and allow a pharmacist to place the "purpose" of the medication on the label that is affixed to every prescription container dispensed to a patient. One of the Foundation's primary focuses is on the reduction of medication errors, and the Foundation believes that clarifying when and how a pharmacist is authorized to place the additional information within the prescription label will improve patient understanding and outcomes.

Consistent with the board's general process to consider legislative proposals, this issue was referred to the Legislation and Regulation Committee for discussion.

During the October 2008 Legislation and Regulation Committee Meeting, the committee discussed the proposal in detail. The proposal was consistent with the recommendations of the SCR 49 Medication Errors Panel. Testimony provided during the meeting included statements that a big problem is that

patients forget what their drugs are for after taking them home and storing them with other medications. Testimony also stated concerns with medication safety for patients in assisted living facilities, which are regulated by the California Department of Social Services. Comments noted that the providers of these facilities who assist seniors with their medications are low paid staff members, and that by adding purpose to the labels on prescription containers would assist patients in such care facilities from duplicate medication therapies and prevent errors. Minutes from this meeting are available at the board's Web site that describes the discussion and deliberation by the board. The committee voted to recommend sponsorship of a proposal to amend section 4076 to include the purpose of the medicine on the prescription label.

Subsequent to the committee meeting, during the October 2008 Board Meeting, the board discussed the issue, heard testimony from the public, deliberated and voted to pursue sponsorship of the proposal as recommended by committee.

A copy of board materials and minutes can be obtained from the board's Web site.

Bill History

After submission to Leg Counsel, the original language was expanded to amend Business and Professions Code section 4040. The bill was introduced on February 26, 2009, and was amended twice. The bill was enrolled on August 27, 2009, and chaptered October 11, 2009.

Summary of Issues

Throughout the process, the board had a broad base of consumer and industry support as detailed below.

Senator Corbett accepted amendments offered by the California Medical Association (CMA) whose original position was Support if Amended.

Senator Corbett accepted amendments offered by the California Retailers Association and National Association of Chain Drug Stores whose original position was Oppose Unless Amended.

Support

California Alliance for Retired Americans

California Medical Association

California Pan Ethnic Health Network

California Retailers Association

California Society of Health-Systems Pharmacists

Kaiser Permanente

National Association of Chain Drug Stores

Pharmacy Foundation of California
UCSF School of Pharmacy

Opposition
None on file

SB 819 (Senate Business, Professions and Economic Development Committee) – Omnibus

Bill Originator

California State Board of Pharmacy

Strategic Plan Reference

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the board of pharmacy.

Outcome: Improve the health and safety of Californians.

Overall Legislative Intent

Keep pharmacy law current and pursue non-controversial changes to benefit consumers, consistent with the board's consumer protection mandate.

Consumer Protection Factors

1. Ensure the continuity of care for patients requiring prescription medications.
2. Clarify the board's requirements for the pharmacist-in-charge (PIC). The PIC is the pharmacist responsible for overall pharmacy operations, including ensuring adherence to pharmacy law.
3. Keep Pharmacy Law current and clear so practitioners know and can comply with legal requirements.

Background

The omnibus provisions included in SB 819 were categorized into four types of changes:

1. Omnibus provisions to correct erroneous code citations resulting from the recodification of Business and Professions Code section 4052 several years before.
2. General omnibus provisions.
3. Authorization to use mobile pharmacies in disaster response activities or during renovation or reconstruction of a damaged pharmacy.

4. Changes resulting from a comprehensive legal review by board staff and counsel on the legal requirements surrounding the pharmacist-in-charge and designated representative-in-charge.

Provisions Contained Within the Proposal

Omnibus Provisions Resulting from Recodification of Business and Professions Code §4052

In 2006 Business and Professions Code section 4052 was recodified into four sections. As a result, the following references in the Business and Professions Code and Health and Safety Code to §4052 required technical amendments.

The sections affected are:

§733 – Dispensing Prescription Drugs and Devices

§4027 – Skilled Nursing Facility; Intermediate Care Facility; Other Health Care Facilities

§4040 – Prescription; Content Requirements

§4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist

§4060 – Controlled Substances – Prescription Required, Exceptions

§4076 – Prescription Container – Requirements for Labeling

§4111 – Restrictions on Prescriber Ownership

§4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner

H&SC §11150 – Persons Authorized to Write or Issue a Prescription

General Omnibus Provisions

The following provisions are a miscellaneous aggregation of general modifications to the identified code sections.

Amend §4059.5 - Who May Order Dangerous Drugs or Devices, Exceptions.

This section was amended to clarify that a designated representative must sign for and receive delivery of drugs by a wholesaler.

Amend §4081 – Records of Dangerous Drugs or Devices Kept Open for Inspection; Maintenance of Records, Current Inventory

This section replaced the term “representative-in-charge” with the correct “designated representative-in-charge” as a result of changes in SB 1307 (Chapter 857, Statutes of 2006).

Amend §4126.5 – Furnishing Dangerous Drugs by Pharmacy

This section was amended to clarify who in the supply chain may receive dangerous drugs furnished by a pharmacy.

Amend §4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee

This section was amended to authorize the board to inactivate a pharmacist license when a pharmacist who certifies completion of the required 30 units of continuing education as part of a renewal fails to provide proof of completion of these credits either when audited or when investigated by the board.

Amend §4301 – Unprofessional Conduct

This section was amended to reference the definition of a long-term care facility to the Health and Safety Code section 1418.

Amend H&SC 11165 – Controlled Substance Utilization Review and Evaluation System (CURES): Establishment; Operation; Funding; Reporting to Legislature

This section was amended to require that a clinic that dispenses Schedule III and Schedule IV controlled substances must report this information to the CURES system, consistent with the reporting requirements for pharmacies, hospitals, and others that dispense controlled drug to patients.

Use of Mobile Pharmacies

Amend §4062 Furnishing Dangerous Drugs During an Emergency

This section was amended to allow the use of a mobile pharmacy in the event of a declared natural disaster, if certain criteria are met.

Amend §4110 License Required, Temporary Permit Upon Transfer of Ownership

This section was amended to allow the use of a mobile pharmacy on a temporary basis when a pharmacy is destroyed, damaged or otherwise under repair.

Pharmacist-in-Charge and Designated Representative-in-Charge

In 2007 board staff and counsel completed a comprehensive review of the legal requirements surrounding the requirements of a pharmacist-in-charge as well that of a designated representative-in-charge. A designated representative-in-charge is the non-pharmacist who is specially licensed by the board to oversee operations in a drug wholesaler. As a result of this review, several changes were recommended including technical changes as well as refining the definitions of the pharmacist-in-charge and designated representative-in-charge, and clarifying the reporting requirements to the board when a change in either occurs.

Amend §4022.5 – Designated Representative; Designated Representative-in-Charge

This section was amended to clarify the definition of "designated representative-in-charge" as well as the responsibilities of a licensee serving as such.

Add §4036.5 – Pharmacist-in-Charge

This section was added to define the term "pharmacist-in-charge" as well as the responsibilities of a pharmacist serving as such.

Amend §4161 – Non-Resident Wholesaler; Requirements

This section was amended to clarify the duties that constitute a business operating as a non-resident wholesaler. This definition is already provided in B&PC § 4043, but was needed here to provide clarity to non-resident wholesaler requirements.

Amend §4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action

This section was amended to specify that failure to meet notification requirements to the board about when a PIC quits serving as a PIC will constitute grounds for disciplinary action.

Amend §4329 – Non-pharmacists; Prohibited Acts

This section was amended to prohibit a non-pharmacist from acting as a supervisor or pharmacist-in-charge.

Amend §4330 – Proprietors; Prohibited Acts

This section was amended to specify that any pharmacy owner that subverts or intends to subvert the efforts of a pharmacist-in-charge is guilty of a misdemeanor.

Research and Approval Timeline

These changes were approved by the board in 2007 and many were incorporated in SB 1779 (2008) as omnibus provisions. This bill was vetoed by the Governor at the end of the 2008 session for reasons unrelated to the contents of the bill.

At the October 2008 Board Meeting, the board voted to again pursue all of the omnibus provisions approved for sponsorship in 2008.

Bill History

This bill was introduced on March 10, 2009 and was amended nine times. The bill was enrolled on September 15, 2009 and chaptered on October 11, 2009.

Summary of Issues

This bill also contained provisions for several of the healing arts boards within the DCA. This board is unaware of any concerns with the board's provisions. As a condition of being in an omnibus bill, any opposition to a provision must be removed or the provision is removed from the bill.

SB 821 (Senate Business, Professions and Economic Development Committee) – Omnibus

Bill Originator

California State Board of Pharmacy

Strategic Plan Reference

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Outcome: Improve the health and safety of Californians.

Overall Legislative Intent

Keep pharmacy law current and pursue non-controversial changes to benefit consumers, consistent with the board's consumer protection mandate.

Consumer Protection Factors

1. Provide a safe and legal manner for Californians to dispose of used sharps.
2. Clarify the board's requirements for the pharmacist-in-charge (PIC) and designated representative-in-charge (DRIC). The PIC is the pharmacist responsible for overall pharmacy operations including ensuring adherence to pharmacy law. The DRIC is a licensee responsible for overall operations of a wholesaler.
3. Provide for an efficient and quick method of communication to notify board-licensed facilities of alerts and other messages from the board.

Background

These proposals were identified over the course of 2008 and were brought to the board for consideration as legislative proposals in October 2008. Several proposals were identified from legal counsel advice to remedy questions on the interpretation of pharmacy law; however, two provisions had specific triggering events detailed below.

1. During the early months of 2008, five separate recalls of heparin were issued by for various manufacturers to remove potentially dangerous heparin from the marketplace. Heparin is a widely used drug in hospitals for anticoagulation therapy. By April 2008, tainted heparin had been

linked to 81 deaths in the US. Board staff sent out a series of e-mail alerts regarding the recalls. However, board staff, conducting specialized inspections of a sample of hospitals, discovered recalled heparin in 40 percent of hospitals initially inspected.

As a result, the board immediately began inspections of all 533 hospitals in the state to ensure that all recalled heparin was removed from patient care areas and had either been returned to the manufacturer or was properly quarantined. By the end of June 2009, the board identified 94 hospitals where recalled heparin had been found by the board at least two months following the last recall (18 percent of California's hospitals).

A recommendation resulting from this series of events was the need to develop a quick and efficient method to contact all board-licensed facilities. As a result, a provision was created that all board-licensed facilities need to join the board's subscriber alert system by July 1, 2010.

2. SB 1305 (Figueroa, Chapter 64, Statutes of 2006) prohibited any person after September 1, 2008 to knowingly place home-generated sharps in residential or commercial waste or recycle containers. This made disposal of used sharps a bit more complex, but pharmacies where not authorized to accept used sharps back from patients. The board drafted a new section to the Business and Professions Code (as section 4146) to allow pharmacies to accept back used sharps in appropriate containers from patients to ensure appropriate disposal and reduce a very serious public health risk.

Provisions Contained Within Bill

Add §4013 – Subscriber Alert

This section added a requirement that all board-licensed facilities must join the board's e-mail notification list. Such a requirement will allow the board to quickly disseminate information to board licensees at minimal cost. The board will also use this system to distribute its biannual newsletter.

Add §4146 – Disposal of Returned Sharps by a Pharmacy

This section was added to authorize a pharmacy to accept returned sharps containers from consumers for disposal.

Amend §4101 – Pharmacist-in-Charge; Designated Representative-in-Charge; Termination of Status; Duty to Notify the Board.

This section was amended to clarify about when a pharmacist-in-charge or designated representative-in-charge must notify the board that he or she has ceased to serve in such a capacity.

Amend §4112 – Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation

This section was amended to explicitly state that a person cannot act as a nonresident pharmacy unless he or she has obtained a license from the board.

Amend §4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications

This section was amended to clarify procedures to be followed by a pharmacy when identifying a pharmacist-in-charge as well as the procedures to notify the board when a change in pharmacist-in-charge has occurred. In addition, this section allows for the use of an interim pharmacist-in-charge, for a period not greater than 120 days, when a pharmacy is unable to identify a permanent new pharmacist-in-charge within 30 days.

Amend §4160 – Wholesaler Licenses

This section was amended to clarify the procedures to be followed by a wholesaler when identifying a designated representative-in-charge as well as the procedures to notify the board when a change in the designated representative-in-charge has occurred.

Amend §4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked

This section was amended to clarify the procedures to be followed by a veterinary food-animal drug retailer when identifying a designated representative-in-charge as well as the procedures to notify the board when a change in the designated representative-in-charge has occurred.

Research and Approval Timeline

At the October 2008 Board Meeting, the board voted to pursue these several new omnibus provisions, which were introduced in SB 821 in 2009.

Bill History

This bill was introduced on March 1, 2009 and was amended six times. The bill was enrolled on September 4, 2009 and chaptered on October 11, 2009.

Summary of Issues

This bill contains provisions for several of the healing arts boards within the DCA. We are unaware of any concerns in any of the board's provisions. As a provision in an omnibus bill, any opposition must be resolved or the provision will be removed from the bill.

2010 Legislation Sponsored by the Board of Pharmacy:

Omnibus Provisions for Sponsorship in 2010

Bill Originator

California State Board of Pharmacy

Strategic Plan Reference

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the board of pharmacy.

Outcome: Improve the health and safety of Californians.

Overall Legislative Intent

Keep pharmacy law current and pursue non-controversial changes to benefit consumers, consistent with the board's consumer protection mandate.

Consumer Protection Factors

Keep pharmacy law current.

Background

The omnibus provisions for sponsorship in 2010 are categorized into two types of changes:

1. Amendments to update references to the California Department of Public Health and California Department of Health Care Services (formerly known as the Department of Health Services) and one amendment to update a reference to the Physical Therapy Board of California (formerly known as the Physical Therapy Examining Committee of California).
2. General omnibus provisions.

Provisions Contained Within Proposal

Effective July 1, 2007, pursuant to the California Public Health Act of 2006 (Chapter 241, Statutes of 2006), the Department of Health Services was split into two agencies: the Department of Public Health and the Department of Health Care Services. Several sections within the Business and Professions Code require amendment to correctly reference the appropriate agency as a result of this change.

The sections affected are:

§4017 – Authorized Officers of the Law

§4027 – Skilled Nursing Facilities – Intermediate Care Facilities – Other Health Care Facilities

§4028 – Licensed Hospital

§4037 – Pharmacy

§4052.3 – Emergency Contraception Drug Therapy; Requirements and Limitations

§4059 – Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions

§4072 – Oral or Electronic Transmission of Prescriptions – Health Care Facility

§4119 – Furnish Prescription Drug to Licensed Health Care Facility – Secured Emergency Supplies

§4127.1 – License to Compound Injectable Sterile Drug Products Required

§4169 – Prohibited Acts

§4181 -- License Requirements; Policies and Procedures; Who May Dispense

§4191 -- Compliance with California Department of Public Health; Who May Dispense Drugs

§4425 – Pharmacy Participation in Medi-Cal Program; Conditions; California Department of Health Care Services Utilization Review and Monitoring

§4426 – California Department of Health Care Services to Study Reimbursement Rates

General Omnibus Provisions

Amend Section §4196(e) – Veterinary Food Animal Drug Retailer; Designated Representative in Charge

At its October 2008 Board Meeting, the board approved provisions to be included in the 2009 Omnibus Bill (Senate Business, Professions and Economic Development Committee, SB 821). However, the chaptered version of SB 821 contained a drafting error and the section requires correction.

§4200.1 – Retaking Examinations; Limits; Requirements (North American Pharmacist Licensure Examination (NAPLEX) and California Practice Standards and Jurisprudence Examination (CPJE) Four-time Failure)

Since 1998, the Business and Professions Code has required that pharmacist applicants who fail either the CPJE four times or the NAPLEX four times must take 16 semester hours in a school of pharmacy before retaking the examination failed four times.

In October 2008, the board approved a proposal to eliminate a sunset date of January 1, 2010 within §4200.1 that had been extended several times but not repealed. Though the Senate Business, Professions and Economic Development Committee did approve the proposal for inclusion in the 2009 omnibus bill, the proposed text was not printed in any omnibus measure. As a result, the provisions in §4200.1 were repealed.

This amendment to restore §4200.1 has been proposed to the Senate BP&ED Committee for inclusion in the 2010 Omnibus bill.

Research and Approval Timeline

During the January 2010 Board Meeting, the board voted to pursue the omnibus changes.

Bill History

These provisions are not yet contained in legislation.

Summary of Issues

We are unaware of any concerns with the board's provisions, as the provision has been law for 12 years. However, as a condition of being in an omnibus bill, any opposition to a provision must be removed or the provision is removed from the bill.

Consumer Protection Enforcement Initiative – Board of Pharmacy Specific Provisions

Bill Originator

Department of Consumer Affairs

California State Board of Pharmacy

Strategic Plan Reference

Goal 1: Exercise oversight on all pharmacy activities

Outcome: Improve consumer protection.

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the board of pharmacy.

Outcome: Improve the health and safety of Californians.

Overall Legislative Intent

Improved consumer protection

Consumer Protection Factors

1. Reduce time to complete investigations.
2. Ensure licensees providing pharmacy related services to Californians do not have a revoked license.

Background

Over the prior year, the Department of Consumer Affairs has initiated a number of initiatives aimed at strengthening the enforcement activities of the health care boards. These changes were initiated following problems identified at the Board of Registered Nursing by the *Los Angeles Times*.

The first major change was prioritization of fingerprinting of all licensees. Fingerprinting allows a board to obtain federal and state background checks of applicants with respect to arrests and convictions entered into federal and state data bases by the courts and law enforcement agencies. It also enables boards to obtain "subsequent" arrest and conviction information if a licensee is arrested or convicted in California.

The second major problem reported in the *LA Times* was the time it was taking the Board of Registered Nursing to investigate complaints and complete enforcement actions, which exceeded 3.5 years. The BRN uses the department's Division of Investigation to investigate its complaints, and problems with recruitment and retention of investigators there has been a problem. This delayed investigations. Additionally the time it takes to secure complete work by the Attorney General's Office and Office of Administrative Hearings further added delays.

The DCA has responded with a series of proposals to strengthen the BRN's enforcement program as well as that of other health care boards.

In addition to the efforts of the department, board staff developed provisions to enhance the board's enforcement activities.

Provisions Contained Within Proposal

Amend §4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory

Amend this section to specify that upon request of a board inspector, an owner, corporation officer or manager shall provide requested records within 72 hours unless an extension by the board is granted.

§4104 – Licensed Employee, Theft or Impairment, Pharmacy Procedure

Amend this section to clarify that a pharmacy shall provide the board, within 14 days, evidence of a licensee's theft of drugs or impairment. The amendment would also require a pharmacy to conduct an audit to determine the scope of a drug loss and to provide the board with a certified copy of the audit results.

§4112 – Nonresident Pharmacy; Registration; Provision of Information to Board; Maintaining Records; Patient Consultation

Amend this section to require that a nonresident pharmacy cannot allow a pharmacist, whose license has been revoked in California, from providing pharmacist-related services to Californians.

Research and Approval Timeline

At the October 2009 Board Meeting, the board voted to pursue these provisions and seek that they are included in the department's enforcement enhancement proposals.

During the January 2010 Board Meeting, the board reaffirmed sponsorship of these proposed changes.

Bill History

These provisions are not yet contained in legislation.

Summary of Issues

The board has requested that these provisions be included in the DCA health care boards' enforcement program enhancement legislation.

Reverse Distributor Provisions for Sponsorship in 2010

Bill Originator

California State Board of Pharmacy

Strategic Plan Reference

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Outcome: Improve the health and safety of Californians.

Overall Legislative Intent

Specify the operations of reverse distributors, and differentiate these duties from the scope of practice authorized to a California licensed integrated waste hauler.

Consumer Protection Factors

1. Provide a safe and effective method for consumers to dispose of unwanted medicine, besides flushing it down the toilet or throwing it into the trash.

Background

For over two years, the board has been working with state and some local agencies to develop model guidelines for the take back of unwanted prescription drugs from patients. In February 2009, the California Integrated Waste Management Board finalized these guidelines, which were developed pursuant to SB 966 (Simitian, Chapter 542, Statutes of 2007). The guidelines provide components for three types of drug take back programs: 1) in pharmacies or other stationary locations, 2) at one-time or periodic community events, and 3) return via mail back to a licensed integrated waste hauler.

In 2008 while working with the California Integrated Waste Management Board and the California Department of Public Health on guidelines regarding what types of businesses could pick up aggregated pharmaceutical waste returned by patients, there appeared potential clarity issues about what a reverse drug distributor (licensed by the Board of Pharmacy) and a licensed integrated waste hauler (licensed by the California Department of Public Health) could do. The board began working on provisions to provide clearer delineation for what a reverse distributor could do, and when a reverse distributer desired to perform the duties of an integrated waste hauler, the company would need to be licensed by the CDPH as well.

The California Board of Pharmacy recently disciplined two pharmacies and the pharmacists involved in fraud involving a reverse distributor who submitted claims on behalf of the pharmacies for refunds for the return of drugs to manufacturers where the pharmacies claimed they were returning the drugs from their unused inventory. However, the reverse distributor had actually obtained the drugs from other sources.

Provisions Contained Within Proposal

Amend section 4040.5 – Reverse Distributor

Specifies that a reverse distributor may not accept previously dispensed medicine returned by patients, and specifies that previously dispensed medicine returned to a pharmacy can only be handled by a licensed integrated waste hauler (it is already classified in the Health and Safety Code as aggregated pharmaceutical waste). A reverse distributor may handle drugs that have never been dispensed by a pharmacy. This provision was approved by the board in January 2009, and later refined by staff after the meeting. It was not approved for sponsorship until January 2010.

Amend section 4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory

Specifies minimum requirements for reverse distributors to document the return of drugs from a pharmacy to include the quantity or weight of the drugs being returned, the date returned and the company to which the drugs were provided. This provision was approved by the board in January 2009, and later refined by staff after the meeting. It was not approved for sponsorship until January 2010.

Amend section 4126.5 – Furnishing Dangerous Drugs by a Pharmacy

Authorizes a pharmacy to provide drugs returned from patients in a take back program to a licensed integrated waste hauler. The provisions will need additional refinement to authorize a pharmacy to accept returned product from a consumer in the event of a product recall. This provision was not previously considered by the board.

Research and Approval Timeline

During the January 2010 Board Meeting, the board voted to sponsor a bill containing to specify the operations of reverse distributors.

Bill History

These provisions are not yet contained in legislation, and will likely not be pursued until 2011.

Summary of Issues

The board did not seek a sponsor for these provisions for a 2010 introduction.

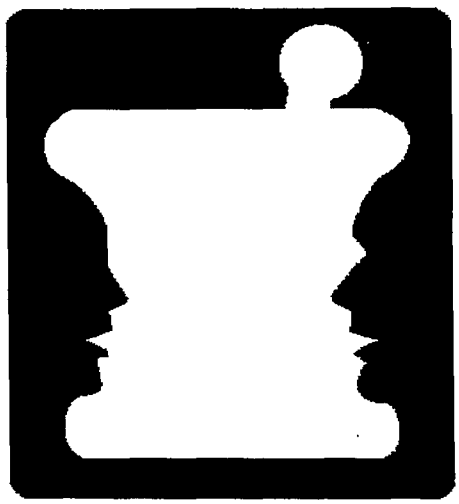
Attachment C:

Prescription Drug: Labeling Requirements (January 2010)

State of California

Board of Pharmacy

Report to the Legislature



Prescription Drugs: Labeling Requirements

January 2010

Arnold Schwarzenegger, Governor
Kenneth H. Schell, PharmD, President, Board of Pharmacy
Virginia Herold, Executive Officer, Board of Pharmacy

Summary

The California Patient Medication Safety Act (Chapter 470, Statutes 2007) requires the Board of Pharmacy to promulgate regulations on or before January 1, 2011, that require a standardized, patient-centered prescription drug container label for all prescription drugs dispensed to patients in California. This Act further requires the board to report to the Legislature by January 1, 2010, on its progress in implementing these regulations.

This report summarizes the Board of Pharmacy's efforts to establish a standardized, patient-centered prescription drug label.

After approximately 18 months of public discussion regarding a standardized, patient-centered prescription label and gathering information at public forums, hearings, board and committee meetings, and conducting patient surveys, the board issued on November 20, 2009 proposed regulatory text to add section 1707.5 to Title 16 of the California Code of Regulations. This proposed section contains California's requirements for patient-centered prescription labels. The board will take action on this proposed regulation at its next scheduled meeting scheduled in January of 2010.

Background

In 2005, Senator Jackie Speier authored Senate Concurrent Resolution 49 (SCR 49), Chapter 123 Statutes of 2005, to create a multidisciplinary panel to study the causes of medication errors and recommend changes in the health care system that would reduce errors associated with the delivery of prescription and over-the-counter medication to consumers. As required, that panel prepared and submitted to specific legislative committees a final report (referenced as the SCR 49 Report) containing its conclusions and recommendations. The report reflected improvements, additions or changes which would reduce errors associated with the delivery of prescription and over-the-counter medications to consumers.

One bill was pursued based on the recommendations of the SCR 49 panel's report. Senator Ellen Corbett authored SB 472, resulting in enactment of the California Patient Medication Safety Act (Chapter 470, Statutes of 2007), Business and Professions Code section 4076.5. Therein, the Legislature stated the importance of reducing medication-related errors and increasing health care literacy regarding prescription drugs and prescription container labeling—which could increase consumer protection and improve the health, safety and well-being of consumers. Additionally, the Legislature affirmed the importance of identifying deficiencies in, and opportunities for improving, patient medication safety systems to identify and encourage the adoption of structural safeguards related to prescription drug container labels. To further these objectives, the Legislature mandated that the Board of Pharmacy adopt regulations to implement a standardized, "patient-centered" prescription drug container label in California.

SB 472 Medication Label Subcommittee

Legislation required that the board initiate public hearings to collect information from the public to facilitate the development of a regulatory proposal. The Board of Pharmacy president appointed a SB 472 Medication Label Subcommittee in January of 2008 to conduct public forums and to work with organizations and individuals to develop recommendations to implement the provisions of SB 472 to establish a patient-centered prescription drug label.

The SB 472 Medication Label Subcommittee held public forums on the following dates, apart from regularly-scheduled board meetings.

April 12, 2008	January 27, 2009
November 20, 2008	March 12, 2009

Agendas for these meetings are provided in Attachment 1.

At these public forums and at other board and board sub-committee meetings, as directed by the SB 472 Label Subcommittee, the board considered testimony and information provided from the public, the pharmaceutical industry, pharmacy professionals and literacy subject matter experts on medical literacy research, improved directions for use, improved font types and sizes, the placement of information that is patient-centered, the needs of patients with limited English proficiency, the needs of senior citizens, and technology requirements necessary to implement the standards developed. Board members were also provided with research

articles on designing patient-centered labels. The information and data received helped frame draft regulatory text to implement the provisions of SB 472.

Public and Community Outreach / Survey

Responding to minimal public input regarding the public's concerns about the current medication prescription labels that are used, the board developed a survey (Attachment 2) that could be provided and/or conducted one-on-one with participants at public outreach events, such as health fairs, where the board provides consumer information. This survey was provided in English and in Spanish. The survey was posted on the board's public Web site from May 2008 through November 2009. Survey questions were open-ended, allowing participants to provide as little or as much information as desired, but the questions did not direct participants to pre-defined responses. Survey results were provided to the board at SB 472 Subcommittee meetings, and also at regularly-scheduled board meetings.

Attachment 3 lists those organizations and individuals to which the survey was distributed to solicit input. Attachment 3 also contains a list of public outreach events at which board staff interviewed consumers and provided printed surveys to solicit input.

At public outreach events and at board and committee meetings, the public was provided with fact sheets entitled "Do you understand the directions on your Rx medicine label?" (Attachment 4) and demonstrated samples of faux prescription labels serving as visual aids.

The board also worked with the Pharmacy Foundation of California to develop a multi-choice survey of four questions that were available via a radio-sponsored survey. The goal was to identify key attitudes, knowledge and behaviors of California consumers related to prescription drug labels. The survey was conducted via Entercom Broadcasting and was made available in January 2009 on radio station Web sites that stream their audio. Results of this survey were provided to the SB 472 Medication Label Subcommittee at its meeting held March 12, 2009.

Proposed Regulatory Text

To implement the provisions of Business and Professions Code section 4076.5 (the California Medical Safety Practice Act) the board proposed text to add section 1707.5 to Title 16 of the California Code of Regulations (Attachment 5).

By providing a uniform, standardized format for prescription drug container labels and requiring pharmacies to provide oral language translations to patients with limited English proficiency, the Board believes that this proposed regulation will aid in the reduction of medication errors associated with the delivery of prescription drugs dispensed to patients in California.

Specifically, the regulatory language proposed on November 20, 2009, specifies the following:

- What components of a prescription label are considered "patient-centered"
- The font type, font size, wording and placement of specified components of a prescription label
- The Board will publish on its Web site by October 2011 translations of specified directions for use into at least five (5) languages other than English
- The Board will publish on its Web site by October 2010 examples of prescription labels that conform to the requirements of the regulation
- A pharmacy, upon request of a patient, shall provide oral interpretive services of the "patient-centered" elements of the prescription label, and
- The Board will re-evaluate the requirements of the regulation by December 2013 to ensure optimal conformance with the California Patient Medication Safety Act (Business and Professions Code section 4076.5)

Contained within the provisions of the proposed regulation, the board will publish on its Web site by October 2011 translations of the "directions for use" as specified in the proposed regulations, into at least five (5) languages other than English. The board will work with research health care advocates to develop these translations.

To assist those with limited English proficiency, and upon request by a patient, the proposed regulations will require a pharmacy to provide an oral language translation of the "patient-

centered" components of a prescription label, as specified in the proposed regulatory language. At its board meeting held October 20, 2009, representatives from chain and retail pharmacy representatives stated that their existing oral language translation services provided to insured patients would be extended to cover all non-English speaking patients, if requested, with no further economic impact on their industry. The board commends the pharmacy industry for recognizing this significant component of delivering prescription drugs, and for meeting the needs of these patients.

Finally, the board included in its proposed regulations a requirement that it will re-evaluate the requirements of the regulations by December 2013 to ensure the effectiveness of the regulation in light of the factors contained in the California Patient Safety Medication Act (e.g., new developments in technology).

Regulation Schedule

The board issued proposed regulatory text on November 20, 2009. A 45-day comment period will close on January 4, 2010.

In addition, the board has scheduled a regulation hearing for January 20, 2010, in Sacramento. At that time, the board will accept written and verbal testimony and comments concerning the draft proposal. This hearing will be conducted prior to its regularly scheduled public Board Meeting that

same day and the board, at that time, may take action to adopt, amend, or to not move forward with the proposed regulation.

The board also scheduled a public Board Meeting for February 17, 2010, in anticipation of the need for a 15-day comment period of modified text following the regulation hearing and Board Meeting.

The board believes this regulation schedule will allow industry approximately ten months to prepare for the implementation of new regulatory requirements. The board also believes its current Board Meeting schedule will allow it to address the needs of industry and the public, and provide for the required reviews prior to implementing a regulation by the January 2011 mandate contained in SB 472.

California State Board of Pharmacy
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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Communication and Public Education Committee

Senate Bill 472 Medication Label Subcommittee

Notice of Public Meeting
April 12, 2008

Wally Pond Irvington Community Center
41885 Blacow Road
Fremont, CA

10 a.m. – 2 p.m.

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Michelle Leech at (916) 574-7912, at least five working days prior to the meeting. All times are approximate and subject to change. Action may be taken on any item on the agenda.

Opportunities are provided to the public to address the committee on each open agenda item. A quorum of the Board members who are not on the committee may attend the meeting as observers, but may not participate or vote.

Call to Order **10 a.m.**

1. Invitation to Participate in the Redesign of Prescription Container Labels
   Committee Chair Ken Schell, PharmD

2. Opening Remarks
   The Honorable Ellen Corbett, California Senator, District 10

3. Presentation of SCR 49 findings, and the need for patients to understand their drug therapy as a source of reducing medication errors.
   Michael Negrete, PharmD

4. Requests for Public Comment on the Following: What works on prescription container labels? What does not? How can prescription container labels be improved to make them patient-centered?

5. Timeline for Project

6. Future Meeting Dates

Adjournment **2 p.m.**

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

NOTICE OF PUBLIC BOARD MEETING OF THE CALIFORNIA STATE BOARD OF PHARMACY

FORUM ON DESIGNING PATIENT-CENTERED PRESCRIPTION LABELS
November 20, 2008
1:30 p.m. - 4:30 p.m.

The Westin Los Angeles Airport Hotel
5400 West Century Boulevard
Lindberg A and B Meeting Rooms
Los Angeles, CA 90045

Contact: Virginia Herold
(916) 574-7911

This forum is hosted by the California State Board of Pharmacy as part of the board's efforts to develop standards for prescription labels by 2011 that will be patient-centered, and to implement the California Medication Safety Act (SB 472, Corbett, Chapter 470, Statutes of 2007). The goal is to foster better patient understanding of the information on a label as a means to reduce medication errors, and improved patient well-being. The public is invited to attend.

This meeting is open to the public (no pre-registration is required) and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Michelle Gallagher at (916) 574-7912, at least five working days prior to the meeting. Opportunities are provided to the public to address the board on each open agenda item. Action may be taken on any item on the agenda by the Board of Pharmacy. All times are approximate and subject to change.

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1. **Welcoming Remarks** 1:30 p.m.
   Kenneth Schell, PharmD, President, California State Board of Pharmacy
2. **Improving Prescription Container Labels – What is the Status of the Research**
   Michael S. Wolf, PhD, MPH, Feinberg School of Medicine, Northwestern University
   Stacy Cooper Bailey, MPH, Feinberg School of Medicine, Northwestern University
3. **Patient Health Literacy in the U.S. and its Impact on Health**
   Michael Villaire, MSLM, Director Programs and Operations, Institute for Healthcare Advancement
4. **Perspective of the Latino Coalition for a Healthy California to Improve Prescription Container Labeling**
   Vanessa Cajina, Director, Regional Networks Coordinator, Latino Coalition for a Healthy California
5. **Perspective of California's Seniors to Improve Prescription Container Labeling**
6. **Summary of Patient Surveys Collected During 2008 by the California State Board of Pharmacy**
   Virginia Herold, Executive Officer, California State Board of Pharmacy
7. Next Steps
8. Public Comments for Items Not on the Agenda
9. Adjournment 4:30 p.m.

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1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Communication and Public Education Committee

Senate Bill 472 Medication Label Subcommittee

Notice of Public Meeting
January 27, 2009

Sheraton Hotel - Mission Valley
1433 Camino Del Rio South
San Diego, CA, 92108
(619) 260-0111

1 – 5 p.m.

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Tess Fraga at (916) 574-7912, at least five working days prior to the meeting. All times are approximate and subject to change. Action may be taken on any item on the agenda.

Opportunities are provided to the public to address the committee on each open agenda item. A quorum of the board members who are not on the committee may attend the meeting as observers, but may not participate or vote.

Call to Order **1 p.m.**

1. Welcoming Remarks
   Subcommittee Chair Ken Schell, PharmD
2. Review of Consumer Surveys Conducted by the Board of Pharmacy
3. Review of Survey Results from a Joint Survey Developed by the California Pharmacy Foundation and the Board of Pharmacy
4. Review of California's Requirements for Prescription Container Labels (California Business and Professions Code Section 4076
5. Timelines for Project Deliverables
6. Public Comment
7. Future Meeting Dates

Adjournment **5 p.m.**

California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Communication and Public Education Committee

Senate Bill 472 Medication Label Subcommittee

Notice of Public Meeting

March 12, 2009

Department of Consumer Affairs
First Floor Hearing Room
1625 N. Market Boulevard
Sacramento, CA 95834
(916) 574-7900
6 - 9 p.m.

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Tess Fraga at (916) 574-7912, at least five working days prior to the meeting. All times are approximate and subject to change. Action may be taken on any item on the agenda.

Opportunities are provided to the public to address the committee on each open agenda item. A quorum of the board members who are not on the committee may attend the meeting as observers, but may not participate or vote.

Call to Order **6 p.m.**

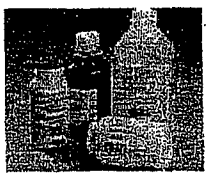
1. Welcoming Remarks
2. Review of SB 472 and the Charge to the Board in Developing Patient-Centered Labels
3. Overview of SB 853 (Escutia, Chapter 713, Statutes of 2003) Health Care Language Assistance
4. Review of Consumer Surveys Conducted by the Board of Pharmacy for SB 472
5. Review of Survey Results from a Joint Survey Developed by the California Pharmacy Foundation and the Board of Pharmacy for SB 472
6. Patient-Focused Elements of Prescription Container Labels (California Business and Professions Code Section 4076)
7. Legislative Proposal to Add "Purpose" to Prescription Container Labels
8. Public Comment for Items Not on the Agenda
   (Note: the committee may not discuss or take action on any matter raised during the Public Comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a))

Adjournment **9 p.m.**

CONSUMERS – we want to hear from you!

Do you have suggestions to improve prescription container labels? The California State Board of Pharmacy welcomes your feedback to make labels more patient-friendly with directions that are easier to read and understand.

Examples of warning labels



Examples of different container shapes and sizes requiring different types of labels

What information on the label is most important to you?

_____

_____

Do you understand the directions?

_____

_____

What would you change on the label?

_____

_____

What would make the label easier to read?

_____

_____

Other suggestions:

_____

_____

City: _____ Date: _____

Printed information in different colors

Directions for use or how to take the drug

THANK YOU for your feedback.
Please return your completed form to:

Virginia Herold, Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219
Sacramento, CA 95834

CONSUMIDORES – ¡Queremos oír de usted!

¿Tiene usted sugerencias para mejorar las etiquetas del envase de recetas? La Junta de Farmacia del Estado de California da la bienvenida a su reacción para hacer etiquetas más-paciente amistosas con las indicaciones que son más fáciles de leer y comprender. Gracias por su reacción.

¿Qué información en la etiqueta de la receta es más importante para usted?

¿Comprende usted las instrucciones en la etiqueta de la receta?

¿Qué cambiaría usted en la etiqueta de la receta?

¿Qué haría la etiqueta de la receta más fácil de leer?

Ciudad: _____ **Fecha:** _____

Vuelva por favor su forma completada a: Virginia Herold, California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834

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¿Qué cambiaría usted en la etiqueta de la receta?

¿Qué haría la etiqueta de la receta más fácil de leer?

Ciudad: _____ **Fecha:** _____

Vuelva por favor su forma completada a: Virginia Herold, California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834

California State Board of Pharmacy Prescription Label Survey

OBJECTIVE: To elicit feedback from consumers in California regarding development of patient-centered prescription drug labels pursuant to Senate Bill 472 (Chapter 470, Statutes of 2007)

METHODOLOGY: A survey was developed by the California State Board of Pharmacy (Board) in May 2008. The questions were open-ended, allowing participants to provide as little or as much information as desired. Board staff used the survey to interview consumers at public outreach events including health/community fairs in Sacramento, Elk Grove, Los Angeles, Riverside, San Diego, Merced, and San Francisco. Printed surveys and self-addressed return envelopes were provided to attendees who chose to return responses by mail. The survey was provided in English and Spanish. The board also provided fact sheets entitled, "Do you understand the directions on your Rx medicine label?" and samples of faux prescription labels serving as visual aids. The survey was posted on the Board's public website and to interested parties and organizations including the Gray Panthers and the Latino Coalition for a Healthy California. Board members also interviewed consumers, and returned the responses by mail.

RESULTS: A total of 622 surveys were received as of March 3, 2009. The majority of respondents provided one or more answers to the first two questions, but did not always provide answers to subsequent questions. Respondents gave similar answers to multiple questions within a survey (i.e., request for large print). Attached graphs reflect detailed responses; most frequent responses summarized below.

When asked what information on the prescription label was most important, the top responses were:

Directions for use (224 of 1,207 responses = 18.6%)
Name of drug; if generic, state generic name AND brand name (222 of 1,207 responses = 18.4%)
Dosage prescribed (213 of 1,207 responses = 17.6%)
Side effects/warnings/interactions/contraindications (122 of 1,207 responses = 10.1%)
Purpose of drug – state what condition medication is prescribed to treat (84 of 1,207 responses = 7%)

When asked what to change on the prescription label, the top responses were:

Print should be larger or darker (170 of 568 responses = 30%)
Nothing needs to be changed on the label (139 of 568 responses = 24.5%)
Include purpose of drug – state what condition medication is intended to treat (69 of 568 responses = 12.1%)

When asked what would make prescription labels easier to read, the top response was:

Larger or bolder print (314 of 522 responses = 60%)

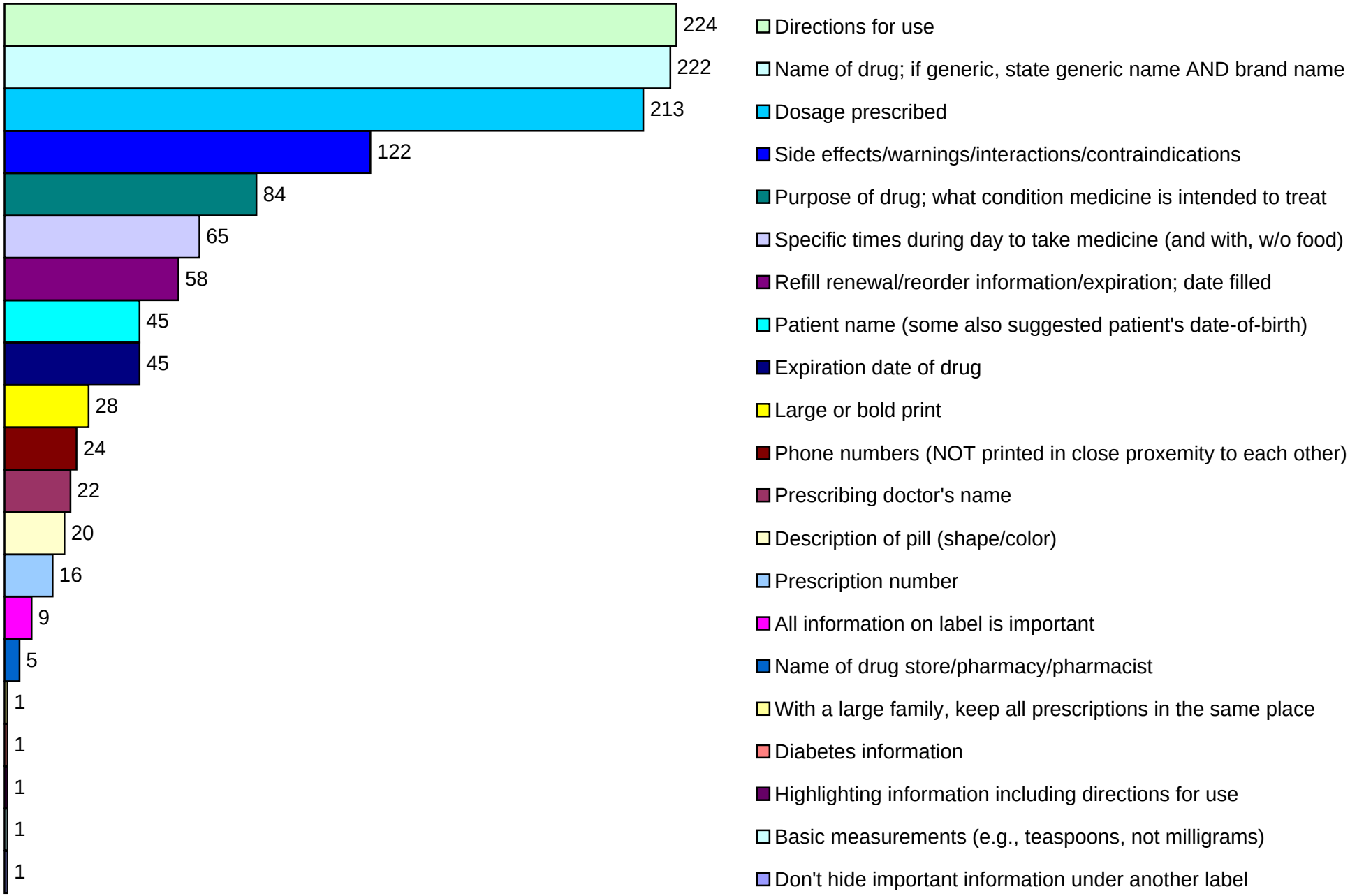
When asked for other suggestions, the top responses were:

Easy-open lids/packages should be used; no child-proof caps for seniors (20 of 134 responses = 14.9%)
Include purpose of drug - state what condition medication is intended to treat (17 of 134 responses = 12.7%)

CONCLUSIONS: Most consumers participating in this survey requested larger/bolder type font on prescription labels to increase readability. Many participants suggested that if a generic drug is provided, the prescription label should state the name of the generic drug name AND the brand-name it is generic for. They also noted that color printing and highlighting on labels brings attention to important information. Some participants suggested that the labels themselves be color-coded to help differentiate between multiple medications and family members. Many consumers want to know 'what the drug is for' and suggested that 'purpose of drug' be printed directly on prescription labels.

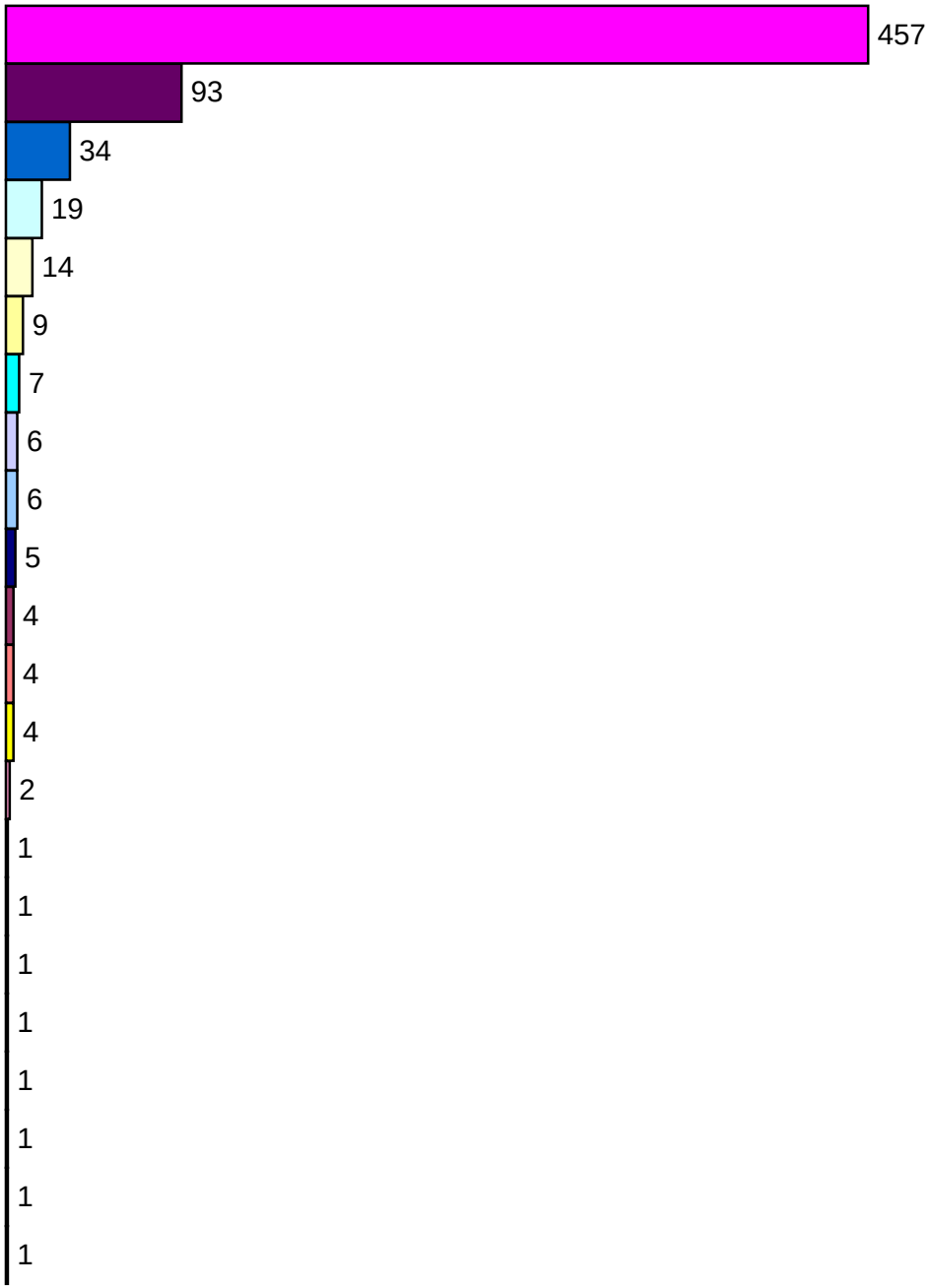
QUESTION #1: What information on the label is most important to you?

622 surveys returned (1,207 responses to Question #1) as of March 3, 2009



QUESTION #2: Do you understand the directions on the prescription label?

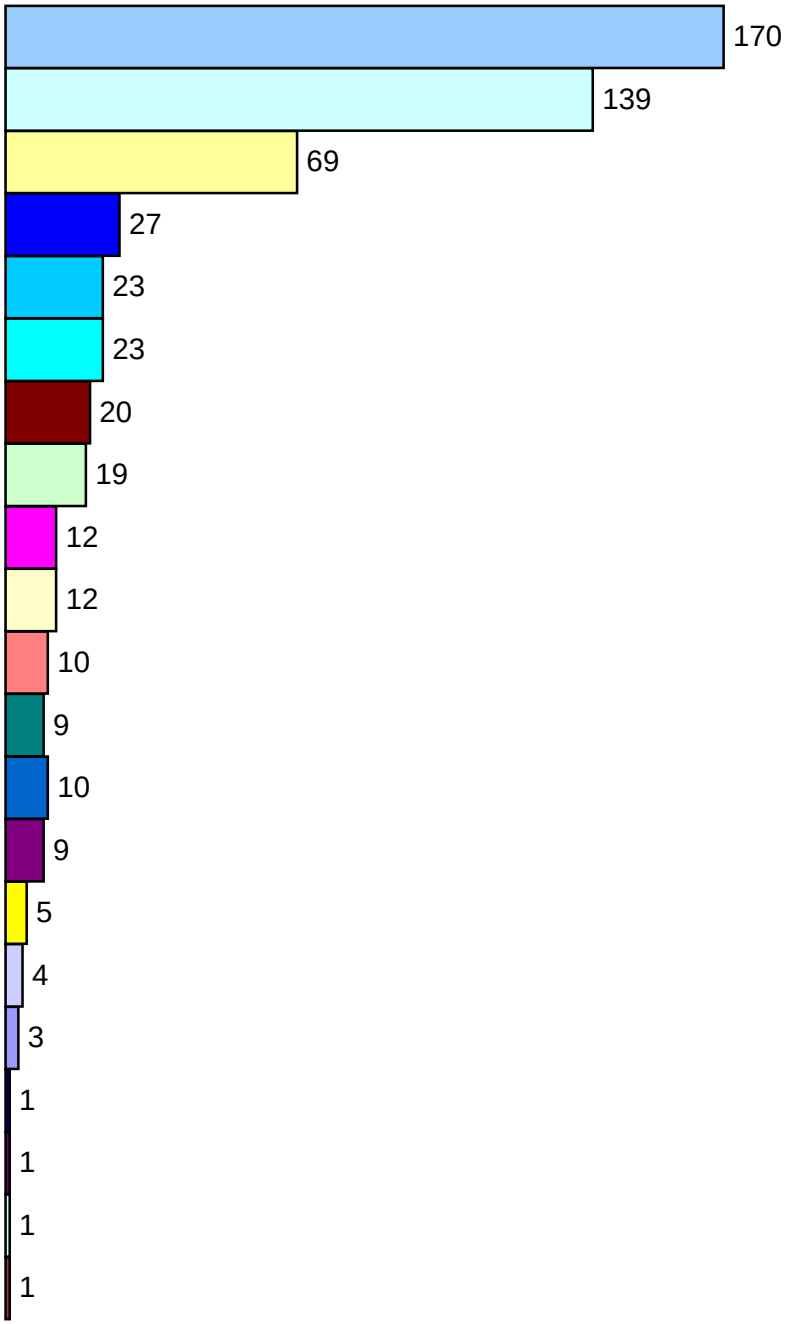
622 surveys returned (672 responses to Question #2) as of March 3, 2009



- Yes
- Usually (though print may be too small, directions/warnings unclear)
- Sometimes
- No (i.e., trouble understanding or not enough space for directions)
- Directions should state what time(s) to take medicine and how much
- Would be helpful to know whether to take with or without food
- I understand because I'm RN, Dr, health worker, have biology degree
- Not when there is a language barrier
- What does 2x (or 3x, or 4x) a day mean?
- Directions need clarity (2 pills = 1 pill twice/day or 2 pills twice/day?)
- Instructions should be in English and Spanish
- Instructions should be in English and Spanish
- Abbreviations should be eliminated
- I do not understand directions that only say "Take as directed"
- No long paragraphs on prescription label
- Label from Kaiser understandable, label from Rite Aid not as clear
- Bullets and spacing on label would be helpful
- Handout should be more readable
- Accompanying paper shouldn't be complicated - use bullets/spacing
- When I don't understand the directions, I ask the pharmacist
- Pharmacist's directions are vague during consultation
- The directions often conflict with the doctor's orders

QUESTION #3: What would you change on the prescription label?

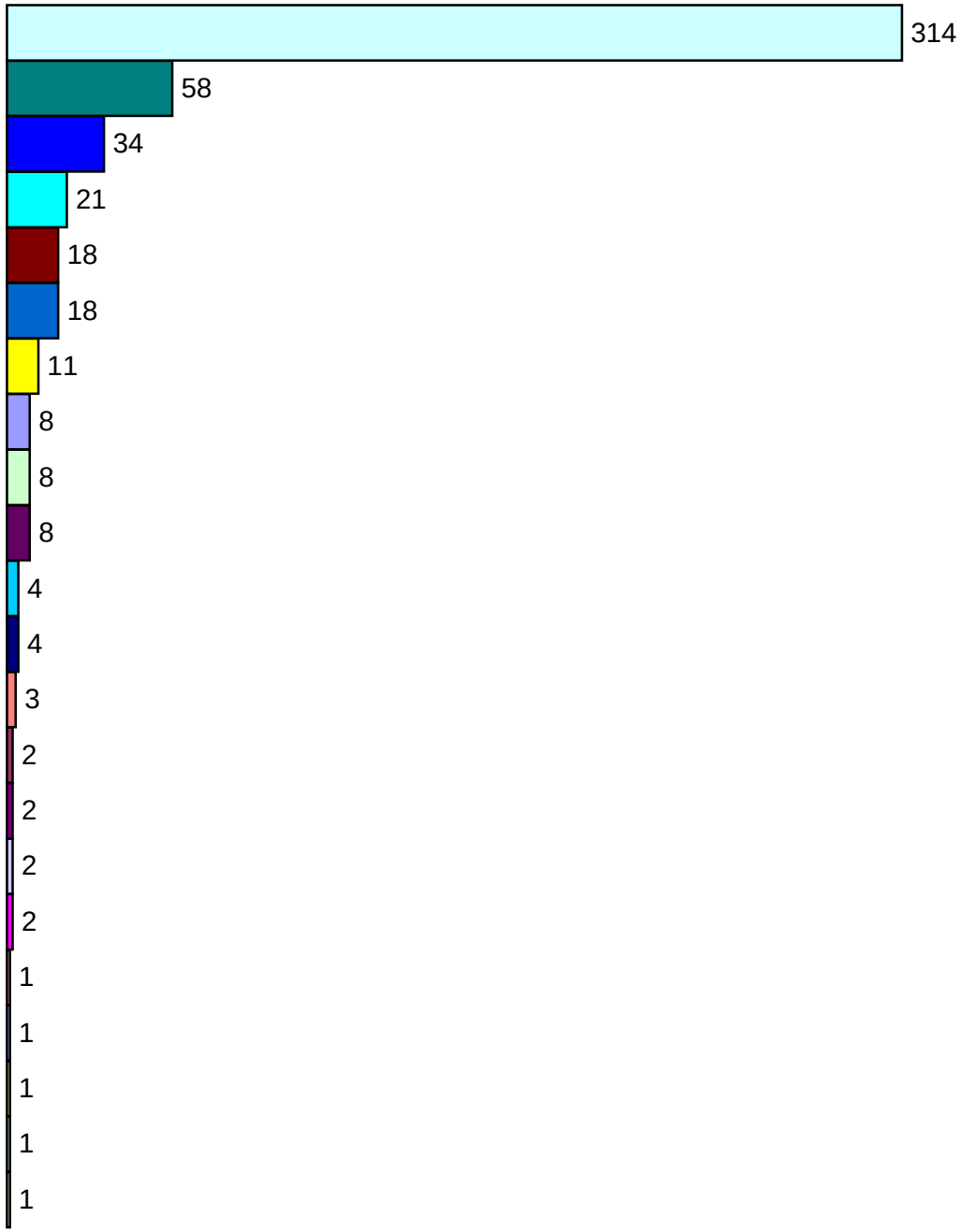
622 surveys returned (568 responses to Question #3) as of March 3, 2009



- Print should be larger or darker (legibility)
- Nothing needs to be changed (some referred to Kaiser, Target, Raley's, CVS)
- Include purpose of drug - state what condition medication is intended to treat
- Information printed should be understandable for all ages; layman's terms
- Use bold or highlighted print or capital letters; red/blue ink for warning labels
- Use different colors for different medicines, strengths/doses, family members
- Directions should include specific times (or morning/night) to take medicine
- Make warning labels easier to read or print directly on label instead of auxilliary
- Name of drug; if generic, state generic name AND brand name
- Refill info (i.e., date to reorder or if no refills remain, state "0 refills remain")
- Include direct phone numbers for easier communication with doctor/pharmacy
- Print in patient's primary language; bilingual wording
- Standardize location of info; uniform label; show information in same order
- Delete unneeded info (i.e., don't say take tab "by mouth" or show address)
- Should be less advertising on label; remove unnecessary information
- Use ink that does not disappear, fade, rub off, or smudge
- Make "fold-out" label or "lift-open flap" stating side effects or purpose of drug
- If more than 1 label, show as "label #1" and "label #2"
- Use only one color on label
- More than one name for medicine is confusing at times
- Label should not refer patient to internet web site

QUESTION #4: What would make the prescription label easier to read?

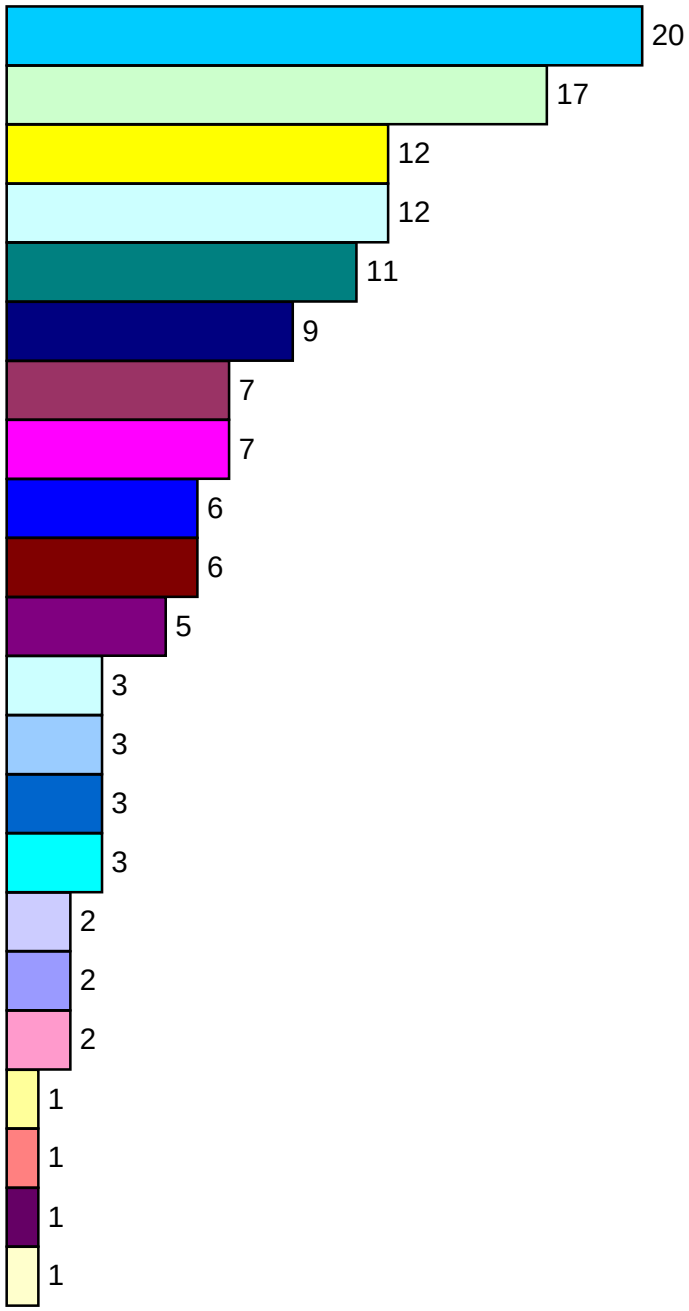
622 surveys returned (522 responses to Question #4) as of March 3, 2009



- Larger print (or bolder print)
- Highlighting directions & other info in colors (or color-coded label)
- Nothing
- Info should be in layman's terms; easy wording; don't abbreviate
- Bilingual wording
- Better description of directions (how/when to take; interactions)
- Refill renewal information including renewal expiration date
- Increase container size so large labels can have large print
- Eliminate clutter (i.e., multiple colors, icons, logos, name of PIC)
- Standard labeling for all pharmacies; standard placement of info
- Underline info or separate directions for use into different lines
- Drawings would help or symbols (or chart of meds & time to take)
- Dark background with light/flourescent print (or glow-in-the-dark)
- Print on label with ink that does not fade or disappear
- Yellow or white warning labels are easier to read than red
- Directions could be printed in all CAPS or bold
- Information on label should NOT be written by hand
- Lower and higher case letters are easier to read than ALL CAPS
- Beige background is easier for seniors to read than white
- List emergency phone number on label
- Standard placement of drug expiration date
- Print in braille for visually-imparied patients

QUESTION #5: Other suggestions?

622 surveys returned (134 responses to Question #5) as of March 3, 2009



- Easy-open lids/packages should be used; no child-proof caps for seniors
- Include purpose of drug - state what condition medication is intended to treat
- Bigger or darker font (i.e., drug expiration date, directions for use, warnings)
- Use different color for printing some info (i.e., directions for use, pharmacy phone #)
- Make directions simple/clear/understandable; print in patient's primary language
- Make bottles rectangular or square w/flat surface and directions printed on long side
- Put picture of pill on label or photo of pill or description of pill
- Side effects/interactions should be stated (i.e., dry mouth may cause dental caries)
- Different colored bottles or caps would help identify medications
- Standardize location of info so all prescriptions show information in same order
- Make label easy to remove (to recycle bottle or for privacy/security when discarding)
- Note on label when the manufacturer of the medicine changes
- Show where to return outdated meds or option to dispose via phamacy
- Don't cover prescription number with warning labels; use symbols as warnings
- Bottles should be in travel/airplane size; large bottles are clumsy and take up space
- Use top of lid for info; containers opening at bottom leave room for larger label
- Note change in size, color, shape of pills, so won't be perceived as medication error
- State what to do if you miss a dose
- Allow NP's name to appear on Rx bottle when submitting electronic prescriptions
- Labels should be waterproof
- Don't allow label to completely cover bottle; leave space to see medication remains
- Include a plan w/multiple meds (i.e., interactions, don't take with Calcium, etc.)

Attachment 3

COMMUNITY ORGANIZATIONS AND OTHER ENTITIES PROVIDED WITH BOP PRESCRIPTION LABEL SURVEYS 2008/09

The organizations and individual entities listed below were provided with English and Spanish versions of the California State Board of Pharmacy Prescription Label Survey during 2008/09.

1. Casey Young
   AARP State Legislative Director
   1415 L Street, #960
   Sacramento, CA 95814
   (916) 556-3018
   cyoung@aarp.org

2. Sam Totah
   Kaiser Permanente
   10990 San Diego Mission Road
   San Diego, CA 92108
   sammy.r.totah@kp.org

3. Vanessa Cajina
   Latino Coalition for a Healthy California
   1225 8th Street, Suite 500
   Sacramento, CA 95814
   (916) 448-3234
   vcajina@lchc.org

4. Nancy Kawahara, PharmD
   Associate Professor of Pharmaceutical Sciences
   11262 Campus St, West Hall, Room 1334
   Loma Linda, CA 92350
   nkawahara@llu.edu

5. Barry Goggin, President
   Better Business Bureau of Sacramento Valley
   400 S Street
   Sacramento, CA 95814
   (916) 443-6843 info@necal.bbb.org

6. Lu Molberg
   Ca. Assn. of Area Agencies on Aging
   980 9th Street, Suite 2200
   Sacramento, CA 95814
   (916) 443-2800
   C4a@pacbell.net

7. Sandra Fitzpatrick, Director
   California Commission on Aging
   1300 National Drive, Suite #173
   Sacramento, CA 95834
   (916) 419-7591
   sfitzpatrick@ccoa.ca.gov

8. Steve Blackledge
   CalPIRG
   1107 9th Street, Suite #601
   Sacramento, CA 95814
   (916) 448-4516
   Sblackledge@calpirg.org

9. Betty Williams, Executive Director
   Network for Elders
   1555 Burke Avenue, Suite A
   San Francisco, CA 94123
   (415) 647-5353
   bwilliams@networkforelders.org

10. Julia Ling, Executive Director
    Chinese Newcomers Foundation
    777 Stockton Street, #104
    San Francisco, CA 94108
    (415) 421-2111
    julialing@msn.com
    cnsc@chinesenewcomers.org

11. Gary Passmoore, Legislative Coordinator
    Congress of California Seniors
    1228 N Street, #29
    Sacramento, CA 95814
    (916) 442-4474 GaryP@seniors.org

12. Joe Ridout, Consumer Advice Counselor
    Consumer Action
    221 Main Street, Suite #480
    San Francisco, CA 94105
    (415) 777-9648

jridout@consumer-action.org

13. Kathy Li, Director
National Consumer Resource Center
221 Main Street, Suite #480
San Francisco, CA 94105
(415) 777-9648
kathy.li@consumer-action.org

14. Jason Wimbley
Special Programs Manager
Dept. of Community Services & Development
700 N. 10th Street, Room #258
Sacramento, CA 95814
(916) 341-4200
jwimbley@csd.ca.gov

15. Ed Mendoza
Office of Patient Advocacy
980 9th Street, Suite #550
Sacramento, CA 95814
(916) 342-6407
Emendoza@dmhc.ca.gov

16. Laurel Pallock, Investigator
Consumer & Environmental Protection Unit
District Attorney's Office
732 Brannan Street
San Francisco, CA 94103
(415) 551-9575
consumer.mediation@sfgov.org

17. Brad Chibos
Santa Clara County Commission on Consumer Affairs
540 Bird Avenue, #200
San Jose, CA 95125
(408) 998-1694 Chibos@aol.com

18. Marina Community Center
Senior Services Office
15301 Wicks Blvd.
San Leandro, CA 94579

19. Lavender Seniors of the East Bay
1395 Bancroft Avenue
San Leandro, CA 94577

20. East Bay Services for the Developmentally Disabled
797 Montague Ave.
San Leandro, CA 94577

21. Evergreen Senior Program/Wisdom Path
985 Suerro Street
Hayward, CA 94541

22. Hayward Area Senior Center
22325 N. 3rd Street
Hayward, CA 94546-6969

23. Kenneth Aitken Senior & Community Center
17800 Redwood Road
Castro Valley, CA 94546

24. Ralph & Mary Ruggieri Senior Center
33997 Alvarado-Niles Road
Union City, CA 94587

25. Newark Senior Center
7401 Enterprise Drive
Newark, CA 94560

26. Fremont Multi-Service Senior Center
40086 Paseo Padre Parkway
Fremont, CA 94538

27. Barbara Lee Senior Center
540 S. Abel Street
Milpitas, CA 95035

28. Shauna McKeever
Safeway Pharmacy #2707
6445 N. Pacific Avenue
Stockton, CA 95207

29. Fred S. Mayer, RPh, MPH
President, PPSI
101 Lucas Valley Road, #384
San Rafael, CA 94903

30. Chris Oliva, PharmD
Pharmacy Services Manager
Kaiser Permanente Santa Clara
Medical Center
710 Lawrence Expressway,
Department #194
Santa Clara, CA 95051

31. Jennifer Hall
8041 Belgian Court
Sacramento, CA 95830

32. Suzy Hackworth
11144 Traditions Court
Riverside, CA 92503

33. Kathy Besinque, PharmD
USC School of Pharmacy
1985 Zonal Avenue, #301
Los Angeles, CA 90033

34. Tony Yee, PharmD
1220 Broadway Street
Placerville, CA 95667

35. RoseAnn L. Jankowski, PharmD
Memorial Health Services
17360 Brookhurst Street
Fountain Valley, CA 92708

36. Doris Cheng
6481 Atlantic Avenue, Apt. #120
Long Beach, CA 90805

37. Dawn Bronsema
9026 Bushman Avenue
Downey, CA 90240

38. Doreena P. Wong, Staff Attorney
NHelp - National Health Law Program
2639 S. La Cienega Blvd.
Los Angeles, CA 90034

39. Anita Hong-Ha Le
Program Director, PALS for Health
605 W. Olympic Blvd., #600
Los Angeles, CA 90015

40. Michael Villaire, MSLM
Director, Programs & Operations
Institute for Healthcare Advancement
501 S. Idaho Street, Suite #300
La Habra, CA 90631

41. Brian Hui, Program Coordinator
Tongan Community Service Center
14112 S. Kingsley Drive
Gardena, CA 90249

42. Tina Tarsitano, RPh, MBA
Pharmacy Supervisor, Walgreen Co.
711 W. Kimberly Avenue, Suite #200
Placentia, CA 92870

43. Margie Metzler, Executive Director
Gray Panthers
1121 Wayland Avenue
Sacramento, CA 95825

44. Frank Whitney, President
Better Business Bureau of Mid-Counties,
Inc.
11 S. San Joaquin Street, Suite #803
Stockton, CA 95202
(209) 948-4880

45. Michael Winter
UCSF Department of Clinical Pharmacy
winterm@pharmacy.ucsf.edu

46. Eunice Chung, Associate Professor
Western University
echung@westernu.edu

47. Helen Park
helen.park@va.gov

PUBLIC OUTREACH EVENTS WHERE BOP STAFF INTERVIEWED ATTENDEES AND COMPLETED BOP PRESCRIPTION LABEL SURVEYS

1. Meet The Pharmacist – San Diego – May 2008
2. Senior Day in The Park – Elk Grove – May 2008
3. Better Business Bureau Community Alliance Day – Merced – June 2008
4. Eddie Smith Senior Center – Riverside – June 2008
5. Safetyville Family Safety Expo – Sacramento – June 2008
6. Lotus Festival – Los Angeles – July 2008
7. California State Fair – Sacramento – August 2008
8. Celebrando Nuestra Salud – Sacramento – October 2008
9. Evans Community Adult School Consumer Fair – Los Angeles – March 2009

CALIFORNIA STATE BOARD OF PHARMACY

Do you understand the directions on your Rx medicine label?

Approximately 46% of American adults do not.

A prescription label says to "Take two tablets by mouth twice daily." Sounds simple, doesn't it?

But patients have understood this to mean:

- Take it every 8 hours
- Take it every day
- Take one every 12 hours

Better directions might be "Take 2 tablets by mouth at 8 in the morning, and take 2 tablets at 9 at night."

FACT: Six out of 10 people have taken their medicines incorrectly, due to:

- confusing directions on the container label,
- poor health literacy (the ability to read, understand, and act on healthcare information), and
- inability to read and/or understand directions written in English of those whose first language is not English.

FACT: Medicine errors are among the most common medical errors, harming at least 1.5 million people every year. More than one third of these take place outside a hospital in a home setting, costing close to $1 billion annually.

FACT: Up to one-half of all medicines are taken incorrectly or mixed with other medicines that can cause dangerous reactions that can lead to injury and death.

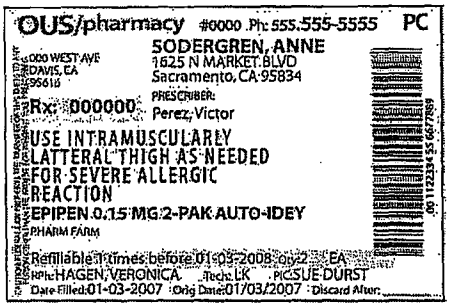
Medicine-related errors must be reduced. One way to begin is by providing patients with easy to read and understand prescription container labeling. This can be a giant step toward increasing consumer protection and improving the health, safety, and well-being of consumers.

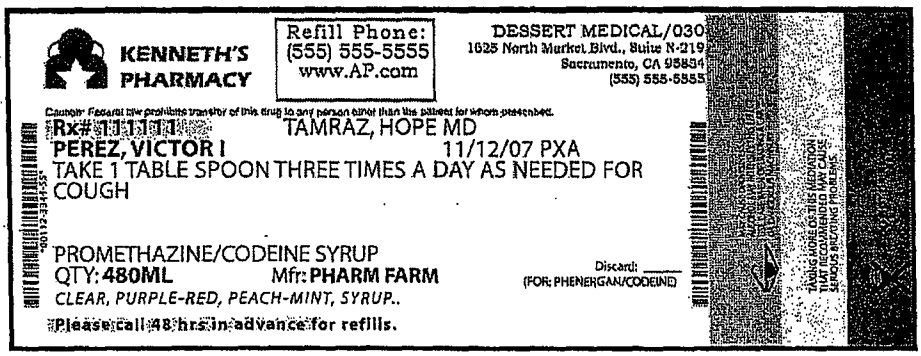
California recognizes the importance of improving medicine container labels. In 2007, the Legislature and Governor Schwarzenegger enacted Senate Bill 472, mandating the Board of Pharmacy to develop requirements for standardized, patient-centered, prescription drug labels on all prescription medicine dispensed to patients in California.

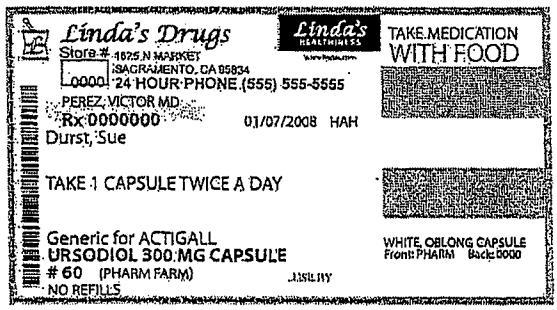
In 2008, the Board will hold statewide public meetings to consult with patients and health providers to improve prescription container labels. The meetings will focus on improving directions for the drug's use, using better type fonts and sizes, and placement of information that is patient-centered. The needs of senior citizens and patients with limited English reading skills also will be identified.

(916) 574-7900
WWW.PHARMACY.CA.GOV
1625 N. MARKET BLVD.
SUITE N-219
SACRAMENTO, CA 95834

sample prescription labels


OUS/pharmacy #0000 Ph: 555.555-5555 PC
1000 WEST AVE
DAVIS, CA
95616
SODERGREN, ANNE
1625 N MARKET BLVD
Sacramento, CA 95834
Rx: 000000
PRESCRIBER:
Perez, Victor
USE INTRAMUSCULARLY
LATTERAL THIGH AS NEEDED
FOR SEVERE ALLERGIC
REACTION
EPIPEN 0.15 MG/2-PAK AUTO-IDEY
PHARM FARM
Refillable 1 times before 01-03-2008 0002 EA
Rph: HAGEN, VERONICA Techs: LK PICSUE DURST
Date Filled: 01-03-2007 Orig Date: 01/03/2007 Discard After:


KENNETH'S PHARMACY
Refill Phone: (555) 555-5555 www.AP.com
DESSERT MEDICAL/030
1625 North Market Blvd., Suite N-219
Sacramento, CA 95834
(555) 555-5555
Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom prescribed.
Rx# 111111 TAMRAZ, HOPE MD
PEREZ, VICTOR I 11/12/07 PXA
TAKE 1 TABLE SPOON THREE TIMES A DAY AS NEEDED FOR COUGH
PROMETHAZINE/CODEINE SYRUP
QTY: 480ML Mfr: PHARM FARM
CLEAR, PURPLE-RED, PEACH-MINT, SYRUP..
Please call 48 hrs in advance for refills.
Discard: ____
(FOR: PHENERGAN/CODEINE)


Linda's Drugs
Store #
1625 N MARKET
SACRAMENTO, CA 95834
0000 24 HOUR PHONE (555) 555-5555
Linda's HEALTHINESS
TAKE MEDICATION WITH FOOD
PEREZ, VICTOR MD
Rx 0000000 01/07/2008 HAH
Durst, Sue
TAKE 1 CAPSULE TWICE A DAY
Generic for ACTIGALL
URSODIOL 300 MG CAPSULE
60 (PHARM FARM)
NO REFILLS
WHITE, OBLONG CAPSULE
Front: PHARM Back: 0000

Title 16. Board of Pharmacy
Proposed Language

To Add Section 1707.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1707.5 Patient Centered-Labels on Medication Containers

(a) Labels on drug containers dispensed to patients in California shall conform to the following format to ensure patient-centeredness.

(1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point, sans serif typeface, and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name, or the generic name and the name of the manufacturer.

(C) Directions for use

(D) Purpose or condition, if entered onto the prescription by the prescriber, or otherwise known to the pharmacy and its inclusion on the label is desired by the patient.

(2) For added emphasis, the label may also highlight in bold typeface or color, or use "white space" to set off the items listed in subdivision (a)(1).

(3) The remaining required elements for the label specified in Business and Professions Code section 4076 and other items shall be placed on the container in a manner so as to not interfere with emphasis of the primary elements specified in subdivision (a)(1), and may appear in any style and size typeface.

(4) When applicable, directions for use shall use one of the following phrases:

(A) Take 1 tablet at bedtime

(B) Take 2 tablets at bedtime

(C) Take 3 tablets at bedtime

(D) Take 1 tablet in the morning

(E) Take 2 tablets in the morning

(F) Take 3 tablets in the morning

(G) Take 1 tablet in the morning, and Take 1 tablet at bedtime

(H) Take 2 tablets in the morning, and Take 2 tablets at bedtime

(I) Take 3 tablets in the morning, and Take 3 tablets at bedtime

(J) Take 1 tablet in the morning, 1 tablet at noon, and 1 tablet in the evening

(K) Take 2 tablets in the morning, 2 tablets at noon, and 2 tablets in the evening

(L) Take 3 tablets in the morning, 3 tablets at noon, and 3 tablets in the evening

(M) Take 1 tablet in the morning, 1 tablet at noon, 1 tablet in the evening, and 1 tablet at bedtime

(N) Take 2 tablets in the morning, 2 tablets at noon, 2 tablets in the evening, and 2 tablets at bedtime

(O) Take 3 tablets in the morning, 3 tablets at noon, 3 tablets in the evening, and 3 tablets at bedtime

(P) Take 1 tablet as needed for pain. You should not take more than __ tablets in one day

(Q) Take 2 tablets as needed for pain. You should not take more than __ tablets in one day

(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

(c) Beginning in October 2010, the board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

(d) For patients who have limited English proficiency, upon request by the patient, the pharmacy shall provide an oral language translation of the prescription container label's information specified in subdivision (a)(1) in the language of the patient.

(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

Authority cited: Sections 4005 and 4076.5, Business and Professions Code.
Reference: Sections 4005, 4076, and 4076.5, Business and Professions Code.

Attachment C:

Report on the Requirement that Candidates Failing the CPJE Four Times

California State Board of Pharmacy
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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Report on the Requirement that Candidates Failing the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) Four Times Must Obtain Additional Education in Pharmacy

Pursuant to California Business and Professions Code section 4200.1, the California State Board of Pharmacy is pleased to provide the following report detailing the impact of requiring candidates for pharmacist licensure who fail the licensure examination four times to take remedial education before they can retake the licensure examination.

The board is required to submit this report for examinations taken between January 1, 2004, and July 1, 2008, inclusive.

Summary

Between January 1, 2004, and July 1, 2008, 7,578 candidates took California's pharmacist licensure examination. The pass rate during this period was 79.3 percent. There were 41 candidates who failed the exam four times. There were 21 candidates who requalified to retake the California pharmacist licensure examination who retook 16 units of pharmacy coursework. Of these 21, 11 passed the exam (52 percent).

Background

Since 1999, candidates for the California pharmacist licensure examination who fail the examination four or more times have been required to take 16 units of education in pharmacy from a school of pharmacy approved by the Accreditation Council for Pharmacy Education. This provision was set to be repealed January 1, 2005. However, subsequent legislation enacted in 2004 (Senate Bill 1913, Senate Business and Professions Committee, Chapter 695) extended the sunset date for this provision until January 1, 2008. Additional legislation enacted in 2006 (Senate Bill 1476, Senate Business, Professions and Economic Development Committee, Chapter 658) extended the sunset date for this provision until January 1, 2010.

The board sponsored the initial requirement for candidates to take remedial education after four attempts at passing the pharmacist licensure examination for various reasons. One reason was to remove a number of applicants from the licensure examination who had repeatedly failed the examination. For example, there were several applicants who had taken the examination more than 25 times (the examination was given twice a year until January 2004). A major concern was that these individuals were taking the examination only to memorize questions that could be provided to preparation course providers.

The requirement to take remedial education took effect July 1, 1998. To implement the statutory provisions, the board adopted a regulation that took effect November 4, 1998 (California Code of Regulations, Title 16, section 1725). This regulation specifies that the remedial education of 16 units must be taken in a school of pharmacy approved by the American Council on Pharmaceutical Education (which in 2003 became known as the Accreditation Council for Pharmacy Education - ACPE) or a school recognized by the board. The ACPE accredits schools of pharmacy in the United States. The Board of Pharmacy never separately recognized any school.

From July 1, 1998, until January 1, 2004, the board gave 10 examinations (January and June, 1999-2003). Each of these examinations was written and graded exclusively for California by the California State Board of Pharmacy. The examination was developed by a team of 22 subject matter experts, under the guidance of a psychometric consulting firm selected to assure that the examination met all required components for job relevancy and validity.

In January 2004, there was a substantial change in the California pharmacist licensure examination made by SB 361 (Figueroa, Chapter 539, Statutes 2003). The new provisions require the use of the National Association of Boards of Pharmacy examination called NAPLEX and a second, California-specific and jurisprudence examination initially called the California Pharmacist Jurisprudence Exam and later renamed California Practice Standards and Jurisprudence Examination for Pharmacists (or CPJE). Both are multiple-choice examinations and are given via computer, six days per week at testing centers nationwide. Testing began under the new format in late March 2004.

Data:

The board is required to report on three components. Each of these components is individually discussed below. For each of presentation the required component appears in bold.

1. **The number of applicants taking the examination and the number who fail the examination for the fourth time.** [Business and Professions Code, Section 4200.1 (f) (1)]

Year	Candidates	Failed 4th Time	Percent
2004	1733	11	0.63
2005	1804	10	0.55
2006	1613	9	0.56
2007	1665	3	0.18
2008	763	8	1.05
Total	7578	41	0.54

2. **The number of applicants who, after failing the examination for the fourth time, complete a pharmacy studies program in California or another state to satisfy the requirements of this section and who apply to take the licensure examination required by Section 4200.** [Business and Professions Code, Section 4200.1 (f) (2)]

Year	Candidates	Requalified	Percent
2004	1733	3	0.17
2005	1804	1	0.06
2006	1613	1	0.06
2007	1665	13	0.78
2008	763	3	0.39
Total	7578	21	0.28

Of the 21 candidates that requalified to take the CPJE, 11 of the 21 passed (a pass rate of 52 percent).

3. **To the extent possible, the school from which the applicant graduated and the school's location and the pass/fail rates on the examination for each school.** [Business and Professions Code, Section 4200.1 (f) (3)]

Schools with Candidates Failing 4 Times[1] 1/1/04-7/1/08				
Pharmacy Schools and Locations	Number of Candidates Failing their 4th Time	All Candidates		
		Total	Pass (Percent)	Fail (Percent)
University of Arizona Tucson, AZ	1	39	82.05	17.95
University of the Pacific Stockton, CA	1	896	93.19	6.81
University of Southern California Los Angeles, CA	1	810	93.09	6.91
Howard University Washington, DC	1	32	53.13	46.88
Mercer University Atlanta, GA	1	23	56.52	43.48
University of Georgia Athens, GA	3	49	69.39	30.61
Xavier University of Louisiana New Orleans, LA	1	36	75.00	25.00
Massachusetts College of Pharmacy-Boston Boston, MA	4	535	71.59	28.41
Wayne State University Detroit, MI	1	22	54.55	45.45
St. Louis College of Pharmacy St. Louis, MO	1	60	48.33	51.67
Creighton University Omaha, NE	1	180	73.33	26.67
Western University Pomona, CA	1	491	93.89	6.11
Long Island University Brooklyn, NY	1	124	66.13	33.87
Ohio Northern University Ada, OH	1	19	68.42	31.58
University of the Sciences in Philadelphia Philadelphia, PA	2	85	70.59	29.41
Wilkes University Wilkes-Barre, PA	1	15	73.33	26.67
Midwestern University-Glendale Glendale, AZ	1	74	70.27	29.73
University of Southern Nevada Henderson, NV	2	234	76.92	23.08
Foreign Graduates Various countries	16	1315	63.35	36.65
CPJE	41	7578	79.29	20.71

[1] As candidates may take the examination multiple times, statistics are based on each examination attempt by each candidate.

Schools with Candidates Requalifying After Completed Remedial Education[1] 1/1/04-7/1/08				
Pharmacy Schools and Locations	Number of Candidates Failing their 4th Time	All Candidates		
		Total	Pass (Percent)	Fail (Percent)
University of Arizona Tucson, AZ	1	39	82.05	17.95
University of the Pacific Stockton, CA	2	896	93.19	6.81
University of Southern California Los Angeles, CA	1	810	93.09	6.91
Xavier University of Louisiana New Orleans, LA	1	36	75.00	25.00
Massachusetts College of Pharmacy-Boston Boston, MA	1	535	71.59	28.41
Long Island University Brooklyn, NY	3	124	66.13	33.87
University of Puerto Rico San Juan, PR	1	5	20.00	80.00
Midwestern University-Glendale Glendale, AZ	1	74	70.27	29.73
University of Southern Nevada Henderson, NV	1	234	76.92	23.08
Foreign Graduates Various countries	9	1315	63.35	36.65
CPJE	21	7578	79.29	20.71

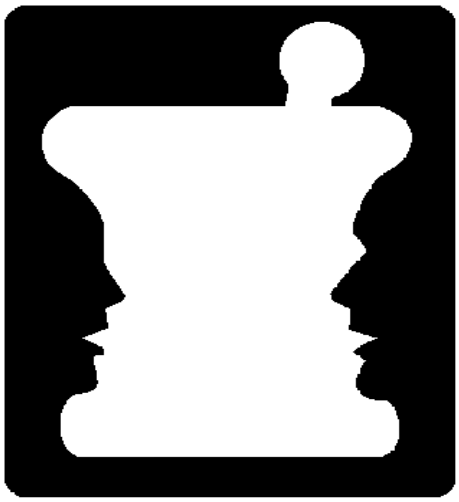
[1] As candidates may take the examination multiple times, statistics are based on each examination attempt by each candidate.

Attachment C:

Disciplinary Guidelines

DISCIPLINARY GUIDELINES

A Manual of Disciplinary Guidelines
and Model Disciplinary Orders



BE AWARE & TAKE CARE:
Talk to your pharmacist!

California State Board of Pharmacy
Department of Consumer Affairs
(Rev. 10/2007)

STATE BOARD OF PHARMACY

DEPARTMENT OF CONSUMER AFFAIRS

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Additional copies of these disciplinary guidelines
may be downloaded from the board's website

BOARD OF PHARMACY

DISCIPLINARY GUIDELINES

TABLE OF CONTENTS

Introduction 1
Factors to be Considered in Determining Penalties 3
Mitigating Evidence 4

Pharmacist/Intern Pharmacist 5
Terms of Probation – Pharmacist/Intern Pharmacist 5
Categories of Violation and Recommended Penalties 5
Category I – Penalty 6
Category II – Penalty 11
Category III – Penalty 15
Category IV – Penalty 18
Model Disciplinary Language – Pharmacist/Intern Pharmacist 19
Standard Conditions 23
Optional Conditions.....27

Pharmacy Technician 43
Terms of Probation – Pharmacy Technician 43
Category III – Penalty 44
Model Disciplinary Language – Pharmacy Technician.....44
Standard Conditions 48
Optional Conditions.....52

Designated Representative 55
Terms of Probation –Designated Representative 55
Category III – Penalty 55
Model Disciplinary Language –Designated Representative.....56
Standard Conditions 60
Optional Conditions.....64

Premises 67
Terms of Probation – Premises.....67
Category I – Penalty 68
Category II – Penalty 73
Category III – Penalty 77
Category IV – Penalty 79
Model Disciplinary Language – Premises 80
Standard Conditions 84
Optional Conditions.....87

DEPARTMENT OF CONSUMER AFFAIRS
STATE BOARD OF PHARMACY

DISCIPLINARY GUIDELINES
(Rev. 10/2007)

INTRODUCTION

The Board of Pharmacy (board) is responsible for the enforcement of statutes and regulations related to the practice of pharmacy (the Pharmacy Law) and to the regulation of controlled substances (the Uniform Controlled Substances Act). The board serves the public by:

- protecting the health, safety, and welfare of the people of California with integrity and honesty;
- advocating the highest quality of affordable pharmaceutical care;
- providing the best available information on pharmaceutical care; and
- promoting education, wellness and quality of life.

Pharmacists are patient advocates who provide pharmaceutical care and exercise clinical judgment for the citizens of California, enlightening them about their drug therapy through effective communicating and listening, assessing, collaborating, understanding and intervening. Enforcement officials act quickly, consistently and efficiently in the public's interest to ensure the safe, effective delivery of these services.

The board recognizes the importance of ensuring the safe and effective delivery of dangerous drugs and controlled substances for therapeutic purposes. At the same time, and given the historical and current abuse and diversion of drugs, particularly controlled substances, the board believes there should be no tolerance for licensees who traffic in drugs or who, in the absence of appropriate evidence of rehabilitation, personally abuse drugs or alcohol.

In accordance with Section 1760 of the California Code of Regulations, the board has produced this booklet for those involved in and affected by the disciplinary process: the general public, attorneys from the Office of the Attorney General, administrative law judges from the Office of Administrative Hearings, defense attorneys, board licensees, the courts, board staff and board members who review and vote on proposed decisions and stipulations.

These guidelines are to be followed in Board of Pharmacy disciplinary actions. Subject to judicial review, the board has the final authority over the disposition of its cases, and, to complete its work, it uses the services of the Office of the Attorney General and the Office of Administrative Hearings. The board recognizes that individual cases may necessitate a departure from these guidelines. In such cases, the mitigating or aggravating circumstances shall be detailed in any proposed decision or any transmittal memorandum accompanying a proposed stipulation, especially where Category III violations are involved.

In general, the position of the board is that revocation should always be an option whenever grounds for discipline are found to exist. Board policy is that revocation is generally an

appropriate order where a respondent is in default, such as when he or she fails to file a notice of defense or fails to appear at a disciplinary hearing.

Board policy is that a suspension, where imposed, should be at least 30 days for an individual and at least 14 days for a licensed premises.

The board seeks recovery of all investigative and prosecution costs up to the hearing in all disciplinary cases. This includes all charges of the Office of the Attorney General, including, but not limited to, those for legal services, and includes charges by expert consultants. The board believes that the burden of paying for disciplinary cases should fall on those whose conduct requires investigation and prosecution, not upon the profession as a whole.

The board recognizes there may be situations where an individual licensee deserves a stronger penalty than the pharmacy for which he or she works, but the board also believes in holding a pharmacy owner, manager, and/or pharmacist-in-charge responsible for the acts of pharmacy personnel. Similarly, the board recognizes that in some cases a licensed premises may well be more culpable than any individual licensed by or registered with the board.

For purposes of these guidelines “board” includes the board and/or its designees.

FACTORS TO BE CONSIDERED IN DETERMINING PENALTIES

Section 4300 of the Business and Professions Code provides that the board may discipline the holder of, and suspend or revoke, any certificate, license or permit issued by the board.

In determining whether the minimum, maximum, or an intermediate penalty is to be imposed in a given case, factors such as the following should be considered:

1. actual or potential harm to the public
2. actual or potential harm to any consumer
3. prior disciplinary record, including level of compliance with disciplinary order(s)
4. prior warning(s), including but not limited to citation(s) and fine(s), letter(s) of admonishment, and/or correction notice(s)
5. number and/or variety of current violations
6. nature and severity of the act(s), offense(s) or crime(s) under consideration
7. aggravating evidence
8. mitigating evidence
9. rehabilitation evidence
10. compliance with terms of any criminal sentence, parole, or probation
11. overall criminal record
12. if applicable, evidence of proceedings for case being set aside and dismissed pursuant to Section 1203.4 of the Penal Code
13. time passed since the act(s) or offense(s)
14. whether the conduct was intentional or negligent, demonstrated incompetence, or, if the respondent is being held to account for conduct committed by another, the respondent had knowledge of or knowingly participated in such conduct
15. financial benefit to the respondent from the misconduct.

No single one or combination of the above factors is required to justify the minimum and/or maximum penalty in a given case, as opposed to an intermediate one.

MITIGATING EVIDENCE

A respondent is permitted to present mitigating circumstances at a hearing or in the settlement process and has the burden of demonstrating any rehabilitative or corrective measures he or she has taken. The board does not intend, by the following references to written statements, letters, and reports, to waive any evidentiary objections to the form or admissibility of such evidence. The respondent must produce admissible evidence in the form required by law in the absence of a stipulation to admissibility by the complainant.

The following are examples of appropriate evidence a respondent may submit to demonstrate his or her rehabilitative efforts and competency:

a. Recent, dated written statements and/or performance evaluations from persons in positions of authority who have on-the-job knowledge of the respondent's current competence in the practice of pharmacy including the period of time and capacity in which the person worked with the respondent. Such reports must be signed under penalty of perjury and will be subject to verification by board staff.
b. Recent, dated letters from counselors regarding the respondent's participation in a rehabilitation or recovery program, which should include at least a description and requirements of the program, a psychologist's diagnosis of the condition and current state of recovery, and the psychologist's basis for determining rehabilitation. Such letters and reports will be subject to verification by board staff.
c. Recent, dated letters describing the respondent's participation in support groups, (e.g., Alcoholics Anonymous, Narcotics Anonymous, professional support groups, etc.). Such letters and reports will be subject to verification by board staff.
d. Recent, dated laboratory analyses or drug screen reports, confirming abstention from drugs and alcohol. Such analyses and reports will be subject to verification by board staff.
e. Recent, dated physical examination or assessment report by a licensed physician, confirming the absence of any physical impairment that would prohibit the respondent from practicing safely. Such assessments and reports will be subject to verification by board staff.
f. Recent, dated letters from probation or parole officers regarding the respondent's participation in and/or compliance with terms and conditions of probation or parole, which should include at least a description of the terms and conditions, and the officer’s basis for determining compliance. Such letters and reports will be subject to verification by board staff.

TERMS OF PROBATION – PHARMACIST/INTERN PHARMACIST

A minimum three-year probation period has been established by the board as appropriate in most cases where probation is imposed. A minimum five-year probation period has been established by the board as appropriate where self-administration or diversion of controlled substances is involved. Terms and conditions are imposed to provide consumer protection and to allow the probationer to demonstrate rehabilitation. A suspension period may also be required as part of the probation order. The board prefers that any stayed order be for revocation rather than for some period of suspension.

Probation conditions are divided into two categories: (1) standard conditions that shall appear in all probation cases, and (2) optional conditions that depend on the nature and circumstances of a particular case. These conditions may vary depending on the nature of the offense(s).

The board may also impose any other condition appropriate to the case where the condition is not contrary to public policy.

CATEGORIES OF VIOLATIONS AND RECOMMENDED PENALTIES

The California Pharmacy Law identifies offenses for which the board may take disciplinary action against the license. Included among grounds for discipline are violations of the Pharmacy Law itself, violations of regulations promulgated by the board, and violations of other state or federal statutes or regulations.

The following are categories of possible violations used by the board to determine appropriate disciplinary penalties. These categories represent the judgment of the board as to the perceived seriousness of particular offenses.

Under each category, the board has grouped statutes and regulations where violations would typically merit the recommended range of minimum to maximum penalties for that category. These lists are representative, and are not intended to be comprehensive or exclusive. Where a violation not included in these lists is a basis for disciplinary action, the appropriate penalty for that violation may be best derived by comparison to any analogous violation(s) that are included. Where no such analogous violation is listed, the category descriptions may be consulted.

These categories assume a single violation of each listed statute or regulation. For multiple violations, the appropriate penalty shall increase accordingly. Moreover, if an individual has committed violations in more than one category, the minimum and maximum penalties shall be those recommended in the highest category.

The board also has the authority, pursuant to Business and Professions Code section 4301(n), to impose discipline based on disciplinary action taken by another jurisdiction. The discipline imposed by the board will depend on the discipline imposed by the other jurisdiction, the extent of the respondent's compliance with the terms of that discipline, the nature of the conduct for which the discipline was imposed, and other factors set forth in these guidelines.

CATEGORY I

Minimum: Revocation; Revocation stayed; one year probation. All standard terms and conditions shall be included and optional terms and conditions as appropriate.

Maximum: Revocation

Category I discipline is recommended for:

- violations which are relatively minor but are potentially harmful
- repeated violations of a relatively minor nature:

Violations of the following codes are representative of this category:

BUSINESS AND PROFESSIONS CODE

Article 3. Scope of Practice and Exemptions

4052.1 Skin Puncture by Pharmacist; Conditions Permitting
4052.5 Pharmacist May Select Different Form of Medication with Same Active Chemical Ingredients; Exceptions
4052.7 Repackage Previously Dispensed Drugs; Requirements
4053 Exemptee Supervisor of Manufacturer, etc.: Requirements
4054 Supply by Manufacturer, etc. of Certain Dialysis Drugs and Devices
4055 Sale of Devices to Licensed Clinics, etc.
4056 Purchase of Drugs at Wholesale – Hospital Containing 100 Beds or Less
4057 Exceptions to Application of this Chapter
4058 Display of Original License
4062 Furnishing Dangerous Drugs During Emergency
4064 Emergency Refill of Prescription Without Prescription Authorization
4065 Injection Card System; Requirements of Administration
4066 Furnishing Dangerous Drugs to Master or First Officer of Vessel
4068 Dispense Dangerous Drug or Controlled Substance to Emergency Room Patient; Requirements

Article 4. Requirements for Prescription

4070 Reduction of Oral or Electronic Prescription to Writing
4071 Prescriber May Authorize Agent to Transmit Prescription; Schedule II Excluded
4072 Oral or Electronic Transmission of Prescription – Health Care Facility
4073 Substitution of Generic Drug – Requirements and Exceptions
4074 Drug Risk: Informing Patient; Providing Consultation for Discharge Medications
4076 Prescription Container – Requirements for Labeling
4077 Dispensing Dangerous Drug in Incorrectly Labeled Container

Article 5. Authority of Inspectors

4082 Names of Owners, Managers and Employees Open for Inspection

Article 6. General Requirements

4100 Change of Address or Name – Notification to Board
4103 Blood Pressure – Taking by Pharmacist

Article 7. Pharmacies

4114 Intern Pharmacist: Activities Permitted
4119 Furnish Prescription Drug to Licensed Health Care Facility – Secured
4119.1 Pharmacy May Provide Services to Health Facility
4119.5 Transfer or Repackaging Dangerous Drugs by Pharmacy
4121 Advertisement for Prescription Drug: Requirements; Restrictions
4122 Required Notice at Availability of Prescription Price Information, General Product Availability, Pharmacy Services; Providing Drug Price Information; Limitations on Price Information Requests
4123 Compounding Drug for Other Pharmacy for Parenteral Therapy; Notice to Board
4124 Dispensing Replacement Contact Lenses: Requirements; Patient Warnings; Registration with Medical Board; Application of Section to Nonresident Pharmacies

Article 9. Hypodermic Needles and Syringes

4141 Furnishing Without License
4142 Prescription Required
4143 Exemption: Sale to Other Entity, Physician, etc.
4144 Industrial Use Exception
4145 Exception: Furnishing for Administration of Insulin, Adrenaline, or Specified Animal Uses; Conditions
4148 Confiscation if Found Outside Licensed Premises
4149 Sale by Distributor

Article 10. Pharmacy Corporations

4151 Licensure Requirements
4152 Corporate Name Requirements
4153 Shareholder Income While Disqualified
4156 Unprofessional Conduct by Corporation

Article 11. Wholesalers and Manufacturers

4161 Nonresident Wholesaler: When License Required; Application
4162 Issuance or Renewal of Wholesaler License; Surety Bond
4163 Unauthorized Furnishing by Manufacturer or Wholesaler
4165 Sale or Transfer of Dangerous Drug or Device Into State: Furnishing Records to Authorized Officer on Demand; Citation for Non-compliance
4166 Shipping of Dangerous Drugs or Devices – Wholesaler or Distributor
4167 Wholesaler: Bar on Obtaining Dangerous Drugs or Devices It Cannot Maintain on Licensed Premises

Article 13. Non-Profit or Free Clinics

4180 Purchase of Drugs at Wholesale Only with License: Eligible Clinics
4181 License Requirements; Policies and Procedures; Who May Dispense
4182 Duties of Professional Director; Consulting Pharmacist Required
4183 No Professional Dispensing Fee
4184 Dispensing Schedule II Substance Prohibited
4186 Automated Drug Delivery Systems

Article 14. Surgical Clinics

4190 Purchase of Drugs at Wholesale: Permitted Uses of Drugs; Required Records and Policies; License Required
4191 Compliance with Department of Health Services Requirements; Who May Dispense Drugs
4192 Duties of Professional Director; Providing Information to Board
4193 Clinic Not Eligible for Professional Dispensing Fee; Ban on Offering Drugs for Sale
4194 Dispensing of Schedule II Substance by Clinic Prohibited; Physician May Dispense; Administration Authorized in Clinic

Article 15. Veterinary Food-Animal Drug Retailers

4196 License Required: Temporary License on Transfer of Ownership; Persons Authorized in Storage Area
4197 Minimum Standards: Security; Sanitation; Board Regulations; Waivers
4198 Written Policies and Procedures Required: Contents; Training of Personnel; Quality Assurance; Consulting Pharmacist

Article 17. Continuing Education

4231 Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee
4232 Content of Course

Article 18. Poisons

4240 Application of Act

Article 20. Prohibitions and Offenses

4341 Advertisement of Prescription Drugs or Devices
4343 Buildings: Prohibition Against Use of Certain Signs Unless Licensed Pharmacy Within

CALIFORNIA CODE OF REGULATIONS, TITLE 16

1704 Change of Address
1705 Notification of Bankruptcy, Receivership or Liquidation
1708.2 Discontinuance of Business
1708.4 Pharmacist Handling Radioactive Drugs

1708.5	Pharmacy Furnishing Radioactive Drugs
1709	Names of Owners and Pharmacist in Charge
1712	Use of Pharmacist Identifiers
1714	Operational Standards and Security
1715.6	Reporting Drug Loss
1716	Variation From Prescriptions
1717	Pharmaceutical Practice
1717.1	Common Electronic Files
1717.4	Electronic Transmission of Prescriptions
1718.1	Manufacturer's Expiration Date
1726	Supervision of Intern Pharmacists
1728	Requirements for Examination
1732.1	Requirements for Accredited Providers
1732.3	Requirements for Continuing Education Courses
1732.4	Provider Audit Requirements
1732.5	Renewal Requirements for Pharmacist
1744	Drug Warnings
1746	Emergency Contraception
1751	Sterile Injectable Compounding Area
1751.01	Facility and Equipment Standards for Sterile Injectable Compounding from Non-Sterile Ingredients
1751.02	Policies and Procedures
1751.1	Laminar Flow Biological Safety Cabinet
1751.2	Labeling Requirements
1751.3	Recordkeeping Requirements
1751.4	Attire
1751.5	Training of Staff, Patient, and Caregiver
1751.6	Disposal of Waste Material
1751.7	Quality Assurance and Process Evaluation
1751.9	Reference Materials
1751.11	Furnishing to Home Health Agencies and Licensed Hospices
1751.12	Obligations of a Pharmacy Furnishing Portable Containers
1771	Posting Notice of Suspension
1772	Disciplinary Condition of Suspension
1780	Minimum Standards for Wholesalers
1780.1	Minimum Standards for Veterinary Food-Animal Drug Retailers
1781	Exemption Certificate
1786	Exemptions
1787	Authorization to Distribute Hemodialysis Drugs and Devices
1790	Assembling and Packaging
1791	Labeling
1792	Receipt for Shipment

HEALTH AND SAFETY CODE

11100	Report of Certain Chemical: Chemicals Included; Exclusions; Penalties
11100.1	Report of Chemicals Received from Outside State; Penalties
11151	Limitation on Filling Prescriptions From Medical Students

11158	Prescription Required for Schedule II, III, IV, or V Controlled Substance; Exception for Limited Dispensing, Administration
11159	Chart Order Exemption for Patient in County or Licensed Hospital; Maintaining Record for Seven Years
11159.1	Chart Order Exemption for Clinic Patient; Maintaining Record for Seven Years
11159.2	Exception to Triplicate Prescription Requirement
11167	Emergency Dispensing of Schedule Il Substance: Circumstances and Requirements
11167.5	Oral or Electronic Prescriptions for Scheduled II Controlled Substances for Specified Inpatients, Residents, and Home Hospice Patients; Requirements
11171	Prescribing, etc. Controlled Substance Only as Authorized
11172	Antedating or Postdating Prescription Prohibited
11175	Prohibition on Obtaining or Possessing Nonconforming Prescription; Prohibition on Obtaining Controlled Substance by Nonconforming Prescription
11180	Prohibition on Controlled Substance Obtained or Possessed by Nonconforming Prescription
11200	Restrictions on Dispensing or Refilling; Refill of Schedule II Prescription Barred
11201	Emergency Refill of Schedule III, IV, or V Prescription; Circumstances; Requirements
11205	Maintenance and Retention of Records in Separate File
11206	Required information on Prescription
11209	Delivery and Receiving Requirements for Schedule II, III, and IV Substances; Violation
11210	Issuing Prescription: By Whom; For What Purpose; Quantity to Be Prescribed
11250	Authorized Retail Sale by Pharmacists to Physicians, etc.; Required Order Form
11251	Authorized Wholesale Sale by Pharmacists
11252	Preservation of Federally Required Forms
11253	Duration of Retention
11255	Actions Constituting Sale
11256	Required Report of Order By or Sale to Out-of-State Wholesaler or Manufacturer
111225 to 111655	Adulterated or Misbranded Drugs or Devices

CODE OF FEDERAL REGULATIONS, TITLE 21

1301.11	Persons required to register.
1301.12	Separate registrations for separate locations.
1301.71	Security requirements generally.
1301.72	Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas.
1301.73	Physical security controls for non-practitioners; compounders for narcotic treatment programs; manufacturing and compounding areas.
1301.74	Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.
1301.75	Physical security controls for practitioners.
1301.76	Other security controls for practitioners.
1301.90	Employee screening procedures.
1301.91	Employee responsibility to report drug diversion.
1301.92	Illicit activities by employees.
1302.03	Symbol required; exceptions.
1302.04	Location and size of symbol on label and labeling.

1302.05 Effective dates of labeling requirements.
1302.06 Sealing of controlled substances.
1302.07 Labeling and packaging requirements for imported and exported substances.
1304.11 Inventory requirements.
1304.21 Inventories of importers and exporters
1304.31 Reports from manufacturers importing narcotic raw materials.
1304.32 Reports of manufacturers importing coca leaves.
1304.33 Reports to ARCOS.
1305.03 Distributions requiring a Form 222 or a digitally signed electronic order.
1305.04 Persons entitled to order Schedule I and II controlled substances.
1305.05 Power of attorney.
1305.06 Persons entitled to fill orders for Schedule I and II controlled substances.
1305.11 Procedure for obtaining DEA Forms 222.
1305.12 Procedure for executing DEA Forms 222.
1305.14 Procedure for endorsing DEA Forms 222.
1305.15 Unaccepted and defective DEA Forms 222.
1305.16 Lost and stolen DEA Forms 222.
1306.03 Persons entitled to issue prescriptions.
1306.05 Manner of issuance of prescriptions.
1306.14 Labeling of substances and filling of prescriptions.
1306.24 Labeling of substances and filing of prescriptions.
1306.25 Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes.
1306.26 Dispensing without a prescription.
1307.11 Distribution by dispenser to another practitioner or reverse distributor.
1307.12 Distribution to supplier or manufacture.
1307.13 Incidental manufacture of controlled substances.
1307.21 Procedure for disposing of controlled substances.
1700.1 to
1707.15 Child-resistant containers.

CATEGORY II

Minimum: Revocation; Revocation stayed, three years probation (five years probation where self-administration or diversion of controlled substances is involved). All standard terms and conditions shall be included and optional terms and conditions as appropriate.

Maximum: Revocation

Category II discipline is recommended for:

- violations with a serious potential for harm
- violations which involve greater disregard for pharmacy law and public safety
- violations which reflect on ethics, care exercised or competence or a criminal conviction not involving dangerous drugs or controlled substances or involving possession or use of dangerous drugs or controlled substances.

Violations of the following codes are representative of this category:

BUSINESS AND PROFESSIONS CODE

650 Rebates or Discounts for Referral Prohibited
650.1 Lease Prohibition – Hospitals or Prescribers
651 Professional Advertising Requirements

Article 3. Scope of Practice and Exemptions

4051(b) Conduct Authorized by Pharmacist
4052 Furnishing to Prescriber; Permissible Procedures by Pharmacist in Health Care Facility or Clinic or for Other Health Care Provider
4060 Controlled Substance – Prescription Required; Exceptions
4061 Distribution of Drug as Sample; Written Request Required
4063 Refill of Prescription for Dangerous Drug or Device; Prescriber Authorization
4067 Internet; Dispensing Dangerous Drugs or Devices without Prescription
4075 Proof of Identity Required – Oral or Electronic Prescription
4078 False or Misleading Label on Prescription

Article 6. General Requirements

4101 Pharmacist in Charge, Exemptee: Termination of Employment; Notification to Board
4104 Licensed Employee, Theft or Impairment: Pharmacy Procedures
4105 Retaining Records of Dangerous Drugs and Devices on Licensed Premises; Temporary Removal; Waivers; Access to Electronically Maintained Records

Article 7. Pharmacies

4112 Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation
4113 Pharmacist in Charge: Notification to Board; Responsibilities
4115 Pharmacy Technician: Activities Permitted; Required Supervision; Activities Limited to Pharmacist; Registration; Requirements for Registration; Ratios
4115.5 Pharmacy Technician Trainee; Placement; Supervisions; Requirements
4116 Security of Dangerous Drugs and Devices in Pharmacy: Pharmacist Responsibility for Individuals on Premises; Regulations
4117 Admission to Area Where Narcotics are Stored, etc. – Who May Enter
4120 Nonresident Pharmacy: Registration Required
4125 Pharmacy Quality Assurance Program Required; Records Considered Peer Review Documents

Article 9. Hypodermic Needle and Syringes

4140 Unlawful Possession
4147 Disposal of Needle or Syringe

Article 11. Wholesalers and Manufacturers

4160 Wholesaler: License Required
4163 Unauthorized Furnishing by Manufacturer or Wholesaler

4164 Reports Required
4169(a)(1) Prohibited Acts

Article 13. Non-Profit of Free Clinics

4185 Inspection Permitted

Article 14. Surgical Clinics

4195 Inspection Permitted

Article 19. Disciplinary Proceedings

4301 Unprofessional Conduct - subsections (a)-(h), (j), and (l)-(q)
4302 Discipline of Corporate Licensee for Conduct of Officer, Director, Shareholder
4303 Nonresident Pharmacy: Grounds for Discipline
4304 Out-of-state Distributor: Authority to Discipline
4305 Disciplinary Grounds: Failure of Pharmacy, Pharmacist to Notify Board of Termination of Pharmacist in Charge; Continuing to Operate Without Pharmacist
4305.5 Disciplinary Grounds: Failure of Other Entity Licensed by Board, of Pharmacist or Exemptee to Notify Board of Termination of Pharmacist in Charge or Exemptee; Continuing to Operate Without Pharmacist or Exemptee
4306 Violation of Professional Corporation Act as Unprofessional Conduct
4306.5 Misuse of Education, etc. by Pharmacist Outside Course of Practice of Pharmacy as Unprofessional Conduct

Article 20. Prohibitions and Offenses

4326 Misdemeanor: Obtaining Needle or Syringe by Fraud, etc.; Unlawful Use of Needle or Syringe Obtained from Another
4328 Misdemeanor: Permitting Compounding, Dispensing, or Furnishing by Non-pharmacist
4330 Misdemeanor: Non-pharmacist Owner Failing to Place Pharmacist in Charge, Dispensing or Compounding Except by Pharmacist, Interfering with Pharmacist in Charge
4331 Misdemeanor: Medical Device Retailer, Wholesaler, Veterinary Food-Animal Drug Retailer Failing to Place Pharmacist or Exemptee in Charge, Permitting Dispensing or Compounding Except by Pharmacist or Exemptee
4333 Maintaining Prescriptions, Other Drug Records on Premises, Open to Inspection; Waiver; Willful Failure to Keep or Permit Inspection of Records of Prescriptions, Other Records as Misdemeanor
4340 Unlawful Advertising by Nonresident Pharmacy Not Registered with Board

Article 22. Unfair Trade Practices

4380 Resale of Preferentially Priced Drugs: Prohibition; Exceptions
4381 Violation of Section 4380 as Unfair Competition; Right of Private Action to Enforce
4382 Board May Audit Sales to Walk-in Customers

CALIFORNIA CODE OF REGULATIONS, TITLE 16

1707.1	Duty to Maintain Medication Profiles (Patient Medication Records)
1707.2	Notice to Consumers and Duty to Consult
1707.3	Duty to Review Drug Therapy and Patient Medication Record Prior to Delivery
1709.1	Designation of Pharmacist in Charge
1714.1	Pharmacy Operations During the Temporary Absence of a Pharmacist
1715	Self-Assessment of a Pharmacy by the Pharmacist-in-Charge
1715.5	Implementation of Electronic Monitoring of Schedule II Prescriptions
1716.1	Compounding Unapproved Drugs for Prescriber Office Use
1716.2	Record Requirements-Compounding for Future Furnishing
1717.3	Preprinted, Multiple Checkoff Prescription Blanks
1723.1	Confidentiality of Examination Questions
1745	Partial Filling of Schedule II Prescriptions
1751.10	Furnishing to Parenteral Patient at Home
1761(a)	Erroneous or Uncertain Prescriptions
1764	Unauthorized Disclosure of Prescriptions
1765	Commissions, Gratuities, and Rebates
1766	False or Misleading Advertising
1775.3	Compliance with Orders of Abatement
1782	Reporting Sales of Drugs Subject to Abuse
1783	Manufacturer or Wholesaler Furnishing Drugs or Devices
1793.1	Duties of a Pharmacist
1793.2	Duties of a Pharmacy Technician
1793.3	Other Non-Licensed Pharmacy Personnel
1793.7	Requirements for Pharmacies Employing Pharmacy Technicians
1793.8	Technicians in Hospitals with Clinical Pharmacy Programs

HEALTH AND SAFETY CODE

11103	Report of Theft, Loss, or Shipping Discrepancy
11150	Persons Authorized to Write or Issue a Prescription
11152	Nonconforming Prescriptions Prohibited
11154	Prescription, etc, Must Be for Treatment; Knowing Solicitation of Unlawful Prescription, etc.
11156	Prescribing, etc. Controlled Substances to Addict Only as Authorized
11164	Prescriptions for Schedule II, III, IV and V Controlled Substances: Form and Content; Record of Practitioner Dispensing Schedule II Controlled Substances
11166	Time Limit for Filling Schedule II Prescription; Knowingly Filling Mutilated, Forged, or Altered Prescription Prohibited
11170	Prohibition on Prescribing, etc. Controlled Substance for Self
11179	Retention of Controlled Substance Prescription
11207	Only Pharmacist or Intern Authorized to Fill Prescription
11209	Delivery and Receiving Requirements for Schedule II, III, and IV Substances; Violation
11350	Possession of Specified Controlled Substance
11377	Unlawful Possession of Specified Substance
11165(d)	CURES Transmission
150204	Surplus Medication Collection and Distribution Program

CODE OF FEDERAL REGULATIONS, TITLE 21

1304.03 Persons required to keep records and file reports.
1304.04 Maintenance of records and inventories.
1304.11 Inventory requirements .
1304.21 General requirements for continuing records.
1304.22 Records for manufacturers.
1305.07 Special procedure for filling certain orders.
1305.13 Procedure for filling DEA Forms 222.
1306.04 Purpose of issue of prescription.
1306.06 Persons entitled to fill prescriptions.
1306.07 Administering or dispensing of narcotic drugs.
1306.11 Requirement of prescription.
1306.12 Refilling prescription.
1306.13 Partial filling of prescriptions.
1306.21 Requirement of prescription.
1306.22 Refilling of prescriptions.
1306.23 Partial filling of prescriptions.

CATEGORY III

Minimum: Revocation; Revocation stayed, 90 days actual suspension, three to five years probation (five years probation where self-administration or diversion of controlled substances is involved). All standard terms and conditions and optional terms and conditions as appropriate.

Maximum: Revocation

Category III discipline is recommended for:

- most criminal convictions involving dangerous drugs or controlled substances
- knowing or willfully violating laws or regulations pertaining to dispensing or distributing dangerous drugs or controlled substances
- fraudulent acts committed in connection with the licensee's practice
- drug shortages
- violation of a licensee's corresponding responsibility.

Violations of the following codes are representative of this category:

BUSINESS AND PROFESSIONS CODE

Article 3. Scope of Practice and Exemptions

4034 Pedigree
4051(a) Conduct Limited To Pharmacist
4059 Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions
4059.5 Who May Order Dangerous Drugs or Devices: Exceptions

Article 5. Authority of Inspectors

4080	Stock of Dangerous Drugs and Devices Kept Open for Inspection
4081	Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory
4085(a)	Unlawful to Remove, Sell, Dispose of Embargoed Dangerous Drug or Dangerous Device

Article 6. General Requirements

4105	Retaining Records of Dangerous Drugs and Devices on Licensed Premises; Temporary Removal; Waivers; Access to Electronically Maintained Records

Article 7. Pharmacies

4110	Licensed Required; Temporary Permit Upon Transfer of Ownership
4111	Restrictions on Prescriber Ownership

Article 11. Wholesalers and Manufacturers

4169(a)(2) to 4169(a)(5)	Prohibited Acts

Article 15. Veterinary Food-Animal Retailers

4199	Labeling Requirements; Maintaining Prescription Records

Article 19. Disciplinary Proceedings

4301	Unprofessional Conduct - subsections (i) - (k) and (o)
4307	Prohibition of Association of Individual with Entity License by Board: Length of Prohibition; Individuals Covered; Imposition of Prohibition Through Administrative Act Proceeding
4308	Prohibited Association: Notification of Affected Licensees Known to Board

Article 20. Prohibitions and Offenses

4322	Misdemeanor or Infraction: False Representations to Secure License for Self or Others; False Representation of Licensure; Penalties
4323	Misdemeanor: False Representation of Self as Physician, Agent of Physician, etc. to Obtain Drug
4324	Felony or Misdemeanor: Forgery of Prescription; Possession of Drugs Obtained Through Forged Prescription
4325	Misdemeanor: Manufacture, Possession, etc. of False Prescription Blank
4327	Misdemeanor: Sale, Dispensing, or Compounding While Under the Influence of Drugs or Alcoholic Beverages
4329	Misdemeanor: Non-pharmacist Acting as Manager, Compounding, Dispensing or Furnishing Drugs
4332	Misdemeanor: Failure or Refusal to Maintain or Produce Required Drug or Device Records; Willful Production of False Records

4335 Voided License: Knowing Failure to Arrange for Disposition of Stock as Misdemeanor
4336 Felony: Knowing or Willful Use of Minor to Violate Specified Sections of Pharmacy Law: Exception for Pharmacist Furnishing Pursuant to a Prescription

Article 22. Unfair Trade Practices

4380 Resale of Preferentially Priced Drugs: Prohibition; Exceptions

CALIFORNIA CODE OF REGULATIONS, TITLE 16

1707 Waiver Requirements for Off-Site Storage of Records
1718 Current Inventory Defined
1761(b) Erroneous or Uncertain Prescriptions
1771 Posting of Notice of Suspension
1772 Disciplinary Condition of Suspension
1773 Disciplinary Conditions of Probation of Pharmacist
1774 Disciplinary Conditions of Probation of Permit

HEALTH AND SAFETY CODE

11104 Providing Chemical for Illicit Manufacturing; Evasion of Reporting Requirements; Penalties
11105 False Statement in Report
11150 Persons Authorized to Write or Issue a Prescription
11153 Responsibility for Legitimacy of Prescription; Corresponding Responsibility of Pharmacist; Knowing Violation
11153.5 Wholesaler or Manufacturer Furnishing Controlled Substance Other Than for Legitimate Medical Purpose; Knowing Violation; Factors in Assessing Legitimacy
11157 No False or Fictitious Prescriptions
11162.5 Counterfeiting or Possession of Counterfeit Triplicate Prescription Blank; Penalty
11173 Fraud, Deceit, Misrepresentation or False Statement; False Representation; False Label
11174 Prohibition on Providing False Name or Address in Connection with Prescription, etc.
11351 Possession or Purchase for Sale of Specified Controlled Substance
11368 Forged or Altered Prescriptions
11375 Possession for Sale or Selling Specified Substance
11378 Possession for Sale
11550 Using or Being Under Influence of Controlled Substance
11167.5 Pharmacy Generated Prescription for Schedule II Controlled Substances in a Skilled Nursing Facility
111295 Manufacturing, Selling, or Offering for Sale an Adulterated Drug or Device
111300 Unlawful to Adulterate a Drug
111305 Unlawful to Receive in Commerce an Adulterated Drug
111440 Unlawful Manufacturer, Selling a Misbranded Drug
111445 Unlawful for a Person to Misbrand
111450 Unlawful to Receive into Commerce a Drug that is Misbranded

CATEGORY IV

Penalty: Revocation

Revocation is recommended for violations of the Uniform Controlled Substance Act (Heath and Safety Code 11000 et seq.) involving:

- possession for sale
- transportation
- importation
- sale
- use of a minor for the unlawful sale of controlled substances

Revocation is also recommended when:

- a respondent fails to file a notice of defense or to appear at a disciplinary hearing where the board has requested revocation in the accusation
- a respondent violates the terms and conditions of probation from a previous disciplinary order
- prior discipline has been imposed, as progressive discipline unless the respondent can demonstrate satisfactory evidence of rehabilitation.

Violations of the following codes are representative of this category:

HEALTH AND SAFETY CODE

11352 Importing, Selling, Furnishing Controlled Substance
11353 Adult Inducing Minor to Violate Provisions
11379 Transporting, Importing, Selling Controlled Substance
11380 Adult Using, Soliciting or Intimidating Minor for Violation

MODEL DISCIPLINARY LANGUAGE – PHARMACIST/INTERN PHARMACIST

The following standardized language shall be used in every decision where the order or condition is imposed.

Revocation

License number _____, issued to respondent _____,is revoked.

Respondent shall relinquish his or her wall license and pocket renewal license to the board within 10 days of the effective date of this decision. Respondent may not reapply or petition the board for reinstatement of his or her revoked license for three years from the effective date of this decision.

Respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____ within fifteen (15) days of the effective date of this decision.

Option: As a condition precedent to reinstatement of his or her revoked license, respondent shall reimburse the board for its costs of investigation and prosecution in the amount of $_____. Said amount shall be paid in full prior to the reapplication or reinstatement of his or her license unless otherwise ordered by the board.

Suspension

As part of probation, respondent is suspended from the practice of pharmacy for _____ beginning the effective date of this decision.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances.

Respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

Standard Stay/Probation Order

License number _____, issued to respondent is revoked; however, the revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Issuance of Probationary License (In cases where a Statement of Issues has been filed.)

Upon satisfaction of all statutory and regulatory requirements for issuance of a license, a license shall be issued to respondent and immediately revoked; the order of revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Surrender

Respondent surrenders license number _____ as of the effective date of this decision. Respondent shall relinquish his or her wall license and pocket renewal license to the board within ten (10) days of the effective date of this decision.

The surrender of respondent's license and the acceptance of the surrendered license by the board shall constitute the imposition of discipline against respondent. This decision constitutes a record of discipline and shall become a part of respondent's license history with the board.

Respondent understands and agrees that if he or she ever files an application for licensure or a petition for reinstatement in the State of California, the board shall treat it as a new application for licensure.

Respondent may not apply for any license, permit, or registration from the board for three years from the effective date of this decision. Respondent stipulates that should he or she apply for any license from the board on or after the effective date of this decision, all allegations set forth in the [accusation or petition to revoke probation] shall be deemed to be true, correct and admitted by respondent when the board determines whether to grant or deny the application. Respondent shall satisfy all requirements applicable to that license as of the date the application is submitted to the board, including, but not limited to taking and passing the California Pharmacist Licensure Examination prior to the issuance of a new license. Respondent is required to report this surrender as disciplinary action.

Respondent further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution in the amount of $_____ within _____ days of the effective date of this decision.

Option: Respondent stipulates that should he or she apply for any license from the board on or after the effective date of this decision the investigation and prosecution costs in the amount of $_____ shall be paid to the board prior to issuance of the new license.

Public Reprimand

It is hereby ordered that a public reprimand be issued against licensee, _____. Respondent is required to report this reprimand as a disciplinary action.

Adoption of Stipulation

It is understood by respondent that, in deciding whether to adopt this stipulation, the board may receive oral and written communication from its staff and the Office of the Attorney General. Communications pursuant to this paragraph shall not disqualify the board or other persons from future participation in this or any other matter affecting respondent. In the event this settlement is not adopted by the board, the stipulation will not become effective and may not be used for any purpose, except this paragraph, which shall remain in effect.

STANDARD CONDITIONS - To be included in all probation decisions/orders.

1. Obey All Laws
2. Report to the Board
3. Interview with the Board
4. Cooperate with Board Staff
5. Continuing Education
6. Notice to Employers
7. No Supervision of Interns, Serving as Pharmacist-In-Charge (PIC), or Serving as a Consultant
8. Reimbursement of Board Costs
9. Probation Monitoring Costs
10. Status of License
11. License Surrender While on Probation/Suspension
12. Notification of a Change in Name, Residence Address, Mailing Address or Employment
13. Tolling of Probation
14. Violation of Probation
15. Completion of Probation

OPTIONAL CONDITIONS

16. Restricted Practice
17. Pharmacist Examination
18. Mental Health Examination
19. Psychotherapy
20. Medical Evaluation
21. Pharmacists Recovery Program (PRP)
22. Random Drug Screening
23. Abstain from Drugs and Alcohol Use
24. Prescription Coordination and Monitoring of Prescription Use
25. Community Service Program
26. Restitution
27. Remedial Education
28. Pharmacy Self-Assessment Mechanism (PSAM)
29. Intern Pharmacist Experience
30. Supervised Practice
31. No Supervision of Ancillary Personnel
32. No Ownership of Licensed Premises
33. Separate File of Records
34. Report of Controlled Substances
35. No Access to Controlled Substances
36. Criminal Probation/Parole Reports
37. Consultant for Owner or Pharmacist-In-Charge
38. Tolling of Suspension
39. Surrender of DEA Permit
40. Ethics Course

STANDARD CONDITIONS: TO BE INCLUDED IN ALL PROBATIONS

1. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's _____ license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

2. Report to the Board

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff

Respondent shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his or her probation. Failure to cooperate shall be considered a violation of probation.

5. Continuing Education

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

6. Notice to Employers

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number _____ and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his or her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number _____, and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify his or her direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in case number _____ in advance of the respondent commencing work at each licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause his or her direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he or she has read the decision in case number _____ and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgments to the board shall be considered a violation of probation.

> "Employment" within the meaning of this provision shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacist or any position for which a pharmacist license is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

7. No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant

During the period of probation, respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board nor serve as a consultant unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

8. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____. Respondent shall make said payments as follows: _____.

There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent shall not relieve respondent of his or her responsibility to reimburse the board its costs of investigation and prosecution.

9. Probation Monitoring Costs

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

10. Status of License

Respondent shall, at all times while on probation, maintain an active, current license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

11. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent’s license history with the board.

Upon acceptance of the surrender, respondent shall relinquish his or her pocket and wall license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

12. Notification of a Change in Name, Residence Address, Mailing Address or Employment

Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number.

Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

13. Tolling of Probation

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of _____ hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of _____ hours per calendar month in California, respondent must notify the board in writing within ten (10) days of the cessation of practice, and must further notify the board in writing within ten (10) days of the resumption of practice. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

> "Cessation of practice" means any calendar month during which respondent is not practicing as a pharmacist for at least _____ hours, as defined by Business and Professions Code section 4000 et seq . "Resumption of practice" means any calendar month during which respondent is practicing as a pharmacist for at least _____ hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.

Option: Respondent is required to practice as a pharmacist in a licensed pharmacy setting that dispenses medication for a minimum of one year prior to the completion of probation. After the first year of probation, the board or its designee may consider a modification of this requirement. If respondent fails to comply with this requirement or a subsequent modification thereto, such failure shall be considered a violation of probation.

14. Violation of Probation

If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

15. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, respondent's license will be fully restored.

OPTIONAL CONDITIONS OF PROBATION

16. Restricted Practice

Respondent's practice of pharmacy shall be restricted to [specify setting or type of practice] for the first _____ years of probation. Respondent shall submit proof satisfactory to the board of compliance with this term of probation.

Option: Respondent shall not prepare, oversee or participate in the preparation of injectable sterile products during the first _____ year(s) of probation. Respondent shall submit proof satisfactory to the board of compliance with this term of probation. Failure to abide by this restriction or to timely submit proof to the board of compliance therewith shall be considered a violation of probation.

17. Pharmacist Examination

Respondent shall take and pass the [California Pharmacist Jurisprudence Examination (CPJE) and/or the North American Pharmacist Licensure Examination (NAPLEX)] within six (6) months of the effective date of this decision. If respondent fails to take and pass the examination(s) within six (6) months after the effective of this decision, respondent shall be automatically suspended from practice. Respondent shall not resume the practice of pharmacy until he or she takes and passes the [CPJE and/or NAPLEX] and is notified, in writing, that he or she has passed the examination(s) and may resume practice. Respondent shall bear all costs of the examination(s) required by the board.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

If respondent fails to take and pass the [CPJE and/or NAPLEX] after four attempts, respondent shall successfully complete, at a minimum, sixteen (16) additional semester units of pharmacy education as approved by the board. Failure to complete coursework as required shall be considered a violation of probation. Failure to take the examination(s) within one (1) year of the effective date of this decision shall be considered a violation of probation.

18. Mental Health Examination (Appropriate for those cases where evidence demonstrates that mental illness or disability was a contributing cause of the violations.)

Within thirty (30) days of the effective date of this decision, and on a periodic basis as may be required by the board or its designee, respondent shall undergo, at his or her own expense, psychiatric evaluation(s) by a board-appointed or board-approved licensed mental health practitioner. The approved evaluator shall be provided with a copy of the board's [accusation or petition to revoke probation] and decision. Respondent shall sign a release authorizing the evaluator to furnish the board with a current diagnosis and a written report regarding the respondent's judgment and ability to function independently as a pharmacist with safety to the public. Respondent shall comply with all the recommendations of the evaluator if directed by the board or its designee.

If the evaluator recommends, and the board or its designee directs, respondent shall undergo psychotherapy. Within thirty (30) days of notification by the board that a recommendation for psychotherapy has been accepted, respondent shall submit to the board or its designee, for prior approval, the name and qualification of a licensed mental health practitioner of respondent's choice. Within thirty (30) days of approval thereof by the board, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved licensed mental health practitioner. Should respondent, for any reason, cease treatment with the approved licensed mental health practitioner, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment therewith, submit the name of a replacement licensed mental health practitioner of respondent's choice to the board for its prior approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved replacement. Failure to comply with any requirement or deadline stated by this paragraph shall be considered a violation of probation.

Upon approval of the initial or any subsequent licensed mental health practitioner, respondent shall undergo and continue treatment with that therapist, at respondent's own expense, until the therapist recommends in writing to the board, and the board or its designee agrees by way of a written notification to respondent, that no further psychotherapy is necessary. Upon receipt of such recommendation from the treating therapist, and before determining whether to accept or reject said recommendation, the board or its designee may require respondent to undergo, at respondent's expense, a mental health evaluation by a separate board-appointed or board-approved evaluator. If the approved evaluator recommends that respondent continue psychotherapy, the board or its designee may require respondent to continue psychotherapy.

Psychotherapy shall be at least once a week unless otherwise approved by the board. Respondent shall provide the therapist with a copy of the board's [accusation or petition to revoke probation] and decision no later than the first therapy session. Respondent shall take all necessary steps to ensure that the treating therapist submits written quarterly reports to the board concerning respondent's fitness to practice, progress in treatment, and other such

information as may be required by the board or its designee.

If at any time the approved evaluator or therapist determines that respondent is unable to practice safely or independently as a pharmacist, the licensed mental health practitioner shall notify the board immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice until notified by the board that practice may be resumed.

Option: Commencing on the effective date of this decision, respondent shall not engage in the practice of pharmacy until notified in writing by the board that respondent has been deemed psychologically fit to practice pharmacy safely, and the board or its designee approves said recommendation.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

(Option language to be used in addition to standard language)
Option: If recommended by the evaluating licensed mental health practitioner and approved by the board, respondent shall be suspended from practicing pharmacy until respondent's treating therapist recommends, in writing, stating the basis therefor, that respondent can safely practice pharmacy, and the board or its designee approves said recommendation.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

19. Psychotherapy (Appropriate for those cases where the evidence demonstrates mental illness or alcohol or drug abuse was involved in the violations.)

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, the name and qualifications of a licensed mental health practitioner of respondent's choice. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved licensed mental health practitioner. Should respondent, for any reason, cease treatment with the approved licensed mental health practitioner, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment, submit the name of a replacement psychotherapist or licensed mental health practitioner of respondent's choice to the board for its prior approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved replacement. Failure to comply with any requirement or deadline stated by this paragraph shall be considered a violation of probation.

Upon approval of the initial or any subsequent licensed mental health practitioner, respondent shall undergo and continue treatment with that therapist, at respondent's own expense, until the therapist recommends in writing to the board, and the board or its designee agrees by way of a written notification to respondent, that no further psychotherapy is necessary. Upon receipt of such recommendation from the treating therapist, and before determining whether to accept or reject said recommendation, the board or its designee may require respondent to undergo, at respondent's own expense, a mental health evaluation by a board-appointed or board-approved psychiatrist or psychologist. If the approved evaluator recommends that respondent continue psychotherapy, the board or its designee may require respondent to continue psychotherapy.

Psychotherapy shall be at least once a week unless otherwise approved by the board. Respondent shall provide the therapist with a copy of the board's accusation and decision no later than the first therapy session. Respondent shall take all necessary steps to ensure that the treating therapist submits written quarterly reports to the board concerning respondent's fitness to practice, progress in treatment, and such other information as may be required by the board or its designee.

If at any time the treating therapist determines that respondent cannot practice safely or independently, the therapist shall notify the board immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice until notified by the board that practice may be resumed.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

20. Medical Evaluation (Appropriate for those cases where the evidence demonstrates that the respondent has had a physical problem/disability which was a contributing cause of the violations and which may affect the respondent's ability to practice.)

Within thirty (30) days of the effective date of this decision, and on a periodic basis thereafter as may be required by the board or its designee, respondent shall undergo a medical evaluation, at respondent's own expense, by a board-appointed or board-approved physician who shall furnish a medical report to the board. The approved physician shall be provided with a copy of the board's [accusation or petition to revoke probation] and decision. A record of this notification must be provided to the board upon request. Respondent shall sign a release authorizing the physician to furnish the board with a current diagnosis and a written report regarding the respondent's ability to function independently as a pharmacist with safety to the public. Respondent shall comply with all the recommendations of the physician if directed by the board or its designee.

If the physician recommends, and the board or its designee directs, that respondent undergo medical treatment, respondent shall, within thirty (30) days of written notice from the board, submit to the board or its designee, for prior approval, the name and qualifications of a licensed physician of respondent's choice. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of treatment with the approved physician. Should respondent, for any reason, cease treatment with the approved physician, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment, submit the name of a replacement physician of respondent's choice to the board or its designee for prior approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of treatment with the approved replacement. Failure to comply with any deadline stated by this paragraph shall be considered a violation of probation.

Upon approval of the initial or any subsequent physician, respondent shall undergo and continue treatment with that physician, at respondent's own expense, until the treating physician recommends in writing to the board, and the board or its designee agrees by way of a written

notification to respondent, that no further treatment is necessary. Upon receipt of such recommendation from the treating physician, and before determining whether to accept or reject said recommendation, the board or its designee may require respondent to undergo, at respondent's own expense, a medical evaluation by a separate board-appointed or board-approved physician. If the approved evaluating physician recommends that respondent continue treatment, the board or its designee may require respondent to continue treatment.

Respondent shall take all necessary steps to ensure that any treating physician submits written quarterly reports to the board concerning respondent's fitness to practice, progress in treatment, and other such information as may be required by the board or its designee.

If at any time an approved evaluating physician or respondent's approved treating physician determines that respondent is unable to practice safely or independently as a pharmacist, the evaluating or treating physician shall notify the board immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice until notified by the board that practice may be resumed.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

(Option language to be used in addition to standard language)
Option: Commencing on the effective date of this decision, respondent shall not engage in the practice of pharmacy until notified in writing by the board that respondent has been deemed medically fit to practice safely and independently, and the board or its designee approves said recommendation.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the

board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs or controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

(Option language to be used in addition to standard language)
Option: If recommended by the evaluating physician and approved by the board, respondent shall be suspended from practicing pharmacy until the treating physician recommends, in writing, stating the basis therefor, that respondent can safely and independently resume the practice of a pharmacist, and the board or its designee approves said recommendation. Respondent shall not resume practice until notified by the board that practice may be resumed.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

21. Pharmacists Recovery Program (PRP) (Appropriate for chemical dependency (alcohol, drugs), or psychiatric disorders (mental illness, emotional disturbance, gambling)

Within thirty (30) days of the effective date of this decision, respondent shall contact the Pharmacists Recovery Program (PRP) for evaluation, and shall immediately thereafter enroll, successfully participate in, and complete the treatment contract and any subsequent addendums as recommended and provided by the PRP and as approved by the board or its designee. The costs for PRP participation shall be borne by the respondent.

If respondent is currently enrolled in the PRP, said participation is now mandatory and as of the effective date of this decision is no longer considered a self-referral under Business and Professions Code section 4362(c)(2). Respondent shall successfully participate in and complete his or her current contract and any subsequent addendums with the PRP.

Failure to timely contact or enroll in the PRP, or successfully participate in and complete the treatment contract and/or any addendums, shall be considered a violation of probation.

Probation shall be automatically extended until respondent successfully completes the PRP. Any person terminated from the PRP program shall be automatically suspended by the board. Respondent may not resume the practice of pharmacy until notified by the board in writing.

Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall result in the automatic suspension of practice by respondent and shall be considered a violation of probation. Respondent may not resume the practice of pharmacy until notified by the board in writing.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

Respondent shall pay administrative fees as invoiced by the PRP or its designee. Fees not timely paid to the PRP shall constitute a violation for probation. The board will collect unpaid administrative fees as part of the annual probation monitoring costs if not submitted to the PRP.

(Option language to be used in addition to standard language)
Option: Respondent shall work in a pharmacy setting with access to controlled substances for six (6) consecutive months before successfully completing probation. If respondent fails to do so, probation shall be automatically extended until this condition has been met. Failure to satisfy this condition within six (6) months beyond the original date of expiration of the term of probation shall be considered a violation of probation.

22. Random Drug Screening (If PRP provision is required, this term is also to be included to allow for continued fluid monitoring by the Board in cases where a respondent successfully completes the PRP before completion of the probation period; terms is also appropriate for those cases where the evidence demonstrates that the respondent may have a problem with chemical dependency (drugs, alcohol) but where the PRP is not required.)

Respondent, at his or her own expense, shall participate in random testing, including but not limited to biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other drug screening program as directed by the board or its designee. Respondent may be required to participate in testing for the entire probation period and the frequency of testing will be determined by the board or its designee. At all times, respondent shall fully cooperate with the board or its designee, and shall, when directed, submit to such tests and samples for the detection of alcohol, narcotics, hypnotics, dangerous drugs or other controlled substances as the board or its designee may direct. Failure to timely submit to testing as directed shall be considered a violation of probation. Upon request of the board or its designee, respondent shall provide documentation from a licensed practitioner that the prescription for a detected drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall be considered a violation of probation and shall result in the automatic suspension of practice of pharmacy by respondent. Respondent may not resume the practice of pharmacy until notified by the board in writing.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During suspension. respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

23. Abstain from Drugs and Alcohol Use

Respondent shall completely abstain from the possession or use of alcohol, controlled substances, dangerous drugs and their associated paraphernalia except when the drugs are lawfully prescribed by a licensed practitioner as part of a documented medical treatment. Upon request of the board or its designee, respondent shall provide documentation from the licensed practitioner that the prescription for the drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be

considered a violation of probation. Respondent shall ensure that he or she is not in the same physical location as individuals who are using illicit substances even if respondent is not personally ingesting the drugs. Any possession or use of alcohol, controlled substances, or their associated paraphernalia not supported by the documentation timely provided, and/or any physical proximity to persons using illicit substances, shall be considered a violation of probation.

24. Prescription Coordination and Monitoring of Prescription Use (Appropriate for chemical dependency (alcohol, drugs), or psychiatric disorders (mental illness, emotional disturbance, gambling)

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board, for its prior approval, the name and qualifications of a single physician, nurse practitioner, physician assistant, or psychiatrist of respondent's choice, who shall be aware of the respondent's history [with the use of alcohol, controlled substances, and/or dangerous drugs, and/or of mental illness, and/or of gambling addiction] and who will coordinate and monitor any prescriptions for respondent for dangerous drugs, controlled substances or mood-altering drugs. The approved practitioner shall be provided with a copy of the board's [accusation or petition to revoke probation] and decision. A record of this notification must be provided to the board upon request. Respondent shall sign a release authorizing the practitioner to communicate with the board about respondent's treatment(s). The coordinating physician, nurse practitioner, physician assistant, or psychiatrist shall report to the board on a quarterly basis for the duration of probation regarding respondent's compliance with this condition. If any substances considered addictive have been prescribed, the report shall identify a program for the time limited use of any such substances. The board may require that the single coordinating physician, nurse practitioner, physician assistant or psychiatrist be a specialist in addictive medicine, or consult a specialist in addictive medicine. Should respondent, for any reason, cease supervision by the approved practitioner, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment, submit the name of a replacement physician, nurse practitioner, physician assistant, or psychiatrist of respondent's choice to the board or its designee for its prior approval. Failure to timely submit the selected practitioner or replacement practitioner to the board for approval, or to ensure the required reporting thereby on the quarterly reports, shall be considered a violation of probation.

If at any time an approved practitioner determines that respondent is unable to practice safely or independently as a pharmacist, the practitioner shall notify the board immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice until notified by the board that practice may be resumed.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

25. Community Services Program

Within sixty (60) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, a community service program in which respondent shall provide free health-care related services on a regular basis to a community or charitable facility or agency for at least _____ hours per _____ for the first _____ of probation. Within thirty (30) days of board approval thereof, respondent shall submit documentation to the board demonstrating commencement of the community service program. A record of this notification must be provided to the board upon request. Respondent shall report on progress with the community service program in the quarterly reports. Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

26. Restitution (Appropriate in cases of drug diversion, theft, fraudulent billing, or patient harm resulting from negligence or incompetence.)

Within _____ days of the effective date of this decision, respondent shall pay restitution to _____ in the amount of $ _____. Failure to make restitution by this deadline shall be considered a violation of probation.

27. Remedial Education

Within [thirty (30), sixty (60), ninety (90)] days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to [the grounds for discipline]. The program of remedial education shall consist of at least _____ hours, which shall be completed within _____ months/year at respondent's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes.

Failure to timely submit or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee.

Following the completion of each course, the board or its designee may require the respondent, at his or her own expense, to take an approved examination to test the respondent's knowledge of the course. If the respondent does not achieve a passing score on the examination, this failure shall be considered a violation of probation. Any such examination failure shall require respondent to take another course approved by the board in the same subject area.

Option: Respondent shall be restricted from the practice of [areas where a serious deficiency has been identified] until the remedial education program has been successfully completed.

28. Pharmacy Self-Assessment Mechanism

Within the first year of probation, respondent shall complete the Pharmacist Self-Assessment Mechanism (PSAM) examination provided by the National Association of Boards of Pharmacy (NABP). Respondent shall submit a record of completion to the board demonstrating he/she has completed this examination. Respondent shall bear all costs for the examination. Continuing education hours received for this examination shall not be used as part of the required continuing education hours for renewal purposes.

Failure to timely complete the PSAM or submit documentation thereof shall be considered a violation of probation.

Option A: Respondent shall waive any rights to confidentiality and provide examination results to the board or its designee.

Option B: (This term must be accompanied by the "Remedial Education" term. [Include/Modify Remedial Education Term to Conform].) Respondent shall waive any rights to confidentiality and provide examination results to the board or its designee. Based on the results of the examination, the board shall determine which courses are appropriate for remedial education.

29. Intern Pharmacist Experience

Within ninety (90) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, a pharmacy intern training program consisting of _____ hours to be served as an intern pharmacist in a community and/or institutional pharmacy as directed. Respondent shall successfully complete the intern hours within the first year of probation and shall, by no later than one (1) year from the effective date of this decision, submit proof satisfactory to the board of completion of this experience signed under penalty of perjury by both the respondent and supervising pharmacist. Failure to timely complete or document the required intern experience shall be considered a violation of probation.

30. Supervised Practice

During the period of probation, respondent shall practice only under the supervision of a licensed pharmacist not on probation with the board. Upon and after the effective date of this decision, respondent shall not practice pharmacy and his or her license shall be automatically suspended until a supervisor is approved by the board or its designee. The supervision shall be, as required by the board or its designee, either:

Continuous – At least 75% of a work week
Substantial - At least 50% of a work week
Partial - At least 25% of a work week
Daily Review - Supervisor's review of probationer's daily activities within 24 hours

Within thirty (30) days of the effective date of this decision, respondent shall have his or her supervisor submit notification to the board in writing stating that the supervisor has read the decision in case number _____ and is familiar with the required level of supervision as determined by the board or its designee. It shall be the respondent's responsibility to ensure

that his or her employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.

If respondent changes employment, it shall be the respondent's responsibility to ensure that his or her employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Respondent shall have his or her new supervisor, within fifteen (15) days after employment commences, submit notification to the board in writing stating the direct supervisor and pharmacist-in-charge have read the decision in case number _____ and is familiar with the level of supervision as determined by the board. Respondent shall not practice pharmacy and his or her license shall be automatically suspended until the board or its designee approves a new supervisor. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.

Within ten (10) days of leaving employment, respondent shall notify the board in writing.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

31. No Supervision of Ancillary Personnel

During the period of probation, respondent shall not supervise any ancillary personnel, including, but not limited to, pharmacy technicians or designated representatives in any entity licensed by the board.

Failure to comply with this provision shall be considered a violation of probation.

32. No Ownership of Licensed Premises

Respondent shall not own, have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm,

partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

Option: Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

33. Separate File of Records (For pharmacist owners and pharmacists-in-charge)

Respondent shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

34. Report of Controlled Substances (For pharmacist owners and pharmacists-in-charge)

Respondent shall submit quarterly reports to the board detailing the total acquisition and disposition of such controlled substances as the board may direct. Respondent shall specify the manner of disposition (e.g., by prescription, due to burglary, etc.) or acquisition (e.g., from a manufacturer, from another retailer, etc.) of such controlled substances. Respondent shall report on a quarterly basis or as directed by the board. The report shall be delivered or mailed to the board no later than ten (10) days following the end of the reporting period. Failure to timely prepare or submit such reports shall be considered a violation of probation.

35. No Access to Controlled Substances

During the period of probation and as directed by the board or its designee, respondent shall not order, possess, dispense or otherwise have access to any controlled substance(s) in Schedule II, III, IV or V (Health and Safety Code sections 11055-11058 inclusive). Respondent shall not order, receive or retain any security prescription forms. Failure to comply with this restriction shall be considered a violation of probation.

36. Criminal Probation/Parole Reports

Respondent shall provide a copy of the conditions of any criminal probation/parole to the board, in writing, within ten (10) days of the issuance or modification of those conditions. Respondent shall provide the name of his or her probation/parole officer to the board, in writing, within ten (10) days after that officer is designated or a replacement for that officer is designated. Respondent shall provide a copy of all criminal probation/parole reports to the board within ten (10) days after respondent receives a copy of such a report. Failure to timely make any of the submissions required hereby shall be considered a violation of probation.

37. Consultant for Owner or Pharmacist-In-Charge

(Option #1 for pharmacist owners - primarily intended for appropriate cases where the respondent is the sole owner and pharmacist-in-charge of his or her own pharmacy, the standard language should be used in most cases.)

During the period of probation, respondent shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the board. Respondent may be a pharmacist-in-charge. However, if during the period of probation respondent serves as a pharmacist-in-charge, respondent shall retain an independent consultant at his or her own expense who shall be responsible for reviewing pharmacy operations on a [monthly/quarterly] basis for compliance by respondent with state and federal laws and regulations governing the practice of pharmacy and for compliance by respondent with the obligations of a pharmacist-in-charge. The consultant shall be a pharmacist licensed by and not on probation with the board and whose name shall be submitted to the board or its designee, for prior approval, within thirty (30) days of the effective date of this decision. Respondent shall not be a pharmacist-in-charge at more than one pharmacy or at any pharmacy of which he or she is not the sole owner. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.

(Option #2 - appropriate for pharmacists who are not pharmacy owners, but who wish, because of their current employment, to remain as the pharmacist-in-charge, and have provided documented mitigating evidence to warrant this option.)

During the period of probation, respondent shall not supervise any intern pharmacist, or serve as a consultant to any entity licensed by the board. In the event that the respondent is currently the pharmacist-in-charge of a pharmacy, the pharmacy shall retain an independent consultant at its own expense who shall be responsible for reviewing pharmacy operations on a [monthly/quarterly] basis for compliance by respondent with state and federal laws and regulations governing the practice of pharmacy and for compliance by respondent with the obligations of a pharmacist-in-charge. The consultant shall be a pharmacist licensed by and not on probation with the board and whose name shall be submitted to the board or its designee, for prior approval. Within thirty (30) days of the effective date of this decision. Respondent shall not be a pharmacist-in-charge at more than one pharmacy or at any pharmacy of which he or she is not the current PIC. The board may, in case of an employment change by respondent or for other reasons as deemed appropriate by the board or its designee, preclude the respondent from acting as a pharmacist-in-charge. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.

38. Tolling of Suspension

During the period of suspension, respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of the (10) days during suspension shall be considered a violation of probation. Moreover, any absence from California during the period of suspension exceeding ten (10) days shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days respondent is absent from California. During any such period of tolling of suspension, respondent must nonetheless comply with all terms and conditions of probation.

Respondent must notify the board in writing within ten (10) days of departure, and must further notify the board in writing within ten (10) days of return. The failure to provide such notification(s) shall constitute a violation of probation. Upon such departure and return, respondent shall not resume the practice of pharmacy until notified by the board that the period of suspension has been satisfactorily completed.

39. Surrender of DEA Permit

Within thirty (30) days of the effective date of this decision, respondent shall surrender his or her federal Drug Enforcement Administration (DEA) permit to the DEA, for cancellation. Respondent shall provide documentary proof of such cancellation to the board or its designee. Respondent is prohibited from prescribing until the board has received satisfactory proof of cancellation. Thereafter, respondent shall not apply/reapply for a DEA registration number without the prior written consent of the board or its designee.

Option: Respondent may obtain a DEA permit restricted to Schedule(s) _____ controlled substance(s).

Option: Respondent shall not order, receive, or retain any federal order forms, including 222 forms, for controlled substances.

40. Ethics Course

Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll in a course in ethics, at respondent's expense, approved in advance by the board or its designee. Failure to initiate the course during the first year of probation, and complete it within the second year of probation, is a violation of probation.

Respondent shall submit a certificate of completion to the board or its designee within five days after completing the course.

PHARMACY TECHNICIAN

The board files cases against pharmacy technicians where the violation(s) involve significant misconduct on the part of the licensee. The board believes that revocation is typically the appropriate penalty when grounds for discipline are found to exist. Grounds for discipline include, but are not limited to the following violation(s) of law(s) involving:

- Possession of dangerous drugs and/or controlled substances
- Use of dangerous drugs and/or controlled substances
- Possession for sale of dangerous drugs and/or controlled substances
- Personal misuse of drugs or alcohol

If revocation is not imposed, the board recommends a minimum Category III level of discipline be imposed on the pharmacy technician. This would include suspension and probation.

In addition, a pharmacy technician would be required to obtain certification as defined by Business and Professions Code section 4202(a)(4) prior to resuming work as a pharmacy technician. The board believes that certification prior to resuming work is always warranted in cases where a pharmacy technician license is disciplined but not revoked.

Pharmacy technicians are issued a license based on minimal education, training requirements or certification. No examination is required for issuance of the registration. Pharmacy technicians are not independent practitioners and must work under the supervision of a pharmacist. To place a pharmacy technician on probation places an additional burden on the pharmacist (who may or may not be on probation) to ensure that the respondent pharmacy technician complies with the terms and conditions of his or her probation.

TERMS OF PROBATION – PHARMACY TECHNICIAN

A minimum three-year probation period has been established by the board as appropriate in most cases where probation is imposed. A minimum five-year probation period has been established by the board as appropriate where self-administration or diversion of controlled substances is involved. Terms and conditions are imposed to provide consumer protection and to allow the probationer to demonstrate rehabilitation. A suspension period may also be required as part of the probation order. The board prefers that any stayed order be for revocation rather than for some period of suspension.

Probation conditions are divided into two categories: (1) standard conditions that shall appear in all probation cases, and (2) optional conditions that depend on the nature and circumstances of a particular case. These conditions may vary depending on the nature of the offense(s).

The board may also impose any other condition appropriate to the case where the condition is not contrary to public policy.

CATEGORY OF VIOLATIONS AND RECOMMENDED PENALTIES

CATEGORY III - Penalty

Minimum: Revocation; Revocation stayed, 90 days actual suspension, three years probation. All standard terms and conditions shall be included and optional terms and conditions as appropriate.

Maximum: Revocation

Applies to all applicable statutes and regulations

MODEL DISCIPLINARY LANGUAGE – PHARMACY TECHNICIAN

The following standardized language shall be used in every decision where the order of condition is imposed.

Revocation

Pharmacy technician license number _____, issued to respondent _____ is revoked. Respondent shall relinquish his or her technician license to the board within ten (10) days of the effective date of this decision. Respondent may not reapply or petition the board for reinstatement of his or her revoked technician license for three (3) years from the effective date of this decision.

A condition of reinstatement shall be that the respondent is certified as defined in Business and Professions Code section 4202(a)(4) and provides satisfactory proof of certification to the board.

Respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____ within fifteen (15) days of the effective date of this decision.

Option: As a condition precedent to reinstatement of his or her revoked technician license respondent shall reimburse the board for its costs of investigation and prosecution in the amount of $_____. Said amount shall be paid in full prior to the reapplication or reinstatement of his or her revoked technician license, unless otherwise ordered by the board.

Suspension

As part of probation, respondent is suspended from working as a pharmacy technician for _____ beginning the effective date of this decision.

During suspension, respondent shall not enter any pharmacy area or any portion of or any other board licensed premises (wholesaler, veterinary food-animal drug retailer or any other distributor of drugs) any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not do any act involving drug selection, selection of stock, manufacturing, compounding or dispensing; nor shall respondent manage, administer, or assist any licensee of the board. Respondent shall not have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances.

Respondent shall not direct, control or perform any aspect of the practice of pharmacy. Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

Standard Stay/Probation Order

Pharmacy technician license number _____ is revoked; however the revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Issuance of Probationary License (In cases where a Statement of Issues has been filed.)

Upon satisfaction of all statutory and regulatory requirements for issuance of a license, a license shall be issued to respondent and immediately revoked; the order of revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Surrender

Respondent surrenders pharmacy technician license number _____ as of the effective date of this decision. Respondent shall relinquish his or her pharmacy technician license to the board within ten (10) days of the effective date of this decision.

The surrender of respondent's license and the acceptance of the surrendered license by the board shall constitute the imposition of discipline against respondent. This decision constitutes a record of discipline and shall become a part of respondent's license history with the board.

Respondent understands and agrees that if he or she ever files an application for licensure or a petition for reinstatement in the State of California, the board shall treat it as a new application for licensure.

Respondent may not apply for any license, permit, or registration from the board for three (3) years from the effective date of this decision. Respondent stipulates that should he or she apply for any license from the board on or after the effective date of this decision, all allegations set forth in the [accusation or petition to revoke probation] shall be deemed to be true, correct and admitted by respondent when the board determines whether to grant or deny the application. Respondent shall satisfy all requirements applicable to that license as of the date the application is submitted to the board, including, but not limited to certification by a nationally recognized body prior to the issuance of a new license. Respondent is required to report this surrender as disciplinary action.

Respondent further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution in the amount of $_____ within _____ days of the effective date of this decision.

Option: Respondent stipulates that should he or she apply for any license from the board on or after the effective date of this decision, investigation and prosecution costs in the amount of $_____ shall be paid to the board prior to issuance of the license.

Public Reprimand

It is hereby ordered that a public reprimand be issued against pharmacy technician license, _____. Respondent is required to report this reprimand as a disciplinary action.

Adoption of Stipulation

It is understood by respondent that, in deciding whether to adopt this stipulation, the board may receive oral and written communication from its staff and the Office of the Attorney General. Communications pursuant to this paragraph shall not disqualify the board or other persons from future participation in this or any other matter affecting respondent. In the event this settlement is not adopted by the board, the stipulation will not become effective and may not be used for any purpose, except this paragraph, which shall remain in effect.

STANDARD CONDITIONS – To be included in all probation decisions/orders.

1. Certification Prior to Resuming Work
2. Obey All Laws
3. Report to the Board
4. Interview with the Board
5. Cooperate with Board Staff
6. Notice to Employers
7. Reimbursement of Board Costs
8. Probation Monitoring Costs
9. Status of License
10. License Surrender While on Probation/Suspension
11. Notification of a Change in Name, Residence Address, Mailing Address or Employment
12. Tolling of Probation
13. Violation of Probation
14. Completion of Probation

OPTIONAL CONDITIONS

15. No Ownership of Licensed Premises
16. Attend Substance Abuse Recovery Relapse Prevention and Support Groups
17. Random Drug Screening
18. Work Site Monitor
19. Notification of Departure
20. Abstain from Drugs and Alcohol Use
21. Tolling of Suspension
22. Restitution

STANDARD CONDITIONS: TO BE INCLUDED IN ALL PROBATIONS

1. Certification Prior to Resuming Work

Respondent shall be automatically suspended from working as a pharmacy technician until he or she is certified as defined by Business and Professions Code section 4202(a)(4) and provides satisfactory proof of certification to the board. Respondent shall not resume working as a pharmacy technician until notified by the board. Failure to achieve certification within one (1) year shall be considered a violation of probation. Respondent shall not resume working as a pharmacy technician until notified by the board.

During suspension, respondent shall not enter any pharmacy area or any portion of any other board licensed premises (wholesaler, veterinary food-animal drug retailer or any other distributor of drugs) any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not do any act involving drug selection, selection of stock, manufacturing, compounding or dispensing; nor shall respondent manage, administer, or assist any licensee of the board. Respondent shall not have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances. Respondent shall not resume work until notified by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises by the board in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

2. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's _____ license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

3. Report to the Board

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports

in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

4. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear at two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

5. Cooperate with Board Staff

Respondent shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his or her probation. Failure to cooperate shall be considered a violation of probation.

6. Notice to Employers

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number _____ and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his or her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number _____and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgement(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify his or her direct supervisor, pharmacist-in-charge and owner at every pharmacy of the terms and conditions of the decision in case number _____ in advance of the respondent commencing work at each pharmacy. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause his or her direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he or she has read the decision in case number _____ and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgements to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary or relief service or pharmacy management service as a pharmacy technician or in any position for which a pharmacy technician license is a requirement or criterion for employment, whether the respondent is considered an employee, independent contractor or volunteer.

7. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____. Respondent shall make said payments as follows: _____. There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent shall not relieve respondent of his or her responsibility to reimburse the board its costs of investigation and prosecution.

8. Probation Monitoring Costs

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

9. Status of License

Respondent shall, at all times while on probation, maintain an active, current pharmacy technician license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If respondent's pharmacy technician license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

10. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease work due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her pharmacy technician license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish his or her pharmacy technician license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent may not reapply for any license, permit, or registration from the board for three (3) years from the effective date of the surrender. Respondent shall meet all

requirements applicable to the license sought as of the date the application for that license is submitted to the board.

11. Notification of a Change in Name, Residence Address, Mailing Address or Employment

Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address and mailing address, or phone number.

Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

12. Tolling of Probation

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacy technician in California for a minimum of _____ hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease working as a pharmacy technician for a minimum of _____ hours per calendar month in California, respondent must notify the board in writing within ten (10) days of cessation of work and must further notify the board in writing within ten (10) days of the resumption of the work. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

> "Cessation of work" means calendar month during which respondent is not working for at least _____ hours as a pharmacy technician, as defined in Business and Professions Code section 4115. “Resumption of work” means any calendar month during which respondent is working as a pharmacy technician for at least _____ hours as a pharmacy technician as defined by Business and Professions Code section 4115.

13. Violation of Probation

If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a

violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction, and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

14. Completion of Probation

Upon written notice by the board indicating successful completion of probation, respondent's pharmacy technician license will be fully restored.

OPTIONAL CONDITIONS OF PROBATION

15. No Ownership of Licensed Premises

Respondent shall not own, have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

Option: Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective of this decision. Violation of this restriction shall be considered a violation of probation.

16. Attend Substance Abuse Recovery Relapse Prevention and Support Groups (Appropriate for those cases with chemical dependency (alcohol, drugs))

Within thirty (30) days of the effective date of this decision, respondent shall begin regular attendance at a recognized and established substance abuse recovery support group in California, (e.g., Alcoholics Anonymous, Narcotics Anonymous, etc.) which has been approved by the board or its designee. Respondent must attend at least one group meeting per week unless otherwise directed by the board or its designee. Respondent shall continue regular attendance and submit signed and dated documentation confirming attendance with each quarterly report for the duration of probation. Failure to attend or submit documentation thereof shall be considered a violation of probation.

17. Random Drug Screening (Appropriate for those cases with chemical dependency (alcohol, drugs))

Respondent, at his or her own expense, shall participate in random testing, including but not limited to biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other drug screening program as directed by the board or its designee. Respondent may be required to participate in testing for the entire probation period and the frequency of testing will be

determined by the board or its designee. At all times respondent shall fully cooperate with the board or its designee, and shall, when directed, submit to such tests and samples for the detection of alcohol, narcotics, hypnotics, dangerous drugs or other controlled substances as the board or its designee may direct. Failure to timely submit to testing as directed shall be considered a violation of probation. Upon request of the board or its designee, respondent shall provide documentation from a licensed practitioner that the prescription for a detected drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall be considered a violation of probation and shall result in the automatic suspension of work by respondent. Respondent may not resume work as a pharmacy technician until notified by the board in writing.

During suspension, respondent shall not enter any pharmacy area or any portion of or any other board licensed premises (wholesaler, veterinary food-animal drug retailer or any other distributor of drugs) any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not do any act involving drug selection, selection of stock, manufacturing, compounding or dispensing; nor shall respondent manage, administer, or assist any licensee of the board. Respondent shall not have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances. Respondent shall not resume work until notified by the board.

Respondent shall not direct, control or perform any aspect of the practice of pharmacy. Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

18. Work Site Monitor (Appropriate for those cases with chemical dependency (alcohol, drugs))

Within ten (10) days of the effective date of this decision, respondent shall identify a work site monitor, for prior approval by the board, who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the board quarterly. Should the designated work site monitor determine at any time during the probationary period that respondent has not maintained sobriety, he or she shall notify the board immediately, either orally or in writing as directed. Should respondent change employment, a new work site monitor must be designated, for prior approval by the board, within ten (10) days of commencing new employment. Failure to identify an acceptable initial or replacement work site monitor, or to ensure quarterly reports are submitted to the board, shall be considered a violation of probation.

19. Notification of Departure (Appropriate for those cases with chemical dependency (alcohol, drugs))

Prior to leaving the probationary geographic area designated by the board or its designee for a period greater than twenty-four (24) hours, respondent shall notify the board verbally and in writing of the dates of departure and return. Failure to comply with this provision shall be considered a violation of probation.

20. Abstain from Drugs and Alcohol Use (Appropriate for those cases with chemical dependency (alcohol, drugs))

Respondent shall completely abstain from the possession or use of alcohol, controlled substances, dangerous drugs and their associated paraphernalia except when the drugs are lawfully prescribed by a licensed practitioner as part of a documented medical treatment. Upon request of the board or its designee, respondent shall provide documentation from the licensed practitioner that the prescription for the drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Respondent shall ensure that he or she is not in the same physical location as individuals who are using illicit substances even if respondent is not personally ingesting the drugs. Any possession or use of alcohol, controlled substances, or their associated paraphernalia not supported by the documentation timely provided, and/or any physical proximity to persons using illicit substances, shall be considered a violation of probation.

21. Tolling of Suspension

During the period of suspension, respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of ten (10) days during suspension shall be considered a violation of probation. Moreover, any absence from California during the period of suspension exceeding ten (10) days shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days respondent is absent from California. During any such period of tolling of suspension, respondent must nonetheless comply with all terms and conditions of probation.

Respondent must notify the board in writing within ten (10) days of departure, and must further notify the board in writing within ten (10) days of return. The failure to provide such notification(s) shall constitute a violation of probation. Upon such departure and return, respondent shall not return to work until notified by the board that the period of suspension has been satisfactorily completed.

22. Restitution (Appropriate in cases of drug diversion, theft, fraudulent billing, or patient harm resulting from negligence or incompetence.)

Within _____ days of the effective date of this decision, respondent shall pay restitution to _____ in the amount of $ _____. Failure to make restitution by this deadline shall be considered a violation of probation.

DESIGNATED REPRESENTATIVE

The board files cases against designated representatives where the violation(s) involve significant misconduct on the part of the licensee. The board believes that revocation is typically the appropriate penalty when grounds for discipline are found to exist. Grounds for discipline include, but are not limited to, the following violation(s) of law(s) involving:

- Possession of dangerous drugs and/or controlled substances
- Use of dangerous drugs and/or controlled substances
- Possession for sale of dangerous drugs and/or controlled substances
- Personal misuse of drugs or alcohol

If revocation is not imposed, the board recommends a minimum Category III level of discipline be imposed on the designated representative. This would include suspension and probation.

TERMS OF PROBATION – DESIGNATED REPRESENTATIVE

A minimum three-year probation period has been established by the board as appropriate in most cases where probation is imposed. A minimum five-year probation period has been established by the board as appropriate where self-administration or diversion of controlled substances is involved. Terms and conditions are imposed to provide consumer protection and to allow the probationer to demonstrate rehabilitation. A suspension period may also be required as part of the probation order. The board prefers that any stayed order be for revocation rather than for some period of suspension.

Probation conditions are divided into two categories: (1) standard conditions that shall appear in all probation cases, and (2) optional conditions that depend on the nature and circumstances of a particular case. These conditions may vary depending on the nature of the offense(s).

The board may also impose any other condition appropriate to the case where the condition is not contrary to public policy.

CATEGORY OF VIOLATIONS AND RECOMMENDED PENALTIES

CATEGORY III - Penalty

Minimum: Revocation; Revocation stayed, 90 days actual suspension, three years probation. All standard terms and conditions shall be included and optional terms and conditions as appropriate.

Maximum: Revocation

Applies to all applicable statutes and regulations

MODEL DISCIPLINARY LANGUAGE – DESIGNATED REPRESENTATIVE

The following standardized language shall be used in every decision where the order of condition is imposed.

Revocation

Designated Representative license number _____, issued to respondent _____ is revoked. Respondent shall relinquish his or her designated representative license to the board within ten (10) days of the effective date of this decision. Respondent may not petition the board for reinstatement of his or her revoked designated representative license for three (3) years from the effective date of this decision.

Respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____ within fifteen (15) days of the effective date of this decision.

Option: As a condition precedent to reinstatement of his or her revoked designated representative license respondent shall reimburse the board for its costs of investigation and prosecution in the amount of $_____. Said amount shall be paid in full prior to the reinstatement of his or her revoked designated representative license, unless otherwise ordered by the board.

Suspension

As part of probation, respondent is suspended from working as a designated representative for _____ beginning the effective date of this decision.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs licensed by the board, or any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not perform any of the duties of a designated representative, nor do any act involving drug selection, selection of stock, manufacturing, dispensing; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices and controlled substances. Respondent shall not resume work until notified by the board.

Respondent shall not direct, control or perform any aspect involving the distribution of dangerous drugs and devices and controlled substances. Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed entity in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

Standard Stay/Probation Order

Designated representative license number _____ is revoked; however, the revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Issuance of Probationary License (In cases where a Statement of Issues has been filed.)

Upon satisfaction of all statutory and regulatory requirements for issuance of a license, a license shall be issued to respondent and immediately revoked; the order of revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Surrender

Respondent surrenders designated representative license number _____ as of the effective date of this decision. Respondent shall relinquish his or her designated representative license to the board within ten (10) days of the effective date of this decision.

The surrender of respondent's license and the acceptance of the surrendered license by the board shall constitute the imposition of discipline against respondent. This decision constitutes a record of discipline and shall become a part of respondent's license history with the board.

Respondent understands and agrees that if he or she ever files an application for licensure or a petition for reinstatement in the State of California, the board shall treat it as a new application for licensure.

Respondent may not apply for any license, permit or registration from the board for three (3) years from the effective date of this decision. Respondent stipulates that should he or she apply for any license from the board on or after the effective date of this decision, all allegations set forth in the [accusation or petition to revoke probation] shall be deemed to be true, correct and admitted by respondent when the board determines whether to grant or deny the application. Respondent shall satisfy all requirements applicable to that license as of the date the application is submitted to the board prior to issuance of a new license. Respondent is required to report this surrender as disciplinary action.

Respondent further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution in the amount of $_____ within _____ days of the effective date of this decision.

Option: Respondent stipulates that should he or she apply for any license from the board on or after the effective date of this decision, investigation and prosecution costs in the amount of $_____ shall be paid to the board prior to issuance of the new license.

Public Reprimand

It is hereby ordered that a public reprimand be issued against designated representative license, _____. Respondent is required to report this reprimand as a disciplinary action.

Adoption of Stipulation

It is understood by respondent that, in deciding whether to adopt this stipulation, the board may receive oral and written communication from its staff and the Office of the Attorney General. Communications pursuant to this paragraph shall not disqualify the board or other persons from future participation in this or any other matter affecting respondent. In the event this settlement is not adopted by the board, the stipulation will not become effective and may not be used for any purpose, except this paragraph, which shall remain in effect.

STANDARD CONDITIONS – To be included in all probation decisions/orders.

1. Obey All Laws
2. Report to the Board
3. Interview with the Board
4. Cooperate with Board Staff
5. Notice to Employers
6. No Being Designated Representative-in-Charge
7. Reimbursement of Board Costs
8. Probation Monitoring Costs
9. Status of License
10. License Surrender While on Probation/Suspension
11. Notification of a Change in Name, Residence Address, Mailing Address or Employment
12. Tolling of Probation
13. Violation of Probation
14. Completion of Probation

OPTIONAL CONDITIONS

15. No Ownership of Licensed Premises
16. Attend Substance Abuse Recovery Relapse Prevention and Support Groups
17. Random Drug Screening
18. Work Site Monitor
19. Notification of Departure
20. Abstain from Drugs and Alcohol Use
21. Tolling of Suspension
22. Restitution

STANDARD CONDITIONS - TO BE INCLUDED IN ALL PROBATIONS

1. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- an arrest or issuance of a criminal complaint for violation of any state or federal law
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's _____ license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distribution or billing or charging for of any drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

2. Report to the Board

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, upon request at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff

Respondent shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his or her probation. Failure to cooperate shall be considered a violation of probation.

5. Notice to Employers

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number _____ and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his or her direct supervisor, designated representative-in-charge (including each new designated representative-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number _____ and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgement(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify his or her direct supervisor, designated representative-in-charge and owner at each entity licensed by the board of the terms and conditions of the decision in case number _____ in advance of the respondent commencing work at each licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause his or her direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he or she has read the decision in case number _____ and the terms and conditions imposed thereby. It shall be the respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgements to the board shall be considered a violation of probation.

> "Employment" within the meaning of this provision shall include any full-time, part-time, temporary or relief service or pharmacy management service as a designated representative or in any position for which a designated representative license is a requirement or criterion for employment, whether the respondent is considered an employee or independent contractor or volunteer.

6. No Being Designated Representative-in-Charge

During the period of probation, respondent shall not be the designated representative-in-charge of any entity licensed by the board unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

7. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____. Respondent shall make said payments as follows: _____. There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent shall not relieve respondent of his or her responsibility to reimburse the board its costs of investigation and prosecution.

8. Probation Monitoring Costs

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

9. Status of License

Respondent shall, at all times while on probation, maintain an active, current designated representative license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If respondent's designated representative license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

10. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease work due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her designated representative license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent’s license history with the board.

Upon acceptance of the surrender, respondent shall relinquish his or her designated representative license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent may not reapply for any license, permit, or registration from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

11. Notification of a Change in Name, Residence Address, Mailing Address or Employment

Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving and the address of the new employer, supervisor and owner and work schedule, if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address and mailing address, or phone number.
Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

12. Tolling of Probation

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a designated representative in California for a minimum of _____ hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease working as a designated representative for a minimum of _____ hours in California, respondent must notify the board in writing within ten (10) days of cessation of work and must further notify the board in writing within ten (10) days of the resumption of work. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

> "Cessation of work" means any calendar month during which respondent is not working as a designated representative for at least _____ hours as a designated representative as defined by Business and Professions Code section 4053.
> "Resumption of work" means any calendar month during which respondent is working as a designated representative for at least _____ hours as a designated representative as defined by Business and Professions Code section 4053.

13. Violation of Probation

If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction, and the period of probation shall be automatically extended, until the petition to revoke probation or accusation is heard and decided.

14. Completion of Probation

Upon written notice by the board indicating successful completion of probation, respondent's designated representative license will be fully restored.

OPTIONAL CONDITIONS OF PROBATION

15. No Ownership of Licensed Premises

Respondent shall not own, have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

Option: Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

16. Attend Substance Abuse Recovery Relapse Prevention and Support Groups (Appropriate for those cases with chemical dependency (alcohol, drugs))

Within thirty (30) days of the effective date of this decision, respondent shall begin regular attendance at a recognized and established substance abuse recovery support group in California, (e.g., Alcoholics Anonymous, Narcotics Anonymous, etc.) which has been approved by the board or its designee. Respondent must attend at least one group meeting per week unless otherwise directed by the board or its designee. Respondent shall continue regular attendance and submit signed and dated documentation confirming attendance with each quarterly report for the duration of probation. Failure to attend or submit documentation thereof shall be considered a violation of probation.

17. Random Drug Screening (Appropriate for those cases with chemical dependency (alcohol, drugs))

Respondent, at his or her own expense, shall participate in random testing, including but not limited to biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other drug screening program as directed by the board or its designee. Respondent may be required to participate in testing for the entire probation period and the frequency of testing will be determined by the board or its designee. At all times respondent shall fully cooperate with the board or its designee, and shall, when directed, submit to such tests and samples for the detection of alcohol, narcotics, hypnotics, dangerous drugs or other controlled substances as the board or its designee may direct. Failure to timely submit to testing as directed shall be considered a violation of probation. Upon request of the board or its designee, respondent shall provide documentation from a licensed practitioner that the prescription for a detected drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall be considered a violation of probation and shall result

in the automatic suspension of work by respondent. Respondent may not resume work as a designated representative until notified by the board in writing.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs licensed by the board, or any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not perform any of the duties of a designated representative, nor do any act involving drug selection, selection of stock, manufacturing, dispensing; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices and controlled substances. Respondent shall not resume work until notified by the board.

Respondent shall not direct, control or perform any aspect involving the distribution of dangerous drugs and devices and controlled substances. Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed entity in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

18. Work Site Monitor (Appropriate for those cases with chemical dependency (alcohol, drugs))

Within ten (10) days of the effective date of this decision, respondent shall identify a work site monitor, for prior approval by the board, who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the board quarterly. Should the designated work site monitor determine at any time during the probationary period that respondent has not maintained sobriety, he or she shall notify the board immediately, either orally or in writing as directed. Should respondent change employment, a new work site monitor must be designated, for prior approval by the board, within ten (10) days of commencing new employment. Failure to identify an acceptable initial or replacement work site monitor, or to ensure quarterly reports are submitted to the board, shall be considered a violation of probation.

19. Notification of Departure (Appropriate for those cases with chemical dependency (alcohol, drugs))

Prior to leaving the probationary geographic area designated by the board or its designee for a period greater than twenty-four (24) hours, respondent shall notify the board verbally and in writing of the dates of departure and return. Failure to comply with this provision shall be considered a violation of probation.

20. Abstain from Drugs and Alcohol Use (Appropriate for those cases with chemical dependency (alcohol, drugs))

Respondent shall completely abstain from the possession or use of alcohol, controlled substances, dangerous drugs and their associated paraphernalia except when the drugs are lawfully prescribed by a licensed practitioner as part of a documented medical treatment. Upon request of the board or its designee, respondent shall provide documentation from the licensed practitioner that the prescription for the drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be

considered a violation of probation. Respondent shall ensure that he or she is not in the same physical location as individuals who are using illicit substances even if respondent is not personally ingesting the drugs. Any possession or use of alcohol, controlled substances, or their associated paraphernalia not supported by the documentation timely provided, and/or any physical proximity to persons using illicit substances, shall be considered a violation of probation.

21. Tolling of Suspension

During the period of suspension, respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of ten (10) days during suspension shall be considered a violation of probation. Moreover, any absence from California during the period of suspension exceeding ten (10) days shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days respondent is absent from California. During any such period of tolling of suspension, respondent must nonetheless comply with all terms and conditions of probation.

Respondent must notify the board in writing within ten (10) days of departure, and must further notify the board in writing within ten (10) days of return. The failure to provide such notification(s) shall constitute a violation of probation. Upon such departure and return, respondent shall not resume work until notified by the board that the period of suspension has been satisfactorily completed.

22. Restitution (Appropriate in cases of drug diversion, theft, fraudulent billing, or patient harm resulting from negligence or incompetence.)

Within _____ days of the effective date of this decision, respondent shall pay restitution to _____ in the amount of $ _____. Failure to make restitution by this deadline shall be considered a violation of probation.

TERMS OF PROBATION – PREMISES

A minimum three-year probation period has been established by the board as appropriate in most cases where probation is imposed. A minimum five-year probation period has been established by the board as appropriate where self-administration or diversion of controlled substances has occurred at a licensed premises. Terms and conditions are imposed to provide consumer protection. A suspension period may also be required as part of the probation order. The board prefers that any stayed order be for revocation rather than for some period of suspension.

Probation conditions are divided into two categories: (1) standard conditions that shall appear in all probation cases, and (2) optional conditions that depend on the nature and circumstances of a particular case. These conditions may vary depending on the nature of the offense(s).

The board may also impose any other condition appropriate to the case where the condition is not contrary to public policy.

CATEGORIES OF VIOLATIONS AND RECOMMENDED PENALTIES

The California Pharmacy Law identifies offenses for which the board may take disciplinary action against a license. Included among grounds for discipline are violations of the Pharmacy Law itself, violations of regulations promulgated by the board, and violations of other state or federal statutes or regulations.

The following are categories of possible violations used by the board to determine appropriate disciplinary penalties. These categories represent the judgment of the board as to the perceived seriousness of particular offenses.

Under each category, the board has grouped statutes and regulations where violations would typically merit the recommended range of minimum to maximum penalties for that category. These lists are representative, and are not intended to be comprehensive or exclusive. Where a violation not included in these lists is a basis for disciplinary action, the appropriate penalty for that violation may be best derived by comparison to any analogous violation(s) that are included. Where no such analogous violation is listed, the category descriptions may be consulted.

These categories assume a single violation of each listed statute or regulation. For multiple violations, the appropriate penalty shall increase accordingly. Moreover, if an individual has committed violations in more than one category, the minimum and maximum penalties shall be those recommended in the highest category.

The board also has the authority, pursuant to Business and Professions Code section 4301(n), to impose discipline based on disciplinary action taken by another jurisdiction. The discipline imposed by the board will depend on the discipline imposed by the other jurisdiction, the extent of the respondent's compliance with the terms of that discipline, the nature of the conduct for which the discipline was imposed, and other factors set forth in these guidelines.

CATEGORY I

Minimum: Revocation; Revocation stayed; one-year probation. All standard terms and conditions shall be included and optional terms and conditions as appropriate.

Maximum: Revocation

Category I discipline is recommended for:

- violations which are relatively minor but are potentially harmful
- repeated violations of a relatively minor nature:

Violations of the following codes are representative of this category:

BUSINESS AND PROFESSIONS CODE

Article 3. Scope of Practice and Exemptions

4053 Exemptee Supervisor of Manufacturer, etc.: Requirements
4054 Supply by Manufacturer, etc. of Certain Dialysis Drugs and Devices
4056 Purchase of Drugs at Wholesale – Hospital Containing 100 Beds or Less
4057 Exceptions to Application of this Chapter
4058 Display of Original License
4062 Furnishing Dangerous Drugs During Emergency
4064 Emergency Refill of Prescription Without Prescriber Authorization
4065 Injection Card System; Requirements for Administration
4066 Furnishing Dangerous Drugs to Master or First Officer of Vessel

Article 4. Requirements for Prescription

4070 Reduction of Oral or Electronic Prescription to Writing
4071 Prescriber May Authorize Agent to Transmit Prescription; Schedule II Excluded
4072 Oral or Electronic Transmission of Prescription - Health Care Facility
4073 Substitution of Generic Drug - Requirements and Exceptions
4074 Drug Risk: Informing Patient; Providing Consultation for Discharge Medications
4076 Prescription Container - Requirements for Labeling
4077 Dispensing Dangerous Drug in Incorrectly Labeled Container

Article 5. Authority of Inspectors

4082 Names of Owners, Managers and Employees Open for Inspection

Article 6. General Requirements

4100 Change of Address or Name – Notification to Board
4103 Blood Pressure - Taking by Pharmacist

Article 7. Pharmacies

4114 Intern Pharmacist: Activities Permitted
4119.5 Transfer or Repackaging Dangerous Drugs by Pharmacy
4120 Nonresident Pharmacy: Registration Required
4121 Advertisement for Prescription Drug: Requirements; Restrictions
4122 Required Notice at Availability of Prescription Price Information, General Product Availability, Pharmacy Services; Providing Drug Price Information; Limitations on Price Information Requests
4123 Compounding Drug for Other Pharmacy for Parenteral Therapy; Notice to Board
4124 Dispensing Replacement Contact Lenses: Requirements; Patient Warnings; Registration with Medical Board; Application of Section to Nonresident Pharmacies

Article 9. Hypodermic Needles and Syringes

4141 Furnishing Without License
4142 Prescription Required
4143 Exemption: Sale to Other Entity, Physician, etc.
4144 Industrial Use Exception
4145 Exception: Furnishing for Administration of Insulin, Adrenaline, or Specified Animal Uses; Conditions
4148 Confiscation if Found Outside Licensed Premises
4149 Sale by Distributor

Article 10. Pharmacy Corporations

4151 Licensure Requirements
4152 Corporate Name Requirements
4153 Shareholder Income While Disqualified
4156 Unprofessional Conduct by Corporation

Article 11. Wholesalers and Manufacturers

4161 Nonresident Wholesaler: When License Required; Application
4162 Issuance or Renewal of Wholesaler License; Surety Bond
4164 Reports Required
4165 Sale or Transfer of Dangerous Drug or Device Into State: Furnishing Records to Authorized Officer on Demand; Citation for Non-compliance
4166 Shipping of Dangerous Drugs or Devices – Wholesaler or Distributor
4167 Wholesaler: Bar on Obtaining Dangerous Drugs or Devices It Cannot Maintain on Licensed Premises

Article 13. Non-Profit or Free Clinics

4180 Purchase of Drugs at Wholesale Only with License: Eligible Clinics
4181 License Requirements; Policies and Procedures; Who May Dispense
4182 Duties of Professional Director; Consulting Pharmacist Required
4183 No Professional Dispensing Fee
4184 Dispensing Schedule II Substance Prohibited
4186 Automated Drug Delivery Systems

Article 14. Surgical Clinics

4190 Purchase of Drugs at Wholesale: Permitted Uses of Drugs; Required Records and Policies; License Required
4191 Compliance with Department of Health Services Requirements; Who May Dispense Drugs
4192 Duties of Professional Director; Providing Information to Board
4193 Clinic Not Eligible for Professional Dispensing Fee; Ban on Offering Drugs for Sale
4194 Dispensing of Schedule II Substance by Clinic Prohibited; Physician May Dispense; Administration Authorized in Clinic

Article 15. Veterinary Food-Animal Drug Retailers

4196 License Required: Temporary License on Transfer of Ownership; Persons Authorized in Storage Area
4197 Minimum Standards: Security; Sanitation; Board Regulations; Waivers
4198 Written Policies and Procedures Required: Contents; Training of Personnel; Quality Assurance; Consulting Pharmacist

Article 17. Continuing Education

4231 Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee
4232 Content of Courses

Article 18. Poisons

4240 Application of Act

Article 20. Prohibitions and Offenses

4341 Advertisement of Prescription Drugs or Devices
4343 Buildings: Prohibition Against Use of Certain Signs Unless Licensed Pharmacy Within

CALIFORNIA CODE OF REGULATIONS, TITLE 16

1704 Change of Address
1705 Notification of Bankruptcy, Receivership or Liquidation
1708.2 Discontinuance of Business
1708.4 Pharmacist Handling Radioactive Drugs
1708.5 Pharmacy Furnishing Radioactive Drugs
1709 Names of Owners and Pharmacist in Charge
1714 Operational Standards and Security
1715.6 Reporting Drug Loss
1716 Variation from Prescriptions
1717 Pharmaceutical Practice
1717.1 Common Electronic Files
1717.4 Electronic Transmission of Prescriptions
1718.1 Manufacturer's Expiration Date

1726	Supervision of Intern Pharmacists
1728	Requirements for Examination
1732.1	Requirements for Accredited Providers
1732.3	Requirements for Continuing Education Courses
1732.4	Provider Audit Requirements
1732.5	Renewal Requirements for Pharmacist
1744	Drug Warnings
1751	Sterile Injectable Compounding Area
1751.01	Facility and Equipment Standards for Sterile Injectable Compounding from Non-Sterile Ingredients
1751.02	Policies and Procedures
1751.11	Furnishing to Home Health Agencies and Licensed Hospices
1751.12	Obligations of a Pharmacy Furnishing Portable Containers
1771	Posting of Notice of Suspension
1772	Disciplinary Condition of Suspension
1780	Minimum Standards for Wholesalers
1780.1	Minimum Standards for Veterinary Food-Animal Drug Retailers
1781	Exemption Certificate
1786	Exemptions
1787	Authorization to Distribute Hemodialysis Drugs and Devices
1790	Assembling and Packaging
1791	Labeling
1792	Receipt for Shipment

HEALTH AND SAFETY CODE

11100	Report of Certain Chemical: Chemicals Included; Exclusions; Penalties
11100.1	Report of Chemicals Received from Outside State; Penalties
11151	Limitation on Filling Prescriptions From Medical Students
11158	Prescription Required for Schedule II, III, IV, or V Controlled Substance; Exception for Limited Dispensing, Administration
11159	Chart Order Exemption for Patient in County or Licensed Hospital; Maintaining Record for Seven Years
11159.1	Chart Order Exemption for Clinic Patient; Maintaining Record for Seven Years
11159.2	Exception to Triplicate Prescription Requirement
11167	Emergency Dispensing of Schedule II Substance: Circumstances and Requirements
11167.5	Oral or Electronic Prescriptions for Schedule II Controlled Substance for Specified Inpatients, Residents, and Home Hospice Patients; Requirements
11171	Prescribing, etc. Controlled Substance Only as Authorized
11172	Antedating or Postdating Prescription Prohibited
11175	Prohibition on Obtaining or Possessing Nonconforming Prescription; Prohibition on Obtaining Controlled Substance by Nonconforming Prescription
11180	Prohibition on Controlled Substance Obtained or Possessed by Nonconforming Prescription
11200	Restrictions on Dispensing or Refilling; Refill of Schedule II Prescription Barred
11201	Emergency Refill of Schedule III, IV, or V Prescription; Circumstances; Requirements
11205	Maintenance and Retention of Records in Separate File
11206	Required Information on Prescription

11209 Delivery and Receiving Requirements for Schedule II, III, and IV Substances; Violation
11210 Issuing Prescription: By Whom; For What Purpose; Quantity to Be Prescribed
11250 Authorized Retail Sale by Pharmacists to Physicians, etc.; Required Order Form
11251 Authorized Wholesale Sale by Pharmacists
11252 Preservation of Federally Required Forms
11253 Duration of Retention
11255 Actions Constituting Sale
11256 Required Report of Order By or Sale to Out-of-State Wholesaler or Manufacturer
111225 to
111655 Adulterated or Misbranded Drugs or Devices

CODE OF FEDERAL REGULATIONS, TITLE 21

1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.
1301.14 Filing of application; acceptance for filing; defective applications.
1301.71 Security requirements generally.
1301.72 Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas.
1301.73 Physical security controls for non-practitioners; compounders for narcotic treatment programs; manufacturing and compounding areas.
1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.
1301.77 Security controls for freight forwarding facilities.
1301.90 Employee screening procedures.
1301.91 Employee responsibility to report drug diversion.
1301.92 Illicit activities by employees.
1302.03 Symbol required; exceptions.
1302.04 Location and size of symbol on label and labeling.
1302.05 Effective dates of labeling requirements.
1302.06 Sealing of controlled substances.
1302.07 Labeling and packaging requirements for imported and exported substances.
1304.11 Inventory requirements.
1304.31 Reports from manufacturers importing narcotic raw material.
1304.32 Reports of manufacturers importing coca leaves.
1304.33 Reports to ARCOS.
1305.03 Distributions requiring a Form 222 or a digitally signed electronic order.
1305.04 Persons entitled to order Schedule I and II controlled substances.
1305.05 Power of attorney.
1305.06 Persons entitled to fill orders for Schedule I and II controlled substances.
1305.11 Procedure for obtaining DEA Forms 222.
1305.12 Procedure for executing DEA Forms 222.
1305.14 Procedure for endorsing DEA Forms 222.
1305.15 Unaccepted and defective DEA Forms 222.
1305.16 Lost and stolen DEA Forms 222.
1306.03 Persons entitled to issue prescriptions.
1306.05 Manner of issuance of prescriptions.
1306.14 Labeling of substances and filling of prescriptions.

1306.24 Labeling of substances and filing of prescriptions.
1306.25 Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes.
1306.26 Dispensing without a prescription.
1307.11 Distribution by dispenser to another practitioner or reverse distributor.
1307.12 Distribution to supplier or manufacturer.
1307.13 Incidental manufacture of controlled substances.
1307.21 Procedure for disposing of controlled substances.
1700.1 to
1707.15 Child-resistant containers.

CATEGORY II

Minimum: Revocation; Revocation stayed, three years probation (five years probation where self-administration or diversion of controlled substances occurred at the licensed premises). All standard terms and conditions shall be included and optional terms and conditions as appropriate.

Maximum: Revocation

Category II discipline is recommended for:

- violations with a serious potential for harm
- violations which involve greater disregard for pharmacy law and public safety
- violations which reflect on ethics, care exercised or competence or a criminal conviction not involving dangerous drugs or controlled substances or involving possession or use of dangerous drugs or controlled substances.

Violations of the following codes are representative of this category:

BUSINESS AND PROFESSIONS CODE

650 Rebates or Discounts for Referral Prohibited
650.1 Lease Prohibition – Hospitals or Prescribers
651 Professional Advertising Requirements

Article 3. Scope of Practice and Exemptions

4051(b) Conduct Authorized by Pharmacist
4052 Furnishing to Prescriber; Permissible Procedures by Pharmacist in Health Care Facility or Clinic or for Other Health Care Provider
4060 Controlled Substance – Prescription Required; Exceptions
4061 Distribution of Drug as Sample; Written Request Required
4064 Emergency Refill of Prescription Without Prescriber Authorization
4067 Internet; Dispensing Dangerous Drugs or Devices without Prescription
4075 Proof of Identity Required – Oral or Electronic Prescription
4078 False or Misleading Label on Prescription

Article 6. General Requirements

4101 Pharmacist in Charge, Exemptee: Termination of Employment; Notification to Board
4104 Licensed Employee, Theft or Impairment: Pharmacy Procedures
4105 Retaining Records of Dangerous Drugs and Devices on Licensed Premises; Temporary Removal; Waivers; Access to Electronically Maintained Records

Article 7. Pharmacies

4112 Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation
4113 Pharmacist in Charge: Notification to Board; Responsibilities
4115 Pharmacy Technician: Activities Permitted; Required Supervision; Activities Limited to Pharmacist; Registration; Requirements for Registration; Ratios
4115.5 Pharmacy Technician Trainee; Placement; Supervision; Requirements
4116 Security of Dangerous Drugs and Devices in Pharmacy: Pharmacist Responsibility for Individuals on Premises; Regulations
4117 Admission to Area Where Narcotics are Stored, etc. – Who May Enter
4120 Nonresident Pharmacy: Registration Required
4125 Pharmacy Quality Assurance Program Required; Records Considered Peer Review Documents

Article 9. Hypodermic Needle and Syringes

4140 Unlawful Possession
4147 Disposal of Needle or Syringe

Article 11. Wholesalers and Manufacturers

4161 Nonresident Wholesaler: When License Required; Application
4163 Unauthorized Furnishing by Manufacturer or Wholesale
4164 Reports Required
4169(a)(1) Prohibited Acts

Article 13. Non-Profit of Free Clinics

4185 Inspection Permitted

Article 14. Surgical Clinics

4195 Inspection Permitted

Article 19. Disciplinary Proceedings

4301 Unprofessional Conduct - subsections (a)-(h), (j), and (l) - (q)
4302 Discipline of Corporate Licensee for Conduct of Officer, Director, Shareholder
4303 Nonresident Pharmacy: Grounds for Discipline
4304 Out-of-state Distributor: Authority to Discipline
4305 Disciplinary Grounds: Failure of Pharmacy, Pharmacist to Notify Board of Termination of Pharmacist in Charge; Continuing to Operate Without Pharmacist

4305.5 Disciplinary Grounds: Failure of Other Entity Licensed by Board, of Pharmacist or Exemptee to Notify Board of Termination of Pharmacist in Charge or Exemptee; Continuing to Operate Without Pharmacist or Exemptee
4306 Violation of Professional Corporation Act as Unprofessional Conduct
4306.5 Misuse of Education, etc. by Pharmacist Outside Course of Practice of Pharmacy as Unprofessional Conduct

Article 20. Prohibitions and Offenses

4326 Misdemeanor: Obtaining Needle or Syringe by Fraud, etc.; Unlawful Use of Needle or Syringe Obtained from Another
4328 Misdemeanor: Permitting Compounding, Dispensing, or Furnishing by Non-pharmacist
4330 Misdemeanor: Non-pharmacist Owner Failing to Place Pharmacist in Charge, Dispensing or Compounding Except by Pharmacist, Interfering with Pharmacist in Charge
4331 Misdemeanor: Medical Device Retailer, Wholesaler, Veterinary Food-Animal Drug Retailer Failing to Place Pharmacist or Exemptee in Charge, Permitting Dispensing or Compounding Except by Pharmacist or Exemptee
4333 Maintaining Prescriptions, Other Drug Records on Premises, Open to Inspection; Waiver; Willful Failure to Keep or Permit Inspection of Records of Prescriptions, Other Records as Misdemeanor
4340 Unlawful Advertising by Nonresident Pharmacy Not Registered with Board

Article 22. Unfair Trade Practices

4380 Resale of Preferentially Priced Drugs; Prohibition; Exceptions
4382 Board May Audit Sales to Walk-in Customers

CALIFORNIA CODE OF REGULATIONS, TITLE 16

1707.1 Duty to Maintain Medication Profiles (Patient Medication Records)
1707.2 Notice to Consumers and Duty to Consult
1707.3 Duty to Review Drug Therapy and Patient Medication Record Prior to Deliver
1709.1 Designation of Pharmacist in Charge
1714.1 Pharmacy Operation During Temporary Absence of a Pharmacist
1715 Self-Assessment of a Pharmacy by the Pharmacist-in-Charge
1715.5 Implementation of Electronic Monitoring of Schedule II Prescriptions
1716.1 Compounding Unapproved Drugs for Prescriber Office Use
1716.2 Record Requirements-Compounding for Future Furnishing
1717.2 Notice of Electronic Prescription Files
1717.3 Preprinted, Multiple Checkoff Prescription Blanks
1723.1 Confidentiality of Examination Questions
1745 Partial Filling of Schedule II Prescriptions
1751.10 Furnishing to Parenteral Patient at Home
1761(a) Erroneous or Uncertain Prescriptions
1764 Unauthorized Disclosure of Prescriptions
1765 Commissions, Gratuities, and Rebates
1766 False or Misleading Advertising
1775.3 Compliance with Orders of Abatement

1782	Reporting Sales of Drugs Subject to Abuse
1783	Manufacturer or Wholesaler Furnishing Drugs or Devices
1793.1	Duties of a Pharmacist
1793.2	Duties of a Pharmacy Technician
1793.3	Other Non-Licensed Pharmacy Personnel
1793.4	Qualifications for Registration as a Pharmacy Technician
1793.7	Requirements for Pharmacies Employing Pharmacy Technicians
1793.8	Technicians in Hospitals with Clinical Pharmacy Programs

HEALTH AND SAFETY CODE

11103	Report of Theft, Loss, or Shipping Discrepancy
11150	Persons Authorized to Write or Issue a Prescription
11152	Nonconforming Prescriptions Prohibited
11154	Prescription, etc. Must Be for Treatment; Knowing Soliciting of Unlawful Prescription, etc.
11156	Prescribing, etc. Controlled Substances to Addict Only as Authorized
11164	Prescriptions for Schedule II, III, IV and V Controlled Substance: Form and Content; Record of Practitioner Dispensing Schedule II Controlled Substance
11165(d)	CURES Transmission
11166	Time Limit for Filling Schedule II Prescription; Knowingly Filling Mutilated, Forged, or Altered Prescription Prohibited
11170	Prohibition on Prescribing, etc. Controlled Substance for Self
11179	Retention of Controlled Substance Prescription
11207	Only Pharmacist or Intern Authorized to Fill Prescription
11209	Delivery and Receiving Requirements for Schedule II, III, and IV Substances; Violation
11350	Possession of Specified Controlled Substance
11377	Unlawful Possession of Specified Substance

CODE OF FEDERAL REGULATIONS, TITLE 21

1304.03	Persons required to keep records and file reports.
1304.04	Maintenance of records and inventories.
1304.11	Inventory requirements.
1304.21	General requirements for continuing records.
1304.22	Records for manufacturers, distributors, dispensers, researchers, importers and exporters.
1305.07	Special procedures for filling certain orders.
1305.13	Procedure for filling DEA Forms 222.
1306.04	Purpose of issue of prescription.
1306.06	Persons entitled to fill prescriptions.
1306.11	Requirement prescription.
1306.12	Refilling prescriptions.
1306.13	Partial filling of prescriptions.
1306.21	Requirement of prescription.
1306.22	Refilling of prescriptions.
1306.23	Partial filling of prescriptions.

CATEGORY III

Minimum: Revocation; Revocation stayed, 90 days actual suspension, three to five years probation (five years probation where self-administration or diversion of controlled substances occurred at the licensed premises). All standard terms and conditions and optional terms and conditions as appropriate.
For a licensed premises, a minimum 14-28 days actual suspension.

Maximum: Revocation

Category III discipline is recommended for:

- most criminal convictions involving dangerous drugs or controlled substances
- knowing or willfully violating laws or regulations pertaining to dispensing or distributing dangerous drugs or controlled substances
- fraudulent acts committed in connection with the licensee's practice
- drug shortages
- violation of a licensee's corresponding responsibility.

Violations of the following codes are representative of this category:

BUSINESS AND PROFESSIONS CODE

Article 3. Scope of Practice and Exemptions

4051(a) Conduct Limited to Pharmacist
4059 Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions
4059.5 Who May Order Dangerous Drugs or Devices: Exceptions

Article 5. Authority of Inspectors

4080 Stock of Dangerous Drugs and Devices Kept Open for Inspection
4081 Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory
4085(a) Unlawful to Remove, Sell, Dispose of Embargoed Dangerous Drug or Dangerous Device

Article 7. Pharmacies

4110 License Required; Temporary Permit Upon Transfer of Ownership
4111 Restrictions on Prescriber Ownership

Article 11. Wholesalers and Manufacturers

4169(a)(2) to
4169(a)(5) Prohibited Acts

Article 15. Veterinary Food-Animal Retailers

4199 Labeling Requirements; Maintaining Prescription Records

Article 19. Disciplinary Proceedings

4301 Unprofessional Conduct - subsections (i) - (k) and (o)
4307 Prohibition of Association of Individual with Entity License by Board: Length of Prohibition; Individuals Covered; Imposition of Prohibition Through Administrative Act Proceeding
4308 Prohibited Association: Notification of Affected Licensees Known to Board

Article 20. Prohibitions and Offenses

4322 Misdemeanor or Infraction: False Representations to Secure License for Self or Others; False Representation of Licensure; Penalties
4323 Misdemeanor: False Representation of Self as Physician, Agent of Physician, etc. to Obtain Drug
4324 Felony or Misdemeanor: Forgery of Prescription; Possession of Drugs Obtained Through Forged Prescription
4325 Misdemeanor: Manufacture, Possession, etc. of False Prescription Blank
4327 Misdemeanor: Sale, Dispensing, or Compounding While Under the Influence of Drugs or Alcoholic Beverages
4329 Misdemeanor: Non-pharmacist Acting as Manager, Compounding, Dispensing or Furnishing Drugs
4332 Misdemeanor: Failure or Refusal to Maintain or Produce Required Drug or Device Records; Willful Production of False Records
4335 Voided License: Knowing Failure to Arrange for Disposition of Stock as Misdemeanor
4336 Felony: Knowing or Willful Use of Minor to Violate Specified Sections of Pharmacy Law: Exception for Pharmacist Furnishing Pursuant to a Prescription

Article 22. Unfair Trade Practices

4380 Resale of Preferentially Priced Drugs: Prohibition; Exceptions

CALIFORNIA CODE OF REGULATIONS, TITLE 16

1718 Current Inventory Defined
1761(b) Erroneous or Uncertain Prescriptions
1771 Posting of Notice of Suspension
1772 Disciplinary Condition of Suspension
1773 Disciplinary Conditions of Probation of Pharmacist
1774 Disciplinary Conditions of Probation of Permit

HEALTH AND SAFETY CODE

11104 Providing Chemical for Illicit Manufacturing; Evasion of Reporting Requirements; Penalties
11105 False Statement in Report
11150 Persons Authorized to Write or Issue a Prescription
11153 Responsibility for Legitimacy of Prescription; Corresponding Responsibility of Pharmacist

11153.5 Wholesaler or Manufacturer Furnishing Controlled Substance Other Than for Legitimate Medical Purpose; Knowing Violation; Factors in Assessing Legitimacy
11157 No False or Fictitious Prescriptions
11162.5 Counterfeiting or Possession of Counterfeit Triplicate Prescription Blank; Penalty
11167.5 Pharmacy Generated Prescription for Schedule II Controlled Substance in a Skilled Nursing Facility
11173 Fraud, Deceit, Misrepresentation or False Statement; False Representation; False Label
11174 Prohibition on Providing False Name or Address in Connection with Prescription, etc.
11351 Possession or Purchase for Sale of Specified Controlled Substance
11368 Forged or Altered Prescriptions
11375 Possession for Sale or Selling Specified Substance
11378 Possession for Sale
11550 Using or Being Under Influence of Controlled Substance
111295 Manufacturing, Selling or Offering for Sale an Adulterated Drug or Device
111300 Unlawful to Adulterate a Drug
111305 Unlawful to Receive in Commerce an Adulterated Drug
111440 Unlawful Manufacturer, selling a misbranded Drug
111445 Unlawful for a Person to Misbrand
111450 Unlawful to Receive into Commerce a Drug that is Misbranded

CATEGORY IV

Penalty: Revocation

Revocation is recommended for violations of the Uniform Controlled Substance Act (Heath and Safety Code 11000 et seq.) involving:

- possession for sale
- transportation
- importation
- sale
- use of a minor for the unlawful sale of controlled substances

Revocation is also recommended when:

- a respondent fails to file a notice of defense or to appear at a disciplinary hearing where the board has requested revocation in the accusation
- a respondent violates the terms and conditions of probation from a previous disciplinary order
- prior discipline has been imposed, as progressive discipline unless the respondent can demonstrate satisfactory evidence of rehabilitation.

Violations of the following codes are representative of this category:

HEALTH AND SAFETY CODE

11352 Importing, Selling, Furnishing Controlled Substance
11353 Adult Inducing Minor to Violate Provisions
11379 Transporting, Importing, Selling Controlled Substance
11380 Adult Using, Soliciting or Intimidating Minor for Violation

MODEL DISCIPLINARY LANGUAGE - PREMISES

The following standardized language shall be used in every decision where the order or condition is imposed.

Revocation

License number _____, issued to respondent _____, is revoked.

Respondent owner shall, by the effective date of this decision, arrange for the destruction of, the transfer to, sale of or storage in a facility licensed by the board of all controlled substances and dangerous drugs and devices. Respondent owner shall provide written proof of such disposition, submit a completed Discontinuance of Business form and return the wall and renewal license to the board within five days of disposition.

Respondent owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent owner shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Suspension

License number _____, issued to respondent _____ is suspended for a period of _____ days beginning the effective of this decision.

Respondent shall cease all pharmacy operations during the period of suspension. Failure to comply with this suspension shall be considered a violation of probation.

Standard Stay/Probation Order

License number _____, issued to respondent is revoked; however, the revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Issuance of Probationary License (In cases where a Statement of Issues has been filed.)

Upon satisfaction of all statutory and regulatory requirements for issuance of a license, a license shall be issued to respondent and immediately revoked; the order of revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Surrender

Respondent owner surrenders license number _____ as of the effective date of this decision. Respondent owner shall relinquish the premises wall license and renewal license to the board within ten (10) days of the effective date of this decision.

The surrender of respondent's license and the acceptance of the surrendered license by the board shall constitute the imposition of discipline against respondent. This decision constitutes a record of discipline and shall become a part of respondent's license history with the board.

Respondent owner shall, within ten (10) days of the effective date, arrange for the destruction of, the transfer to, sale of or storage in a facility licensed by the board of all controlled substances and dangerous drugs and devices. Respondent owner shall further provide written proof of such disposition and submit a completed Discontinuance of Business form according to board guidelines.

Respondent owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent owner shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent owner understands and agrees that if he or she ever files an application for a licensed premises or a petition for reinstatement in the State of California, the board shall treat it as a new application for licensure.

Respondent owner may not reapply for any license from the board for three (3) years from the effective date of this decision. Respondent owner stipulates that should he or she apply for any license from the board on or after the effective date of this decision, all allegations set forth in the [accusation or petition to revoke probation] shall be deemed to be true, correct and admitted by respondent when the board determines whether to grant or deny the application. Respondent shall satisfy all requirements applicable to that license as of the date the application is submitted to the board. Respondent is required to report this surrender as disciplinary action.

Respondent owner further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution in the amount of $_____ within _____ days of the effective date of this decision.

Option: Respondent owner stipulates that should he or she apply for any license from the board on or after the effective date of this decision the investigation and prosecution costs in the amount of $_____ shall be paid to the board prior to issuance of the new license.

Public Reprimand

It is hereby ordered that a public reprimand be issued against licensee, _____. Respondent owner is required to report this reprimand as a disciplinary action.

Adoption of Stipulation

It is understood by respondent owner that, in deciding whether to adopt this stipulation, the board may receive oral and written communication from its staff and the Attorney General's Office. Communications pursuant to this paragraph shall not disqualify the board or other persons from future participation in this or any other matter affecting respondent. In the event this settlement is not adopted by the board, the stipulation will not become effective and may not be used for any purpose, except this paragraph, which shall remain in effect.

STANDARD CONDITIONS - To be included in all probation decisions/orders.

1. Obey All laws
2. Report to the Board
3. Interview with the Board
4. Cooperate with Board Staff
5. Reimbursement of Board Costs
6. Probation Monitoring Costs
7. Status of License
8. License Surrender While on Probation/Suspension
9. Notice to Employees
10. Owners and Officers: Knowledge of the Law
11. Posted Notice of Probation
12. Violation of Probation
13. Completion of Probation

OPTIONAL CONDITIONS

14. Community Services Program
15. Restitution
16. Separate File of Records
17. Report of Controlled Substances
18. Surrender of DEA Permit
19. Posted Notice of Suspension

STANDARD CONDITIONS: TO BE INCLUDED IN ALL PROBATIONS

1. Obey All Laws

Respondent owner shall obey all state and federal laws and regulations.

Respondent owner shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's _____ license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

2. Report to the Board

Respondent owner shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent owner shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. Interview with the Board

Upon receipt of reasonable prior notice, respondent owner shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff

Respondent owner shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his or her probation. Failure to cooperate shall be considered a violation of probation.

5. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent owner shall pay to the board its costs of investigation and prosecution in the amount of $_____. Respondent owner shall make said payments as follows: _____. There shall be no

deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent owner shall not relieve respondent of his or her responsibility to reimburse the board its costs of investigation and prosecution.

6. Probation Monitoring Costs

Respondent owner shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

7. Status of License

Respondent owner shall, at all times while on probation, maintain current licensure with the board. If respondent owner submits an application to the board, and the application is approved, for a change of location, change of permit or change of ownership, the board shall retain continuing jurisdiction over the license, and the respondent shall remain on probation as determined by the board. Failure to maintain current licensure shall be considered a violation of probation.

If respondent license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

8. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent owner discontinue business, respondent owner may tender the premises license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, respondent owner shall relinquish the premises wall and renewal license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent owner shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer. Respondent owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent owner shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent owner may not apply for any new licensure from the board for three (3) years from the effective date of the surrender. Respondent owner shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

Respondent owner further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

9. Notice to Employees

Respondent owner shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent owner shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, respondent owner shall submit written notification to the board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to submit such notification to the board shall be considered a violation of probation.

> "Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

10. Owners and Officers: Knowledge of the Law

Respondent shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in respondent or respondent's stock, and any officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

11. Posted Notice of Probation

Respondent owner shall prominently post a probation notice provided by the board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation.

Respondent owner shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

Failure to post such notice shall be considered a violation of probation.

12. Violation of Probation

If a respondent owner has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent license, and probation shall be automatically extended until all terms and conditions have been satisfied or the board has taken other action

as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent owner violates probation in any respect, the board, after giving respondent owner notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

13. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, respondent license will be fully restored.

OPTIONAL CONDITIONS OF PROBATION

14. Community Services Program

Within sixty (60) days of the effective date of this decision, respondent owner shall submit to the board or its designee, for prior approval, a community service program in which respondent shall provide free health-care related services to a community or charitable facility or agency for at least _____ hours per _____ for the first _____ of probation.

Within thirty (30) days of board approval thereof, respondent owner shall submit documentation to the board demonstrating commencement of the community service program. Respondent owner shall report on progress with the community service program in the quarterly reports.

Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

15. Restitution (Appropriate in cases of drug diversion, theft, fraudulent billing, or patient harm resulting from negligence or incompetence.)

Within _____ days of the effective date of this decision, respondent owner shall pay restitution to _____ in the amount of $ _____. Failure to make restitution by this deadline shall be considered a violation of probation.

16. Separate File of Records

Respondent owner shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

17. Report of Controlled Substances

Respondent owner shall submit quarterly reports to the board detailing the total acquisition and disposition of such controlled substances as the board may direct. Respondent owner shall specify the manner of disposition (e.g., by prescription, due to burglary, etc.) or acquisition (e.g., from a manufacturer, from another retailer, etc.) of such controlled substances. Respondent owner shall report on a quarterly basis or as directed by the board. The report shall be delivered or mailed to the board no later than ten (10) days following the end of the reporting period. Failure to timely prepare or submit such reports shall be considered a violation of probation.

18. Surrender of DEA Permit

Within thirty (30) days of the effective date of this decision, respondent pharmacy shall surrender its federal Drug Enforcement Administration (DEA) permit to the DEA, for cancellation. Respondent pharmacy shall provide documentary proof of such cancellation to the board or its designee. Thereafter, respondent pharmacy shall not apply/reapply for a DEA registration number without the prior written consent of the board or its designee.

Option: Respondent pharmacy may obtain a DEA permit restricted to Schedule(s) _____ controlled substance(s).

Option: Respondent pharmacy shall not order, receive, or retain any federal order forms, including 222 forms, for controlled substances.

19. Posted Notice of Suspension

Respondent owner shall prominently post a suspension notice provided by the board in a place conspicuous and readable to the public. The suspension notice shall remain posted during the entire period of suspension ordered by this decision.

Respondent owner shall not, directly or indirectly, engage in any conduct or make any statement, orally, electronically or in writing, which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the closure of the licensed entity.

6/2007

Attachment C:

Strategic Plan for the California State Board of Pharmacy 2006-2011

STRATEGIC PLAN

2006 – 2011

CALIFORNIA STATE BOARD OF PHARMACY

Healthy Californians Through Quality Pharmacist's Care

REVISED 2010

STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

Strategic Plan

California State Board of Pharmacy

2006
2011

Members:

Stanley C. Weisser, Pharmacist Member, President
Randy Kajioka, Pharmacist Member, Vice President
Gregory N. Lippe, Public Member, Treasurer

Ryan Brooks, Public Member
Ramón Castellblanch, PhD, Public Member
Rosalyn Hackworth, Public Member
Kenneth Schell, PharmD, Pharmacist Member
Deborah Veale, Pharmacist Member
Shirley Wheat, Public Member
Tappan Zee, Esq., Public Member

Virginia Herold, Executive Officer

California State Board of Pharmacy
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Revised July 2010

TABLE OF CONTENTS

President's Message 4

Vision and Mission Statements 5

Agency Description – About the Board of Pharmacy. 5

Strategic Issues To Be Addressed 6

Summary of Goals 10

Goals and Related Objectives, Measures, Tasks and Resource Assumptions . . . 11

Goal Alignment Matrix to Objectives 20

Scanning Assessment and Methodology 21

Shared Values/Core Principles 22

Internal/External Assessment 22

President's Message

The strategic planning process of the California State Board of Pharmacy is an annual effort of the board members, staff and the public to anticipate and plan for events and issues for the coming year. Although the board considers its current strategic plan when going through the planning exercise, the board also attempts to predict upcoming changes in pharmacy practice, consumer needs and demands and health care trends. After a lengthy discussion of potential and existing issues, the participants go through a process to categorize, consolidate and finally prioritize the issues and then set the goals for the coming year. The resulting strategic plan keeps the board focused on established goals while allowing the flexibility of handling new questions and challenges as they arise.

Each board committee considers its individual strategic plan goals at every meeting and the progress on the goals are reviewed at each of the quarterly full board meetings. The careful planning and continuous monitoring of the strategic plan assures that the board achieves its stated objectives and performs with optimal efficiency.

The board publishes advance notice for each strategic planning meeting and encourages participation and contribution by all interested citizens of California who attend. Involvement of the board, its staff and the public results in a strategic plan that truly represents the public interest and serves the consumers of this state.

CALIFORNIA STATE BOARD OF PHARMACY

VISION STATEMENT

Healthy Californians through quality pharmacists care.

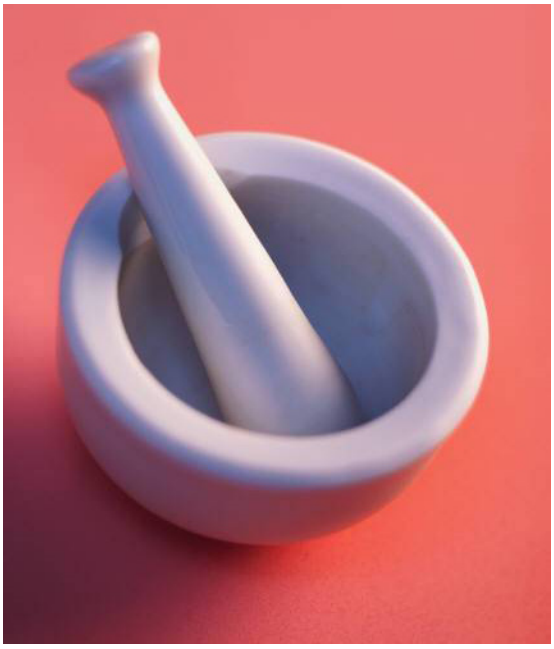
MISSION STATEMENT

The Board of Pharmacy protects and promotes the health and safety of Californians by pursuing the highest quality of pharmacists care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation, and enforcement.

ABOUT THE CALIFORNIA STATE BOARD OF PHARMACY

The California State Board of Pharmacy (board) was established in 1891 to protect consumers by licensing and regulating those responsible for dispensing medications to the public. Today the board oversees all aspects of the practice of pharmacy in California: the practitioner (the pharmacists), the practice site (the pharmacies), and the product (drugs and devices). Additionally the board regulates drug wholesalers and other practitioners and specialized facilities that store and furnish prescription drugs. With an annual budget of nearly $12 million and a staff of over 60, the board licenses nearly 120,000 individuals and firms, and enforces 13 complex and varied regulatory programs.

The board has five policy development committees to fulfill its charge. The five committees are: Enforcement, Communication and Public Education, Licensing, Legislation and Regulation, and Organizational Development. Each of these committees corresponds to a mission-related goal.



The board supports an active Web site, www.pharmacy.ca.gov, that provides consumer education material, application material for licensing and information for ensuring compliance with California Pharmacy Law . The Web site also provides times and information on board meetings as well as other critical forums vital to pharmacy services were public comments and input are sought and encouraged.

STRATEGIC ISSUES TO BE ADDRESSED

1. Cost of medical/pharmaceutical care

Providing necessary medication for all Californians is a concern; there is an increasing demand for affordable health care services. Also, spiraling medical care and prescription drug costs may influence people to take short cuts on their drug therapy or to seek medications from nontraditional pharmacy sources. Tiered pricing is a global reality. Due to global communication, patients can access drugs at different prices, worldwide. Patients seek lower cost medications from these sources because patients assume that prescription drugs are of the same quality as they are accustomed to obtaining from their neighborhood pharmacies. However, the cost of drugs drives unscrupulous individuals (such as counterfeiters and diverters) as well as conscientious health care providers to operate in this marketplace, the former endanger public health and confidence in the prescription drugs patients take.

2. Aging population

There are increasingly more senior citizens, and that population is living longer. Aging consumers often have decreased cognitive skills, eyesight and mobility. Consequently as the senior population increases so will the volume of prescriptions and the impact on pharmacists and pharmacy personnel to meet the demand. Specialized training of pharmacists may be necessary to better serve the needs of aging patients.

Many senior citizens, who previously may not have had prescription drug insurance coverage, will benefit from the new prescription drug benefit of Medicare that started in January 2006. However, this new benefit has been implemented with significant problems for some seniors, and as a complicated new program, will require public education and perhaps statutory modification.

3. Pharmacists' ability to provide care

The ability of pharmacy to provide optimal care for patients with chronic conditions is being challenged. Drugs are becoming more powerful and it is anticipated that more intervention by pharmacists will be required. The challenge is even greater when consumers fill multiple prescriptions at different pharmacies. The pharmacist shortage, increased consumer demand for prescription drugs, patient compliance in taking medications and polypharmacy are issues which will impact pharmacists' ability to provide care.

4. Changing demographics of California patients

The diversity of California's population is growing with respect to race, ethnicity and linguistic skills, as is the segment that seeks drugs and products from foreign countries. This requires greater knowledge, understanding and skills from health care practitioners. The increasing diversity of patients is coupled with culturally-based beliefs that undervalue the need for licensed pharmacists and pharmacies, and instead encourage purchase of prescription drugs from nontraditional locations and providers.

There also is widespread belief that there must be a medication solution for every condition or disease state.

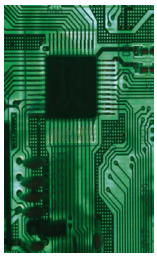
5. Laws governing pharmacists

New laws enhancing pharmacists' roles as health care providers are needed. The laws must address several key issues including: expansion of the scope of pharmacy practice, the ratio of personnel overseen by pharmacists, delineation of the role of pharmacists relative to selling versus nonselling duties of personnel, and the responsibility for legal and regulatory compliance of the pharmacist-in-charge.

6. Integrity of the drug delivery system

Implementation of the e-pedigree for prescription drugs will reduce the growing incidence of counterfeit, damaged, adulterated or misbranded medications in California's pharmacies. Additionally the federal government has demonstrated an increasing interest in regulating health care to safeguard consumer interests. New legislation and regulation may be created in response to emergency preparedness, disaster response and pandemics. Changes in the prescription drug benefits provided to Medicare beneficiaries will continue to command attention.

7. Technology Adaptation



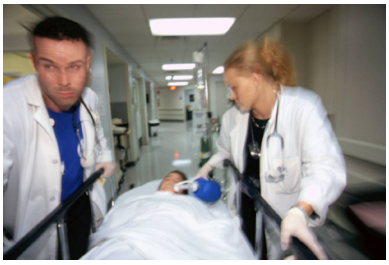
Technology will greatly impact the processing and dispensing of medication. Electronic prescribing and "channeling" to locations other than a traditional pharmacy may become the business model Automated pharmacy systems and electronic prescribing will impact pharmacy. New methods of dispensing medications raise additional liability issues. New medication, perhaps engineered for specific patients, will become available at high costs and require special patient monitoring systems.

8. Internet issues

The availability of prescription drugs over the Internet is on the rise. Multiple and easy access of drugs without pharmacist participation is dangerous. Entities promoting illegal drug distribution schemes have taken advantage of the Internet. Monitoring and protecting the public from improper drug distribution from these Internet pharmacies is severely impaired with continued resource constraints by both the federal and state agencies with jurisdiction.

9. Disaster planning and response

Pharmacists need to be ready to be positioned to provide emergency care and medication in response to natural disasters, pandemics and terrorism. This requires specialized knowledge, advance planning and integration of local, state and federal resources that can be quickly mobilized. Specialized drug distribution channels will need to be authorized to permit emergency response.



Additionally, regulatory adjustments to the September 11 terrorism may affect persons' rights to privacy.

10. Qualified staff and Board Members

The state's fiscal crisis has affected the board's ability to investigate customer complaints or hire staff. The board lost 20 percent of its staff positions during the prior five years due to the state's hiring freezes. Loss of these staff has altered the provision of services by the board. The salary disparity between the private and public sectors in compensation for pharmacists will make it difficult to recruit and retain pharmacist inspectors. Moreover, for all staff, if wages remain essentially frozen, the retention of current employees could be impacted.

The diversity and involvement of all board members in policy development is important for public health and protection. At least a quorum of board members is needed to ensure the board can make decisions and act timely.

11. Pharmacy/health care in the 21st century

The state's health care practitioners (pharmacists, physicians, nurses) are being influenced by a variety of internal and external factors that affect and will continue to effect health care provided to patients. Improved patient care will result from improved integration among these professions. Also, a renewed emphasis on patient consultation will benefit patient knowledge about their drug therapy and thus improve their care.

12. Information Management

Creation, maintenance and transfer of electronic patient records and prescription orders will be the norm in the future. Patient records need to remain confidential and secured from unauthorized access. Pharmacies and wholesalers need to ensure the availability of an e-pedigree for drugs obtained, transferred and dispensed. It is likely that all controlled drugs dispensed in California will be tracked electronically by the CURES system.

Patient records need to remain confidential and secured from unauthorized access. Pharmacies and wholesalers need to ensure the availability of an e-pedigree for drugs obtained, transferred and dispensed.

Summary of Goals

Goal One

Exercise oversight on all pharmacy activities.

Goal Two

Ensure the qualifications of licensees.

Goal Three

Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Goal Four

Provide relevant information to consumers and licensees.

Goal Five

Achieve the board's mission and goals.

GOALS, OUTCOMES, OBJECTIVES, AND MEASURES

ENFORCEMENT COMMITTEE

Goal 1: Exercise oversight on all pharmacy activities.

Outcome: Improve consumer protection.

Objective 1.1 Measure:	Achieve 100 percent closure on all board investigations within 6 months. Percentage of cases closed.
Tasks:	1. Complete all desk investigations within 90 days (for cases closed during quarter). 2. Complete all field investigations within 120 days (for cases closed during quarter). 3. Close (e.g., no violation, issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days.
Objective 1.2 Measure:	Manage enforcement activities for achievement of performance expectations Percentage compliance with program requirements
Tasks:	1. Administer the Pharmacists Recovery Program. 2. Administer the probation monitoring program. 3. Issue citations and fines within 30 days 4. Issue letters of admonition within 30 days 5. Obtain immediate public protection sanctions for egregious violations. 6. Submit petitions to revoke probation within 30 days for noncompliance with terms of probation.
Objective 1.3 Measure:	Achieve 100 percent closure on all administrative cases (excluding board investigation time) within one year by June 30, 2011. Percentage closure of administrative cases within one year.
Objective 1.4 Measure:	Inspect 100 percent of all licensed facilities once every 3 years by June 30, 2011. Percentage of licensed facilities inspected once every 3 year cycle.
Tasks:	1. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public. 2. Inspect sterile compounding pharmacies initially before licensure and annually before renewal. 3. Initiate investigations based upon violations discovered during routine inspections.

Objective 1.5 Measure:	Initiate policy review of 25 emerging enforcement issues by June 30, 2011. The number of issues.
Tasks:	1. Monitor the implementation of e-pedigree on all prescription medications sold in California. 2. Implement federal restrictions on ephedrine, pseudoephedrine or phenylpropanolamine products. 3. Monitoring the efforts of the Drug Enforcement Administration and Department of Health and Human Services to implement e-prescribing for controlled substances. 4. Evaluate establishment of an ethics course as an enforcement option. 5. Participate in emerging issues of the national level affecting the health of Californians regarding their prescription medicine. 6. Provide information about legal requirements involving e-prescribing to support the Governor's Health Care Initiative and its promotion of e-prescribing. 7. Implement in California the Center for Medicare and Medicaid Service requirements for security prescription forms that will be required in only four months for all written Medicaid and Medicare prescriptions. 8. Liaison with other state and federal agencies to achieve consumer protection. 9. Work with the California Integrated Waste Management Board to implement requirements for model programs to take back unwanted prescription medicine from the public. 10. Inspect California hospitals to ensure recalled heparin has been removed from patient care areas. 11. Promulgate regulations required by SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) for recovery programs administered by Department of Consumer Affairs health care boards. 12. Develop and release Request for Proposal for vendor for Department of Consumer Affairs health care boards that operate license recovery programs. 13. Participate in Department of Consumer Affairs Consumer Protection Enforcement Initiative to strengthen board enforcement activities and reduce case investigation completion times for formal discipline. 14. Initiate criminal conviction unit to review and investigate rap sheets received on licenses for arrests or convictions. 15. Complete comprehensive review of investigative and enforcement internal processing to identify process improvements. 16. Complete review of pharmacies dispensing prescriptions for Internet web site operators. 17. Provide updates on the board's reporting to the Healthcare Integrity and Protections Data Bank (HIPDB).

LICENSING COMMITTEE

Goal 2: Ensure the qualifications of licensees.

Outcome: Qualified licensees

Objective 2.1 Measure:	Issue licenses within three working days of a completed application by June 30, 2011. Percentage of licenses issued within three work days
Tasks:	1. Review 100 percent of all applications within seven work days of receipt. 2. Process 100 percent of all deficiency documents within five work days of receipt. 3. Make a licensing decision within three work days after all deficiencies are corrected. 4. Issue professional and occupational licenses to those individuals and firms that meet minimum requirements. • Pharmacists • Intern pharmacists • Pharmacy technicians • Pharmacies • Non-resident pharmacies • Wholesaler drug facilities • Veterinary food animal drug retailers • Designated Representatives (the non-pharmacists who may operate sites other than pharmacies) • Out-of-state distributors • Clinics • Hypodermic needle and syringe distributors • Sterile Compounders 5. Withdrawn licenses to applicants not meeting board requirements. 6. Deny applications to those who do not meet California standards. 7. Respond to e-mail status requests and inquiries to designated e-mail addresses. 8. Respond to telephone status request and inquiries.
Objective 2.2 Measure:	Cashier 100 percent of all revenue received within two working days of receipt by June 30, 2011. Percentage of revenue cashiered application within 2 working days.
Tasks:	1. Cashier application fees. 2. Cashier renewal fees. 3. Cashier citations with fines. 4. Cashier probation and cost recovery fees. 5. Cashier request for information/license verification fees. 6. Cashier fingerprint fees.

Objective 2.3 Measure:	Update 100 percent of all information changes to licensing records within five working days by June 30, 2011. Percentage of licensing records changes within five working days
Tasks:	1. Make address and name changes. 2. Process off-site storage applications. 3. Transfer intern hours to other states
Objective 2.4 Measure:	Implement at least 25 changes to improve licensing decisions by June 30, 2011. Number of implemented changes
Tasks:	1. Determine why 26 states do not allow the use of a CA license as the basis for transfer a pharmacist license to that state. 2. Evaluate the drug distribution system of clinics and their appropriate licensure. 3. Work with the Department of Corrections on the licensure of pharmacies in prisons. 4. Work with local and state officials on emergency preparedness and planning for pandemic and disasters. Planning to include the storage and distribution of drugs to as sure patient access and safety. 5. Evaluate the need to issue a provisional license to pharmacy technician trainees. 6. Evaluate use of a second pharmacy technician certification examination (ExCPT) as a possible qualifying route for registration of technicians. 7. Review requirements for qualifications of pharmacy technicians with stakeholders. 8. Implement the Department of Consumer Affairs Applicant Tracking System to facilitate implementation of I-Licensing system, allowing online renewal of licenses by 2008. Note: I-Licensing system has been cancelled and the BreEZe system will take its place. 9. Participate with California's Schools of Pharmacy in reviewing basic level experiences required of intern pharmacists, in accordance with new ACPE standards. 10. Implement new test administration requirements for the CPJE. 11. Participate in ACPE reviews of California Schools of Pharmacy. 12. Initiate review of Veterinary Food Animal Drug Retailer Designated Representative training. 13. Convene Committee to evaluate drug distribution within hospitals. 14. Improve reporting of and accounting for intern hours. 15. Participate in initiatives to increase the number of pharmacists in California to meet demand. 16. Assess the operations of specialty pharmacy services. 17. Encourage use of technology where it benefits the public. 18. Secure the implementation of e-prescribing in California by the earliest possible date. 19. Ensure the public receives necessary pharmaceuticals in emergency response activities to the H1N1 pandemic. 20. Automate fingerprint background results with the Department of Justice. 21. Evaluate pharmacy technician application process to identify areas for improvement. 22. Implement Fingerprint Requirement for Pharmacist Renewal. 23. Evaluate licensing requirements for businesses seeking licensure that are under common ownership. 24. Evaluate Continuing Education Requirement for Pharmacists.

LEGISLATION AND REGULATION COMMITTEE

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Outcome: Improve the health and safety of Californians.

Objective 3.1	Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.
Measure:	100 percent successful enactment of promoted legislative changes.
Tasks:	1. Secure extension of board's sunset date. 2. Sponsor legislation to update pharmacy law. 3. Advocate the board's role and its positions regarding pharmacists' care and dispensing of dangerous drugs and devices. 4. Secure statutory standards for pharmacies that compound medications. 5. Secure implementation of e-pedigrees on prescription drugs dispensed in California. 6. Advocate the board's position on pending legislation affecting pharmacy practice and/or the board's jurisdiction. 7. Expand the conditions under which a pharmacist may administer an immunization independent of physician protocol. 8. Advocate the board's role as an advocate for consumers by redesigning prescription label for all medicines dispensed to California patients. 9. Secure statutory fee increase to ensure sufficient funding to fulfill all of the boards statutory obligations as a consumer protection agency. 10. Advocate legislation to enhance the board's enforcement activities.

Objective 3.2 Measure:	Annually identify and respond with regulatory changes to keep pharmacy regulations current and consistent with the board's mission. Percentage successful enactment of promoted regulatory changes
Tasks:	1. Authorize technicians to check technicians in inpatient pharmacies with clinical pharmacist programs (sections 1793.7-1793.8). 2. Authorize the use of prescription drop boxes and automated delivery machines for outpatient pharmacies (sections 1713 and 1717(e)). 3. Make technical changes in pharmacy regulations to keep the code updated. Section 1706.2 criteria for abandonment of files Section 1775.4 contested citations Section 1709.1 designation of pharmacist-in-charge Section 1780 standards for wholesalers Section 1780.1 standards for veterinary food animal drug retailers Section 1781 Designated Representative certificate Section 1786 Designated Representative 4. Repeal the requirement to post a notice regarding electronic files (section 1717.2). 5. Revise and update Disciplinary Guidelines revision and update (section 1760). 6. Self-assessment of a wholesaler by the designated representative (section 1784). 7. Exempt the address of records of interns from display on the board's Web site (section 1727.1). 8. Modification of building standards for pharmacies – rulemaking by the California Building Standards Commission. 9. Update Notice to Consumers Poster in conformance with AB 2583 (Chapter 487, Statutes 2006)(Section 1707.2). 10. Secure changes without regulatory effect (Section 100 changes) to pharmacy regulations to keep them accurate and current. 11. Increase fees to keep the board's contingency fund solvent and maintain operations. 12. Secure regulatory standards for pharmacies that compound. 13. Establish an ethics course. 14. Pharmacist renewal requirements. 15. Dishonest conduct euring pharmacist examination; confidentiality of exam questions. 16. Standardized, patient-centered prescription labels. 17. Update protocol for pharmacists furnishing emergency contraception (EC). 18. Board issued continuing education (CE) credit. 19. Notice to Consumers re: Patient-Centered Prescription Labels. 20. Update references to USP Standards (§1780) 21. Veterinarian Food-Animal Drug Retailer Self-Assessment (§1785) 22. Accreditation Agencies for Pharmacies that Compound (§1751.x)
Objective 3.3 Measure:	Review five areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2011. Number of areas of pharmacy law reviewed
Tasks:	1. Initiate review of the pharmacist-in-charge requirement.

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Goal 4: Provide relevant information to consumers and licensees.

Outcome: Improved consumer awareness and licensee knowledge.

Objective 4.1 Measure:	Develop a minimum of 10 communication venues to the public by June 30, 2011. Number of communication venues developed to the public.
Tasks:	1. Assess the effectiveness of the board's educational materials and outreach: survey consumers to identify whether board-produced materials are valued and what new materials are desired. 2. Restructure the board's Web site to make it more user friendly. 3. Work with the California Health Communication Partnership on integrated public information campaigns on health-care topics. 4. Continue collaboration with schools of pharmacy for pharmacist interns to develop consumer fact sheets on health topics. 5. Develop a Notice to Consumers to comply with requirements of AB 2583 (Nation) on patients' rights to secure legitimately prescribed medication from pharmacies. 6. Evaluate the practice of pill splitting as a consumer protection issue. 7. Evaluate the SCR 49 Medication Errors Report for implementation. 8. Develop patient-centered standardized prescription container labels by 2011. 9. Address and promote licensee and public education on minimizing prescription errors. 10. Educate consumers about steps they can take to prevent receiving a medication error.
Objective 4.2 Measure:	Develop 10 communication venues to licensees by June 30, 2011. Number of communication venues developed to licensees.
Tasks:	1. Publish *The Script* two times annually. 2. Develop board-sponsored continuing education programs in pharmacy law and coordinate presentation at local and annual professional association meetings throughout California. 3. Maintain important and timely licensee information on Web site.
Objective 4.3 Measure:	Develop communication venues for other health care professionals (e.g., physicians, nurses). Number of communication venues developed to other health care professionals.
Tasks:	
Objective 4.4 Measure:	Participate in 12 forums, conferences and public education events annually. Number of forums participated.
Tasks:	1. Participate in forums, conferences and educational fairs.

ORGANIZATIONAL DEVELOPMENT COMMITTEE

Goal 5: Achieve the board's mission and goals.

Outcome: An effective organization.

Objective 5.1 Measure:	Obtain 100 percent approval for identified program needs by June 30, 2011. Percentage approved for identified program needs.
Tasks:	1. Review workload and resources to streamline operations, target backlogs and maximize services. 2. Develop budget change proposals to secure funding for needed resources. 3. Perform strategic management of the board through all committees and board activities. 4. Manage the board's financial resources to ensure fiscal viability and program integrity.
Objective 5.2 Measure:	Maintain 100 percent staffing of all board positions. Percentage staffing of board positions.
Tasks:	1. Continue active recruitment of pharmacists for inspector positions. 2. Vigorously recruit for any vacant positions. 3. Perform annual performance and training assessments of all staff.
Objective 5.3 Measure:	Succession planning and workforce retention. Secure enhanced training of staff to improve job proficiency.
Tasks:	1. Identify training for staff development.
Objective 5.4 Measure:	Implement 10 strategic initiatives to automate board processes by June 30, 2011. Number of strategic initiatives implemented to automate board processes
Tasks:	1. Implement automated applicant tracking (ATS). 2. Implement online license renewal and application submission features (BreEZe). 3. Integrate telephone features to improve board services without adding staff resources. 4. Use the department's newly created "ad hoc" system to generate data for reports. 5. Secure equipment needed to perform staff duties optimally. 6. Implement automated program for staff-conducted drug audits. 7. Implement template for drug audits completed by pharmacies. 8. Develop template for hospital inspections to identify recalled heparin. (Completed April 2008) 9. Participate in Department of Consumer Affairs pilot program to achieve scanning of paper files.

Objective 5.5 Measure:	Provide for communication venues to communicate within the board by June 30, 2011. Number of communication venues to communicate within the board.
Tasks:	1. Continue the Communication Team to improve communication among staff and host biannual staff meetings. 2. Continue Enforcement Team meetings with board members and enforcement staff. 3. Convene annual inspector meetings to ensure standardized investigation and inspection processes, law and practice updates and earn continuing education credit. 4. Transition from paper packets for board meeting materials to e-copies. 5. Explore electronic voting of mail ballots for disciplinary decisions.
Objective 5.6 Measure:	Annually conduct at least two outreach programs where public policy issues on health care are being discussed. Number of outreach programs conducted in one year.
Tasks:	1. Outreach programs 2006/2007. 2. Outreach programs 2007/2008. 3. Outreach programs 2008/2009. 4. Professionals Achieving Consumer Trust Summit - November 2008. 5. Board provides three presentations at the annual California Pharmacists Association Meeting. 6. Workgroup on E-Pedigree holds March 2009 meeting where presentations made on FDA proposed standards for a unique identification number for serialization, Congressman Buyer's Office on federal legislation, and standards setting by GS1. 7. Executive Officer attends National Association of Boards of Pharmacy Meeting with other state boards of pharmacy. 8. Executive Staff attend Consumer Advisory Councils day-long presentation in San Francisco on substance abuse recovery programs for health care licensees. 9. Outreach programs 2009/2010.
Objective 5.7 Measure:	Perform succession planning to ensure continuity for board operations during staff retirements. Number of staff trained for advanced duties and promoted.
Tasks:	
Objective 5.8 Measure:	Respond to all public record requests within 10 days. Percentage response to public record requests within 10 days
Tasks:	1. Respond to public records requests within 10 days (e.g., license verifications, investigative information, licensing information). 2. Respond to subpoenas within the timeline specified. 3. Respond to specific requests for data reports list.

Goal Alignment Matrix – Strategic Issues					
Strategic Issues	**Goal 1: Exercise oversight on all pharmacy activities**	**Goal 2: Ensure the qualifica-tions of licensees.**	**Goal 3: Advocate legislation and promulgate regulations that advance the Vision and Mission of BOP.**	**Goal 4: Provide relevant information to consumers and licensees.**	**Goal 5: Achieve the Board's Mission and Goals.**
1. Cost of medical/ pharma-ceutical care	X		X	X	X
2. Aging population	X	X		X	X
3. Pharmacists' ability to provide care	X	X	X	X	X
4. Changing demographics of CA patients	X	X	X	X	X
5. Laws governing pharmacists	X	X	X	X	
6. Integrity of the drug delivery system	X	X	X		
7. Technology adaptation	X		X	X	X
8. Internet Issues	X			X	X
9. Disaster planning and Response	X	X	X	X	X
10. Qualified staff	X	X			X
11. Pharmacy/ Healthcare Integration in the 21st century	X	X	X	X	X
12. Information Management	X	X	X	X	X

SCANNING ASSESSMENT AND METHODOLOGY

In assessing the critical data that will influence the board's ability to fulfill its vision and mission, the strategic planning team completed several scanning activities in 2006. Board members, all staff and stakeholders participated in completing a survey questionnaire that was submitted to the strategic planning team for synthesis and analysis. This included review of the board's mission, vision, goals and strategic issues. Additionally a "SWOT" analysis (an acronym for strengths, weaknesses, opportunities and threats) was conducted during the survey as part of the scanning assessment.

In developing its strategic plan, the board relied upon the full participation of its entire staff, its board members and its interested stakeholders. The participation of each group has provided important information necessary for a dynamic strategic plan, capable of guiding the board in fulfilling its mission for several years.

In developing its strategic plan, the board relied upon the full participation of its entire staff, its board members and its interested stakeholders.

After each group performed the SWOT analyses described above, the board refined the strategic issues to be addressed during the April 2006 Meeting, and the results are summarized in this plan under **"Strategic Issues to be Addressed."**

Additional refinement of board objectives and activities was conducted during late spring 2006 by each of the board's strategic committees, and the final strategic plan for 2006-11 was approved at the July 2006 Board Meeting.

SHARED VALUES/CORE PRINCIPLES

The Board of Pharmacy will exhibit:

- Vision
- Integrity
- Flexibility
- Commitment
- Loyalty to its mission
- Relevance to important issues
- Compassion, and
- Open-mindedness

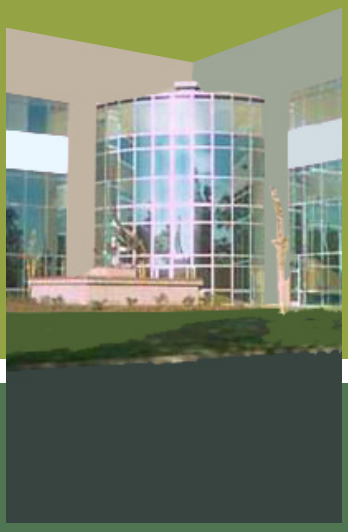
These values will be exhibited when considering all matters before the board affecting the consumers of California and the profession of pharmacy.

INTERNAL/EXTERNAL ASSESSMENT

The critical data stemming from the SWOT analysis is reflected below. The information represents a deliberative process of multiple iterations conducted with the board members, staff and stakeholders.

Strengths	Weaknesses
1. Staff/Inspectors: Staff's teamwork, dedication, diversity, and knowledge. Pharmacist inspectors provide necessary, specialized knowledge. 2. Leadership: Support and communication provided by management, diversity and experience of board members.	1. Resources: Budget constraints and insufficient resources to meet mandated duties at desired levels 2. Staffing Shortages: Insufficient staff to perform, manage, and review consumer protection activities of licensing, enforcement, and education programs.
Opportunities	**Threats**
1. Pharmacist's Role: Pharmacy profession has large potential role in healthcare delivery. Pharmacists have opportunities in roles associated with patient care and not exclusively dispensing. 2. Technology/Automation: Promoting legislation and regulations to foster the use of technological advances by pharmacies, attainment of operational efficiencies, decreased administrative burdens, and enhanced patient care services. 3. Consumer Safety/Privacy: Promoting a nonpunitive learning environment approach to improving pharmacy patient safety. Continuing emphasis on patient safety by involving the pharmacist in patient care. 4. Public education: Increasingly informed consumers means the profession must be able to deliver public education on drug use safety and healthcare issues.	1. Board of Pharmacy staffing is insufficient to perform mandated duties at desired levels. 2. Board funding: Lack of funding for new programs; lack of fiscal control of board over much of its budget; budget constraints and deficits; hiring freeze. 3. Cost of pharmaceuticals: Impacts of the increasing costs of pharmaceuticals cannot be managed or controlled by the consumer or the board. 4. Pharmacy personnel shortage: Lack of licensees impedes the ability of patients to receive quality pharmacists care.

Healthy Californians Through Quality Pharmacist's Care



STRATEGIC PLAN

California State Board of Pharmacy
1625 North Market Blvd., Suite N-219
Sacramento, CA 95834
916 574.7900
916 574.8618 fax
www.pharmacy.ca.gov

Attachment C:

Health Notes
Alternative Medicines

HEALTH NOTES

Alternative Medicines

California State Board of Pharmacy

Dedicated to building bridges of communication with those Californians whose health depends on proper drug therapy, compliance with a treatment regimen and a healthier lifestyle.

Gray Davis, *Governor*

Aileen Adams, *Secretary, State and Consumer Services Agency*

Kathleen Hamilton, *Department of Consumer Affairs*

MEMBERS, California State Board of Pharmacy

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Richard Mazzoni, R.Ph.

William Powers, Public Member

Holly Strom, R.Ph.

Andrea Zinder, Public Member

Patricia Harris, *Executive Officer*

A Note from the Editor

Alternative medicine, by definition, is anything but conventional. Nonetheless, consumers are pushing one component of alternative medicine, the dietary supplements, into the main stream. The focus on herbal products and nutritional supplements in this issue of HEALTH NOTES stems from their widespread use, the potential they have for interactions with prescription and non-prescription medication, and the confusion surrounding their safety and effectiveness.

The contributors to this issue are physicians, pharmacists and lawyers who have researched the literature and addressed the use of these products in their own practices. To enhance our understanding of the subject matter, the authors have taken an evidence-based approach to the evaluation of herbal and nutritional supplements and balanced the factual information with real cases to illustrate key concepts. I thank them for sharing their expertise.

While editing, I was struck by two observations 1) almost 20% of prescription drug users also take dietary supplements and 2) people who take dietary supplements are essentially medicating themselves. Both have huge implications for pharmacists. While many of us have not been formally trained in the use of these products, we are the health professionals who are responsible for identifying and preventing drug interactions or adverse effects resulting from their combined use with conventional medicines. Pharmacists are on the front lines and are in the best position to promote safe and responsible self-medication, whether that is with prescription, non-prescription or dietary supplement products. This issue of HEALTH NOTES is dedicated to helping pharmacists fulfill these important responsibilities. On behalf of the faculty of the Center for Consumer Self Care at the UCSF School of Pharmacy, I thank the State Board of Pharmacy for giving us this opportunity to develop a practical resource on dietary supplements for pharmacists and consumers.

Barbara Sauer

Barbara Sauer, Pharm.D.
Project Coordinator
Center for Consumer Self Care
UCSF School of Pharmacy

Introduction

HEALTH NOTES is a series of monographs published by the California State Board of Pharmacy's Communication and Public Education Committee to help California pharmacists and other healthcare providers become better informed on subjects of importance to their patients. The information will also be of value to the public.

Today, more than ever in the history of medicine, healthcare professionals are addressing the goals of integrated healthcare. They are providing patient care that focuses on physical wellness, service-satisfaction, and cost effectiveness. Patients themselves are looking for their own remedies and solutions to health problems and concerns.

Pharmacists, by virtue of their close relationship with patients, can quickly respond to patients' medication needs and can satisfy patients' desires to be informed about their treatment and the medications they are taking. They can also assist with information about herbal products and dietary supplements.

Access to information is an important component in attaining wellness. Pharmacists who develop programs that assist patients to better manage their medications and to meet their treatment objectives will help Californians reach higher levels of wellness.

As healthcare evolves into a system focused on integrated patient care, one fact becomes very clear: healthcare professionals who provide disease management programs and prescription information that increases medication compliance will help reduce hospital admissions and the need for follow-up care.

HEALTH NOTES is designed to be a reference source for pharmacists and other health care providers to use in helping patients better understand their illness, comply with prescribed treatment regimens and take greater responsibility for their health.

This issue of HEALTH NOTES addresses the area of alternative medicines and dietary supplements and the potential for interactions with prescription and non-prescription medication – in short, the problems that can be encountered with self-medicating.

Caleb K. Zia
Chair, Communication and
Public Education Committee
California State Board of Pharmacy

Learning Objectives

After reading the articles in this issue, you should be able to:

1. Describe the regulatory process for dietary supplements and explain how it differs from that for prescription and non-prescription medications.
2. List one or two common uses for frequently purchased dietary supplements and describe the scientific evidence to support each of these uses.
3. Recognize appropriate dosing regimens and common adverse effects of frequently used dietary supplements.
4. List five herbs or herbal products that are toxic to the liver.
5. List five dietary supplements that should be avoided when taking anticoagulants or anti-platelet medication.
6. Cite three additional examples of potentially harmful drug interactions reported with dietary supplements (other than those listed above).
7. List five medical conditions or diseases in which dietary supplements should be avoided.
8. List three alternative medicine resources that provide reliable information and are suitable for consumer use.
9. Identify five risk management strategies for pharmacists who sell or counsel consumers about dietary supplements.
10. Describe the pharmacist's role in promoting safe and appropriate use of dietary supplements.

References for this issue are available, upon written request, from the California State Board of Pharmacy.

Health Notes

Volume 1, Number 5

Alternative Medicines

TABLE OF CONTENTS

Introduction

4 Complementary and Alternative Medicine: Does It Work? Is It Safe? Why Are So Many People Using It?
Ellen Hughes, M.D.

Part One: Top Selling Dietary Supplements

7 Keeping Up With the Top Selling Herbs
Cathi Dennehy, Pharm.D.

16 Dietary Supplements: Sorting Through the Evidence
Candy Tsourounis, Pharm.D.

At-a-Glance

Garlic	8	Black Cohosh	14
Ginkgo	8	Melatonin	17
St. John's Wort	9	Glucosamine	17
Kava Kava	11	Chondroitin Sulfate	18
Saw Palmetto	12	Shark Cartilage	19
Ginseng	12	DHEA	19
Echinacea	13	Coenzyme Q 10	20

Part Two: Risks Associated With Use

23 Potential for Harm
Mary Chavez, Pharm.D.

29 Adverse Events Associated with Alternative Medicines – Recent Cases Reported to the California Poison Control Center
Christine A. Haller, M.D. and Thomas E. Kearney, Pharm.D. ABAT

Part Three: Information for Pharmacists

35 Inquiring Minds: Frequently Asked Consumer Questions About Herbs and Dietary Supplements
Mitra Assemi, Pharm.D.

39 Sources of Reliable Information on Alternative Medicine
Mary J. Ferrill, Pharm.D.

44 Legal Considerations Pertaining To Dietary Supplements
Richard R. Abood, R.Ph., J.D.

49 What's In a Claim?
Barbara Sauer, Pharm.D.

The views expressed by the individual authors are not necessarily the views of the Board of Pharmacy.

Does it work? Is it safe? Wh

Complementary and Alternative Medicine:

Ellen Hughes, M.D.
Associate Clinical Professor of Medicine
Interim Director, Osher Center for Integrative Medicine, School of Medicine
University of California, San Francisco

More than four out of ten Americans used some form of alternative medicine in 1997, paying an impressive $27 billion out-of-pocket for therapies such as herbal medicine, chiropractic, and acupuncture.[1] The same year, patients made a staggering 629 million visits/year to alternative practitioners, more than they made to all U.S. primary care providers. Who are these patients? Why do they discuss less than 40% of their alternative therapies with their medical doctors? Why are they willing to pay so much out-of-pocket for services that have rarely been scientifically validated?

Definition of Alternative Medicine

Various terms have been used to describe therapies that fall outside of mainstream medical practice, including "alternative," "non-traditional," "unconventional," "holistic," "complementary," and "complementary and alternative medicine" (CAM). Almost a decade ago, Eisenberg defined alternative medicine as "medical interventions not widely taught at U.S. medical schools or generally available at U.S. hospitals."[2] A more recent term, "integrative medicine," is gaining popularity as it emphasizes the growing trend to try to combine the best of both CAM and conventional care.

Who Seeks Alternative Care and Why?

Although the press initially portrayed most patients seeking CAM as terminally ill people hoping for miracle cures, the average person using CAM is actually a well educated health consumer with a chronic, but not life-threatening, condition who can afford CAM services. A higher level of education and living on the West Coast are two strong predictors of CAM use.[1]

CAM is attractive to many people because of its emphasis on treating the whole person, its promotion of good health (not just treatment of illness), its placement of value on prevention, and often a more personalized approach to patient concerns. A mail survey of more than 1000 Americans recently verified that 40% of adults used at least one type of CAM.[3] These consumers were asked why they sought out alternative therapies. Independent predictors of CAM use included: higher level of education, poorer health status, a "holistic" approach to health, and a world view that included an interest in personal growth and spirituality. People with conditions such as anxiety, back difficulties, chronic pain, and urinary problems were more likely to have used CAM in the previous year. Less than 5% of those who responded relied primarily on alternative medicine for their health care. Despite the popular belief that many patients seek out CAM because they are not happy with conventional medicine, dissatisfaction was NOT shown to predict greater use of alternative modalities.[3] The majority of CAM users appear to seek care for their chronic problems with BOTH alternative and conventional medicine, because CAM seems more congruent with their values and orientation towards health and is perceived to be as or more effective.

How is the Traditional Healthcare Community Responding?

Despite increasing public demand for CAM services, the lack of high quality data regarding safety and efficacy frustrates both patients and providers. In response to this lack of information, Congress established the Office of Alternative Medicine in 1992. It began as a very small division within the National Institutes of Health (NIH), but has recently been elevated to a full NIH Center (National Center for Complementary and Alternative Medicine, NCCAM). Part of their $70 million/year budget goes toward funding nine national research centers at universities such as Columbia, Maryland, Michigan, Oregon, and Arizona. These investigators are researching CAM's safety and efficacy in areas such as chronic disease, women's health, pediatrics, and chiropractic. High quality research is desperately needed to help patients and health care providers answer the crucial questions: Is CAM safe? Does it work? Is it cost-effective?

Health Insurance Coverage for CAM: Integration into Mainstream?

Virtually no third party payers were offering CAM services ten years ago, but a 1999 national survey of health maintenance organizations (HMOs) revealed that two-thirds are now offering at least one CAM modality - most commonly chiropractic (65%) followed by acupuncture (35%).[4] The top reasons given by the insurers for offering these services were "enrollees asked for them" or "they were

mandated." Half of all HMO enrollees reported that they were willing to pay a higher premium for CAM services.

The most common model of CAM insurance coverage is when enrollees pay a supplemental premium for access to independently contracted networks of CAM practitioners. Members receive coupons redeemable for a variety of discounted CAM and wellness services that they can often access without needing a referral from their primary care provider. Such plans are popular, offering enrollees independent access to a variety of CAM providers and services such as chiropractic, massage, acupuncture, and stress management. They do not, however, help bridge the communication gap that exists between patients and their primary care providers. Many patients are turning to pharmacists for first line advice about the fastest growing alternative medicine modality in the United States: herbal medicines and dietary supplements.

Epidemiology of Herbal Use

One out of three Americans purchased herbal medicines in 1997, spending more than $5 billion.[1] Fifteen million people in the United States (44% of all adults who regularly take prescription medications) took prescription medicines concurrently with one or more herbals, high dose vitamins, or both. This represented almost 20% of all prescription drug users.[1]

Can consumers trust what's on the market? Not always! The major reason that herbal medicines remain essentially unregulated in the United States is the passage of the Dietary Supplement Health and Education Act of 1994, DSHEA. In the early 1990's, consumers who were concerned that the FDA might begin to regulate the herbal industry wrote more letters to Congress than had been received since the Vietnam War! DSHEA was passed and all vitamins, minerals, herbs, and amino acids were classified as nutritional or dietary supplements. This means that they can be marketed without proof of efficacy, safety, or manufacturing standards, as long as they make no claim to diagnose, treat, cure, or prevent disease. In addition, before an herbal product can be taken off the market, the FDA must prove in court that it is unsafe, unlike OTC and prescription drugs that must be proven safe and effective by manufacturers before they are marketed.[5]

Economics: Big Pharmaceutical Firms Entering the Market

It is not surprising that until recently, proprietary drug manufacturers haven't been interested in producing herbal products, because plants cannot be patented. Within the last few years, however, large companies have entered the herbal market with brand name products. These often contain standardized extracts imported from European pharmaceutical firms. Some examples are:

- Warner Lambert: Quanterra® brands (ginkgo, saw palmetto, St. John's wort)
- Bayer Corporation: One-A-Day® products, Cold Season® (Echinacea, zinc, vitamin C) and Cholesterol Health® (garlic, soy extract, Vitamin E, lecithin)
- Whitehall-Robins Healthcare: six Centrum® Herbal Formulas
- Pharmaton® (Boeringer Ingelheim): Movana® (St. John's wort) and Ginkgoba®

Many feel that these large pharmaceutical companies will bring improved quality control, safety, and credibility to the herbal industry. (But, possibly with a higher price tag!)

Safety of Herbal Medicines: Buyer Beware!

A recent review of the risks associated with taking herbal medicines chronicles many examples of why the herbal consumer needs to beware.[6] There are often unanticipated or unwanted effects of the herb itself. For example, acute hepatitis has been associated with the Chinese herbal product Jin Bu Huan, a combination of germander and ma-huang. In another case, a combination of eight herbs (PC-SPEC) marketed to balance the immune system in patients with prostate cancer was found to contain potent estrogenic activity in vitro, in animals and in eight men with prostate cancer who developed breast tenderness, decreased libido, and deep venous thrombosis.[7] Other harmful effects have been described as a result of the herb interacting with prescription medication. St. John's wort has been reported to lower drug levels of indinavir in HIV patients[8] and it may affect the levels of other medicines metabolized by the cytochrome P-450 system.[9]

Consumers of herbal medicines have no guarantee that the plant was accurately identified in the field or that another less effective plant part or species wasn't substituted. There is also no assurance that the herb is pure (i.e., no microbial, pesticide or heavy metal contamination), safe, effective, or that the next bottle will have the same ingredients at the same dose.

Future of Alternative Medicine

A recent editorial in the prestigious *New England Journal of Medicine* stated the following: "There cannot be two kinds of medicine - conventional and alternative. There is only medicine that has been adequately tested and medicine that has not, medicine that works and medicine that may or may not work."[10] The demand for high quality research to make evidence-based decisions about health care is increasing in both conventional and alternative medicine. A lecturer at a recent CAM research conference said: "We should really just be aiming to be practicing 'best medicine,' no matter where it comes from and as long as its been proven safe and effective. In God we trust, all others must produce data!"

Part One: Top Selling Dieta

Keeping Up With The Top Selling Herbs

Cathi Dennehy, Pharm.D.
Assistant Clinical Professor
School of Pharmacy
University of California, San Francisco

A recent survey estimating that 42% of Americans used some form of alternative therapy studied 16 types of CAM.[1] The prevalence of herbal medicine use (12%) was second only to relaxation techniques (16%) and slightly ahead of massage (11%). In 1998, herbal sales increased 55% over the previous year. But, in the first eight months of 1999, sales increased only 11%, suggesting the trend is now leveling off.[2] Available primarily in health food stores in the past, herbs and other dietary supplements are now frequently stocked by retail pharmacies.

It is increasingly important for pharmacists to know what evidence supports the use of herbs, what potential they have for adverse effects, and what dosing is appropriate. This review will focus on the top selling herbs of 1999, in order of most to least frequently used.[2] Where possible, products available in the United States that are equivalent to those used in European trials are listed. Pharmacists and consumers, however, should be aware that product content is not guaranteed. Standardized markers, when listed on package labeling, can accurately reflect product content, but may also exceed or be drastically less than what is indicated.

Garlic – *Allium sativum*

An intact bulb of garlic contains many organosulfur compounds, but research into the activity of the herb has focused on allicin, the odiferous constituent.[3] Allicin is generated by a chemical reaction that brings its precursor, alliin, in contact with the enzyme allinase.[3] Disruption of a garlic bulb (e.g. chewing, chopping) causes this reaction. Allinase is highly unstable and is easily broken down by stomach acid and excessive heat.[4] Many commercial products are enteric-coated to prevent this breakdown and allow for maximal allicin formation. Clinical trials frequently used an enteric-coated powdered formulation called Kwai®, which is available in the United States. Garlic formulations that are properly freeze-dried and powdered can retain a high allicin-generating potential, while oil formulations are more likely to contain the breakdown products of allicin.[4]

The organosulfur constituents in garlic have a variety of properties that relate to its use in supporting cholesterol, blood pressure, and atherosclerosis. Garlic has been shown *in vitro* to inhibit hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase, the rate-limiting step in cholesterol biosynthesis. It also enhances production of nitric oxide, a potent vasodilator. In animals, it reduces aortic smooth muscle proliferation. In humans, garlic reduces atherosclerotic plaque formation and has been shown to have antioxidant, antiplatelet, and fibrinolytic effects.[3, 5]

Clinical Trials

Garlic is most often studied for its effects on cholesterol. Older meta-analyses estimated a 9-12% reduction in total cholesterol, with 600-900 mg/day of powdered garlic taken for at least one month.[6, 7] Recent well-designed trials (randomized, double-blind, placebo-controlled) were inconsistent, demonstrating either a reduction in LDL cholesterol of 5-14% or no effect.[8-12] A meta-analysis of eight trials suggested that garlic may have a mild effect on blood pressure, lowering systolic pressure by 7.7 mm Hg and diastolic pressure by 5 mm Hg.[13] Only a few clinical trials evaluated the anti-atherosclerotic effects of garlic. Those that did reported reductions in carotid and femoral artery plaque volumes of 5-18% and less aortic stiffening with prolonged consumption for up to four years.[5,14,15]

Adverse Effects, Drug Interactions and Dosing

In clinical trials, body odor and stomach upset were the most commonly reported adverse effects.[3] A small percentage of patients (1%), reported lower blood pressure.[3] Individuals taking antihypertensive agents should monitor their blood pressure when initiating garlic therapy. Patients taking antiplatelet or blood-thinning medications (e.g., aspirin, ibuprofen, warfarin) may be at increased risk for bleeding, as garlic has been shown to have similar properties. Garlic should be avoided for 7 to 10 days pre- or post-operatively, to avoid potential bleeding complications. Garlic has not been shown to reduce blood sugar in patients with type 2 diabetes; thus, additional monitoring of blood sugar is unnecessary.[16,17] Consumers should be told to purchase a standardized formulation with 1.3% alliin or 0.6% allicin.[3] Powdered garlic should be enteric-coated and dosed at 600 to 900 mg/day in two to three divided doses.[3] An equivalent dose of raw garlic (i.e., one-half to one clove) may also be taken.[6]

Summary

Without further research, the benefits of garlic in supporting cholesterol, blood pressure and atherosclerosis are inconclusive. At best, garlic may have a mild effect on reducing LDL cholesterol, similar to that achieved with dietary modification. Effects on blood pressure are weakly established and are likely to be mild. The anti-atherosclerotic potential of garlic is promising, based on preliminary studies. The low potency of garlic precludes its use as a substitute for prescription drug therapy. However, it may be a useful adjuvant, given its favorable adverse effect profile.

Ginkgo – *Ginkgo biloba*

A concentrated extract of ginkgo can be prepared from the leaves of the tree. Extracts are typically standardized to contain 24% flavonoid glycosides and 6% terpenes.[3] Ginkgo is most often used for symptoms associated with vascular insufficiency to the brain

(cognitive insufficiency) and legs (peripheral arterial occlusive disease). Recent attention has focused on the use of ginkgo in dementia of the Alzheimer's type, which involves heightened levels of brain oxidation and changes in neurochemical transmission (e.g. low levels of acetylcholine).[18] Ginkgo and its constituents were shown to inhibit platelet-activating factor (PAF) and enhance nitric oxide production *in vitro*.[19,20] In animals, it enhances central nervous system levels of acetylcholine and norepinephrine and reduces corticosteroid secretion.[21-23] In humans, ginkgo enhances blood flow, reduces platelet aggregation and reduces markers of oxidative stress (i.e., has antioxidant and free radical scavenging properties).[20,24,25]

Clinical Trials

Two large clinical trials (randomized, double-blind, placebo-controlled) lasting 1 year and 6 months respectively, evaluated the effect of ginkgo extract, EGb 761, in patients with mild to moderate multi-infarct dementia or dementia of the Alzheimer's type.[26,27] In the year-long trial, patients receiving 120 mg/day of ginkgo showed significant improvements in tests assessing activities of daily living and cognition, but not in one assessing the clinician's perception of patient improvement.[26] This study had a high patient drop out rate (almost 50%), and used an analysis that compared data from the point of patient withdrawal to data from patients who completed the one-year observation period. The latter is problematic, since dementia typically worsens over time. In the second trial, clinicians perceived a significant benefit for patients receiving 240 mg/day of ginkgo extract.[27] Assessment scales for cognition and the clinician's perception of patient improvement were both significantly improved, while a scale assessing activities of daily living was not. Two recent reviews confirmed the findings of these two trials, noting a small, but significant, advantage of ginkgo over placebo for improving cognition in patients with dementia.[28,29]

The use of ginkgo to improve pain-free walking distance requires additional study, but appears promising. Initial trials have shown a two-fold increase in walking distance in subjects receiving ginkgo, as compared to those receiving placebo.[30,31]

Adverse Effects, Drug Interactions and Dosing

Adverse effects from ginkgo are rare. They typically consist of stomach upset, headache, anxiety, insomnia, and allergy.[3] Ginkgo may interact with antiplatelet or blood thinning medications (e.g., aspirin, ibuprofen, warfarin) and should be avoided in individuals using these products. There are a few case reports of hemorrhage and hematoma in people using ginkgo as monotherapy or in combination with other blood-thinning medications.[32] Ginkgo should be avoided for 7 to 10 days pre- or post-operatively to avoid potential bleeding complications. The extract formulation used in many European trials, EGb 761, is manufactured in the U.S. as Ginkgold® (Nature's Way), Ginkoba® (Pharmaton), Gingko 5® (Pharmline) and Quanterra Mental Sharpness® (Warner-Lambert). The extract should be standardized by its flavonoid glycoside and terpene contents. The dose is 120 to 240 mg per day, in two to three divided doses.[3] A delay in onset of 4 to 6 weeks may occur.

Summary

Ginkgo is likely to have a mild, but potentially significant effect on supporting cognitive performance in individuals with mild to moderate dementia. Ginkgo may also be helpful in alleviating symptoms such as painful walking in individuals with vascular disease.

St. John's Wort – *Hypericum perforatum*

An extract prepared from the above-ground portions of the *Hypericum perforatum* plant has been studied for its effects on mild to moderate depression.[3] St. John's wort products are standardized by their content of hypericin, which originally was thought to be the primary antidepressant constituent.[3] Recent attention, however, has focused on hyperforin as the primary antidepressant constituent. Hyperforin inhibits the reuptake of norepinephrine, dopamine, and serotonin *in vitro*.[33,34] With chronic administration, it also influences the density of various receptor subtypes (i.e., down-regulating cortical B-receptors and up-regulating cortical 5HT-2 receptors) in animals. The actual mechanism of action of this herb in humans is complex and may involve a number of different biochemical reactions.

Clinical Trials

In a large meta-analysis of over 23 clinical trials, the efficacy of St. John's wort was found to be superior to placebo and equal to that of tricyclic antidepressants.[35] While these results may seem promising, none of the comparative trials in this review included a placebo-control group. This is noteworthy, because placebo response rates ranging from 30-50% have been reported for studies involving synthetic antidepressants.[36] Most of the trials lasted only eight weeks and some used less than the recommended dose of the prescription drug. In addition, almost all of them used a common depressive rating scale (Hamilton Scale for Depressive Symptoms, HAMD) that is not as comprehensive or sensitive as some of the others (e.g., Inventory of Depressive Symptom Scale, IDS; Montgomery Asberg Depression Rating Scale, MADRS). Despite these shortcomings, St. John's wort did exhibit a more favorable adverse effect profile. More recent reviews include trials conducted subsequent to this meta-analysis. They also report superior outcomes with St. John's wort as compared to placebo and response rates similar to those of tricyclic antidepressants.[37,38] In at least one of these reviews, tests for publication bias were significant, indicating possible over-estimation of the effects of St. John's wort.[38]

Several clinical trials compared St. John's wort to the more commonly used selective serotonin reuptake inhibitors (SSRIs).[39-41] All of these were randomized, double-blind trials that compared St. John's wort (500-900 mg/day) to either fluoxetine 20 mg/day (Prozac®) or sertraline 75 mg/day (Zoloft®) for six weeks. All three trials showed significant reductions in HAMD scores for all treatments (St. John's wort and the SSRIs) when compared to baseline, and these results were not statistically different from one another. Another NIH trial is now comparing St. John's wort, SSRI, and placebo and will likely provide more information about the efficacy of St. John's wort.

Adverse Effects, Drug Interactions and Dosing

The formulation of St. John's wort extract used in many European trials, LI 160 (Jarsin®), can be found in the U.S. as Kira® (Lichtwer Pharma) and Quanterra Emotional Balance® (Warner Lambert). The recommended dose of St. John's wort extract is 900 mg per day in two to three divided doses.[3] A delay in onset of 4 to 6 weeks may occur. Most extracts are still standardized to contain at least 0.3% hypericin, although this ingredient may not be responsible for the antidepressant effects.[33,34] Adverse effects have been reported rarely with recommended doses. They include stomach upset, sedation, headache, restlessness, dizziness, and confusion.[42] An increased sensitivity to sun exposure is primarily due to the hypericin constituent and is unlikely to occur at recommended doses.[3] Nevertheless, it is still advisable to suggest the use of a sunscreen with this product. St. John's wort should not be used in combination with other prescription antidepressant or psychiatric medications to avoid an additive effect known as "serotonin syndrome."[43] St. John's wort should also be used cautiously in patients with a history of mania or bipolar disorder, as hypomania and mania have been observed.[44]

St. John's wort may decrease the efficacy of other prescription agents such as digoxin, theophylline, cyclosporin, warfarin, indinivir, and ethinylestradiol/desogestrel.[45,46] It may induce cytochrome (CYP) P450 enzymes such as CYP2C9 (metabolizes warfarin), CYP1A2 (metabolizes theophylline), and CYP3A4 (metabolizes indinivir, ethinyl estradiol and cyclosporin).[47,48] In the case of digoxin, induction of the drug transporter P-glycoprotein may have reduced drug absorption and enhanced elimination.[47] Individuals taking any of these medications should consult with a physician prior to initiating therapy with St. John's wort. While the mechanism of action of St. John's wort is still under investigation, initial reports of monoamine oxidase inhibition have not been substantiated at recommended doses.[33,34] Thus, dietary restrictions are probably unnecessary when using this product.

Summary

St. John's wort may enhance mood in individuals with mild to moderate depression. Future clinical trials should focus on comparing St. John's wort to the more commonly used SSRIs such as fluoxetine (Prozac®), sertraline (Zoloft®), and paroxetine (Paxil®). The long-term benefits of St. John's wort remain unknown, since a majority of the clinical trials lasted only eight weeks. Individuals should not initiate therapy with St. John's wort if symptoms are worrisome or severe. Pharmacists should question anyone considering the use of St. John's wort about concurrent medications, to limit the potential for adverse drug interactions.

Kava Kava - *Piper methysticum*

For centuries, Pacific Islanders have used kava for ceremonial purposes to encourage socialization and relaxation.[49] The root of the plant contains pharmacologically active fat-soluble constituents known as kavalactones. Commercial formulations are typically standardized to contain 30-70% kavalactones.[50] Kava is most commonly used for its calming properties by individuals who have mild to moderate anxiety. Muscle relaxant, anticonvulsant, analgesic, and anesthetic properties were observed in animals.[3,49] The mechanism of action of kava is not well understood. It may enhance GABA neurotransmission, inhibit sodium and calcium channels, inhibit norepinephrine reuptake in the brain, and affect dopamine neurotransmission.[51-55]

Clinical Trials

Kava does not appear to cause the same level of impairment in reaction time or in information processing as benzodiazepines.[56,57] One six-week trial reported equivalent reductions in the Hamilton Anxiety Scale (HAMA) for patients receiving kava extract 300 mg (WS 1490, Laitan®, which is standardized to contain 70% kavalactones), oxazepam 15mg, and bromazepam 9 mg.[3] This trial, however, did not include a placebo arm. In another six-month trial in patients with moderate to severe generalized anxiety, 300 mg of WS 1490 was significantly better than placebo in reducing HAMA from weeks 8 to 24.[50]

Adverse Effects, Drug Interactions and Dosing

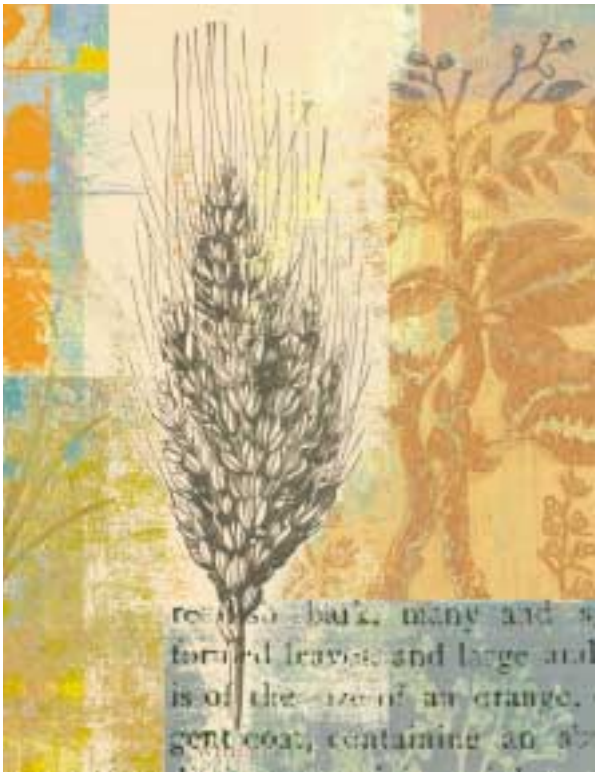
Laitan® is not imported into the United States. Consumers should therefore look for an extract with a similar kavalactone content. At recommended doses of 200 to 300 mg/day (150-210 mg kavalactones in a 70% formulation), kava does not appear to significantly impair motor function.[56,57] Kava withdrawal was not observed in the longest clinical trial, which lasted six months. Tolerance has been difficult to induce in animal models at high doses.[50,58] Kava, however, may accentuate the impairment observed with other sedative hypnotic agents when used in combination. Kava significantly enhances the impairment associated with alcohol as compared to alcohol alone.[59] There is also a case report of a consumer who became semi-comatose after combining kava with alprazolam (Xanax®).[60] Kava should be avoided in people who have Parkinson's disease or schizophrenia due to its potential effects on dopamine.[55] Four case reports of Parkinson-like symptoms have been reported in individuals using kava at recommended doses.[61] When high doses of kava are used for prolonged periods, a scaly yellow skin rash may develop.[49] At recommended doses, side effects are rare and typically consist of stomach upset and allergic skin reactions.[3]

Summary

Kava may promote a feeling of calmness that could be beneficial to individuals with mild to moderate anxiety. Kava has a favorable adverse effect profile at recommended doses. Unlike benzodiazepines, it has not been associated with dependence or tolerance. Kava may have a delayed onset of action of 4 to 8 weeks.[50] It should not be used for more than three months.[3]

Saw Palmetto - *Serenoa repens*

When extracted, the berries of the saw palmetto dwarf palm yield a fat-soluble substance comprised of fatty acids and sterols. The most common formulation used in Europe, Permixon®, is not available in the United States.[62] Standardized products that are available should contain at least 85-95% fatty acids and sterols.[62] Saw palmetto is most often used to alleviate symptoms associated with benign prostatic hyperplasia (BPH). BPH symptoms can improve even without treatment, as evidenced by a high placebo response rate of 40-60%.[62] For this reason, uncontrolled studies provide little proof of efficacy. The mechanism of saw palmetto is poorly understood, but a number of different possibilities have been suggested. These include inhibition of the enzyme that converts testosterone to dihydrotestosterone (DHT), direct antagonism of DHT binding to its receptor, blockade of alpha-1 receptors, antiinflammatory effects, and inhibition of prostate growth factors.[63-67] Saw palmetto does not affect prostate specific antigen (PSA) and therefore should not affect cancer screening.[63]



Clinical Trials

A recent review of 18 randomized controlled trials (16 of them double-blind), reported superior urologic symptom scores and urinary flow measures for patients receiving saw palmetto as compared to placebo.[67] These variables improved 24-28 %. Prostate size was not affected. Study participants had moderately severe BPH and received treatment for a mean of nine weeks. Two non-placebo controlled trials compared the efficacy of saw palmetto (320 mg) to an alpha-adrenergic blocker (either prazosin 4 mg or alfuzosin 7.5 mg.)[68] In both trials, improvements in symptom scores and flow measures favored the alpha-blocker. Saw palmetto 320 mg was as effective as finasteride 5 mg after six months of therapy in a randomized, double-blind trial involving patients with moderately severe BPH.[69] Both agents showed equivalent reductions in the International Prostate Symptom Score (IPSS), and increased quality of life and peak urinary flow. Only finasteride significantly reduced prostate volume and serum levels of PSA.

Adverse Effects, Drug Interactions and Dosing

Saw palmetto has rarely been reported to cause stomach upset and has no known drug interactions.[70] Products that are standardized to 85-95% fatty acid sterols should be selected. The recommended dose is 320 mg/day in two divided doses. The effects may be delayed 4 to 6 weeks.

Summary

Saw palmetto may alleviate certain symptoms associated with mild to moderate BPH. Its adverse effect profile is favorable and superior to that of alpha-blockers and finasteride. Long term benefits beyond six months have not been evaluated. Men wishing to initiate therapy with this product should have a baseline PSA to rule-out more serious disease. Pharmacists should be aware that the FDA discourages self-treatment of prostate problems. Under a new rule, manufacturers are not allowed to list "BPH" or "Helps to maintain urine flow in men over 50 years or age" on their product labels.[71]

Ginseng - *Panax species*

Of the various ginseng species, *Panax ginseng* (the Asian variety) and *Panax quinquefolius* (American ginseng), are most commonly found in the U.S.[72] There is also Siberian ginseng, which comes from the *Eleutherococcus senticosus* plant.[3] The latter is unrelated to the Panax species and has been studied less often in clinical trials. Nonetheless, European experts recommend both Siberian and Panax ginseng for similar conditions.[3] The root of the Panax species contains up to 28 different pharmacologically active ginsenosides.[73] The number and types of ginsenosides can vary between species, thus pharmacological activity may differ.[72] Mechanisms of action of ginseng observed *in vitro* and in animals are extensive and go beyond the scope of this review.

Clinical Trials

Panax ginseng is widely used for a variety of conditions including improved physical and mental performance, enhanced immune

function, and cancer prevention. There is no single, well-documented clinical use. *Panax ginseng* is typically reported to be adaptogenic, which means that it protects and normalizes the body against a variety of different stressors. Given this generalized claim, it is not surprising that many clinical trials have failed to find a reproducible effect. Most of the trials evaluating enhancement of aerobic exercise had small sample sizes and reported either beneficial results or no effect.[73, 74] Similarly, trials evaluating cognitive performance in healthy individuals only found improvement in a few out of a battery of cognitive tests.[75,76]

Other studies evaluated ginseng for its effect on quality of life and immune function.[77,78] A very low dose of *Panax ginseng* extract (40mg) given in a multivitamin complex significantly improved quality of life compared to patients receiving a multivitamin complex without ginseng.[77] Another trial suggested that the use of 100 mg of standardized *Panax ginseng* extract (G 115, Ginsana®) for 12 weeks at the time of flu vaccination significantly reduced the incidence of colds compared to vaccinated patients who received placebo.[78]

> "The majority of Complementary and Alternative Medicine users appear to seek care for their chronic problems with both alternative and conventional medicine."

Adverse Effects, Drug Interactions and Dosing

Ginsana®, a brand frequently used in European clinical trials, is available in the United States. The recommended dose of the Panax extract is 200 mg per day, standardized to contain at least 7% ginsenosides. Adverse effects are rare at recommended doses. High doses have been associated with a stimulatory response (insomnia, hypertension, nervousness) in some individuals.[79] However, these patients were also consuming undisclosed amounts of caffeine. Individuals who use prescription stimulants, should use ginseng cautiously or not at all. The herb may also have estrogenic properties and has been linked to case reports of breast pain and break-through vaginal bleeding in women.[80,81] Ginseng has been reported to cause manic behavior in patients, when used in combination with neuroleptics.[82,83] This combination should be avoided or closely supervised by a physician. Ginseng should be used cautiously in patients taking antiplatelet or blood thinning medications (e.g., aspirin, ibuprofen, warfarin), because of a possible interaction.[73] Pre- or post-operative patients should avoid taking ginseng for 7 to 10 days. Hypoglycemia has been reported following ginseng ingestion, so patients taking diabetic medications should monitor their blood sugar levels.[84] Other drug interactions suggesting increased digoxin levels and diuretic resistance have been challenged, based on the likelihood of product adulteration.[85-87]

Summary

Given the mixed clinical findings for *Panax ginseng* as a cognitive and performance-enhancing herb, and the small number of trials for other indications, there is no clear therapeutic recommendation for it at this time. With more well-designed clinical trials, a defined place in therapy may become apparent.

Echinacea - *Echinacea species*

Echinacea, also known as the purple coneflower, is commonly taken to alleviate symptoms of upper respiratory tract infection (URI). The primary species that are available in the U.S. are *E. pallida*, *E. angustifolia*, and *E. purpurea*. The German Commission E (Table 1.) only recommends the use of the above ground portions of *E. purpurea* and the root extract of *E. pallida*.[3] The most common formulations studied were *E. purpurea* fresh pressed juice (preserved in 22% alcohol by volume), Echinacin®, and *E. pallida* root extract. There has been no clinical research to support the use of the roots of *E. purpurea* or *E. angustifolia*. Investigators are now researching these particular formulations to determine if they have a place in therapy.

Echinacea products are not standardized by any specific constituent, but chicoric acid, alkamides, and the polysaccharide fractions are thought to have immune-modulating effects.[88] When used by itself, the polysaccharide fraction may have immuno-stimulant properties, increasing the production of various cytokines.[89]

However, when the entire extract is used in its marketed form, only enhanced phagocytic activity has been observed in humans.[89,90] One *in vitro* study did demonstrate enhanced cytokine production using *E. purpurea* fresh pressed juice.[91] Further research will likely identify the effects of echinacea *in vivo*.

Clinical Trials

Two recent randomized, double-blind, placebo-controlled trials evaluated the efficacy of echinacea in treating colds.[92,93] Both initiated treatment at the onset of symptoms. In the first trial, 120 people with symptoms of URI took *E. purpurea* fresh pressed juice preserved in 22% alcohol (Echinaguard®, the U.S. equivalent of Echinacin®) or placebo. The echinacea product significantly reduced time to recovery by 50%, from 8 to 4 days. A "full-blown" cold developed in significantly fewer patients receiving the echinacea product (40% versus 60%).[92] In the second trial, a dried ethanolic *E. purpurea* herb extract (Echinaforce®, prepared from 95% herb and 5% root), was significantly better than placebo or *E. purpurea* root extract at reducing cold symptoms.[93] This reaffirms the German Commission E recommendation that only the above ground portions of the *E. purpurea* plant should be used.

The use of echinacea to prevent the incidence of colds has also been studied in two clinical trials.[94,95] In both trials, echinacea or placebo was administered in a randomized, double-blind fashion for 8-12 weeks. One trial used *E. purpurea* fresh pressed juice and found no significant differences in cold incidence or severity.[94] The other trial compared *E. purpurea* root extract, *E. angustifolia* root extract, and placebo and found no significant differences in time to first upper respiratory infection.[95] The latter, however, used formulations of echinacea that are not recommended by the German Commission E.

Adverse Effects, Drug Interactions and Dosing

Echinacea occasionally causes stomach upset, taste disturbances, headache, dizziness and tiredness.[89] Patients with asthma or allergic rhinitis may be at higher risk for allergic reactions, based on the results of skin testing.[96] There are no reported drug interactions. Given the high alcohol content of certain extracts, patients taking metronidazole (Flagyl®), chlorpropamide (Diabenese®), or cefotetan (Cefotan®) are likely to experience a disulfiram-like reaction (nausea, flushing) and should avoid these products. Until the mechanism is fully understood, patients with autoimmune disorders (e.g., rheumatoid arthritis, multiple sclerosis, systemic lupus erythematosus), those who are immune-compromised (e.g., AIDS, cancer), or those using immuno-suppressive agents (e.g., cyclosporine, corticosteroids) should not use this product.[3] The recommended dose is 900 mg/day of the *E. pallida* root extract or 6-9 mL/day of the *E. purpurea* fresh pressed juice prepared from the above the ground portions of the plant (e.g., Echinaguard® by Nature's Way) divided into two to five doses daily.[3] Products should not be used beyond 8 weeks.[3]

Summary

Echinacea may be beneficial in reducing symptoms associated with acute URI. Recent studies do not support its use for cold prevention. It should be taken at the first sign of a cold until symptoms resolve.

Black Cohosh - *Cimicifuga racemosa*

Among all herbs, sales of black cohosh increased the most (almost 500%) in

TABLE 1.

German Commision E

- Formed in Germany
- Comprised of scientists and clinicians with various backgrounds
- Reviewed and wrote monographs for over 300 botanicals between 1982 and 1994
- Rated botanicals as "acceptable" if they displayed "absolute safety" and "reasonable certainty of efficacy"
- Published monographs in the German *Bundesanzeiger*, which is similar to the *U.S. Federal Register*
- Monographs were translated by the American Botanical Society

1999.[2] Black cohosh is commonly used for symptoms associated with menopause.[2] It is available both in Europe and in the United States under the commercial name Remifemin®. The root of the plant is rich in triterpene glycosides, which are considered to be the main active ingredients.9[7] An isopropanolic extract of Remifemin® is available as a 20 mg tablet that is standardized to contain 1 mg of 27-deoxyacetein (a triterpene glycoside).[85] An equivalent dose of the liquid ethanolic extract would be 20 mg or 20 drops. Commercially available isopropanolic and ethanolic extracts do not appear to contain isoflavones.[97,98]

Clinical Trials

Initial studies suggested that compounds in the root of the plant reduced secretion of leutinizing hormone (LH) in menopausal women and bound estrogen *in vitro*.[99,100] Subsequent research did not reveal estrogenic effects on vaginal or uterine tissue in rodents using the ethanolic extract.[101] A recent clinical trial found no effect of Remifemin® on LH secretion, follicle stimulating hormone (FSH) secretion, sex-hormone binding globulin (SHBG), prolactin, or estrogenic markers (hypertrophy of vaginal epithelium).[102] Effects of black cohosh on breast tissue in vivo are not known, but the isopropanolic extract was shown to inhibit growth of an estrogen-dependent breast cancer cell line in vitro.[97] Until further research is done, the mechanism of black cohosh remains unknown.

> "The average person using Complementary and Alternative Medicine is actually a well-educated health consumer with a chronic, but not life-threatening condition."

Two systematic reviews have detailed the results of eight studies published between 1982 and 1997.[97,103] The primary outcome measure in most of these trials was the Kupperman Index of Menopausal Symptoms, a standardized scale that encompasses a variety of menopausal symptoms. All eight trials reported significant benefits in symptom scores using 2 to 8 mg/day of 27-deoxyacetein, equivalent to 40 to 160 mg of Remifemin®, for up to 12 weeks. Of the eight studies, seven were published in the German language, seven had an open study design, two were randomized, and four had control groups. The only double-blind, placebo-controlled study randomized 80 patients to receive 4 mg of Remifemin®, 0.625 mg of conjugated estrogen, or placebo. At 12 weeks, the Kupperman score was significantly reduced for the Remifemin® group as compared to the estrogen and placebo groups. The vaginal epithelium of patients in the Remifemin® group was also notably increased. It should be noted that the manufacturers of Remifemin® now recommend a lower dose of 2 mg per day, based on research showing equivalent efficacy without deleterious effects on the vaginal epithelium.[104]

Adverse Effects, Drug Interactions and Dosing

The recommended dose of Remifemin® is 40 mg of the herb (i.e., one tablet containing 1 mg of 27-deoxyacetein twice daily or 20 drops of the liquid formulation twice daily.)[86] Onset of action may not occur for up to four weeks.[97,103] Benefits beyond 12 weeks have not been adequately studied, so consumers should continue to monitor for improvement.[97,103] Adverse effects are rare at recommended doses and typically involve stomach upset.[92] No drug interactions have been reported. Historically, this herb was used to induce labor and therefore should be avoided in pregnant women. Black cohosh has not been studied for other disorders associated with menopause, such as cardiovascular disease and osteoporosis.

Summary

Preliminary evidence indicates that black cohosh may be beneficial in reducing menopausal symptoms such as hot flashes, mood disturbances, and sleep disturbances. Long term benefits have not been adequately studied. The German Commission E recommends limiting product use to no more than six months.[104]

Dietary Supplements:

Sorting Through the Evidence

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Pharmacists today sell dietary supplements along with non-prescription products. Thus, they are likely to be approached by consumers with questions about supplement quality, efficacy, and safety. This article will focus on the scientific evidence supporting the use of some popular non-botanical, non-vitamin dietary supplements. The following products were selected because they are heavily promoted in the media and frequently considered for purchase by consumers.

Melatonin

Melatonin is a hormone produced by the pineal gland. The pineal gland is located in the base of the brain and is important in controlling normal sleep-wake cycles. Melatonin is released during periods of darkness, between 9 p.m. and 4 a.m. During the day, melatonin release is suppressed. With age, melatonin levels slowly decline such that levels in a 60-year old are much less than those in a 20-year old. For this reason, researchers have suspected that replacing low levels of melatonin may help correct age-associated problems such as insomnia. Insomnia has been estimated to occur in 13 to 33 percent of the U.S. adult population.[1] Young adults typically suffer from sleep onset insomnia (trouble falling asleep), while older adults commonly suffer from sleep maintenance insomnia (trouble staying asleep).[2]

Clinical Trials

Several clinical trials have studied melatonin for insomnia.[3-5] Improvements in the quality of sleep (onset and duration), were noted. However, these studies were poorly designed in that dosing, patient age, timing of drug administration, randomization of subjects, study duration, and type of monitoring varied greatly. According to the largest clinical trial, both immediate- and sustained-release melatonin appeared to help patients with sleep onset insomnia. Sustained-release melatonin did not help patients with sleep maintenance insomnia.[6] Further research is needed to determine the effect of patient age, melatonin dose, duration of therapy, and underlying etiology on melatonin efficacy.

Melatonin has also been studied for preventing jet lag. Jet lag occurs when the external time does not correspond with the internal time. This often occurs with air travel across multiple time zones. Typical symptoms of jet lag include daytime drowsiness, gastrointestinal distress, and frequent awakenings. Non-drug therapy for jet lag involves maximizing exposure to daylight and darkness according to the new time zone. Exogenous melatonin is used to reset peak melatonin levels. Older studies assessed the effects of melatonin in improving jet lag symptoms in passengers and flight crew traveling across multiple time zones.[7-11] These studies used varying melatonin doses (5 to 8 mg immediate release) at different times of administration. Subjective improvements in symptoms were reported, including decreased daytime fatigue, improved mood, and better recovery time. The most recent placebo-controlled clinical trial included 257 subjects traveling between New York City and Oslo, Norway.[12] Patients received placebo or three different doses of melatonin (0.5 mg at bedtime, 5 mg at bedtime, and 0.5 mg given an hour earlier each night). Upon arrival and for the next five days, all patients reported similar jet lag symptoms with no differences between groups. No improvements in napping, sleep onset, sleep duration, or other symptoms were observed.

Adverse Effects and Potential Interactions

The adverse effects of melatonin are mild, but may involve daytime drowsiness, headaches, rapid heart beat, and rarely, depressed mood.[7-11] A rare case of rash and one acute psychotic episode with melatonin overdose have been reported.[13,14] Although melatonin has been associated with daytime drowsiness, it is considered less sedating than over-the-counter antihistamines and other prescription sedatives. High doses of melatonin (75 mg to 300 mg) in combination with a progestin have been associated with partial inhibition of ovulation.[15] Therefore, women who are attempting to conceive, or who are currently pregnant, should avoid taking melatonin. Poorly manufactured melatonin formulations may be associated with adverse effects, as a result of releasing the melatonin all at once or not at all.[16]

Drug interactions with melatonin supplements have not been formally studied. However, combining melatonin with alcohol or other sedative hypnotics may cause excessive sedation or dizziness.

Dosing and Recommendation

Doses used to treat insomnia vary. Therefore, the lowest effective dose of melatonin should be used. Doses of 0.3 mg to 5 mg of the immediate-release formulation should be taken just prior to bedtime.[17] Reading lights should be turned off to help trigger natural melatonin release. Sleep onset should occur within 30 to 45 minutes. If sleep does not ensue, a repeat dose may be taken, up to a maximum of 20 mg. The safety of long-term melatonin use is not known, therefore it should only be used when necessary. As with any sedative-hypnotic, avoid using melatonin for prolonged periods of time (more than one to two weeks).

Melatonin appears to be useful for sleep onset insomnia. Its usefulness in maintenance insomnia and jet lag is less clear and requires further research.

Glucosamine

Glucosamine is an essential component for cartilage nutrition and is also incorporated into cartilage. Osteoarthritis (OA) is a degenerative disease that affects cartilage, bone and other tissues. Cartilage degeneration commonly occurs in the knee joints and spine. Cartilage is composed of cartilage cells and extracellular matrix. The matrix is a mesh of fibers that anchors cartilage cells, collagen, and other proteins. Together these proteins help to strengthen the joint and provide support. Cartilage does not receive blood supply; therefore, all necessary nutrients are supplied by the synovial fluid, bone, and other structures (perichondrium).[18]

Glucosamine incorporates into protein structures called glycosaminoglycans (GAGs). Multiple GAGs form proteoglycans (PGs), which resemble tree branches. When taken as the sulfate form, glucosamine gets incorporated into the GAGs allowing the sulfate structure to help keep the branches apart. Glucosamine also contributes to cartilage cell nutrition.

Clinical Trials

Investigators have studied glucosamine in OA, but many of these trials had serious design flaws.[19] Two adequately designed studies assessed the effects of glucosamine sulfate in patients with mild to moderate OA of the knee or in generalized OA.[20,21] Only one of these used oral glucosamine sulfate; the other used an injectable

form. After one week of oral glucosamine therapy (1,500 mg daily), patients displayed statistically significant improvements in pain scores as compared to placebo.[21] By the second week, patients receiving glucosamine sulfate experienced less joint tenderness and swelling than did those receiving placebo. Both of these studies were short and did not disclose concomitant medications. A recent meta-analysis had similar results, but noted that the published studies tended to overestimate the benefits of glucosamine.[19] These authors concluded that glucosamine may improve OA symptoms about 30%.

Glucosamine HCl has also been studied for OA knee pain. In a three-month study, patients received glucosamine HCl (500 mg three times daily) or placebo.[22] After two months, there were no differences in mobility and joint function. The only statistically significant improvements were in pain relief and objective knee improvements on X-ray. Another study assessed the role of a combination product of glucosamine HCl, chondroitin, and manganese ascorbate (Cosamin DS®) in treating knee and cervical spine OA.[23] While the authors concluded that it improved knee OA, this study was limited by the sample size and a cross-over design that could have resulted in carry-over of effect. Furthermore, the addition of chondroitin may have contributed to this product's effectiveness.

Other salt forms of glucosamine are available, such as glucosamine hydroiodide and N-acetyl-glucosamine. Glucosamine hydroiodide should be avoided because it can interfere with undiagnosed thyroid disease. There are no clinical trials assessing the effectiveness of the hydroiodide salt on knee OA. N-acetyl-glucosamine is thought to increase the incorporation of glucosamine into cartilage, but laboratory studies suggest that it is not incorporated into cartilage cells.[24] There are no clinical trials assessing the value of these or any other additional ingredients.

Adverse Effects and Potential for Interactions

Since glucosamine products are aminosaccharides, the most commonly reported problems are gastrointestinal (nausea, vomiting, diarrhea). One study suggested that glucosamine sulfate may contribute to insulin resistance.[25] While this study demonstrated an increase in fasting insulin concentrations, blood glucose levels were not affected. Patients with diabetes who want to take glucosamine should monitor their blood sugars as usual.

There are no known interactions between glucosamine and other drugs. However, the ingredients that are added to glucosamine products may interact with other drugs or diseases. These include sodium, potassium, manganese, and ascorbic acid. Sodium and potassium are added to increase the stability of glucosamine sulfate and are usually present in small amounts. Manganese and ascorbate are cofactors that are indirectly involved in strengthening cartilage. Ascorbate is added to products to help strengthen collagen fibers. Manganese deficiencies have been associated with abnormal bone and cartilage formation; therefore, manufacturers add manganese to increase glucosamine incorporation into cartilage. The recommended daily intake (RDI) for manganese is 2 mg to 5 mg. Many glucosamine products exceed the RDI and provide nearly 228 mg of manganese daily. While the effects of high dose manganese from glucosamine are unknown, there is potential for manganese-induced headache, confusion and other adverse central nervous system effects with excessive use.

Dosing and Recommendation

Currently, only glucosamine sulfate appears effective in improving the pain associated with OA. Combination products are more costly and require further study. With usual doses of 500 mg three times daily, OA pain relief with glucosamine sulfate typically takes about one week, but may be delayed up to one month.[26] Anti-inflammatory drugs (e.g. ibuprofen) have a faster onset and a shorter duration of action. People who wish to use ibuprofen in combination with glucosamine may do so, especially during the first week of therapy or for an acute flare of OA pain.

Chondroitin Sulfate

Chondroitin sulfate is one type of glycosaminoglycan and consists of repeating glucosamine units. It is often combined with glucosamine to improve the symptoms of OA. Dietary supplement manufacturers claim that chondroitin sulfate inhibits the breakdown of cartilage by blocking cartilage destroying enzymes. While this remains to be proven, there is evidence that chondroitin helps to prevent cartilage breakdown.[27] Early research suggested chondroitin sulfate was not absorbed;[28] however, other studies now suggest that it is, since it is broken down in the stomach to individual glucosamine units.[29,30]

Clinical Trials

A few randomized, double-blind, placebo-controlled trials (three months to one year) have assessed the effects of chondroitin sulfate in improving OA knee pain.[31-33] In one of these, chondroitin sulfate was dosed as either 400 mg three times daily or 1200 mg once daily. Patients had statistically significant improvements in joint pain and function with either regimen as compared to placebo.[31] Only one study compared chondroitin sulfate to a nonsteroidal anti-inflammatory agent, diclofenac sodium.[33] Patients with knee OA were given chondroitin sulfate (400 mg three times daily) for three months followed by placebo for three months. The other group of patients received diclofenac sodium (50 mg three times daily) for one month and then placebo for five months. Patients in the chondroitin group experienced gradual improvements in joint function and pain. These improvements were sustained for up to one month after discontinuation of chondroitin sulfate. Patients who received diclofenac experienced a gradual worsening of symptoms after discontinuation of the drug. While these results were statistically significant, the authors did not take into account the analgesic properties, faster onset and longer duration of action of diclofenac. A recent meta-analysis found that chondroitin sulfate can improve symptoms of OA to a similar degree as glucosamine, usually reducing them by about 30 percent.[19]

Adverse Effects and Potential Interactions

Chondroitin sulfate is well tolerated and has mild gastrointestinal side effects, similar to those of glucosamine. Its effects on glucose and insulin release are not known. Drug interactions have not been formally studied.

Dosing and Recommendation

Chondroitin sulfate has a very slow onset of action and the effects on joint function last longer than those of diclofenac. It can be dosed as either 400mg three times a day or 1200 mg once daily. Improvements may be noted in one week, but may take up to one or two months.

Clinical trials suggest that both glucosamine and chondroitin are effective in relieving symptoms of OA. The value of a combination of both of these products has not been compared to either one alone in clinical trials. The value of ingredients like manganese and ascorbate is unknown and their addition appears unnecessary.

Shark Cartilage

The manufacturers of shark cartilage have claimed for years that sharks do not get cancer and therefore must possess cancer protective substances. Sharks have an abundance of cartilage. Shark cartilage is primarily composed of the protein, chondroitin sulfate.[34] Researchers recently found that sharks do, in fact, get cancer, a form of cartilage cancer known as chondroma.[35] The exact components within shark cartilage that are thought to afford protective anticancer properties are not yet known. Manufacturers of shark cartilage contend that it contains angiogenesis inhibitors and would therefore be of benefit to people with solid tumors. Angiogenesis inhibitors block the formation of new blood vessels and subsequently block the delivery of nutrients tumor cells need for growth. Angiogenesis inhibitors are thought to target tumor cells directly, thereby preventing systemic side effects.

Clinical Trials

The role of shark cartilage in cancer is based on a 1977 *in vitro* study. Two shark extracts, sphyrnastatin 1 and 2, were purified from the hammerhead shark.[36] These extracts were thought to have angiogenesis inhibitor properties, but that still remains to be proven. Few clinical trials are available to support the use of shark cartilage in treating cancer. Only one published clinical trial assessed the effects of shark cartilage in 58 adult patients with advanced cancers, who were unresponsive to conventional chemotherapy. [37] All patients received 1 gm/kg/day in three divided doses. At the end of three months, no patients experienced a complete or partial response to therapy and there were no improvements in quality of life scores.

Adverse Effects and Potential Interactions

Since shark cartilage is composed of chondroitin sulfate, it has the same gastrointestinal side effects. There is one report of hepatotoxicity with shark cartilage; however, the product in question was never analyzed for contaminants.[38] Shark cartilage has not been studied for drug interactions.

Recommendation

Patients who wish to use shark cartilage should know that there is no clinical evidence supporting its use for cancer or solid tumors.

Dihydroepiandrosterone (DHEA)

DHEA is a precursor hormone produced predominantly by the adrenal glands.[39] DHEA is also called the mother hormone, because it is ultimately converted to both estrogen and testosterone. DHEA circulates in the blood as DHEA-S, the sulfate ester form. DHEA-S levels are more commonly measured, since there is less variation in these levels as compared to DHEA levels. DHEA and DHEA-S levels peak between 20-30 years of age[39] and then decline progressively until death. Dietary supplement manufacturers promote DHEA-S supplementation to prevent and slow age-associated disorders.

DHEA, when ingested as a supplement, is converted to both estrogen and testosterone.[40] Initially, this conversion depends upon gender. In non-menopausal women DHEA is predominantly converted to testosterone since levels of estrogen are abundant. In menopausal women and in men, DHEA appears to be converted to both estrogen and testosterone.[41,42] This has been the basis for researching DHEA in a number of disorders.

Clinical Trials

DHEA has been studied for its effects on weight loss, depression, prevention of cardiovascular disease, reduction of cholesterol, and improving the immune system.[43-46] However, these studies enrolled too few patients to adequately evaluate the suspected effects. Until more information is available, DHEA should not be used to treat any of these conditions in place of traditional agents.

DHEA has been studied in Alzheimer's disease, since low endogenous DHEA-S levels have been shown to correspond to dementia. The effects of DHEA supplementation are unknown; however, research is ongoing in this area. The use of DHEA in Systemic Lupus Erythematosus (SLE) appears promising. A few clinical trials found that DHEA doses of 50 mg to 200 mg daily for one year resulted in statistically significant improvements in disease activity measurements.[47-49] Some patients were able to decrease their prednisone dose, although the number was not statistically significant. Nearly 60% of women discontinued DHEA therapy before the study was completed, due to lack of effectiveness and androgenic side effects. Some women reported menstrual irregularities, acne, and emotional changes.[44,45] DHEA may not be effective in all women with SLE, but it may improve the quality of life for some. It has shown enough promise to receive orphan drug status for the treatment of SLE and to reduce steroid doses in steroid-dependent SLE.[50]

Men often wish to supplement declining DHEA-S levels with DHEA, but the effects of supplementation have not been adequately studied. Recent evidence suggests that DHEA may be useful in adult males with impotence.[51,52] Supplementation increases free testosterone

levels by about 5 to 10 percent for six weeks. Whether testosterone levels remain elevated or return to normal with use beyond six weeks is unknown.

In healthy adults, DHEA is most often used to increase testosterone and build muscle mass in athletes and those who are weight training. In these cases, high DHEA doses are used to increase testosterone production. Studies have shown men may experience a small increase in testosterone levels with a more pronounced increase in estrogen.[53] Others use DHEA for its euphoria-like effects and to increase their sense of well-being. These effects wear off with continued use.

During menopause, women may use DHEA to replace their natural levels of estrogen. While DHEA is converted to estrogen in postmenopausal women, there is no evidence to suggest that it can help prevent osteoporosis, cardiovascular disease or improve the symptoms of menopause.[41,54] DHEA is not recommended during menopause because it can decrease HDL cholesterol levels[55] and its effect on breast cancer risk is unknown. The amount of DHEA needed to replace endogenous estrogen levels also needs further study.

Adverse Effects and Potential Interactions

Most adverse effects of DHEA are related to dose. Women may experience mild side effects when taking 25-50 mg once daily.[56] At higher doses (> 50 mg daily), women may experience masculinizing side effects such as deepening of the voice, increased facial hair growth, acne, menstrual irregularities, and others.[41,56] In contrast, men who use more than 100 mg daily may experience estrogenic effects such as breast enlargement and tenderness. Rarely, adverse effects have occurred at replacement doses. One case of cardiac arrhythmia, which occurred with re-challenge, was reported in a person taking 25 to 50 mg of DHEA daily.[57] The product was not analyzed for content or contaminants. At high doses (200-300mg daily for three months) symptoms of mania have been reported.[58]

Since DHEA is converted to estrogen and testosterone, it may possibly contribute to undiagnosed prostate enlargement or prostate cancer in men. Men who wish to start therapy should have baseline DHEA-S levels measured. Men over 45 years of age should undergo yearly digital rectal examinations and a baseline Prostate Specific Antigen (PSA) level should be measured.

There are no reported drug interactions with DHEA. However, it may contribute to the adverse effects associated with drugs sharing a similar pharmacology. DHEA should not be combined with estrogen or testosterone.

Dosing and Recommendation

DHEA has no real clinical value for healthy adults. Its role in SLE is promising, but requires further research. Replacement doses have few adverse effects, depending upon the patient's gender and menopausal status. Doses of 50 mg to 100 mg daily are adequate to replace endogenous DHEA-S levels to those of young adulthood. The hormonal protective effects of DHEA have not been clearly defined or compared to standard pharmaceuticals. Since it is a precursor hormone, women should avoid taking DHEA during pregnancy and lactation. Individuals who choose to replace low levels of DHEA should take the lowest possible dose (25-50 mg once daily). Long term safety and efficacy have not been systematically studied. With long term supplementation, regulation of endogenous DHEA may be altered. The antioxidant properties of DHEA have not been tested, and it is not known if DHEA improves longevity or well being. There is no evidence that DHEA supplementation reverses age-related disease including cancer, cardiovascular disease, or Alzheimer's disease.

Coenzyme Q 10 (Ubiquinone)

Coenzyme Q 10 is also known as ubiquinone. Ubiquinone is naturally found in the body and in the mitochondria of many organ tissues such as the heart, kidney, and liver.[59] It is also found in foods such as spinach, soybeans, walnuts, and almonds. Ubiquinone circulates in the blood in the reduced form called ubiquinol. Ubiquinol is involved in many cell processes and in the generation of cell energy or ATP. Ubiquinol also serves as a natural antioxidant by blocking free radical scavengers. Free radicals contribute to heart disease and other disorders. Ubiquinone levels decline with age and therefore have been associated with an increased risk for heart disease.[59] The dietary supplement, Coenzyme Q10, is used primarily for its protective effects on the heart.

Clinical Trials

Coenzyme Q 10 has been studied as an adjunct for reducing high blood pressure.[60-63] In most studies, patients were allowed to continue their antihypertensive therapy during the administration of coenzyme Q10. Most of these clinical trials were not blinded and lacked a placebo comparison group. Despite these shortcomings, coenzyme Q10 reduced systolic and diastolic blood pressure an average 10 mm Hg after ten weeks of therapy at doses ranging from 100 mg to 225 mg daily. Only one controlled trial compared Coenzyme Q10 to placebo in reducing blood pressure.[63] After ten weeks of therapy, coenzyme Q10 reduced both systolic (SBP) and diastolic blood pressure (DBP) an average of 10 mm Hg and 7 mm Hg respectively. These reductions were statistically significant and were first observed at three to four weeks into treatment.

Numerous clinical trials have studied coenzyme Q10 in people with cardiomyopathy and heart failure. Cardiomyopathy is a general term referring to heart muscle dysfunction. There are many types of cardiomyopathy with various underlying causes, but prolonged cardiomyopathy can lead to heart failure. Most studies of cardiomyopathy and heart failure were poorly designed (e.g. small sample sizes, lack of blinding, lack of placebo control).

Two recent double-blind, crossover trials assessed the effects of coenzyme Q 10 (100 mg/daily) on moderate to severe

cardiomyopathy.[64,65] Patients were classified as having New York Heart Association (NYHA) functional classification stages II, III and IV and were assessed at four and three months respectively. In the first trial, no statistically significant differences were observed in ventricular function, ejection fraction, or calculated cardiac output at the end of four months.[64] No improvements in exercise tolerance or electrocardiogram (ECG) were observed. The second study measured baseline ubiquinone levels. Patients enrolled had ubiquinone levels that were considered low for patients with heart disease (less than 1.2 mcg/mL). Investigators observed statistically significant improvements in stroke volume and ejection fraction at three months. In addition, these patients had ubiquinone levels that were greater than 2 mcg/mL. This suggests that supplementation may help correct low ubiquinone levels and improve symptoms.[65]

One placebo-controlled study assessed the effects of coenzyme Q10 on congestive heart failure.[66] Six patients received placebo or 150 mg of coenzyme Q10 daily for four weeks. No statistically significant increases in exercise tolerance were observed, but patients receiving coenzyme Q10 had statistically significant improvements in ejection fraction and stroke volume. Another placebo-controlled trial found that patients receiving 2 mg/kg coenzyme Q10 were less likely to be hospitalized for worsening of heart failure, as compared to placebo.[67] These effects were statistically significant.

Many of these trials used crude estimates of left ventricular function. Only one clinical trial used Swan-Ganz measurements and echocardiography to assess ventricular heart function.[68] This trial enrolled 27 patients with left heart failure of at least three months duration. Patients received coenzyme Q10 (100 mg daily) or placebo for twelve weeks. There was no difference in cardiac output or any other objective cardiac parameters. There were no differences in well being or quality of life between patients receiving placebo or coenzyme Q10. A recent randomized, double-blind, placebo-controlled study also found no benefit from coenzyme Q10.[69] This trial assigned 55 patients with NYHA class II, III and IV symptoms (ejection fraction less than 40 percent) to receive either coenzyme Q10 (200 mg/day) or placebo. After six months, coenzyme Q10 had no effect on ejection fraction or symptoms. There was no relationship between coenzyme Q10 levels and supplementation.

Two randomized, double-blind, placebo-controlled studies assessed the efficacy of coenzyme Q 10 (120 mg daily for 28 days) in patients with coronary artery disease.[70,71] In the first, patients displayed statistically significant improvements in lipoprotein-a concentrations (a marker for atherosclerosis) and increases in HDL cholesterol levels.[70] In the second trial of patients with acute myocardial infarction, cardiac deaths and rate of re-infarction were significantly reduced, as compared to the placebo group.[71]

Coenzyme Q10 has also been evaluated as to its ability to improve exercise tolerance in patients with chronic stable angina.[72] Twelve patients were given either 150 mg coenzyme Q10 daily or placebo. After four weeks, patients receiving the dietary supplement displayed statistically significant improvements in exercise tolerance and a delay in the time it took to develop ischemic changes on ECG. These trials all suggest marked improvements in patients with angina. However, long-term trials beyond one month are needed to evaluate any protective effects.

Adverse Effects and Potential Interactions

Coenzyme Q10 is well tolerated. Most of the clinical trials report nausea and gastrointestinal distress (nausea, diarrhea, heartburn). Some patients have also experienced maculopapular rash and thrombocytopenia.[73,74] Other reported side effects include irritability, headache, and dizziness.[75-77] One *in vitro* study suggested coenzyme Q10 interferes with glucose regulation.[78] A study in patients with diabetes, however, did not show any effect on blood glucose regulation.[79]

One case report describes an interaction between coenzyme Q10 and warfarin.[80] In that case, the addition of coenzyme Q10 to warfarin therapy decreased the effectiveness of warfarin. Theoretically, co-enzyme Q10 may benefit people taking cholesterol lowering therapy, because ubiquinone is the end product of cholesterol formation. Drugs that block cholesterol formation, such as the HMG-CoA reductase inhibitors, have long been suspected of decreasing ubiquinone levels. Early clinical studies suggested that pravastatin and simvastatin decreased ubiquinone levels and therefore could affect a patient's risk for cardiovascular disease.[81] One study measured the effect of statin therapy on ubiquinone levels in seventeen men taking simvastatin (20 mg to 40 mg) daily for 4.7 years.[75] Simvastatin therapy was stopped for four weeks. After four weeks, serum ubiquinone levels increased by 32%. These patients were then treated with lovastatin (20 to 40 mg daily) and displayed a 25% decrease in serum ubiquinone levels. Despite these changes, the average levels approximated normal ubiquinone levels in healthy adult males. Furthermore, the metabolic consequences of low ubiquinone levels are unknown. Patients who are beginning statin therapy should not require ubiquinone supplementation, because it is likely that the benefits of statin therapy outweigh any potential risk associated with low ubiquinone levels.

Dosing and Recommendation

In healthy adults, doses of 30-60 mg daily can provide antioxidant effects. Most clinical trials in heart disease used doses between 100 to 150 mg daily, administered in three divided doses. These doses increased baseline ubiquinone levels to 2-3 mcg/mL, which some claim to be cardioprotective. Patients who wish to supplement coenzyme Q10 should know that minimal benefits have been observed in people with heart failure or cardiomyopathy. Patients who feel they need coenzyme Q10 should be referred to a physician for evaluation, because they may have symptoms of a more serious condition.

Part Two: Risks Associated C

With Use

Potential for Harm

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During the last century, Americans witnessed the gradual disappearance of herbs and other natural products, which were often misbranded or adulterated, from pharmacy shelves. They were replaced by synthetic drugs produced by the pharmaceutical industry.[1] Interestingly, as the twentieth century drew to a close, there was a resurgence in the use of natural products. Once again, an increasing number of Americans are using herbal remedies.[2]

Although herbs are widely believed to be safe because they are "natural," evidence suggests that these products are not without risks.[3,4] Herbs and dietary supplements have significant pharmacological activity and can potentially cause adverse effects and drug interactions. Assessment of the safety of these remedies is of utmost importance, but ascertaining whether or not a specific product is associated with harmful effects is difficult. Evaluation of these products is more complex than for pharmaceuticals, because herbs and other dietary supplements are often heterogeneous in nature. Additionally, information about them is often limited or anecdotal.[5]

Dietary supplements, including herbal remedies, are not regulated like over-the-counter (OTC) and prescription medications. Prescription medications cannot be marketed without undergoing a multi-step approval process that is designed to provide proof of both efficacy and safety.[1,3] With the passage of DSHEA, the burden of proof shifted away from the manufacturer to the Food and Drug Administration (FDA). No pre-marketing clinical research on the efficacy of the product or ingredients is required before manufacturing dietary supplements.[3] Unlike OTCs and prescription medications, dietary supplements are also not subject to enforceable quality control standards.[6] Thus, there are documented reports of adulteration and contamination of herbal products.[1-6] In addition, dietary supplements can be sold with advocacy third-party literature that may be misleading or does not include information on potential adverse effects and drug interactions.[1,3]

In the past few years, the dietary supplement industry has attempted to improve quality control in the manufacturing of these preparations. Reputable manufacturers strive to assure that their products are authentic, contain the chemical constituents as stated on the label, and are free of contaminants and adulterants. Nevertheless, potential for harm still exists. This article will review some of the primary reasons why pharmacists and consumers should exercise caution in the use of dietary supplements.

Misidentification

It is very important that the manufacturer establishes the authenticity of the plant material before processing herbal remedies. Unless authenticity of a plant is established, there is no way of assuring the true identify of the plant material inside the package. This can result in mislabeling. Inexperienced collectors have mistaken the identity of wild plants. Herbal preparations may not contain the plant as stated on the label, which can cause serious toxicities.[7-9]

Plants can be named using several different methods, including by the common English name, by various translated synonyms, and by the Latin binomial name. It is important to identify plants by their binomial Latin name for genus and species. Mistakes can occur when common names are used.[5] Plants can be misidentified at the time of picking or at the time of bulk purchase by the manufacturer. Often mistakes are not detectable upon gross inspection of samples of the plant material.[5] The authenticity of the material should be verified microscopically and compared with a voucher specimen of the plant held in an herbarium.

Inadvertent substitution because of false authentication or deliberate plant substitution has occurred.[5] There are case reports of rapidly progressive interstitial nephritis in young women who consumed a Chinese slimming tea that contained the nephrotoxic compound aristolochic acid. *Aristolochia fangchi* was used in place of *Stephania tetrandra*.[10] The mistake was thought to be due to confusion between the Chinese names "Fang ji" (*S. tetrandra*) and "Guang fang ji" or "Fang chi" (*A. fanchi*)[4,11] As a consequence, 80 cases have been identified and more than half of these patients have developed end-stage renal failure.[12] Some of these patients have now developed urothelial carcinoma.[13]

Adulteration

There are recent reports of adverse effects associated with the deliberate addition of unreported pharmaceutical drugs by manufacturers of dietary supplements.[14-16] Acute interstitial nephritis, reversible renal failure, loss of blood pressure control, and peptic ulceration have been reported with the multi-component Chinese herbal remedy "Tung shueh" used for arthritis.[17] Chemical analysis of the product found that nonsteroidal anti-inflammatory and sedative drugs had been added to the herbal mixture.[14,16-18] The toxicity caused by this product was most probably due to the addition of the synthetic drugs.

Ayurvedic remedies and traditional Chinese medicines usually contain a complex mixture of various herbs, animal components and mineral substances.[19] Heavy metals such as arsenic, cadmium, lead, mercury, and thallium have been found in appreciable quantities in some of these preparations.[5,19] There are case reports of serious lead poisoning from herbal remedies imported from Asia and India.[20-22]

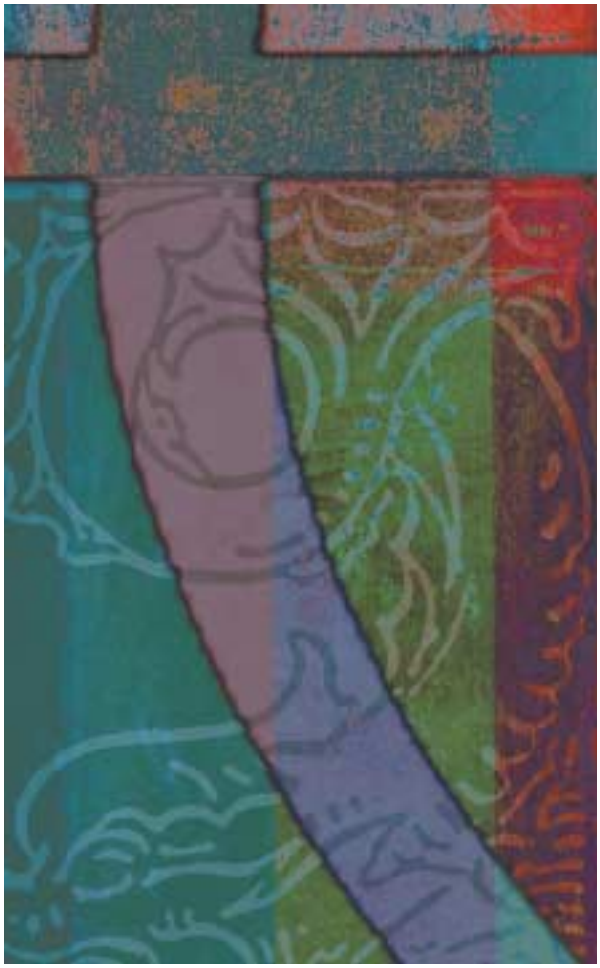
Contamination

Failure to adhere to Good Manufacturing Practices (GMPs) can result in contamination of dietary supplements.[4,5] During growth, plants can be contaminated with microorganisms or their by-products, pesticide residues, or radioactive materials. Bales or cloth sacks used for shipment of medicinal plants may be exposed to bird or rodent excrement, and animal excrement often contains pathogenic bacteria. In addition, plant material can contain the

fungi species, *Aspergillus*, which can produce the carcinogenic toxin, aflatoxin.[19]

Incorrect Preperation

Processing of crude plant material by the manufacturer can affect the pharmacological activity of the finished product.[5] The extraction procedure can vary depending on the type of solvent used, amount of fine plant material exposed to the solvent, degree of agitation, temperature, number of times the sample is extracted, age of the extract, and exposure to oxygen and light.[23] Preparation of concentrated extracts usually involves extraction with ethanol. But, hot water extraction is also used, as well as frozen and freeze-drying processes. Correct processing can affect the extent of adverse reactions and toxicity.[11] Depending on the processing, toxic plants can be made relatively safe if they are processed properly. For example, when the toxic aconite tuber is specially prepared with a heat and water extraction process, it is no longer toxic and appears to be a promising cardiotonic agent.[24]



Lack of Standardization

The chemical constituents of plants vary depending on which part of the plant is used, stages of harvesting, geographic location where the plant was grown, environmental factors such as temperature and rainfall, and drying and storage conditions.[5] Assuring that the herbal product contains the active chemical constituent(s) in the concentration associated with the reputed pharmacological activity is important. Therefore, many herbal preparations are sold as standardized extracts. Standardization is achieved by selecting a chemical constituent or group of constituents and monitoring concentrations of these in each batch of product to demonstrate consistency.[23] However, standardization does not assess the efficacy of the product, because it does not always measure the total active chemical composition.

Batch-to-batch and manufacturer-to-manufacturer variations in concentration of standardized ingredients have been reported.[5] Recent chemical analysis found variations from the labeled potency in some of the most popular herbal supplements including echinacea,[25] ginkgo biloba,[25,26] ginseng,[27] St. John's wort,[28] and saw palmetto,[29] as well as the dietary supplements melatonin[30] and glucosamine/chondroitin.[31]

Drug Interactions

With the increasing use of herbal remedies, there is an increased potential for adverse drug-herb interactions.[32-34] Drug interactions with herbal medicines are under-researched, so much of this information is based on plausibility.[19,33,34] There have been an increasing number of case reports of herb-drug interactions in the medical literature.[32-42] Incidents of bleeding involving anticoagulant therapy and herbs have recently been reported.[35] Bilberry, cayenne, danshen, dong quai, English chamomile, feverfew, garlic, ginkgo, and ginger can potentially increase the risk of bleeding in patients taking anticoagulants or antiplatelet drugs such as warfarin, aspirin, nonsteroidal anti-inflammatory drugs, and ticlopidine. The American Society of Anesthesiologists (ASA) has issued a warning about the use of herbs such as ginger, ginkgo, kava and St. John's wort in patients undergoing surgery.[36] These herbs may prevent blood clotting or prolong the sedative effect of anesthesia. The ASA recommends that patients undergoing surgery discontinue the use of herbal products at least two weeks prior to surgery. Surgical patients should also inform their physicians of any dietary supplements they are taking.

Researchers have found that grapefruit juice increases the serum concentration of antihistamines, benzodiazepines, selected calcium-channel blockers, cyclosporine, estrogens, and quinidine by altering the metabolism of these drugs by the liver.[37] Recent evidence suggests that St. John's wort interacts with drugs metabolized in the liver by the cytochrome P450 system.[38-40] Thus, St. John's wort can potentially decrease the serum concentration of cyclosporine, digoxin, non-nucleoside reverse transcriptase inhibitors, theophylline, oral contraceptives, and other drugs metabolized by this enzyme system.

Patients should not take St. John's wort with selective serotonin reuptake antidepressants, because the combination may cause mild serotonin syndrome, which can result in a number of serious problems.[34] Older reports suggest that St. John's wort should not be taken with monoamine oxidase inhibiting antidepressants (MAOIs).[32] This led to a recommendation that St. John's wort not be taken with decongestants, aged cheese and other foods that interact with MAOIs. More recent information suggests dietary precautions are probably unnecessary. Kava and valerian

Definition of A Dietary Supplement*

- A product (other than tobacco) intended to supplement the diet
- Contains one or more of the following ingredients: vitamin, mineral, herb or other botanical, amino acid, dietary substance used to supplement the diet by increasing total daily intake or a concentrate, metabolite, constituent, extract or combinations of these ingredients
- Is intended for ingestion in pill, capsule, tablet or liquid form
- Is not represented as a food or as the sole item of a meal or diet
- Is labeled as a "dietary supplement"
- Includes certain products that were previously marketed as dietary supplements, unless waived by the Secretary of Health and Human Services.

**U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Dietary Supplement Health and Education Act of 1994. December 1,1995. Accessed www.fda.gov August 3, 2000.*

can potentiate the central nervous system depressant effects of other sedatives, including alcohol.[41] *Aloe vera* juice taken orally may potentiate the effect of cardiac glycosides, antiarrhythmics, licorice, steroids, thiazides, and other potassium wasting drugs.[33]

Adverse Effects

A five-year study conducted by the National Poisons Unit in London demonstrated that herbal remedies and other dietary supplements can produce significant adverse effects, including allergic reactions and hepatotoxicity.[43] The risk and severity of adverse effects secondary to herbs is related to the patient's age, gender, genetic constitution, nutritional state, concomitant diseases and concurrent medications as well as the amount and length of consumption.[5]

Limited evidence suggests that adverse effects secondary to herbs are less common than with conventional medications. Investigators reviewed the charts of patients admitted to a community teaching hospital in Taiwan during a 10-month period and found that 4% of the admissions were drug-related and that herbal remedies ranked third among the categories of medications responsible for causing adverse effects.[44] However, many clinicians feel that under reporting of adverse effects associated with herbs is likely.[19]

Health care practitioners are often not aware that their patients are using herbal remedies and do not ask when taking drug histories.[4] Nor are practitioners and consumers actively encouraged to report adverse effects secondary to herbal remedies. Consumers often consider herbs "natural" remedies that are harmless and therefore do not suspect adverse drug reactions to be associated with these agents as they would with pharmaceuticals.[5]

Some Potentially Dangerous or Ineffective Herbal Remedies

Comfrey *(Symphytum officinale)* is used externally to aid in wound healing, and has been used internally as a tea for bronchitis, diarrhea, and pleuritis. Comfrey, borage (*Borago officinalis)*, and coltsfoot *(Tussilago farfara)* contain small amounts of pyrrolizidine alkaloids. Pyrrolizidine alkaloids have been found to be carcinogenic and hepatotoxic; the use of these herbs should be discouraged.[32]

Other herbs that can induce potentially irreversible liver injury, include chaparral *(Larrea tridentata)*, germander *(Teucrium chamaedrys)*, mistletoe *(Viscum album)*, pennyroyal *(Hedeoma pulegoides or Mentha pulegium)*, sassafras *(Sassafras albidum)*, senna *(Cassia angustifolia)*, skull cap *(Scutellaria)*, and certain traditional Chinese herbal medicines.[45]

Goldenseal (*Hydrastis canadensis)* has been used medicinally by native Americans as a topical anti-infective for inflamed eyes and

wounds. Internally, goldenseal is used for colds and flu and as a treatment for postpartum hemorrhage.[46] There is no clinical evidence supporting its use for any therapeutic application and large amounts can cause nausea, vomiting, diarrhea, hypertension, seizures, and paralysis. In recent years, goldenseal has been used in an attempt to mask urine drug screening tests by illicit-drug users.[47] There is little evidence that it masks drug screening tests, and now it is one of several adulterants commonly screened for in urinalysis samples.

Ma huang *(Ephedra sinica)* and other members of the genus *Ephedra* contain alkaloid mixtures of ephedrine and pseudoephedrine.[3] While these compounds have been commonly used in small doses to treat asthma since ancient times, they can cause vasoconstriction and CNS excitation in high doses. Ma huang is commonly used in weight loss products, but is potentially unsafe when used by patients with diabetes, hypertension, and hyperthyroidism. In addition, it is unsafe when taken in excessive doses or when used in combination with drugs such as caffeine, decongestants, monoamine oxidase inhibiting antidepressants (MAOIs) and theophylline. Since 1993, the FDA has received more than 800 reports of adverse events and more than 17 deaths secondary to the use of approximately 100 different products containing *Ephedra* alkaloids.[3,42] Most of these adverse events were cardiovascular or neurological in nature and occurred primarily in young healthy women who were asymptomatic prior to the events.

Other herbs that are frequently associated with adverse effects include aconite *(Aconitum napellus)*, which can produce palpitations, arrhythmias, nausea, and abdominal pain, and licorice root *(Glycyrrhiza glabra)*, which is associated with hypokalemia, hypertension, arrhythmias, and edema.[4]

Advice to Consumers

Even though herbal remedies and other dietary supplements are becoming increasingly popular, consumers should use these products cautiously. These remedies are not necessarily safe because they are "natural." Unlike prescription medicines, dietary supplements are not tested for proof of safety and efficacy. The efficacy of any dietary supplement or herb depends on its proper usage for the correct diagnosed medical condition. There is inherent danger when patients self-treat with dietary supplements, because of the potential for having a serious undiagnosed condition that requires conventional medical treatment. Consumers with health conditions such as blood clotting disorders, diabetes, heart disease, hypertension, Parkinson's disease, enlargement of the prostate gland, psychiatric disorders or other serious medical problems should not take dietary supplements without first consulting their health care provider.

New Labeling Requirements for Dietary Supplements*

- The words "dietary supplement" must appear on the product label
- Statement of identity of the product
- Net quantity of the contents
- Structure-function claim and the disclaimer statement "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."
- Directions for use
- Supplement Facts panel (lists serving size, amount, active ingredient and part of the plant if a botanical)
- Other ingredients in descending order of prominence
- Name and place of business of the manufacturer, packer or distributor (i.e., the address to write for more information)

** Kurtzweil P. An FDA Guide to Dietary Supplements. FDA Consumer. September-October 1998; revised January 1999. www.fda.gov, accessed August 3, 2000.*

Adverse Events Associated with Alternative Medicines

Recent Cases Reported to California Poison Control

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Introduction

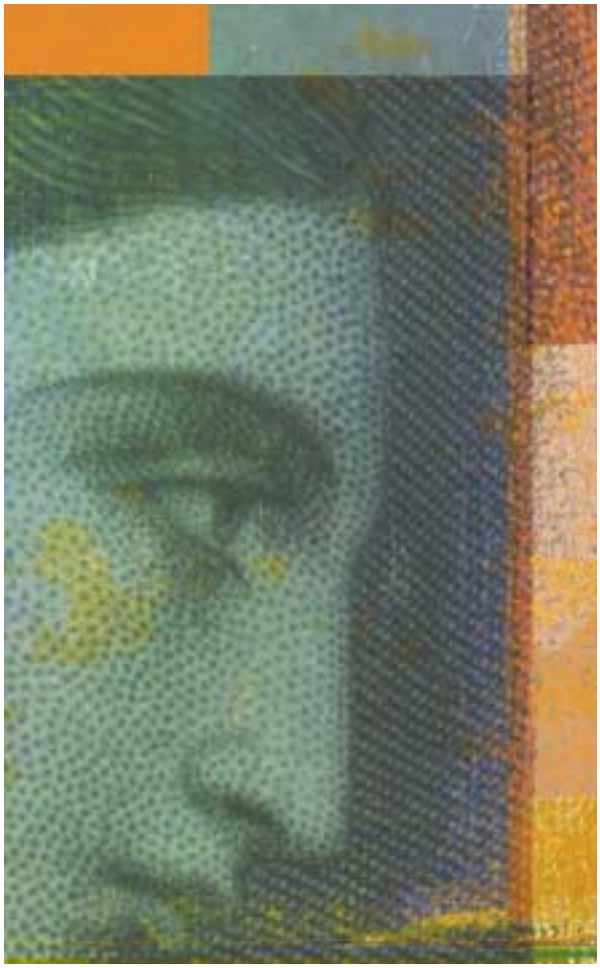
Adverse reactions associated with drugs have been described with herbal medicines[1-3] and have included allergic responses, organ system toxicity, autonomic dysfunction, and impaired levels of consciousness. Consumers may not be aware of the potential harm of alternative medicines, because botanical products are perceived to be more natural and better tolerated than synthetic drugs. However, many botanical products contain natural toxins, as well as toxic impurities or adulterants that may be added during extraction and processing of plant parts.

The extent or prevalence of adverse effects secondary to alternative medicine use in the U.S. is not known. Poison control centers provide a surveillance mechanism for reports of adverse events associated with the use of these products. In California, the San Francisco Division of the California Poison Control System receives approximately 1000 calls each year related to alternative medicines. About two-thirds of these calls are to report adverse symptoms. Symptoms range from minor complaints, such as nausea and headache, to severe reactions which include seizures, cardiac arrhythmias, coma, and death.

This article will present several recent cases of alternative medicine toxicity to illustrate the types and severity of adverse reactions that have been reported.

. . . . . Case 1

A previously healthy 42-year-old Caucasian female began taking three herbal medicines for insomnia on the advice of her homeopathic practitioner. The products were An Shu Ling *(Stephaniae sinica)*, Ignatia Amara, and Relaxed Wanderer. She took the products as directed for approximately ten weeks, then developed nausea, abdominal pain, and jaundice. She stopped using the herbal products and was seen by her primary care physician who diagnosed acute hepatitis. Her peak alanine aminotransferase (ALT) was 3386 U/L (reference range 0-45). Other laboratory parameters were within normal limits. Viral serologic markers for Hepatitis A, Hepatitis B, and Hepatitis C were negative.



The patient called the San Francisco Division of the California Poison Control System when the etiology of the hepatitis could not be identified. Her physician suspected the herbal products might be responsible. Ignatia Amara and Relaxed Wanderer were homepathic products that contained no suspected hepatotoxins. The Poisindex™ (Micromedex, Englewood CO) toxicology database listed the synonym Jin Bu Huan for *Stephaniae sinica*, the botanical name of An Shu Ling. Seven cases of hepatitis have been previously reported in adults using Jin Bu Huan.[4] The herbal products were sent to the California Department of Health Services (CDHS), Food and Drug Branch for laboratory analysis. Levo-tetrahydropalmatine, an active ingredient in Jin Bu Huan, was found in the product An Shu Ling. The product lot was confiscated from the importer/seller and a public health warning was issued by the CDHS.

The patient was presumed to have had a chemical-induced hepatitis due to the ingredient levo-tetrahydropalmatine in the herbal sedative An Shu Ling. Six weeks later the patient's aminotransferases had decreased significantly and she was completely asymptomatic. No additional cases of hepatitis associated with the use of this product were reported. Although Jin Bu Huan is prohibited from importation into the United States, this shipment of An Shu Ling reportedly cleared U.S. Customs because the shipping invoice only listed the Chinese botanical name.

Comment

The Poison Control Center may, as in this case, be presented with a patient that has specific end-organ damage or failure and a history of ingestion of an alternative remedy. The ability to determine an association between the use of these products and an adverse event depends on the recognition of herbs as possible causative agents for specific end-organ toxicity. For example, several herbal products can cause hepatitis and liver failure, including Jin Bu Huan, germander, comfrey, chaparral, and pennyroyal oil.[5] The intended use of the alternative remedy provides another clue. Pennyroyal oil has been used as an abortifacient and may be suspected in liver failure in a pregnant patient. In this case, the patient was attempting to treat insomnia and the hepatotoxic agent, Jin Bu Huan, was used as a sedative. When both patient and physician are aware of the potential for alternative remedies to cause toxicity, and appropriate agencies are notified when an adverse event occurs, prompt action can establish causality, improve patient care, and protect the public from dangerous herbal products.

. . . . . Case 2

A 46-year-old previously healthy Caucasian female was found unconscious in her apartment after suffering a massive right hemispheric stroke. She took no medications except for a weight loss product that contained ma huang, guarana, chromium picolinate, ginseng, bee pollen, and numerous other herbal ingredients. On admission, she was awake, but lethargic, with complete paralysis of her left side. She was unable to speak and her vision was impaired in her left eye. A CT scan of her head showed infarction in the area of the right middle cerebral artery, but no intracranial bleeding. Her medical evaluation revealed no risk factors for stroke. She reported taking the dieting aid as directed on the label for approximately one month before the event. She was not a smoker and did not take any drugs. She denied taking excessive quantities of the weight loss product. The product was lost by the treating hospital and could not be analyzed.

This patient required two weeks of acute hospitalization, three weeks of inpatient rehabilitation, and long-term physical therapy. Because of residual disability, she is unable to work or

live independently. Her caretakers describe emotional lability and poor judgment. She continues to have difficulty writing, walking and balancing. Her sense of taste is altered and her left vision remains impaired.

Comment

Dietary supplements containing ma huang (ephedrine) and guarana (caffeine) are widely promoted and used to boost energy, increase exercise tolerance, enhance athletic performance and promote weight loss. The stimulant actions of ephedrine and caffeine can cause nervousness, insomnia, rapid heart rate, hypertension, cardiac arrhythmias, and strokes. Adverse events have been reported with even modest doses of ephedrine (25 mg). The FDA has received more than 800 reports of adverse events associated with ma huang-containing supplements, raising serious concerns about the safety of these products for general use.[6] Regulatory changes regarding dose limits, label warnings and appropriate marketing are currently being debated by state and federal drug agencies. Pharmacists should be aware and caution consumers about the use of alternative remedies for dieting and enhancing energy. These agents are frequently used by teenagers and adults participating in sports and have been associated with cardiovascular catastrophes and sudden death.

. . . . . Case 3

A nine-year-old Asian male with a history of asthma treated with albuterol and beclomethasone was given a Chinese herbal tea to treat an episode of wheezing. Shortly after drinking the tea he became agitated and disoriented with flushed, dry skin and dilated pupils. In the emergency department, he was awake but uncooperative with the examination, responding only to touch. His heart rate was 150-160 beats minute with normal temperature and blood pressure. His lips and mouth were dry. His skin was hot, dry and flushed. His pupils were dilated and bowel sounds were absent. He was given intravenous fluids and admitted for observation. During the night, he appeared to have some hallucinations. His symptoms persisted for approximately 18 hours and then gradually resolved.

The child's family brought in the herbs used to make the tea and reported they had been steeped in water for one hour. Chemical analysis performed at the CDHS was negative for atropine, scopolamine or other pharmaceuticals. The active constituents of the herbs were thought to be sufficiently extracted during boiling as to be non-detectable by chemical analysis. The family reported prior use of the herbal remedy for the boy's asthma without adverse effects.

Comment

Traditional Chinese remedies can also cause significant adverse reactions. Mistaken identity, toxic contaminants, unapproved active ingredients, variability in dose/potency, and illegal importing have all been cited as reasons for toxicity associated with traditional Chinese medicines.[7] Imported herbal products pose a significant concern for state and federal regulatory agencies, because of limited resources to test them for quality and purity. The important diagnostic feature of this case was the recognition of a toxidrome or constellation of symptoms consistent with a particular toxin or group of toxins. This patient had a characteristic anticholinergic syndrome (dilated pupils, dry and flushed skin, tachycardia, absent bowel sounds, delirium, and hallucinations). Anticholinergics have been extensively used in Chinese medicine for the treatment of respiratory diseases. Abuse of another common plant in California, Jimson weed *(Datura stramonium)*, has also been associated with severe anticholinergic syndromes in teenagers.

. . . . . Case 4

A 13-year-old African American female ingested 8 to 10 tablets of kava 500 mg after an argument with her mother. Police brought her to a local emergency department after she stated that she had tried to hurt herself. On examination she was lethargic, but had normal vital signs. Her laboratory values were unremarkable. She became increasingly somnolent and was responsive only to painful stimuli. The medical staff consulted California Poison Control, San Francisco for advice on the expected clinical course of kava overdose. Poison specialists were not familiar with the toxicity of kava, since it had not been described in the medical literature. They recommended conservative management and she was admitted to the intensive care unit for observation. Overnight her mental status improved and she was discharged the next day for mental health evaluation.

Comment

Overdose management of alternative remedies can be difficult because of limited published data on the pharmacology and toxicology of ingredients. The kava plant *(Piper methysticum)* is indigenous to the South Pacific Islands, where it has been traditionally used as a ceremonial drink. It is now widely available in the U.S. and sold in many forms in health food stores, retail pharmacies, and grocery stores. Although it is considered to have mild anxiolytic and sedative properties, kava may adversely affect motor reflexes and judgment.[8] It also appears to have additive effects with ethanol, barbiturates, and benzodiazepines. There has been one report of an alprazolam and kava interaction causing lethargy and disorientation that necessitated hospitalization.[9] Co-ingestion of sedative hypnotic agents and excessive amounts of kava may cause significant central nervous system depression leading to loss of gag reflex or respiratory drive.

. . . . . Case 5

A 54-year-old Filipino-American male presented to the emergency department complaining of left chest and shoulder pain. His heart rate was 51 beats/minute and irregular. His blood pressure was 143/57 mm Hg and his temperature was normal. He had no murmurs and his chest was clear to auscultation. An electrocardiogram showed bradycardia with first degree AV block. He was admitted for cardiac monitoring and started on aspirin.

The patient had a history of hypertension, but no cardiac disease. He regularly took hydroxyurea (Hydrea®) for essential thrombocythemia. He also complained of migratory arthritis for the last two months affecting his feet, ankles and left shoulder. He had been taking Chinese herbs for several weeks for this. His medical work-up revealed an elevated sedimentation rate of 106 (reference range less than 50) and high platelet count, but was otherwise unrevealing.

By the fourth hospitalization day, the AV block had resolved and his heart was in a normal sinus rhythm. The etiology of his AV conduction defect was not determined, but the consulting cardiologist felt it might be attributable to the herbs. A digoxin level was not done during the hospital admission. Chemical analysis of the herb was negative for cardiac glycosides.

Comment

Cases of herb-induced toxicity can be missed if they are not considered in the differential diagnosis during the medical work-up. Although chemical analysis of herbal products is often possible, results may be negative if the sample deteriorates before analysis or concentrations of the active constituents are below detectable limits. Careful collection and storage of patient specimens, botanical products, dried herbs and liquid teas will reduce the frequency of false negative analyses. This patient's transient bradyarrhythmia and history of Chinese herbal use led to the suspicion of cardiac glycoside poisoning. There are several plants and herbs that contain cardiac glycosides including *Digitalis purpurea* (foxglove), *Nerium oleander* (oleander), *Convallaria majalis* (Lily-of-the-valley), and *Urginea maritima* (squill). In addition, an aphrodisiac called Ch'an Su contains toad venom or bufotoxin (derived from secretions of the parotid and sebaceous glands), which has resulted in deaths from cardiac glycoside toxicity. Other cardiotoxic herbs have been used for arthritis, including aconite from monkshood or wolfsbane.

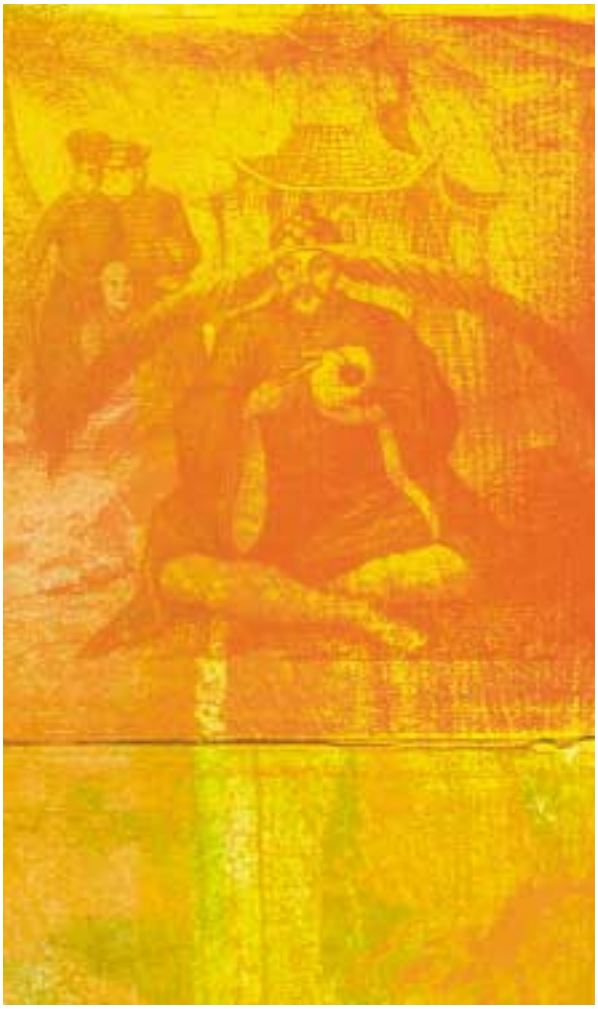
. . . . . Case 6

A 73-year-old male was on a golf course and complained of feeling hot. He took off his shirt and pants and then slumped over and vomited. In the emergency department, he was unconscious with severe hyperthermia (temperature of 108° F), and sinus tachycardia (heart rate 152 beats/min), with a blood pressure of 153/58 mm Hg. The patient was paralyzed with vecuronium and intubated. External evaporative cooling was started and the temperature fell to 103° F. When paralysis wore off after discontinuation of neuromuscular blocking agents, the patient began having tongue and mouth movements and myoclonic jerking.

The patient, a retired psychologist, had Parkinson's Disease and was taking a variety of medications to manage it. His physician reported that he had a habit of changing his drugs and doses on his own, in order to be able to participate in activities such as golf. The patient's medications included: selegiline, ropinirole, bromocriptine, tolcapone, levodopa and carbidopa (Sinemet®), tizanidine, amitriptyline, lorazepam, clonazepam, hydrochlorothiazide, potassium chloride, and multiple herbals including St. John's wort.

Comment

This patient had a life-threatening hyperthermia that most likely resulted from a neurotransmitter imbalance of an excess of dopamine and/or serotonin. Patients exhibit abnormal movements called dyskinesias from excessive dopamine effects. These movements are typically characterized as repetitive and involving small muscle groups (e.g. tongue darting) or may consist of generalized hyperkinetic activity. Excess of serotonin may lead to a serotonin syndrome. This is characterized by muscle rigidity, autonomic instability, and altered mental status, and may culminate in a life-threatening hyperthermia. This patient's hyperthermia may have been caused by a drug-herb interaction. St. John's wort *(Hypericum perforatum)* can inhibit the uptake of serotonin and dopamine in vitro.[10] It has been associated with serotonin syndrome when used in combination with selective serotonin reuptake inhibitors.[11,12] This patient's drug regimen had significant potential for inducing an imbalance of dopamine and serotonin. Ropinirol, bromocriptine and levodopa/carbidopa are dopaminergic agonists. Selegiline and tolcapone may increase dopamine and serotonin by inhibiting their enzymatic breakdown by monoamine oxidase (MAO) and catechol-o-methyltransferase (COMT), respectively. Amitriptyline and St. John's wort inhibit the uptake of dopamine and serotonin, contributing to a neurotransmitter imbalance. Of note, the potential for significant drug-herb interactions with St. John's wort has only recently been highlighted in the medical literature.[13] Two prominent therapeutic monographs *(American Herbal Pharmacopoeia and Therapeutic Compendium* and *The Medical Letter)* did not list any interactions in 1997.



. . . . . Case 7

A 69-year-old female presented in distress to the emergency department with an acute hypersensitivity reaction (generalized pruritis, urticaria, facial swelling) after using a Chinese herbal remedy for her diabetes. The herbal preparation was wafer-shaped and called Radix dioscoreae.

Poison specialists determined that this was the root of the plant *Dioscorea dumatorum*, which is used as a Chinese traditional medication. Fortunately, the patient's symptoms resolved with antihistamines. Epinephrine was avoided, since this patient had a past medical history of cardiovascular disease. This patient's past experience with use of this herbal product was unknown. The treating physician did not cooperate with the Poison Center to analyze the product.

Comment

Herbal medications have the potential for precipitating acute hypersensitivity reactions, including severe anaphylaxis. Causation may be difficult to establish because of the potential for misidentification, adulteration and contamination. It is possible that a patient may tolerate an herbal remedy for an extended period of time, then later develop an acute hypersensitivity reaction from contact with a new allergen from a contaminated lot. Patients may have cross-sensitivities to plant and animal materials or allergens as well. People with known plant sensitivities may need to avoid specific herbal remedies. Examples of known cross-sensitivities between herbal products and plants include: feverfew *(Tanacetum parthenium)* and plants in the daisy family *(Asteraceae)*; ginkgo *(Ginkgo biloba)* and poison oak or ivy *(Toxicodendron sp.)*; echinacea *(Echinacea purpurea)* and sun flowers and ragweed; and royal jelly (secretions from worker bees) and bee sting allergy (hymenoptera).[14,15,16]

. . . . . Conclusion

Alternative remedies may cause adverse effects in some people. Organ-specific toxicity, central nervous system and autonomic nervous system dysfunction, adverse drug-herb interactions and allergic reactions have all recently been described. Physicians and pharmacists should be aware of potentially harmful herbs and take action when a case of herbal toxicity is suspected. The implicated product should be held for future analysis. A regional Poison Control Center should be contacted for guidance on medical management of the poisoning. In California, the toll free number is 1-800-8 POISON. All adverse events related to alternative medicines should be reported to the FDA MedWatch Program. Forms are available online at the FDA website, www.fda.gov. The California Department of Health Services should be notified of adverse reactions to Chinese herbal products, since many of these are not under the jurisdiction of the FDA or are imported illegally.

Part Three: Information for

Inquiring Minds:

Frequently Asked Consumer Questions About Herbs and Dietary Supplements

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Recent FDA changes in labeling requirements expand the allowable claims that dietary supplement manufacturers may place on their product labels. Although intended to clarify product labeling, the new rules may not diminish consumer confusion over indications for use, safety, and efficacy. Perhaps an indicator of the interest and confusion consumers' experience is the increasing numbers who seek information. Seventeen million of the 40 million people logging on to the Internet search it for health-care related information.[1] Pharmacists today have a unique opportunity to serve as trusted sources of information on herbs and dietary supplements. Pharmacists have traditionally been the "gatekeepers" of medication information and therapy. With expanding roles as health-care providers in ambulatory care settings and the proliferation of new pharmacies, pharmacists are more readily accessible than ever before.

The following cases reflect some of the questions most frequently asked by consumers regarding herbs and dietary supplements. These came from questions received in community pharmacies and an "Ask Your Pharmacist" web site.

. . . . . Case 1

Mrs. M approaches the counter with two Echinacea products in her hand. She wants to know the difference between a standardized extract tincture formulation and a capsule formulation.

Herbs come in a wide variety of formulations and dosage forms. For almost all herbs, the exact active ingredient(s) remain unknown. Different parts of the plant can also be used. For medicinal purposes, the active ingredient is either the herb itself or an extract of the herb.[2] Some solid dosage forms contain the crude, dried herb. Most herbal solid and liquid dosage forms, however, contain an extract of the herb.

Fluid extracts are made by chemically treating one part herb with one part solvent, usually water and/or ethanol.[2] Solid extracts are made by evaporating the solvent of the fluid extract. Extracts may be concentrated to contain higher amounts of active chemicals by increasing the ratio of crude herb to extracting solvent. Other formulations of herbs include volatile oils and fresh pressed juices.

A tincture is the liquid dosage form of an alcoholic extract.[2] Most of the clinical trials studying echinacea utilized a 1:5 tincture made from *Echinacea pallida* root and 50% ethanol.[2] The tincture formulation of echinacea may allow the active chemical moieties to reach their primary site of action: oropharnygeal lymphoid tissues.

Mrs. M's question provides an opportunity to educate her about the differences in dosage formulations of herbal products. The pharmacist should also ask Mrs. M about her interest in using echinacea. By doing so, the pharmacist can ensure that she is using the product for an appropriate indication. Appropriate indications include those for which there is some supporting data on efficacy and safety (e.g., treatment versus prophylaxis against the common cold). In addition, the pharmacist could help Mrs. M select a particular product. Reputable large manufacturers are more likely to take measures to ensure that their products contain properly identified plants and no adulterants. Some manufacturers also analyze their final products to ensure uniformity of formulation between different batches.

Mrs. M's question also provides an opportunity to screen for any contraindications to the use of echinacea (e.g., asthma, autoimmune disorders, pregnancy, breast-feeding, any reason to avoid alcohol). The pharmacist should remind Mrs. M to only use the product as directed on the label and not to exceed the manufacturer's dosing recommendations.

. . . . . Case 2

Mr. H came into clinic requesting refills of his d4T, indinavir, and nevirapine. He wants to know about any interactions between his prescription medications and the herbs and dietary supplements he recently started taking. These were ginseng, St. John's wort, and melatonin.

Recent evidence indicates that St. John's wort *(Hypericum perforatum)* induces CYP3A4.[3,4] St. John's wort decreased plasma levels of indinavir and digoxin in pharmacokinetic studies,[3,4] and it also decreases cyclosporin levels.[5] Both indinavir and cyclosporin are substrates for CYP3A4. Other substrates of CYP3A4 include other protease inhibitors, certain calcium channel blockers, HmG CoA reductase inhibitors, sex hormones, erythromycin, ketoconazole, rifampin, cisapride (now off the market), and warfarin.[6] Based on observed pharmacological effects of St. John's wort on a variety of neurotransmitters, it may potentially interact with other antidepressants, adrenergics, and amphetamines.[7,8,9]

To date, ginseng *(Panax ginseng, Panax quinquefolius)* has not been reported to interact with any antiretroviral agents or protease inhibitors. Formal pharmacokinetic studies, however, are lacking. One case report attributed a decreased INR to ginseng in a patient taking warfarin.[10] The mechanism of this interaction remains unknown. The effect of ginseng on the cytochrome P450 enzyme system is unclear.[11] Ginseng may cause insomnia, irritability, and mania in psychiatric patients taking phenelzine, neuroleptics, and lithium.[12-14] Due to observed pharmacological effects on platelet aggregation and observed varying effects on blood pressure, ginseng should be used with caution in patients taking aspirin, NSAIDs, antiplatelets, or antihypertensives.[15-17]

Mr. H should be advised to stop taking St. John's wort because of its potential interaction with indinivir. Decreased plasma levels of indinavir could result in decreased effects and, potentially, therapeutic failure. Mr. H should be encouraged to discuss any depressive or psychiatric symptoms or concerns with his primary care physician. Based upon information currently available, he may use ginseng and melatonin, but he should inform his physician that he is taking these products. The pharmacist should educate him about any potential side effects and other potential drug interactions with ginseng and melatonin.

. . . . . Case 3

Mrs. C is 10 weeks pregnant with her first child. She wants to know whether ginger is safe to take for nausea during pregnancy.

The FDA recently withdrew a new rule that would have allowed dietary supplements to be sold for common pregnancy-related conditions.[18] Birth defects experts had heavily criticized the proposed new rule. Almost all herbal products and dietary supplements lack safety data for use in pregnant or breast-feeding women and children.

Ginger root from *Zingiber officinale* is a common spice and flavoring agent. It is included in the FDA's list of substances "Generally Recognized as Safe" (GRAS).[19] A GRAS listing, however, is not synonymous with approval for therapeutic uses. Ginger is consumed in higher amounts when taken as an herbal supplement than when used as a flavoring agent. One study evaluated the use of ginger as an antiemetic for 26 pregnant women with hyperemesis gravidarum.[20] The results suggested some subjective benefits, but did not measure any significant objective outcomes. Children exposed to ginger in utero were not followed; therefore, the teratogenic risk of ginger when taken as an herbal supplement has not been evaluated.

The pharmacist should tell Mrs. C about the lack of data regarding the use of ginger during pregnancy. In addition, she should be advised that herbs and dietary supplements are not recommended for use during pregnancy and while breast-feeding.[18] She should be encouraged to discuss her symptoms and treatment options with her obstetrician or physician.

. . . . . Case 4

Ms. K is currently taking warfarin for a recent pulmonary embolism (PE). She took hormone replacement therapy for 5 months prior to her PE. During a visit to the anticoagulation clinic, she asks about using an herbal supplement to treat her hot flashes and vaginal dryness. She is especially interested in a combination preparation recommended by a friend. The product label indicates that it contains black cohosh, dong quai, chasteberry, and ginseng.

> "Consumer questions about herbs and dietary supplements present pharmacists with opportunities for patient screening and education."

Dong quai *(Angelica sinensis)* can increase the prothrombin time (INR) in patients taking warfarin.[21] The mechanism behind the interaction may involve interference with the metabolism or protein binding of warfarin.[21] Dong quai also contains several natural coumarins and other constituents with antithrombotic activity.[19,22] Ginseng has been reported to interact with warfarin to decrease the INR. There are no known drug interactions to date with black cohosh *(Cimicifuga racemosa)* or chasteberry *(Vitex agnuscastus)*. No pharmacokinetic studies in humans have been conducted with any of these herbs.

The pharmacist should advise Ms. K to avoid any products containing dong quai and ginseng while taking warfarin, because use of these products could make it difficult to maintain a therapeutic INR. The effects of black cohosh and chasteberry on warfarin remain unknown.

Ms. K's question presents the pharmacist with the opportunity to educate her about the potential risks associated with herbs having hormonal (e.g., estrogenic) activity. Black cohosh may relieve hot flashes and mood disturbances associated with menopause through its estrogenic effects.[23-25] Hormonal effects of dong quai may be derived from its use in combination with other herbs rather than as a single herb alone.[26] Ginseng may have weak estrogenic activity.[27] Chasteberry may exert hormonal effects by altering lutenizing hormone (LH) and prolactin levels.[28] The exact mechanism of hormonal action of all of these herbs has yet to be elucidated. Herbs with estrogenic activity could potentially increase the risks of adverse effects in patients with known contraindications to hormonal replacement therapy (e.g., history of thromboembolic disorder.) Until more information becomes available, Ms. K should be advised against using any herbal products containing herbs with known hormonal effects.

. . . . . Case 5

While picking up his Celebrex prescription, Mr.P asks about the use of SAMe for osteoarthritis.

SAMe, or S-adenosylmethionine, has gained recent notoriety as a dietary supplement in the U.S. Among its purported uses are depression, osteoarthritis, fibromyalgia, liver disease, and migraines.[29] SAMe is made in the body and plays a role in a variety of metabolic pathways.[30] *In vitro* data suggest that it enhances proteoglycan synthesis, which is important for cartilage formation.[31] Animal studies demonstrate that exogenously administered SAMe has anti-inflammatory and analgesic properties,[32] but these do not appear to be mediated by inhibition of prostaglandin synthesis.[33] Limited human trials suggest that SAMe (400 to 1600 mg/daily[29]) may be as effective as NSAIDs for relieving symptoms of osteoarthritis.[33] More research is needed to clarify the mechanism of action and efficacy of SAMe for osteoarthritis. Side effects of SAMe include mild gastrointestinal upset.[29] A few cases of agitation and mania in bipolar patients receiving SAMe have been reported.[29] There is one case report of serotonin syndrome in a patient taking clomipramine and SAMe.[34]

The pharmacist should tell Mr. P that there are limited data suggesting beneficial effects of SAMe for relieving osteoarthritic symptoms. Patients with bipolar disorder should not use it.[29] Patients with depression or depressive symptoms should not use SAMe without first consulting their physician. Based on its potential pharmacological effects on neurotransmitter levels, SAMe should not be used in patients receiving antidepressants.[29] Mr. P should tell his health-care providers if he begins using SAMe so that its efficacy and any adverse effects can be monitored.

. . . . . Conclusion

As the previous cases illustrate, consumer questions about herbs and dietary supplements present pharmacists with opportunities for patient screening and education. Pharmacists should not, however, limit their interventions to consumer questions. Because of their unique role and accessibility, they should proactively screen for use of herbs and dietary supplements. In doing so, they present themselves as trusted sources of information about these products. Proactive screening also allows pharmacists to identify side effects and drug interactions, document them, and report them to the patient's primary health care provider. This growing trend in use of dietary supplements provides pharmacists with a unique opportunity to help consumers.

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Sources of Reliable Information on Alternative Medicine

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Information concerning alternative medicine has exploded. Therefore, it is virtually impossible to cover and critique every reference available. Instead, this review will highlight some references that pharmacists should know about, and those that they might choose for their own personal use or recommend for patient use. The references that follow are listed in alphabetical order by title and not in order of importance.

Several key elements should be considered when evaluating information sources for alternative medicine. These include the reputation of the publisher and editors or authors, how often the reference is updated, and if the information is referenced. These key points should help pharmacists determine if the information is incorrect or biased, but will not ensure that the information is unbiased or totally correct. Readers will need to use their own judgment when encountering new references or information sources.

Readers need to be aware of some basic issues regarding alternative medicine literature. Manufacturers have limited incentive to conduct good, large clinical trials, due to lack of patent protection. To promote their own products, any manufacturer can use the results of any positive clinical trials. Although the trend is slowly changing, many alternative medicine studies are published in foreign languages. Often, those studies published in the English language are published in obscure journals that are usually not indexed in Medline. Many studies are older, and even recent studies often have poor study designs. In addition, studies often lack power (sufficient sample size) to detect a clinically significant difference.

Quality of alternative products can also be a concern, as mentioned in the previous articles.[1-6] Published studies often fail to document that the alternative medicine in question was actually the product tested or in the amount described. Lastly, there is a lack of consensus in the medical community regarding the use of alternative medicines. Considerations range from, but are not limited to, potential therapeutic uses, effectiveness, appropriate doses, monitoring parameters, adverse effects, and drug interactions. Therefore, it is important that multiple alternative medicine sources be examined to ensure that correct and up-to-date information is obtained.

Year & Edition	ISBN/ISSN or contact information	Available	Approximate cost ($)

Alternative Health and Medicine Encyclopedia: The Authoritative Guide to Holistic & Nontraditional Practices

1997	0-7876-007-33	Hardbound	$47.

Contents: *Discusses alternative health topics (e.g., biofeedback, yoga, visualization) and alternative "drugs." Written in textbook rather than monograph format. Good basic overview of CAM. Directed towards consumers. Resources listed at the end of each chapter rather than references.*

Alternative Medicine Alert: A Clinician's Guide to Alternative Therapies

2000 Monthly, yearly index	1096-942X	Newsletter & online	$219.

Contents: *Monthly newsletter on alternative topics directed towards physicians. Provides information on common and timely CAM. Information analyzed and highly referenced. Not as useful as a standard monograph "drug-type" reference.*

American Herbal Products Association's Botanical Safety Handbook: Guide for the Use and Labeling for Herbs in Commerce

1997	0-8493-1675-8	Hardbound	$45.

Contents: *Textbook with 600 commonly sold herbs in the U.S. listed alphabetically. Has information regarding international regulatory status and limited information on standard dosage, side effects and use. Referenced.*

Clinical Pharmacology

2000	1-885966-10-5 www.gsm.com (Registration Required)	CDROM & online	CDROM: $395. Online: Free

Contents: *Contains information on nutraceuticals when reliable clinical data exist. Monographs contain standard information. Referenced.*

Guide to Popular Natural Products

1999	1-57439-063-5	Handbook	$30.

Contents: *125 products abridged from Review of Natural Products. Introductory legal section. Helpful appendices such as therapeutic use index. Selected photographs. Referenced.*

Herb Contraindications and Drug Interactions

1998 2nd ed.	1-8884-8306-7	Handbook	$20.

Contents: *Listed in alphabetical order by common name. Only 95 references in entire text.*

Herbal Medicine: Expanded Commission E Monographs

2000	0-9670772-1-4	Hardbound	$50.

Contents: *107 of the most commonly used herbal monographs, expanded to provide more scientific information on efficacy. Listed alphabetically by common name. Often lacks critical analysis of clinical trials. Referenced.*

Herbal Medicinals: A Clinician's Guide

1998 1st ed.	0-7890-0467-4	Paperback & Hardbound	$40./$60.

Contents: *Information on herbs only. Listed by diseases or syndromes. Textbook-style format rather than monograph. Little on dosing, side effects, and drug interactions. More folklore and history than scientific information. Authors give recommendations on use. Lists cases at the beginning of each section. Referenced.*

IBIS Integrative Body Mind Information System

1999	www.teleport.com~ibis or 877-526-1972	CDROM & online	$200.

Contents: *Information on >2400 alternative medicines, 282 common medical conditions. Offers treatments for >12 systems (e.g., cardiovascular, nervous) of integrative medicine. Has note-taking and report-generating features. Personalized patient education materials possible. Directed towards physicians. Referenced.*

Year & Edition	ISBN/ISSN or contact information	Available	Approximate cost ($)
IBIS Interactions			
1999	www.teleport.com~ibis or 877-526-1972	CDROM & online	$100.
Contents: *Database contains information on drug-herb and drug-nutrient interactions. Referenced.*			
Martindale: The Complete Drug Reference			
1999 (32nd ed.) Updated every 2-3 years	0-85369-429-X	Hardbound & CDROM (Micromedx)	$299
Contents: *A British reference with a section on supplementary drugs. Limited information on physical and pharmaceutical properties. Does not have true monographs on alternative substances. Some "monographs" are longer than others. Referenced.*			
Micromedex			
2000 Updated quarterly	www.mdx.com or 303-486-6444	CDROM (online in beta form)	Varies
Contents: *Computer database with many sections. Sections with CAM topics: AltMedDex (alternative medicine evaluations), RPS (Royal Society's Herbal Medicines), DrugDex (drug evaluations), AltCareDex (pt. education information for CAM), and AltCare Consults (questions and answers related to alternative medicine). AltMedDex contains: summary of interactions, adverse effects, severity, onset, documentation, probable mechanism, and literature reports, if available. Referenced.*			
Natural Medicines Comprehensive Database			
2000 Text updated yearly, online continually	www.naturaldatabase.com or 209 472-2244	Paperback & Online	$85. for each or $132. for both
Contents: *Information on alternative "drugs." Monograph-type information: people use this for, effectiveness, comment, and interactions with herbs and other dietary supplements, drugs, foods, labs, diseases or conditions. States if no interactions known or predicted, insufficient information, or interactions with some expected outcomes or potential problems. Often cites textbooks and newsletters rather than primary literature. Referenced.*			
Natural Products Explorer			
1999 Updated annually	1-57439-069-4	CDROM	$180.
Contents: *Combines both The Review of Natural Products and The German Commission E Monographs.*			
Natural Therapeutics Pocket Guide			
Expected July 2000	0-916589-80-3	Handbook and CDROM	$32. to $40.
Contents: *Topics listed by conditions. Includes herbs, nutritional supplements, homeopathic remedies, and lifestyle modifications.*			
PDR for Herbal Medicines			
2000 2nd ed. Updated annually	1-5636-3292-6	Hardbound	$60.
Contents: *Over 700 monographs. Several indexes: common name, therapeutic use, side effects, manufacturers, Asian, homeopathic, and Indian index. Monographs contain actions, uses, precautions (with drug interactions), adverse drug reactions, & contraindications. Separate drug/herb interactions list and herb ID guide (pictures). Referenced.*			
Professional's Handbook of Complementary Medicine			
1999 1st ed.	0-87434-971-0	Handbook	$40.
Contents: *Monographs list actions, uses, dosage, side effects, drug interactions, special considerations, precautions, and analysis. Drug interaction section includes if combination should be given with caution, any monitoring required or if should be avoided. Appendices include table of therapeutic monitoring guidelines (e.g., labs to monitor), and herb information sheet (can be copied and individualized for patients). Referenced.*			

Year & Edition	ISBN/ISSN or contact information	Available	Approximate cost ($)

Rational Phytotherapy: A Physician's Guide to Herbal Medicine

1998 3rd ed.	3-540-62648-4	Hardbound	$50.

Contents: *Information on herbs only, listed by diseases or syndromes. Textbook-style format rather than monograph. Little on dosing, side effects, and drug interactions. More folklore, history than scientific information. Authors give recommendations on use. Referenced.*

Stedman's Alternative Medicine Words

2000 New edition	0-7817-2161-X	Paperback	$37.

Contents: *More than 40,000 terms, including medical acupuncture, homeopathy, herbs, and traditional Chinese medicine. Includes appendices with items such as illustrations and treatments by indication. No references.*

Textbook of Natural Medicine

1999 2nd ed.	0-443-05945-4	Hardbound 2 volume set	$200.

Contents: *Discusses CAM concepts. Written in textbook rather than monograph format. Several sections, including therapeutic modalities, syndrome & special topics, pharmacology of natural medicines and specific health problems. Referenced.*

The German Commission E Monographs: Therapeutic Guide to Herbal Medicines

1998 1st ed.	0-9655555-0-X	Hardbound & CDROM	Book- $99. CDROM- $165. $199. for both

Contents: *327 herbal monographs; 191 with a favorable listing. There are additional 108 unapproved herbs. Monographs include uses, side effects, drug interactions, dosage, and contraindications. There is a drug-herb interaction table. Very limited information on specific herbs. No references.*

The Pharmacist's Dietary Supplement Alert

2000 Monthly, indexed yearly	1527-7348	Newsletter & online	$229.

Contents: *Monthly newsletter on dietary supplements (vitamins, minerals, amino acids and herbs). Provides objective clinical information using evidence-based medicine. Information analyzed and highly referenced. Not as useful as a standard alternative medicine monograph "drug-type" reference.*

The Review of Natural Products

2000 Monthly updates	1089-5302	Newsletter & CDROM	Newsletter: $195. CDROM: $139. Yearly updates: $139.

Contents: *Newsletters alphabetized by common name. Contains chemistry, pharmacology, summary and patient information. No interactions listed in the monographs. Last drug-herb interaction table dated December 1998. Information more chemistry-based than clinical. Useful appendices such as therapeutic use index. Often references include textbooks and newsletters, rather than primary literature.*

Tyler's Herbs of Choice

1999 Updated every 1-2 years	0-7890-0160-8	Paperback & Hardbound	$20./$50.

Contents: *Information on herbs only. Listed by diseases or syndromes. Textbook-style format rather than monograph. Little on dosing, side effects, and drug interactions. More folklore and history than scientific information. Authors give recommendations on use. Written primarily for consumers, not health professionals. Referenced.*

Tyler's Honest Herbal

1999 Updated every 1-2 years	0-7890-0875-0	Paperback & Hardbound	$25./$50.

Contents: *Information on herbs only. Listed alphabetically by common name. Textbook-style format rather than monograph. Little on dosing, side effects, and drug interactions. More folklore and history rather than scientific information. Authors give recommendations on use. Referenced.*

Free Alternative Medicine Web Sites

Sponsoring Organizations	URL

Alternative Medicine Homepage — **www.pitt.edu/~cbw/altm.html**

Comments: Web site listing alternative Websites on the www. Links to databases, internet resources, newsgroups and mailing lists, and government resources. Covers all areas of CAM.

American Health Consultants — **www.ahcpub.com**

Comments: Commercial site that publishes several newsletters such as "Alternative Medicine Alert." Can search for write-ups on alternative medicine topics.

Health Care Information Resources — **www-hsl.mcmaster.ca/tomflem/altmed.html**

Comments: "Meta-Site" for alternative medicine, international scope. Provides a broad collection of Internet resources in the field of alternative medicine. Organized by treatment categories. Links are from education, organizations, government and commercial sponsors.

Mayo Clinic Health Oasis — **www.mayoclinic.com**

Comments: Information database where you can search for short write-ups. Some alternative medicine topics. Directed towards consumers.

MedlinePlus: Alternative Medicine — **www.nlm.nih.gov/medlineplus/alternativemedicine.html**

Comments: Sponsored by the National Library of Medicine. Directed towards consumers and primarily includes government resources. There is also a link to search Medline for articles on alternative medicine.

Medscape — **www.medscape.com/Home/Topics/specialties.html**

Comments: Information database that allows search for short write-ups. Some alternative medicine topics.

National Center for Complementary and Alternative Medicine — **nccam.nih.gov**

Comments: Allows search of 180,000 bibliographic citations from 1963-1999. Citations extracted from the NIH Medline Database. Some abstracts listed.

NIH Office of Dietary Supplements — **Dietary-supplements.info.nih.gov**

Comments: Allows search of the IBIDS database (International Bibliographic Information on Dietary Supplements.) Has international, scientific literature on dietary supplements, including vitamins, minerals, and botanicals. Currently contains > 300,000 citations and abstracts. Developed and will be maintained by the Office of Dietary Supplements at the NIH.

QuackWatch — **www.quackwatch.com**

Comments: Focuses on health-related frauds, myths, fads, and fallacies that are often propagated via the Internet and the media. An alternative medicine section has a variety of topics such as legal and specific misleading information. There is also a list of non-recommended references such as books, individuals, periodicals and web sites.

RxList - The Internet Drug Index — **www.rxlist.com**

Comments: Commercial site that lists alternative medicines (herbs, homeopathic, vitamins) from A to Z. Provides fairly detailed monograph-type information including dose and drug interactions. Referenced. Updated at an unknown frequency.

The Alternative and Complementary Medicine Center of Health World Online — **www.altmed.net**

Comments: Site contains extensive resources for the most common types of alternative medicine. The Herbal Medicine link includes an online version of Materia Medica, containing monographs of many herbs used for treatment. Each monograph contains indications, doses, and many contain references.

The Natural Pharmacist — **www.tnp.com/home.asp**

Comments: Commercial site with alphabetical list of herbal remedies, drug-herb interactions, and herbal treatments for specific conditions.

Vitamins.com — **www.vitamins.com/encyclopedia/index/herbx.htm**

Comments: Commercial site with monographs on herbs, homeopathic and Chinese medicines. Referenced. Updated at an unknown frequency.

Legal Considerations Pertaining to Dietary Supplements

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No one is in a more ideal position to recommend, sell, and advise patients about dietary supplements than pharmacists. Pharmacists, because of their position in society as drug experts, offer patients unmatched knowledge about dietary supplements. However, selling and providing information about dietary supplements does create legal concerns, as this article will demonstrate. But legal considerations should not be a determinate in whether to engage in the business of dietary supplements, but rather how best to practice that business.

Several potential legal issues may arise when selling and recommending dietary supplements, ranging from statutory violations to civil liability. In particular, this article will highlight liability concerns under the Federal Food Drug and Cosmetic Act (FD&C Act), the Federal Trade Commission (FTC) Act, negligence law and products liability law. Although not addressed directly, the reader should also be aware that many of the potential FD&C Act and FTC Act violations discussed in this article could also violate California law. Some pharmacists might be alarmed at the number of different applicable legal issues. However, the risk of liability becomes quite minimal when pharmacists insure that they are competent to perform the services they offer, understand the law, and follow the risk management suggestions in this article.

Federal Food Drug & Cosmetic Act

Dietary supplements are regulated under the FD&C Act, as amended by DSHEA.[1] As such, pharmacists should be aware of the law related to the following activities.

Making Disease Claims Rather Than Structure/Function Claims

Generally speaking, under the FD&C Act a product becomes a drug if the seller intends for the product to treat a disease or intends for it to affect the structure or function of the body.[2] DSHEA modified the drug definition allowing sellers of dietary supplements to make structure/function claims for their products, so long as the claims can be substantiated as truthful.[3] The FDA requires that disease (health) claims must be pre-approved and very few have been approved. Making disease claims for a dietary supplement product could subject the seller to charges of illegally marketing a new drug without approval and misbranding. (Misbranding occurs when a seller includes drug labeling information other than what was approved by the FDA.) For example, a patient who has had recurring urinary tract infections might ask a pharmacist for a dietary supplement. The pharmacist could recommend cranberry tablets and assert (as a structure/function claim) that the tablets should increase the acidity of the urine and help to maintain a healthy urinary tract. If the pharmacist asserted that the cranberry tablets prevent or treat urinary tract infections, this would be a disease claim. The manufacturer cannot legally make that claim on the product label. Whether the pharmacist has committed an illegal act is quite murky. Arguably, a pharmacist should be able to make a disease claim as part of his or her professional responsibility of providing patient information; and in this context, it would be highly unlikely that the FDA or any state regulatory authority would be concerned about the legality. On the other hand, a pharmacist who actively promotes and advertises a dietary supplement for disease purposes could be in violation of the law. The critical but blurry distinction then, is whether the disease claim was made within the context of patient education or product promotion. This issue becomes even less clear after a recent federal court of appeals decision finding that by requiring pre-market approval for health claims, the FDA violates the First Amendment rights of dietary supplement manufacturers.[4] The court held that the manufacturers should be permitted to make health claims so long as they include a disclaimer stating that the evidence is inconclusive that the product is effective for the claim.

Posting Signs

Signs posted in pharmacies that make disease claims for dietary supplements sold in the store could subject the pharmacy to misbranding violations. The FD&C Act defines labeling as labels and other written, printed or graphic matter either on the article, its container, or "accompanying" the article.[5] The courts have interpreted the word "accompanying" broadly to include literature supplied separately from the product[6] and to include literature displayed by retailers in connection with the sale of a product.[7] The sign could constitute labeling because it accompanies the products. Since the signs make disease claims, the product could be considered a drug and therefore misbranded.

Displaying Publications About Dietary Supplements

Some pharmacies place copies of published articles about dietary supplements in the dietary supplement section of the store. Prior to DSHEA, the act of displaying articles about a product would likely have constituted labeling, subjecting the pharmacy to misbranding. DSHEA, however, excludes certain publications, such as articles, book chapters, and official abstracts of peer-reviewed scientific publications when used in connection with the sale of dietary supplements to consumers. These publications may only be excluded from consideration as labeling provided all of the following conditions are met :

(1) They are reprinted in their entirety.
(2) They are not false or misleading.
(3) They are displayed or presented with other such publications so as to present a balanced view of the available scientific information.
(4) If displayed in an establishment, they are physically separate from the dietary supplements.
(5) They do not have appended to them any information by sticker or any other method.

These stated conditions create several unanswerable questions. How far apart must the articles be from the product? How many articles on each side of the issue constitute a balanced view? Even if a pharmacy complies with DSHEA by separating the publications and providing balance, there is always the danger that the publications might be considered false or misleading by the FDA. The burden of proof, however, falls on the FDA to establish that fact.

Risk Management Suggestions

Pharmacists should not fear violating the FD&C Act when counseling patients and providing educational information to patients. Pharmacists should, however, recognize the difference (where possible) between a structure/function claim and a disease claim. Even when counseling, pharmacists should be cautious about asserting disease claims for a product, especially without including at least a disclaimer that the product has not been proven safe and effective for the treatment of the disease. Pharmacists should not engage in

in-store promotion of dietary supplement products for the treatment of diseases, because this would most likely violate the FD&C Act. Literature about various dietary supplement products should be displayed in a section physically separate from the products themselves; and, if one article advocates a product's safety and efficacy, another, if available, should be displayed that offers another view.

Federal Trade Commision Act: Product Promotion and Advertising Issues

If a claim or statement about a dietary supplement is not labeling, it has to be advertising. While the FDA regulates dietary supplement labeling, the Federal Trade Commission (FTC) regulates dietary supplement advertising.

Deceptive Advertising

The FTC Act, which applies to retailers as well as manufacturers, prohibits "unfair or deceptive acts or practices" and in the case of food products, prohibits "any false advertisement" that "is misleading in a material respect."[8] Historically, the agency devoted priority attention to advertisements in which the accuracy of the claims was difficult for consumers to verify and where adverse health consequences and economic loss could result. Since 1990, the FTC has taken action against several dietary supplement companies including General Nutrition Corporation (GNC), the largest U.S. retailer of dietary supplements.[9]

The FTC cannot require product sellers to submit advertising to it for pre-market approval, but rather must act after the fact. Under the Act, an advertisement is deceptive or misleading when it is likely to mislead reasonable consumers to their detriment. Thus, the FTC need not prove that consumers were actually misled, only that they are likely to be misled. Advertising claims must have a reasonable basis, or in other words, must be substantiated. For example, if the advertisement states that the product reduces inflammation of the joints, the FTC will expect the advertiser to produce scientific evidence supporting that statement.

Perhaps the most significant legal advertising danger to pharmacies occurs when they engage in joint promotional activities with dietary supplement manufacturers. The FTC Act establishes a strict liability standard on all those who participate in false or deceptive advertising. Thus, if a dietary supplement manufacturer mentions a pharmacy in the advertisement and that advertisement is deceptive, the pharmacy is as liable as the manufacturer, regardless of whether or not the pharmacy even had knowledge of the ad's contents.[10]

Risk Management Suggestions

Pharmacies must ensure that safety and efficacy claims made in dietary supplement advertisements can be substantiated. When engaging in joint advertising activities with manufacturers, pharmacies must make it a point to review the advertisements before they are published. Advertisements that simply mention the product's name and price would not normally be a concern under the FTC Act.

Negligence

Under negligence law, pharmacists are expected to exercise that degree of competence expected of a reasonable, prudent pharmacist. Negligence issues can arise when counseling patients about dietary supplement products, as the following scenario provides.

Don is a regular patient of XYZ Pharmacy and has filled all of his prescriptions there, including warfarin. One day Don asks the pharmacist, Sue, if ginkgo is really effective for short-term memory loss. Sue replies that she knows many patients who think that it is effective and some of the literature indicates that it might be helpful. Don purchases the ginkgo and a few weeks later is admitted to the hospital with an abdominal hematoma and nearly dies. An investigation indicates that the ginkgo, which inhibits platelet aggregation, may have potentiated the effect of the warfarin, thereby causing the hematoma. Don files a negligence suit against Sue and XYZ Pharmacy contending that Sue should have warned him of the dangers of taking ginkgo with the warfarin. Are Sue and XYZ Pharmacy liable?

Analysis of Case

For Don to be successful in a negligence lawsuit he must prove four elements: (1) that Sue owed him a duty to exercise a particular standard of care; (2) that Sue breached that duty by acting substandardly; (3) that the substandard act caused his injury; and finally (4) the amount of injury and damages sustained. Starting with the issue of duty, under normal circumstances when a patient purchases a dietary supplement, a pharmacist would not likely owe the patient a legal duty to provide professional advice. In this case, however, Don asked Sue for advice, Sue provided the advice and Don relied upon it. In doing so, Sue has created a legal duty, which must then be exercised to the standard of care of a reasonable, prudent pharmacist.

If Don had asked Sue for advice and Sue refused to comment, Sue might still be negligent on the basis that since Don is a patient of XYZ and Sue, having knowledge of Don's medication history, could have prevented foreseeable harm to Don. The legal duty would be even more likely if XYZ advertised its dietary supplement department and promoted its pharmacists as dietary supplement experts. For example in a Michigan case, a pharmacy advertised that it maintained

a computer software program which would screen prescriptions for potential problems, including drug-drug interactions.[11] A patient suffered a drug-drug interaction from two prescription drugs received from the pharmacy. The pharmacy contended that Michigan law did not establish a duty upon pharmacists other than to fill the prescriptions accurately as written by the prescriber. The court, however, found that the pharmacy created a legal duty to the patient by advertising that its software program would protect the patient from drug-drug interactions, thus inducing the patient to rely upon that advertising.

Under the second element of negligence, the question becomes did Sue breach the legal duty she owed Don? The standard of care of a pharmacist is usually determined through expert witnesses. Don's attorney will introduce one or more pharmacists to testify that a pharmacist who provides advice on ginkgo should know that it inhibits platelet aggregation (especially if XYZ promoted the dietary supplement expertise of its pharmacists). These expert witnesses would also likely testify that since Don is a patient of the pharmacy, the pharmacist should have known that Don was taking warfarin. Therefore, the witnesses would conclude that a reasonable pharmacist would have warned the patient of the potential danger of taking the two products together and have urged the patient to discuss the issue with his physician.

The question then arises: Does Sue still have a duty to know that Don is taking warfarin if he is a patient of another pharmacy and his warfarin prescription was dispensed there? Although less clear, it could certainly be determined that Sue had a legal duty to discover Don's warfarin use by asking Don whether he is taking any prescription medications. If Don does not tell Sue about the warfarin, Sue could not be expected to know and should not be liable.

Pharmacists will not be legally responsible for knowing or warning about all the potential adverse effects or interactions regarding a dietary supplement, since this would not be reasonable. Pharmacists will, however, likely be expected to know and to warn of adverse effects that might be common or severe. This is especially true as software programs capable of detecting potential interactions and adverse effects of dietary supplements become more prevalent and widely used in pharmacies.

Even if Don establishes that Sue is negligent, he still faces a difficult hurdle in order to win the lawsuit. Don must still show that it was more likely than not that the ginkgo actually caused the hematoma. Sue's lawyer will argue that the hematoma occurred for other reasons, not related to the ginkgo. Both sides would have expert witnesses testify as to what caused the hematoma and a jury would evaluate their testimony. The scant availability of science regarding the safety and efficacy of many dietary supplements would likely place the plaintiff at a significant disadvantage in attempting to show causation in many cases.

Risk Management Suggestions

Pharmacists should educate themselves and become knowledgeable about the dietary supplement products they sell. The pharmacy's library should have one or more current dietary supplement reference books and the pharmacy should utilize computer software. Pharmacies should not promote their staff as experts in dietary supplement products unless they truly do have expertise. When counseling or advising patients about dietary supplements, the pharmacist should consider the following actions, depending upon the situation.

1) Emphasize that the product has not been proven safe and effective.
2) Obtain as much patient history as possible, especially any prescription and OTC medications the patient is taking, Elicit use of any other dietary supplements, disease and diet information.
3) Screen for any contraindications.
4) Warn the patient about any common and/or severe side effects or interactions that could occur.
5) Suggest that the patient inform his or her physician of the intended use.
6) Suggest that the patient contact either the pharmacist or physician if any problems arise during the product's use.

Product Liability

As the sellers of retail products in California, pharmacists face not only the possibility of liability for their actions, but liability for the products themselves when those products cause injury. Under a product liability lawsuit, a seller could be liable even when not at fault. Two theories of product liability will be discussed here, warranty and strict tort liability.

Breach of Warranty

When a pharmacy sells a dietary supplement product, a contract is formed between the pharmacy and the purchaser. That contract attaches certain warranties. Failure by the pharmacy to meet these warranties could result in a breach of contract action. Two types of warranties exist, express warranties and implied warranties.

An express warranty occurs when the seller makes an affirmation of fact or a promise, which becomes a part of the basis for the contract. For example, assume in the previous case study that Don asks Sue whether the use of ginkgo is safe when taken in conjunction with warfarin and Sue replies: "Yes. There are no safety problems." Sue's reply could be construed as an express warranty. If Don can establish that he relied on Sue's promise and that ginkgo is not safe when

taken with warfarin, then Sue could be liable for a breach of express warranty.

In addition to express warranties, the law imposes implied (or silent) warranties, which may exist with a contract unless disclaimed by the seller. One type of implied warranty, implied warranty of merchantability, gives buyers recourse when the products are not fit for the ordinary purposes for which they are used, because they are impure or mislabeled. For example, if the ginkgo product Sue sold Don contained much higher doses of ginkgo than labeled, and it can be established that this dose was the cause of Don's injury, Sue and XYZ Pharmacy might be liable because the product was not fit.

Another type of implied warranty, implied warranty of fitness for a particular purpose, would be particularly applicable to this situation. Under this theory, liability can occur when a seller exercises his or her professional judgment in the selection of a dietary supplement, the patient relies on the seller's judgment and then is injured. Unlike with merchantability, this warranty can exist even if the product is perfectly made. Don could argue that Sue breached this warranty by recommending ginkgo to him and that it was not fit for his particular purpose since he was taking warfarin.

Strict Tort Liability

Many jurisdictions, including California, also recognize strict tort liability as a cause of action against product retailers. Under strict tort liability the plaintiff does not have to establish fault by the seller or the existence of a contract, only that the product was in a defective condition, that the defect made the product unreasonably dangerous to the user, and that the defect caused the harm. Under this theory, Don would argue that the ginkgo was defective since no warnings were provided that it might interact with warfarin and that this warning defect made the ginkgo unreasonably dangerous to use, causing his injury. Under strict tort liability, a pharmacy could also be held liable for selling adulterated or misbranded dietary supplements even though it has no knowledge of this fact. This could be significant considering that the dosages of some dietary supplement products, especially herbs, can deviate significantly from bottle to bottle and even tablet to tablet.

Risk Management Suggestions

To protect against product liability actions, pharmacists should avoid making guarantees or promises about product safety and efficacy. Pharmacies should inventory only products that they are confident are pure, labeled properly and manufactured by reputable companies. Ideally and when possible, USP labeled herbs should be purchased.

Dispensing Prescriptions for Dietary Supplements

Many of the same issues previously discussed apply when dispensing dietary supplements pursuant to a prescription. If the product is prescribed for the purpose of treating a disease, the product could become a drug, in particular an unapproved drug prescribed for an unlabeled purpose.[12] In general, this would not violate the FD&C Act or state law, since this is an acceptable practice within the scope of medicine and pharmacy. Technically, a legal problem could exist when the product is compounded.[13] The FD&C Act provides that the ingredients used in compounding must either meet USP standards or be approved by the FDA. In the case of dietary supplements, except for a few herbals, these requirements could not be met. Dispensing dietary supplements might actually present an additional dimension of liability compared to prescription drugs, since the dietary supplement might be prescribed in lieu of conventional therapy. If the dietary supplement is ineffective, leading to further harm to the patient from the disease, the patient could contend that the prescriber was negligent in prescribing the dietary supplement. The pharmacist might be included in the lawsuit for not intervening. When faced with a dietary supplement prescription, pharmacists must determine if in the particular situation foregoing conventional therapy might be harmful to the patient. If the potential for risk warrants it, the pharmacist should contact the prescriber to confirm the accuracy of the prescription and justify it. If dispensed, the patient must be informed of the situation and allowed to consent to the treatment.

Conclusions

Although the sale of dietary supplements can trigger several potentially applicable legal theories, there have been relatively few lawsuits against the manufacturers and sellers of these products. There are several reasons for this. First, aside from contamination or adulteration, most dietary supplement products are relatively safe. Second, the widespread use of these products is relatively recent. Third, the deregulation of dietary supplements is relatively recent. And fourth, most consumers and health care providers do not know or realize that the dietary supplement may be the cause of an adverse effect. Most likely the number of lawsuits will increase with increasing consumer use and increasing consumer expectations resulting from product advertising. Further research will help to reveal more about the safety (or lack thereof) of these products. Although any consumer can be at risk of injury from taking dietary supplements, those most at risk include prescription drug users and those with chronic diseases. They are also the consumers most likely to seek advice from pharmacists. Nonetheless, pharmacists can minimize the risk of liability by following the suggestions in this article.

What's in a Claim?

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Disease claims,[1] also called health claims or risk reduction claims, describe an association between a food or nutrient and a disease or health-related condition. The FDA approves disease (health) claims before a product is marketed. Manufacturers must notify the FDA of their intent to make a disease (health) claim in advance and be able to substantiate the claim with scientific evidence or authoritative statements (e.g., statements made by the National Academy of Sciences).[2] Examples of approved disease (health) claims are: "Folic acid during pregnancy decreases the risk of neural tube defects" and "Calcium can lower the risk of osteoporosis." The FDA has generally allowed disease (health) claims for dietary supplements that prevent a disease or reduce the risk of developing a disease.[3]

The FDA recently denied the following disease (health) claim for Saw Palmetto: "Consumption of 320mg/day of Saw Palmetto extract may improve urine flow, reduce nocturia and reduce voiding urgency associated with mild benign prostatic hyperplasia (BPH)." The denial was based the FDA's position that BPH is an existing disease and the use of the product is intended to treat a disease, not prevent it, or reduce the risk of developing it.[3]

Nutrient-content claims[1] refer to the relative level of a specific nutrient in a product (e.g., "excellent source of Vitamin C" or "high in calcium"). These claims are allowed if one serving of the product meets the threshold amount established by the FDA for a specific nutrient (e.g. products containing 12 mg of Vitamin C or 200mg of calcium, respectively).

Nutrition support claims[1] describe a relationship between a nutrient and a disease or health condition that results from deficiency of that nutrient. An example is "Vitamin C prevents scurvy." Nutrition-support claims must also include the prevalence of the deficiency disease in the United States.

Structure-function claims[1] are a type of nutrition-support claim. They describe the effect of the nutrient on the body's structure or function, or overall effect on a person's well-being. Some examples are: "Calcium builds strong bones," "Antioxidants maintain cell integrity," and "Fiber maintains bowel regularity."

Manufacturers may make structure-function claims without prior FDA review, but must notify the FDA of the claim within 30 days of first marketing the product. The product label must also include the disclaimer "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." Manufacturers must be able to substantiate that the statements are truthful and not misleading, although they are not required to provide any proof of such to the FDA.

The final rule pertaining to structure-function claims (*Federal Register;* January 6, 2000) clarifies the distinction between a disease claim and a structure-function claim.[4] It permits health maintenance claims (e.g., "maintains a healthy circulatory system"), non-disease claims (e.g. "helps you relax"), and claims for common, minor symptoms associated with various life stages (e.g., "for hot flashes") for dietary supplement products. Express or implied claims to treat a disease are not allowed.

Strategies for Promoting Safe and Appropriate Use of Dietary Supplements

1. Learn about dietary supplement products and stay informed. Maintain an up-to-date library of dietary supplement references. Read what your patients are reading.
2. When counseling or advising anyone about dietary supplements:
   a. Determine who will be using the product and that person's age.
   b. Ask about the intended use.
   c. Obtain as much medical history as possible, especially any prescription or non-prescription medications or use of other dietary supplements. Ask about any dietary restrictions.
   d. Screen for any contraindications or reasons to avoid using the product.
   e. Warn about possible adverse effects or drug interactions.
   f. Encourage reporting of any dietary supplement use to the patient's health care provider.
   g. Emphasize that the product has not been proven to be safe or effective.
   h. Remind the patient to report any adverse effects to his or her physician or pharmacist.
3. Anyone with health conditions such as blood clotting disorders, diabetes, heart disease, hypertension, Parkinson's disease, prostate enlargement, psychiatric problems, autoimmune disease or other serious medical conditions should not take dietary supplements without first consulting their physician. Pregnant and breast-feeding women, children and the frail elderly should be discouraged from using these products.
4. Emphasize reading product labels. Consumers should know what the product contains, how much it contains and the suggested use. They should be told to follow the instructions for use.
5. Encourage the use of products manufactured by major companies. Look for expiration dates or other evidence of quality control.
6. Report adverse events to the FDA MedWatch Program (forms can be down-loaded from www.fda.gov).
7. Consult the California Poison Center for assistance in managing any adverse events associated with dietary supplements. The toll-free number is 1-800-8POISON.
8. Be alert to fraudulent products. Products that claim to be a "breakthrough," "miracle cure," or "new discovery" should raise suspicion. Vague medical claims, such as "detoxify," "purify," or "energize," are misleading and difficult to measure. Other possible indicators of fraud are products that claim to be effective against a wide range of unrelated conditions, have only health benefits and no adverse effects, or have claims supported by scientific studies that can not be traced or substantiated, according to Stephen Barrett, M.D. of the National Council of Health Fraud,*.

** Kurtzweil P. An FDA Guide to Dietary Supplements. FDA Consumer. September-October 1998; revised January 1999. www.fda.gov, accessed August 3, 2000.*

Suggested Reading

1. Angell M, Kassirer JP. Alternative medicine-the risks of untested and unregulated remedies. *N Engl J Med* 1998; 339:839-841. Editorial.
2. Astin JA. Why patients use alternative medicine: results of a national study. *JAMA* 1998; 279:1548-1553
3. Cirigliano M, Sun A. Advising patients about herbal therapies. *JAMA* 1998; 280:1565-1566. Letter to Editor.
4. Eisenberg DM. Advising patients who seek alternative medical therapies. *Ann Intern Med* 1997; 127:61-69.
5. Eisenberg DM, Davis RB, Ettner SL et al. Trends in alternative medicine use in the United States, 1990-1997. Results of a follow-up national survey. *JAMA* 1998; 280:1569-1575.
6. Eisenberg DM, Kessler RC, Foster C et al. Unconventional medicine in the United States: prevalence, costs, and patterns of use. *N Engl J Med* 1993; 328(Jan. 28):246-252.
7. Ernst E. Harmless Herbs? A review of the recent literature. *Am J Med* 1998; 104;170-178.
8. Fontanarosa PB, Lundberg GD. Alternative medicine meets science. *JAMA* 1998; 280:1618-1619. Editorial.
9. Fugh-Berman A. Herb-drug interactions. *Lancet* 2000; 355:134-138.
10. Jonas WB. Alternative medicine-learning from the past, examining the present, advancing to the future. *JAMA* 1998; 280:1616-1617. Editorial.
11. Kurtzweil P. An FDA guide to dietary supplements. U.S. Food and Drug Administration, *FDA Consumer*. Sept-Oct 1998; Revised Jan 1999. www.fda.cfsan.gov/~dms/supplmnt.html
12. Lemley B. Why so many doctors hate Andrew Weil. *Discover* 1999 (August); 56-63.
13. Palmer ME. Dietary supplements: "Natural" is not always safe. *Emer Med* 1998; 30:52-74
14. Editor. Herbal Rx: the promise and pitfalls. *Consumer Reports* 1999 (March); 44-48.
15. Editor. The mainstreaming of alternative medicine. *Consumer Reports* 2000 (May); 17-25.

"Alternative Medicines"

A Continuing Education Program for California Pharmacists

Universal Program # 113 - 126 - 00 - 034 - H01 • 3 Contact Hours (0.3 CEU)

Co-sponsored by the California Pharmacists Association
and the California Society of Health-System Pharmacists

LEARNING OBJECTIVES:

After reading these articles, you should be able to:

1. Describe the regulatory process for dietary supplements and explain how it differs from that for prescription and non-prescription medications.
2. List one or two common uses for frequently purchased dietary supplements and describe the scientific evidence to support each of these uses.
3. Recognize appropriate dosing regimens and common adverse effects of frequently used dietary supplements.
4. List five herbs or herbal products that are toxic to the liver.
5. List five dietary supplements that should be avoided when taking anticoagulants or anti-platelet medication.
6. Cite three additional examples of potentially harmful drug interactions reported with dietary supplements (other than those listed above).
7. List five medical conditions or diseases in which dietary supplements should be avoided.
8. List three alternative medicine resources that provide reliable information and are suitable for consumer use.
9. Identify five risk management strategies for pharmacists who sell or counsel consumers about dietary supplements.
10. Describe the pharmacist's role in promoting safe and appropriate use of dietary supplements.

DIRECTIONS FOR OBTAINING CE:

- Read the articles and take the test to receive three (3) hours of continuing education credit. Return the entire test page and include a self-addressed, stamped envelope. Please note that the passing grade is 70%. If necessary, one test will be readministered.
- Type or print your name, address, and license number in the space provided on the form below.
- This continuing education monograph is jointly sponsored by CSHP and CPhA, and you may return your answer sheet to EITHER:

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1112 I Street, Suite 300
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CE Exam
725 30th Street, Suite 208
Sacramento, CA 95816

PLEASE NOTE: It is not necessary to send the exam to both organizations. Select one. Remember to enclose a self-addressed, stamped envelope.

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Please enter your answer to each test question below:

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25. _____

TEST QUESTIONS

1. The number of U.S. adults who take one or more dietary supplements concurrently with prescription medication has been estimated to be:
a. 1 in 3
b. 1 in 4
c. 1 in 5
d. 1 in 10

2. Which of the following statements is NOT true:
a. Dietary supplements can be marketed without proof of safety and efficacy.
b. The FDA does not regulate dietary supplements.
c. Manufacturers of dietary supplements have responsibility for ensuring that their products are safe and properly labeled.
d. Manufacturers of dietary supplements must be able to substantiate any structure or function claims as truthful and not misleading.
e. For structure/function claims, the product label must also bear the statement "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

3. The intended use of a product determines whether it is a food or a drug.
a. True
b. False

4. Which of the following is NOT a dietary supplement:
a. Herbal products
b. Multiple vitamins
c. Glandular products
d. Beverages containing ginseng
e. All of the above are dietary supplements

5. The following information is required on the dietary supplement product label, except:
a. Name of active and inert ingredients
b. Directions for use
c. Supplement Facts panel
d. German Commission E rating, if a botanical
e. Name, place and business of the manufacturer, packer or distributor.

6. The majority of people who use alternative medicines are dissatisfied with the traditional health care system.
a. True
b. False

7. Dietary supplements should be avoided in pregnant or breast-feeding women:
a. True
b. False

8. Glucosamine HCl appears to be effective for relieving symptoms associated with osteoarthritis.
a. True
b. False

9. Garlic lowers LDL cholesterol about the same as dietary restriction.
a. True
b. False

10. Melatonin is effective for which of the following indications:
a. Jet lag
b. Sleep-onset insomnia
c. Sleep maintenance insomnia

11. St. John's wort enhances mood in mild to moderate depression.
a. True
b. False

12. Ginseng is effective in improving physical and mental performance.
a. True
b. False

13. Echinacea is effective in preventing the common cold.
a. True
b. False

14. Saw palmetto can interfere with measurement of prostate specific antigen (PSA).
a. True
b. False

15. Which of the following echinacea products has been shown to be effective in relieving cold symptoms:
a. *E. purpurea* fresh pressed juice preserved in 22% alcohol
b. *E. purpurea* root extract
c. *E. pallida* fresh pressed juice preserved in 22% alcohol
d. *E. angustifolia* root extract
e. All of the above

16. The primary antidepressant constituent in St. John's wort is hypericin.
a. True
b. False

17. Which of the following dietary supplements have been reported to cause liver disease:
a. Ma huang
b. Aconite
c. Germander
d. Jimson weed
e. None of the above

18. Adverse drug interactions may occur with St. John's wort and all of the following except:
a. Simvastatin
b. Paroxetine
c. Indinavir
d. Cyclosporin
e. Warfarin

19. Patients taking anticoagulants or anti-platelet medications should avoid the following dietary supplements, except:
a. Dong quai
b. Ginkgo
c. Garlic
d. Ginseng
e. Black cohosh

20. The following doses are appropriate for the dietary supplement listed, except:
a. Melatonin 100mg
b. Chondroitin sulfate 1200 daily, in one or three divided doses
c. St. John's wort 900mg daily, in two to three divided doses
d. Coenzyme Q10 30-60 mg daily
e. Black cohosh 40mg of the herb twice daily

21. All of the following are sound risk management strategies, except:
a. Suggesting that the patient inform his or her physician of any dietary supplement use
b. Cautioning patients that dietary supplement products have not been proven safe and effective for the stated claims
c. Obtaining as much patient history as possible, including prescription, OTC and other dietary supplement use
d. Relying on manufacturers of dietary supplement products to provide all the literature and advertising for in-store promotions
e. Maintaining a library of reliable references and information resources

22. Dietary supplements differ from OTC products in the following ways, except:
a. Manufacturers must follow GMP
b. They may not claim to diagnose, treat, cure or prevent a disease
c. They can be marketed without proof of safety and efficacy
d. They are regulated by the FDA
e. Product labels must include directions for use

23. All of the following have produced adverse reactions to herbal products, except:
a. Using the wrong plant or plant part during processing
b. Contaminating the plant material with microorganisms, heavy metals, pesticide residues or radioactive materials
c. Inadvertently or intentionally adding prescription drugs during processing
d. Drug interactions with prescription medication
e. Using standardized extracts of the plant material

24. Chinese herbal medicines have been associated with toxic reactions similar to those produced by:
a. Anticholinergic agents
b. Cardiac glycosides
c. Stimulants
d. Sedative hypnotics
e. Both a. and b.
f. None of the above

25. In a case of suspected toxicity from a dietary supplement, the pharmacist should:
a. Obtain the product or a sample of the product
b. Call the California Poison Control Center for guidance on management
c. Report the suspected adverse reaction to the FDA MedWatch Program
d. Notify the California Department of Health Services if the product is imported from China
e. All of the above

HEALTH NOTES
Alternative Medicines

Making a Difference

This issue of HEALTH NOTES is a collaborative effort of the California State Board of Pharmacy and the School of Pharmacy, University of California, San Francisco.

Sponsored by

The UCSF School of Pharmacy
Center for Consumer Self Care
"Helping People Help Themselves"

The Center for Consumer Self Care is an emerging collaborative center whose mission is to ensure optimal and responsible use of medication and dietary supplements by individuals and the public at large. The Center will accomplish its mission through the following program cores: Consumer Education, Research, Professional Education and Public Policy.

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Continuing Education

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Attachment C:

Health Notes
Drug Therapy Considerations in Older Adults

HEALTH NOTES

Drug Therapy Considerations in Older Adults

Communication and Public Education Committee

Dedicated to building bridges of communication with those Californians whose health depends on proper drug therapy, compliance with a treatment regimen and a healthier lifestyle.

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HEALTH NOTES
VOLUME 1, NUMBER 7

Drug Therapy Considerations in Older Adults

TABLE OF CONTENTS

A Note From the Editors 5
Peter J. Ambrose, Pharm.D., FASHP, R. Ron Finley, B.S.Pharm. R.Ph., Barbara L. Sauer, Pharm.D.

Case Histories 6

PART I – PRESCRIBING CHALLENGES IN THE ELDERLY PATIENT
Pharmaceutical Care in the Elderly 9
Bradley R. Williams, Pharm.D., FASCP

Altered Drug Action with Aging 12
Peter J. Ambrose, Pharm.D., FASHP

Evaluating The Risks and Benefits of Drug Therapy 16
Sian Carr-Lopez, Pharm.D.

PART II – MANAGEMENT OF COMMON GERIATRIC DISEASES
Alzheimer's Disease 21
R. Ron Finley, B.S.Pharm., R.Ph.

Depression 26
Michelle M. Fouts, Pharm.D., BCPS, CGP, Sharon Kotabe, Pharm.D., FCSHP, FASCP

Osteoarthritis Pain 31
Darlene Fujimoto, Pharm.D.

Diabetes 35
Lisa Kroon, Pharm.D., CDE

PART III – RESOURCES AND INFORMATION FOR THE PATIENT AND THE PHARMACIST
Geriatric Self-Care 41
Tatyana Gurvich, Pharm.D.

Reimbursement and Access to Care 48
Marilyn Stebbins, Pharm.D.

Continuing Education for Pharmacists 53

William Powers
Chairperson, Communication and Public Education Committee
California State Board of Pharmacy

On behalf of the California State Board of Pharmacy, I am pleased to offer and recommend this publication on drug therapy for seniors to California's pharmacists, patients and other health care providers. The board encourages pharmacists to use the process offered in this monograph to earn continuing education credits for studying the information.

Health Notes is published by the California State Board of Pharmacy's Communication and Public Education Committee to assist California pharmacists and other healthcare providers to be better informed on topics of importance to their patients. Patients, too, should find this information highly useful.

According to the 2000 census, there were approximately 3.6 million seniors in California who were over age 64. This group comprises a large segment of those who take prescription drugs, yet these drugs are most effective when they are prescribed and taken appropriately.

This *Health Notes* addresses drug therapy issues affecting seniors with the intent to improve the quality of pharmacists' care provided to these patients. The articles are on a variety of diseases or issues related to drug therapy and management for seniors, and offer information from experts on such matters as therapeutic goals, metabolic issues affecting drug therapy, and patient counseling tips. The articles also confront and dispel a number of myths involving seniors and prescription medication therapy. These myths include:

- Geriatric patients do not learn new information.
- Older patients are less able to tolerate medication than younger adults.
- A person over the age of 65 will always experience more side effects from medication than someone younger than 65
- Seniors who take opioids for chronic non-cancer pain will become addicted in days to weeks.
- All vitamins are safe, even at large doses.
- Because over-the-counter medicines don't require a prescription, they're not as strong.
- Patients with health insurance do not qualify for patient assistance programs through the pharmaceutical industry.

As Dr. Bradley Williams concludes in his article:

> "Older adults greatly appreciate the care and attention that comes with pharmaceutical care. They rely heavily on medications for disease management and successful treatment that enhances their quality of life. For pharmacists, interventions can be rewarding and ensure that their older patients retain their functions and activity despite the presence of chronic disease."

We believe this issue of *Health Notes* will be of great benefit in advancing the health of our state's seniors.

William Powers
Chairperson, Communication
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A Note From the Editors

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By now, most of us are well aware, either from census reports, newspapers, or by just looking in the mirror each day, of the increasing number of older adults in American society. In 2011, the 76 million baby boomers will begin turning 65 years old and this "age wave" is expected to have great political and social impact.

The statistics from the U.S. 2000 census are frequently in the media and raised in political debates:

- Elders (65 years and older) represent 12.4 percent of our population and number 35 million – or one in every eight Americans.
- Over 2 million people celebrated their 65th birthday in 2000. Their life expectancy is an additional 17.9 years.
- The elderly population is projected to double to 70 million in the next quarter century. By 2030, one in every four Americans will be "geriatric."
- Americans 85 years of age or older are the fastest growing segment in our country. They numbered 4.2 million in 2000 and are projected to increase to 8.9 million by 2030.

Adults over 65 years of age are more likely to suffer from a chronic condition requiring drug therapy: 44 percent have arthritis, 39 percent have hypertension, 28 percent have some form of heart disease, and 20 percent have diabetes mellitus. On average, older adults visit a physician six times annually and receive twelve prescriptions per year (two prescriptions per visit), resulting in 365 million prescriptions written each year in the U.S.

Drug therapy for older adults is frequently less than optimal, which is of significant concern to health professionals and consumers alike. Medications have the potential to improve a person's quality of life, but inappropriate drug therapy may cause adverse reactions and harm, increase health care costs, require emergency room visits or hospitalizations, and could be fatal. By taking an active role in optimizing drug therapy for older adults, pharmacists can improve therapeutic outcomes and reduce adverse consequences.

In this issue of *Health Notes*, we've chosen a case-based format to illustrate key points and to emphasize practical applications of the information presented. The patient cases do not represent any specific individuals, but are rather a composite of typical older adults, common medical problems, and medications. The authors will discuss Mr. and Mrs. Brown, Mrs. Smith, and Mrs. Young throughout the issue, providing their own perspectives on the issues present. Our hope is that you will find this information informative, helpful, and applicable to your practice.

EDUCATIONAL OBJECTIVES

After reading this issue of *Health Notes*, the pharmacist should be able to:

1. Identify four factors that contribute to medication complications in older adults.
2. Give five examples of how aging can affect drug action in older patients.
3. Describe four principles that can be implemented to enhance positive medication outcomes in the elderly.
4. Discuss the role of drug therapy in Alzheimer's disease.
5. Discuss the treatment philosophy for depression in the elderly and how it differs from treatment paradigms in younger adults.
6. Identify treatment options and use of medications in the treatment of osteoarthritis pain.
7. Discuss the treatment options for type 2 diabetes, including specific considerations for the elderly.
8. Discuss precautions for the elderly who self-medicate with over-the-counter medications and dietary supplements.
9. Describe prescription benefit options and cost saving strategies for adults over the age of 65 years.
10. List five strategies for maximizing counseling sessions with older patients.

Case Histories

Case I: Mr. And Mrs. Brown

Mr. and Mrs. Brown live in a small apartment in the inner city. Ted Brown is a 79-year-old retired accountant. His wife of 51 years, Judy Brown, continues to work part time as a substitute teacher. The Browns are active older adults and both enjoy ballroom dancing and taking walks in the park. Mrs. Brown takes no prescription medications, but does take a variety of herbal and nonprescription medications that she purchases by mail. Mr. Brown takes the following medications on a regular basis:

- aspirin 81mg once daily
- hydrochlorothiazide 25 mg once daily
- clonidine patch (Catapres-TTS-1®) weekly for hypertension
- ranitidine (Zantac®) 150 mg twice daily for gastric reflux
- naproxen (Naprosyn®) 375 mg twice daily as needed for arthritis pain
- lovastatin (Mevacor®) 40 mg daily at bedtime
- metformin (Glucophage®) 500 mg three times daily for diabetes
- nitroglycerin 0.4 mg sublingual as needed for chest pain
- diazepam 5mg as needed for occasional anxiety and insomnia

Mr. Brown had a heart attack three years ago, but has not experienced chest pain in over a year. He takes his medications as prescribed, but does occasionally forget to take his cholesterol medication and admits, "My cholesterol could be better."

Case II: Mrs. Smith

Mrs. Smith is a 69-year-old recently retired sales clerk. She has just returned to her suburban home, where she lives alone, after being discharged from the hospital following a blood clot in her leg. During her five-day stay in the hospital, she was started on warfarin (Coumadin®) 5 mg daily. Her dose was increased from 3 mg to 5 mg per day on the day that she was discharged. She is now picking up her new prescription for Coumadin® 5 mg tablets from a community pharmacy. The prescription bottle is labeled, "Take as directed." Mrs. Smith has her prescriptions filled at several pharmacies, because she finds the prices may vary from one pharmacy to the next. Her health insurance does not cover medications that are not administered in a hospital.

Mrs. Smith's medications are:

- warfarin (Coumadin®) 5 mg per day
- digoxin (Lanoxin®) 0.125 mg daily for irregular heart beat
- fluoxetine (Prozac®) 20 mg per day for depression
- rofecoxib (Vioxx®) 25 mg daily for joint pain
- loratadine (Claritin®) one tablet daily for hay fever (OTC)
- omeprazole (Prilosec®) 20 mg per day for stomach distress

As she picks up her new prescription for Coumadin®, she brings Tagamet HB®, Pepto-Bismol®, gingko biloba capsules, vitamin C 500 mg tablets, vitamin E 1,000 unit capsules, and a bottle of Advil® to the checkout counter. She also mentions to the pharmacist that she feels her vision has worsened lately, she feels thirsty a lot, and has been getting up more often in the middle of the night to urinate.

Case III: Mrs. Young

Thelma Young is a 71-year-old retired teacher who was recently diagnosed with "probable mild-to-moderate Alzheimer's disease." Her husband accompanies her to the pharmacy today to purchase vitamin E and Advil®. Mrs. Young tells the pharmacist that she has been experiencing difficulty sleeping and states, "I am having very disturbing dreams that wake me up during the night. Then I can't get back to sleep. The nonprescription sleeping pills that I'm taking help, but I feel groggy in the morning." She demonstrates some difficulty in finding the correct words to say, but can otherwise communicate effectively. Her husband says that his wife frequently forgets where she puts household items and that she has burned several pans on the stove recently. He asks, "How fast will the new memory drug, Aricept®, work?" Mr. Young goes on to say that his wife has had difficulty sleeping off and on for years, but that the disturbing dreams are a change. He asks if it could be a result of her taking the new medicine. He also wants to know if Advil® and vitamin E will help her memory.

PRESCRIBING CHALLENGES IN THE ELDERLY PATIENT

Pharmaceutical Care in the Elderly

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Chronic medical conditions require treatment, and the treatment of choice often remains drug therapy. With increasing use of medications, the rate of noncompliance and the risks of adverse drug reactions, drug interactions, and drug-induced hospitalizations rise. Studies over the past 10-15 years have found that approximately one-quarter of all hospital admissions for people aged 65 years and older are associated with medication-related problems, typically adverse drug reactions or noncompliance. Factors that may contribute to this problem include polymedicine[i], prescribing of medications that are not appropriate for older adults, unsupervised use of nonprescription remedies, and inadequate counseling and education of patients about their medications.

Polymedicine

Polymedicine has been defined in many ways. Most definitions include some specific threshold, such as the use of five or more medications. A more appropriate definition, however, is simply the use of unnecessary medications. For example, Mr. Brown (Case I) requires several medications to manage multiple chronic diseases, but this is not polymedicine (although the choices of some of the medications are not ideal). Mrs. Brown, in contrast, purchases several remedies by mail and many of them may not be necessary. Consequently, she is the person more likely to be exhibiting polymedicine. Mrs. Smith (Case II) appears to be taking an antihistamine routinely, although hay fever is commonly a seasonal condition. Her ibuprofen purchase duplicates her rofecoxib (Vioxx®) prescription. Her Tagamet HB® and Pepto-Bismol® are probably being used to treat the same gastrointestinal problem for which she is taking omeprazole (Prilosec®). This illustrates the important point that polymedicine is not necessarily confined to the overprescribing of medications.

Several factors contribute to polymedicine, as shown in Table 1. In addition, the attitudes of health professionals toward older adults can contribute. Those who view older adults as complainers may respond by quickly writing prescriptions to bring the visit to an end, or they may not provide adequate counseling or education about the appropriate use of medications. As a general rule, the more complex the patient and the more fragmented the care, the greater the risk of polymedicine.

Pharmacists and other health professionals must be alert to the signs of polymedicine, which may not always be obvious. Identifying polymedicine (Table 2) requires effective communication between prescribers, pharmacists, other health care providers, and most importantly, patients. A prescribed medication may not have an apparent indication or the problem may no longer be active. For example, Mr. Brown is receiving diazepam for occasional anxiety and insomnia. These problems often do not require treatment if the frequency is occasional. In addition, non-drug treatment may be as or more effective than using a benzodiazepine. Mrs. Smith exhibits polymedicine by her use of several duplicate medications, as described previously. She also is at risk for the use of

MYTHS & FACTS

MYTH: *Older adults are more noncompliant with medication regimens than younger patients.*

FACT: Noncompliance is more closely related to the numbers of medications and the complexity of the regimen. Because the elderly often take more medications, they have more opportunity for noncompliance.

MYTH: *Geriatric patients do not learn new information.*

FACT: Vision and hearing impairments and slower nerve transmission as we age make it more difficult for some elderly patients to register new information. When delivered in a manner that takes this into account, older adults learn very well.

Table 1. Factors That Contribute to Polymedicine

• Multiple disease states
• Time constraints on health professionals
• Multiple health care providers
• Use of nonprescription medications
• Patient-driven prescribing

Table 2. Evidence of Polymedicine
• Medications with no apparent current indication
• Use of duplicate medications
• Use of interacting medications
• Medications that are contraindicated in concurrent diseases or conditions
• Inappropriately high or low medicine dosages
• Pharmacotherapy of adverse drug reactions

several interacting medications, including cimetidine, fluoxetine, and warfarin. Omeprazole can also affect digoxin absorption and gingko biloba may increase the risk for bleeding when used with warfarin.

Mrs. Smith wishes to take ibuprofen, which may be contraindicated with her warfarin therapy because of the increased risk of bleeding. It also may worsen her stomach distress for which she is taking omeprazole and wishes to purchase Tagamet HB®. Other signs of polymedicine include the use of inappropriately high or low doses of medications, and the treatment of adverse drug reactions with other medications.

Nonadherence

The use of large numbers of medications increases the risk for noncompliance or nonadherence to therapy. Mr. Brown takes eight prescription medications, six of them routinely. The dosage frequencies range from once weekly to twice daily. Although he appears to take his medications conscientiously, he admits to occasionally forgetting to take his lovastatin. Several factors that can affect adherence to therapy, some of which apply to Mr. Brown, are listed in Table 3. A special problem is present with his Catapres-TTS®. It is a topically applied medication that includes two components, the patch containing the clonidine and an adhesive patch. Patients have been known to apply the adhesive cover patch only and discard the active patch containing the drug, not realizing that both must be applied.

Table 3. Factors That Contribute to Nonadherence
• Taking several medications with different schedules (e.g., combination of daily, twice daily, three times daily plus medications to be taken with or without meals)
• High-cost medications
• Delays in ordering medication refills
• Inability to travel to the pharmacy to pick up refills
• Confusing or difficult directions (e.g., bisphosphonates) or changes in directions
• Perceived or actual adverse effects
• Lack of understanding about a medication's intended effect or unclear expectations about outcomes

Adverse Drug Reactions

Elderly patients are often given prescriptions for medications that may be more likely to cause adverse drug reactions due to age-associated physiological changes. For example, Mr. Brown is taking Catapres-TTS® for his hypertension. This medication often causes orthostatic hypotension, dry mouth, and constipation in older adults and may also have an adverse effect on his mood. Given his history of myocardial infarction, an angiotensin converting enzyme inhibitor or a beta-blocker would be a more appropriate choice. He is also taking naproxen for arthritis pain. Nonsteroidal anti-inflammatory drugs (NSAIDs) may antagonize the effect of his antihypertensive medication and worsen his gastric reflux. Acetaminophen is generally considered a more appropriate medication for arthritis pain and will not adversely affect his other conditions. Diazepam and other long-acting benzodiazepines are considered inappropriate for older adults because these drugs accumulate in the body and increase the risks of falls and cognitive impairment.

Patient Consultation

Mrs. Smith (Case II) illustrates the frequent and unsupervised use of nonprescription medications. She wishes to purchase Tagamet HB® and Pepto-Bismol®, which duplicate her omeprazole therapy. The Tagamet®, gingko biloba, and vitamin E may all have additive effects with Coumadin®, causing an increased risk of bleeding. The ibuprofen duplicates her Vioxx® and may cause intestinal bleeding that may be exacerbated by the anticoagulant.

These issues illustrate the importance of counseling and educating older adults about their medications. The pharmacist and prescriber play crucial roles in ensuring patient safety. An excellent initial strategy is for older adults to use a primary care physician who will coordinate services among other physicians and clinicians, such as dentists, podiatrists, and any others who may prescribe medications.

Elderly patients should purchase all of their prescription and nonprescription medications at a single pharmacy so that a comprehensive medication history is available. When seniors obtain nonprescription remedies from other sources, they should inform their pharmacist so that the information can be included in their patient profiles.

Pharmaceutical Care Principles

The use of pharmaceutical care principles provides a systematic approach to ensuring good patient education. These include assessment, development of a care plan, establishment of therapeutic goals, and follow-up. The assessment process includes an understanding of the patient, disease state, and drug therapy. Age-associated physiologic changes must be

considered. The older patient's lifestyle and activity level also may affect the response to medications. The use of alcohol, tobacco, and caffeine must be considered, as well as the effect of a disease state on mobility and function. Mr. Brown's arthritis pain may reduce his ability to exercise and less activity may compromise his cardiovascular conditioning. Mrs. Young has significant functional deficits due to her Alzheimer's disease. This will affect her ability to adhere to a medication regimen and impair her ability to reliably report adverse drug effects. The appropriateness of medication choices must be evaluated with regard to pharmacokinetics, pharmacodynamics, potential for drug interactions, and the ability to adhere to a therapeutic regimen.

High rates of medication use, complex drug regimens, the potential for adverse drug reactions and interactions, self-medication, and the likelihood of noncompliance with a therapeutic plan make developing a pharmaceutical care plan challenging. Suggestions for improving adherence to a medication regimen are listed in Table 4. The pharmacist must work closely with prescribers, the patient, and other care providers to ensure that the therapy maximizes benefit while minimizing risk. Mrs. Smith purchases her prescriptions from several pharmacies, making it difficult to implement a care plan. She compounds the problem by purchasing several nonprescription remedies concurrently. Her pharmacist should educate her about the risks of unsupervised medication use and should work with her to develop a mechanism that will encourage her to use only one pharmacy for all of her medication needs.

Therapeutic Goals and Follow Up

Therapeutic goals should be developed along with the care plan. It is important to recognize that older adults may have goals (e.g., quality of life) that may be very different from those of health professionals. Compliance with a medication regimen will be much better when the patient's lifestyle is considered and incorporated into the therapeutic plan.

Table 4. Strategies For Patients to Improve Compliance

• Use medication calendars, pillboxes, or similar reminder systems.
• Store medications in a location that will serve as a reminder system (e.g., keep mealtime medications at the dining table, or bedtime-only medications at the bedside).
• When traveling, keep medications with a cosmetic or toiletry kit, or some other item that is used on a daily basis.
• If visually impaired, set up a large-type calendar system and place an easily distinguishable marking on each different medication.
• Ask the pharmacist or prescriber if there are dosage forms available that can be taken only once or twice a day to reduce the likelihood of a confusing drug regimen.

Ensuring ongoing effective pharmacotherapy requires follow-up. Older patients will respond well when they understand the importance of treatment and know that the treatment is effective. Elderly patients should be instructed how to self-monitor for chronic diseases such as hypertension and diabetes. This provides them with immediate feedback and helps them reach their goals. Pharmacists should incorporate functional assessment into drug therapy monitoring (e.g., asking how far a patient with arthritis can walk without pain). Follow-up also includes maintaining an ongoing dialogue with prescribers, providing advice regarding self-medication, and offering positive reinforcement to patients regarding their drug therapy success.

Older adults greatly appreciate the care and attention that comes with pharmaceutical care. They rely heavily on medications for disease management and successful treatment enhances their quality of life. For pharmacists, interventions can be rewarding and ensure that their older patients retain their function and activity despite the presence of chronic diseases.

COUNSELING TIPS

- Actively offer counseling to elderly patients. Many are reluctant to interrupt the pharmacist to ask questions.
- Make sure the counseling area is quiet and free of distractions. Hearing aids amplify all sound, including background noise.
- Speak slowly and distinctly while looking at the patient. Older adults with hearing impairments rely to some degree on lip reading.
- Do not shout or raise your voice above normal. Shouting raises the pitch of the voice, and high tone hearing is reduced in older adults.
- Supplement written educational materials with verbal instructions to reinforce learning.
- Make sure written materials are in a type font large enough to be read by a person with impaired vision. High contrast (black type on white surface) is most easily read.
- Allow time for information to "sink in," then ask for feed back to ensure that the information was understood.
- Reinforce information at subsequent visits.
- For metered dose products, transdermal patches, and other unique delivery devices, show, don't just tell, the patient how to use. Have the patient demonstrate proper use and how to use the product.
- For topical ointments and creams, keep a jar of Eucerin or similar product handy and demonstrate how to apply the topical prescription "sparingly." For example, an amount of ointment the size of a green pea will cover the back of the hand. Show and Tell!
- Encourage the use of reminders such as medication calendars or pillboxes. Be sure that the patient can use the reminder system. If not, enlist the assistance of a caregiver or other person who can help set up and monitor the system.
- If a patient is getting refills beyond the expected refill date, ask about the reason for the delay. It may uncover problems with understanding or memory, or indicate prescriber-initiated changes that require the prescription to be updated for accuracy.

Altered Drug Action with Aging

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As a person ages, a number of natural physiological changes occur that alter the way the body handles drugs. In older persons, alterations in drug disposition are related to changes in body composition and organ function. Such age-related changes are generally gradual and follow the normal physiology of aging. Furthermore, the elderly are prone to some pathological conditions that can significantly alter drug disposition (e.g., congestive heart failure). Geriatric patients may also be more sensitive to certain medications; as a result they are more susceptible to the effects of a drug than a younger patient. This places the elder patient at greater risk for experiencing adverse effects from doses of medications typically used in younger persons.

Conceptually, there are two ways to envision drug therapy in individual patients: what the drug does to the body, and what the body does to the drug. Pharmacodynamics is what the drug does to the body. It describes the action of the specific drug and the response of the patient. Conversely, pharmacokinetics is what the body does to the drug and includes such parameters as absorption of the drug, distribution of the drug to the various organs and tissues in the body, metabolism of the drug into other compounds, and renal excretion of the drug and metabolites with subsequent elimination from the body. These two concepts are interrelated in that pharmacokinetic parameters determine the amount of drug that reaches the blood circulation and the site of action, whereas the intensity of the pharmacodynamic effect is generally associated with the amount or concentration of drug at the site of action. Thus, in most cases, there is a concentration-response relationship such that the higher the drug concentration at the site of action, the greater the effect.

Absorption

When a medication is taken orally, the drug needs to be absorbed from the gastrointestinal (GI) tract to get into the blood stream. A number of changes in the GI tract occur with aging that can potentially affect drug absorption after oral administration. The rate and extent of absorption of a drug is influenced by a variety of factors, including changes in GI physiology and function. Alterations in absorption will affect how much and how rapidly a dose will be absorbed.

MYTHS & FACTS

MYTH: *Older patients are less able to tolerate medications than younger adults.*

FACT: Age-related changes in pharmacokinetics and pharmacodynamics are complex. For some medications, elderly patients are more sensitive and for some they are less sensitive. Many differences in dose-response observations can be predicted based on the changes in pharmacokinetic parameters.

Physiological changes in the elderly that may potentially impact drug absorption include a slower rate of gastric emptying, a decrease in intestinal motility, a reduction in intestinal blood perfusion, and a diminished intestinal mucosal surface area. In addition, the extent of absorption may be increased in the elderly for drugs that undergo extensive first-pass metabolism in the liver. This may be expected when there is a decrease in the metabolic biotransformation of the drug, resulting in a greater fraction of a dose entering the systemic blood circulation.

The net effect of the above factors has proven difficult to predict and most frequently does not result in clinically relevant changes in drug absorption after oral administration. Reasons for this include the complex nature of the drug absorption process and bioavailability factors. However, it is prudent to anticipate that the rate of drug absorption and the onset of action may be prolonged in the elderly and that the extent of absorption of drugs that undergo extensive first-pass metabolism may be greater than in younger persons.

Geriatric patients may be prone to other factors that can alter drug absorption. These include: swallowing difficulties, poor nutritional status, erratic meal patterns, and interactions with other prescription and nonprescription medications. A

variety of gastrointestinal conditions not exclusive to older patients, such as Crohn's disease, ulcerative colitis, celiac disease, or surgical procedures (eg., gastrectomy or small bowel resection), may further alter GI absorption of medications.

Distribution

After a drug is absorbed and enters the blood circulation, it distributes to various organs and tissues throughout the body. The distribution of drugs in the body can significantly differ in geriatric patients as compared to younger adults. This difference reflects the various changes in body composition that normally occur as a person ages.

In general, the total body weight of a person declines in old age, particularly in the very old. Specifically, there is a general decline in lean body mass, and an increase in the proportion of body fat. This results in less drug distribution to muscle tissue for drugs such as digoxin, while fat-soluble drugs such as diazepam have a relative increase in drug distribution. Additional changes in body composition in the elderly include a decrease in total body water, a general reduction in the serum albumin concentration, and an increase in α_1-acid glycoprotein. Changes in total body water affect the distribution of water-soluble drugs, such as lithium. A decrease in serum albumin concentration is significant for acidic drugs that are highly bound to this protein, while basic drugs bind to α_1-acid glycoprotein. As the serum albumin concentration declines, the fraction of free or unbound drug increases. Thus, lower total (bound + unbound) drug concentrations are associated with greater pharmacological activity when the free fraction is increased, because the unbound drug is the active entity. This also complicates measuring serum drug concentrations for therapeutic drug monitoring purposes, because total concentrations of the drug are most often measured. This necessitates making some adjustment in the value for proper interpretation. Using phenytoin as an example, the proportion of free drug is normally 10 percent when the serum albumin concentration is 4.4 mg/dL, but it increases to 20 percent when the serum albumin concentration declines to 2.0 mg/dL. Thus, for any given total serum phenytoin concentration, the pharmacological activity would essentially be twice as great when the serum albumin concentration is 2.0 mg/dL versus the normal value of 4.4 mg/dL.

When there is less drug distribution, smaller loading doses of the medications are needed and the half-life of the drug (the time it takes for the blood concentration to decline by 50 percent) will be shortened. Failure to adjust the loading dose in response to a decrease in drug distribution will result in higher blood concentrations of the drug and places the patient at greater risk for toxicity and adverse effects. Conversely, when drug distribution is expanded, relatively higher loading doses are required to achieve desired blood concentrations and the half-life of the drug is extended. Changes in the half-life of a particular drug influence the frequency of dosing when designing dosage regimens. Generally, the longer the half-life, the less frequently a medication needs to be administered, because the effect of the drug is prolonged. The shorter the half-life, the shorter the duration of drug action will be and the medication will need to be administered more frequently.

Metabolism

One of the body's primary mechanisms to detoxify compounds is to transform or metabolize them, which most often inactivates them and allows them to be excreted from the body more readily. For most drugs, metabolism occurs predominantly in the liver. A reduction in the rate of drug metabolism extends the half-life and prolongs the action of the drug. When this occurs, it is appropriate to lower the dose or give the doses less frequently.

Many variables determine metabolic capacity, including nutritional status, diet, genetics, gender, alcohol intake, smoking, environmental factors, and the concomitant use of other medications. In the elderly, several physiological changes are associated with altered drug metabolism, including: a decrease in liver mass, a decrease in blood flow to the liver, and a reduction in the intrinsic activity of drug-metabolizing enzymes. The decrease in liver blood flow essentially decreases the rate at which a drug reaches the liver to be metabolized, while a decrease in the number and activity of metabolic enzymes diminishes the metabolic capacity of the liver.

Drug metabolism is a complex process and there is considerable variability. However, several generalizations can be made in the geriatric patient. The rate of metabolism is often diminished for drugs that are dependent upon hepatic blood flow, such as lidocaine, propranolol, and meperidine. In addition, geriatric patients have been shown to have a reduced rate of Phase I metabolism of some drugs, which involves the oxidation, reduction, dealkylation, or hydroxylation of compounds. Furthermore, this difference may be gender related, with elderly women metabolizing some drugs (e.g., midazolam, doxylamine) as efficiently as younger adults. However, no significant change has been observed in the rate of Phase II metabolism in the elderly, which consists of glucuronidation, acetylation, and sulfation of compounds.

These age-related differences in drug metabolism should be considered when selecting a drug and dosage regimen. For example, chlordiazepoxide, diazepam, and flurazepam undergo Phase I metabolism, and thus, the rate of elimination will be slower than in younger adults. This may result in drug accumulation over time, potentially causing over-sedation,

impaired psychomotor skills, or confusion. Alternatively, lorazepam, oxazepam, and temazepam are metabolized primarily by Phase II reactions, which are not affected by the aging process. However, while their shorter half-life makes these drugs less likely to accumulate, they can also cause the same adverse effects as the previously listed benzodiazepines.

Because older patients are often on multiple medications, there is a greater potential for some medications to alter the metabolism of other medications the patient is taking. Moreover, there are some common conditions in the elderly (e.g., congestive heart failure) that also have a detrimental effect on metabolism of certain drugs. These factors must be taken into consideration when assessing drug therapy in this patient population.

Excretion

Renal excretion of drugs and their metabolites is the major route of elimination from the body. As with metabolism, a reduction in the clearance of a drug via renal excretion will extend the half-life and the duration of action, which often necessitates a reduction in dosage. (See Table 1.)

It is well known that kidney function declines with advancing age. The level of decline varies significantly between individuals, with some healthy older adults experiencing much less of a loss than patients with high blood pressure or diabetes. Physiological changes associated with this age-related decline in renal function include diminished blood flow to the kidneys, a decrease in kidney mass, and a reduction in the size and number of functioning nephrons. Consequently, there is a reduction in the filtration, active secretion, and tubular reabsorption of drugs.

Commonly, clinicians use creatinine clearance to estimate glomerular filtration rate, a standard measurement of renal function. Between the ages of 40 and 80 years, the creatinine clearance decreases at a rate of approximately 1 mL/minute each year. It is important to understand that although the creatinine clearance gradually decreases, the measured serum creatinine concentration may not change significantly. This is because the decrease in creatinine clearance is often accompanied by decreased creatinine production in the aged, which is due to a decline in lean body mass. The net effect is little or no change in the serum creatinine concentration. Thus, age and body mass must be factored into assessments of renal function. One such method that incorporates these factors is the equation developed by Cockcroft and Gault:

$$Cl_{cr} = \frac{(140 - Age)(Wt)}{(72)(S_{cr})} \times S$$

where Cl_{cr} is the creatinine clearance in mL/min
Age is in years
Wt is the lean or ideal body weight in kg
S_{cr} is the serum creatinine concentration in mg/dL
S = 1.0 for males and 0.85 for females

Pharmacodynamics

Pharmacodynamics refers to the actions of a drug and the response that patients experience. With some medications, elderly patients often experience a different degree of response than in younger adults. It is difficult to determine if such differences are due to pure intrinsic pharmacodynamic changes (concentration-response relationships) or age-related alterations in the pharmacokinetics (amount of drug that reaches the site of action).

The normal aging process itself may predispose patients to be more or less sensitive to particular medications, especially drugs that affect the cardiovascular and central nervous systems. It is postulated that this is a result of changes at the receptor site (the site of drug action). Such differences may include changes in the binding affinity for the drug, changes in the number or density of active receptors at the target

Table 1. Medications Requiring Dosage Adjustment for Diminished Renal Function

Anti-infectives	H_2 Blockers	Cardiac	Oral Diabetes Medications	Other
Aminoglycosides	Cimetidine	Atenolol	Chlorpropamide	Allopurinol
Cefixime	Famotidine	Benazepril	Glyburide	Furosemide
Cefodoxime	Ranitidine	Captopril	Metformin	Lithium
Cephalexin	Nizatidine	Digoxin		Methotrexate
Fluconazole		Enalapril		Metoclopramide
Penicillins (various)		Nadolol		
Ciprofloxacin		Procainamide		

organ, biochemical processes, homeostatic regulation, structural features, and physiological processes. Additionally, changes in the anatomy and physiology in the older patient may render them more susceptible to the effects and side effects of medications. For example, elderly patients with impaired balance are at greater risk for drug-induced falls, particularly when the medications cause sedation or dizziness.

Age-related changes at the receptor site may be responsible for an increase in sensitivity to warfarin, benzodiazepines, anticholinergics, and narcotic analgesics. Thus, lower doses are generally required to achieve the same degree of effect as in younger patients. In contrast, the elderly have been shown to be less sensitive than younger adults to beta-adrenergic agonists (e.g., isoproterenol), beta-adrenergic antagonists (e.g., propranolol), allopurinol, and insulin. The antihypertensive effect of calcium channel blockers (e.g., verapamil) has also been observed to be greater in the elderly, whereas the effect on cardiac conduction was less than in younger subjects studied.

Age-related changes occurring in the central nervous system may explain why dizziness, sedation, and confusion are common adverse drug effects experienced by older patients. Similarly, elderly patients are more prone to orthostatic hypotension from medications that affect the cardiovascular system, because they often have a diminished capacity to quickly compensate for postural changes in blood pressure.

Changes in pharmacodynamics in the elderly may be obscured by the age-related changes in pharmacokinetics. For example, elderly patients may be less sensitive to propranolol, but more propranolol may reach the systemic circulation for a given dose due to a decrease in the rate of metabolism. Although clinicians can anticipate these effects, the net effect may be difficult to predict.

Case Discussions

A number of these concepts can be applied to Mr. Brown (Case I) and Mrs. Smith (Case II). Mr. Brown takes diazepam for occasional anxiety and insomnia. The distribution of diazepam is generally increased in the elderly and its rate of metabolism is often reduced. Both of these changes contribute to an increased half-life of diazepam, which results in a prolonged duration of action. As a sleeping aid, drugs with a long duration of action should be avoided because daytime sedation is undesirable and can be problematic. Additionally, older patients are generally more sensitive to the sedative effects of benzodiazepines. This increases the risk of falls and the potential for broken bones. In Mr. Brown's case, such effects are a concern because he enjoys dancing and walks in the park. Sedation and impaired reflexes can also be dangerous in those who continue to drive.

Assuming Mr. Brown's lean body weight is about 60 kg and that his serum creatinine concentration is 0.8 mg/dL (normal: 0.6-1.2 mg/dL), his estimated creatinine clearance is approximately 64 mL/min. The recommended dose of ranitidine is 150 mg orally once daily in patients when Cl_{cr} < 50 mL/min. Since Mr. Brown is borderline with respect to a dosage adjustment, his dosage should eventually be reduced to account for the gradual decline in kidney function that occurs with normal aging. In addition, metformin should be avoided in patients with a creatinine clearance of less than 60 mL/min, because it is eliminated primarily by the kidneys and this may increase the risk of lactic acidosis.

Mrs. Smith's dose of Coumadin® was increased on the day of discharge from the hospital. Thus, the full therapeutic effect of Coumadin® will not be observed for several days because the half-life may be prolonged in older patients and because of the time it takes for a decrease in the synthesis of clotting factors in the liver. Furthermore, because of an increased sensitivity to the effects of warfarin, elderly patients generally require lower doses to achieve the desired degree of inhibition in blood clotting. Mrs. Smith also wishes to purchase Tagamet HB®, which can reduce the metabolism of warfarin. Thus, Mrs. Smith is at greater risk for bleeding complications. Her warfarin therapy should be monitored very closely and her dosage titrated accordingly, until her therapeutic response is stabilized.

Mrs. Smith is also taking digoxin (Lanoxin®), which is eliminated via both metabolic and renal pathways. Further, a decrease in muscle mass in the elderly reduces the distribution volume for digoxin, which binds extensively to skeletal muscle. She is also taking omeprazole (Prilosec®), which has the potential to increase the oral absorption of digoxin. For these reasons, Mrs. Smith should be monitored periodically to prevent concentration-related adverse effects of digoxin, which has a very narrow therapeutic range. Loading and maintenance doses of digoxin must be adjusted in elderly patients to account for reductions in the volume of distribution and elimination.

Conclusion

Age-related alterations in drug action reflect the changes in body composition and organ function associated with the natural aging process. For many medications, age-related changes in pharmacokinetics and pharmacodynamics can be anticipated. Additional factors, such as nutritional status, drug-drug interactions, and co-morbidity with other medical conditions may also contribute to the complexity of drug action in the older patient. Understanding these concepts enables pharmacists and other clinicians to rationally adjust drug doses for older adults and anticipate the effects of drug therapy.

Evaluating The Risks and Benefits of Drug Therapy

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Standards that ensure the safe and effective use of medications in older patients are essential. Adhering to four basic principles will enhance therapeutic outcomes:

- Avoid unsafe medications.
- Recognize when medications worsen activities associated with daily functioning.
- Use evidence-based medicine to determine first-line agents.
- Tailor drug therapy to the individual, considering concomitant disease states and medications.

The nursing home reform amendments contained in the 1987 Omnibus Budget Reconciliation Act (OBRA 87) provide a working template to improve optimal medication use in the frail elderly. This template is useful for the assessment of drug therapy in older individuals because it addresses many of the issues that enhance therapeutic outcomes. It advocates prescribing only when there is a definite indication, monitoring for efficacy and side effects of medications, and considering the effects of the medications on a patient's well being. OBRA 87 was the first major revision of federal nursing home requirements in almost two decades. At that time, excessive sedation of nursing home residents through the use of psychoactive medications was a significant concern. These chemical restraints were being used excessively to avoid troublesome behavior by the nursing home residents, despite the fact that they were known to cause significant side effects and lacked good scientific evidence to support their use.

OBRA 87 regulations require nursing facilities to meet the highest realistic physical, medical, and psychological standards for the well-being of each resident. A pharmacist reviews each resident's medication regimen every month and provides recommendations that improve drug therapy or the monitoring of therapy. The pharmacist ensures that the resident is not prescribed unnecessary drugs. Unnecessary drugs are defined as duplicate therapy, or a drug in an excessive dose, for an excessive duration, without adequate monitoring, without adequate indications for use, or in the presence of adverse effects that should result in a dose reduction or drug discontinuation. As a result of OBRA 87, drug regimens are screened specifically for psychoactive drugs to make sure that a specific condition documented in the clinical records is being treated, and that gradual dosage reductions are attempted in an effort to discontinue these drugs.

Unfortunately, the same government regulations for medication safeguards, including mandates for monthly drug regimen review, do not exist for older individuals outside of the extended care setting. Studies examining the impact of pharmacists working with older persons outside of the extended care setting have consistently shown that pharmacists identify and resolve medication-related problems, reduce unnecessary medications, decrease adverse medication effects, and help avoid unnecessary expenses. Overall, pharmacists promote safer prescribing and enhance medication compliance.

MYTHS & FACTS

MYTH: *Older individuals do not derive real benefits from medication besides treating some symptoms of disease.*

FACT: Appropriate medications, such as blood pressure medication, can reduce the incidence of stroke, heart failure, kidney damage and heart attack, regardless of age.

MYTH: *A person over the age of 65 will always experience more side effects from medication than someone younger than 65.*

FACT: Older individuals can be susceptible to side effects; however, careful selection of medicines proven to be safe in the elderly, along with careful dose titration, can significantly improve the tolerability of most medication.

Avoid Unsafe Medications

Medications are necessary for many older adults to treat illness, improve quality of life, and sometimes extend life. For example, isolated systolic hypertension is a condition where the systolic pressure is too high, but the diastolic pressure is not. It occurs primarily in older individuals. At one time, older persons were assumed to require an elevated systolic blood pressure in order to properly supply the brain and other vital organs with blood. Thus treating isolated systolic hypertension was thought to actually worsen clinical outcomes. On the contrary, when the effects of antihypertensive medications were evaluated in older individuals with isolated systolic hypertension, the evidence showed that elderly individuals derived significant health benefits from medication. Numerous studies have now demonstrated that treating hypertension, and in particular, elevations in systolic pressure, with medications such as thiazide or thiazide-like diuretics (e.g., hydrochlorothiazide or chlorthalidone), beta blockers (e.g., metoprolol, atenolol), and dihydropyridine calcium channel blockers (e.g., nitrendipine), significantly reduces the incidence of total mortality, stroke, heart failure, and myocardial infarction, as compared to placebo.

In general, these medications are well tolerated. However, some place older individuals at greater risk for side effects. In 1997, Beers published criteria that helped to define medications that should be avoided in the elderly. (See Table 1.) Many were included because of their significant anticholinergic side effects (e.g., sedation, confusion, constipation, dry

Table 1. Drugs to be Avoided in the Elderly*

Therapeutic Category	Examples	Reason(s) to Avoid
Tricyclic Antidepressants	Amitriptyline (Elavil®), Doxepin (Sinequan®)	Significant anticholinergic effects
Gastrointestinal antispasmodic drugs	Dicyclomine (Bentyl®), Hyoscyamine (Levsin®), Propantheline (Pro-Banthine®), Belladonna alkaloids (Donnatal®), Clidinium-chlordiazepoxide (Librax®)	Significant anticholinergic effects
Antidiabetic drugs	Chlorpropramide (Diabinese®)	Prolonged and serious low blood sugar and a syndrome of inappropriate antidiuretic hormone
Antihypertensive Drugs	Methyldopa (Aldomet®)	May lower the heart rate and exacerbate depression
Antiarrythmic Drugs	Disopyramide (Norpace®)	May induce heart failure and produce anticholinergic side effects
Benzodiazepines	Flurazepam (Dalmane®), Chlordiazepoxide (Librium®), Diazepam (Valium®)	Prolonged sedation and increased risk of falls and fractures
Narcotic analgesics	Pentazocine (Talwin®)	Causes more confusion and hallucinations than other narcotic agents and does not have pure pain blocking effects
	Meperidine (Demerol®)	Must be given frequently to attain pain control; can cause central nervous system stimulation and seizures in individuals with reduced kidney function
Barbiturates	All, except phenobarbital	Highly addictive and cause more side effects than other sedative or hypnotic drugs
Antiplatelet drugs	Ticlopidine (Ticlid®),	More toxic than other alternatives such as aspirin
Cardiac Drugs	Digoxin for heart failure (doses greater than 0.125mg daily)	Kidney clearance of the drug may be decreased, increasing potential for toxicity

** Rated most problematic ("high severity") by Beers, 1997*

mouth, blurred vision, urinary retention, and increased heart rate). Others were listed because they have greater potential for toxicity in this population. In addition to the drugs listed in Table 1, other drugs associated with less severe complications in the elderly were identified. These included indomethacin, propoxyphene, phenylbutazone, trimethobenzamide, reserpine, diphenhydramine, and muscle relaxants. Medication profiles of older individuals should be screened for these drugs and whenever possible, they should be replaced with safer alternatives.

Recognize When Medications Worsen Activities Associated with Daily Functioning

A significant number of people in their seventies and beyond continue to enjoy excellent health, vitality, and cognition. Significant changes in physical or cognitive health warrant an evaluation by health care professionals. Braun and colleagues described geriatric failure to thrive as a gradual decline in physical or cognitive function usually associated with body weight loss, decreased appetite, and social withdrawal that occurs without immediate explanation. It is important to note that medications can often worsen functional ability, such as performing activities of daily living. (See Table 2).

Medications can affect mood and cognition, ambulation, bodily functions such as urinary or fecal continence, nutritional intake through a variety of mechanisms, and can cause fatigue and weakness. Mr. Brown (Case I) is taking diazepam for occasional anxiety and insomnia. Diazepam and other benzodiazepines can predispose older individuals to falls, depression, fatigue, weakness, confusion, memory impairment, and daytime sedation. Ideally, non-pharmacological strategies (e.g., avoiding daytime naps, eliminating stimulants such as caffeine from mid-afternoon onward, maintaining an active lifestyle that includes physical and mental exercise) should be implemented to manage occasional anxiety and insomnia. Mrs. Young (Case III) has Alzheimer's disease and has been self-treating her insomnia with nonprescription sleeping agents. Alzheimer's disease is associated with decreased effects of the neurotransmitter acetylcholine. Unfortunately, nonprescription sleep aids containing diphenhydramine or doxylamine have significant anticholinergic side effects. It is possible that part of the cognitive impairment associated with her Alzheimer's disease is due to her sleeping pills. Aricept®, an acetylcholinesterase inhibitor, blocks the breakdown of acetylcholine in the brain, thereby increasing central nervous system concentrations. Use of medications with anticholinergic side effects should generally be avoided in patients with Alzheimer's disease, because they may worsen symptoms or diminish the effects of prescription medications.

Table 2. Medications that Impact Activities of Daily Living (Functional Ability)

Undesirable Effect	Medications Implicated
Constipation	Anticholinergics (e.g., diphenhydramine), diuretics, narcotic analgesics (e.g., codeine, morphine), resins (e.g., cholestyramine), cations (e.g., iron, aluminum), verapamil, vincristine
Urinary Incontinence	Sedatives, diuretics, anticholinergics, alpha receptor blockers (e.g., terazosin in women) and adrenergic agonists (e.g., pseudoephedrine in men)
Falls	Benzodiazepines (e.g., diazepam), anti-hypertensive agents (e.g., prazosin), antidepressants (e.g., amitriptyline), antipsychotics (e.g., chlorpromazine), cancer chemotherapy agents
Cognitive Impairment (delirium, depression, dementia)	Anticholinergics, sedatives, dopamine agonists (e.g., levodopa), antihypertensive agents (e.g., methyldopa), opiates (e.g., morphine), steroids (e.g., prednisone), digoxin, muscle relaxants

Use Evidenced-based Medicine to Determine First-Line Agents

Evidence-based medicine is the process of using the results from well-designed clinical trials to develop treatment strategies. These trials involve a very large number of patients, include a comparison of two or more medications or one medication with a placebo, are continued for a reasonable length of time, and have safeguards to ensure that the interpretation of the results is not biased. Fortunately, nationally published treatment guidelines, created by panels of experts in their field using evidence-based medicine are available for most common disease states. (See Table 3.) The experts decide, based on the published evidence, which agents have superior efficacy and safety. It is prudent in most situations to use these recommended first-line agents.

An application of published guidelines for the treatment of hypertension could result in modifying the drug therapy for Mr. Brown (Case I). According to the Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC-VI), the clonidine patch (Catapres-TTS-1®) is considered a second-line agent for hypertension. Clonidine has a central mechanism of action and therefore may lead to a greater

Table 3. Selected Websites for Treatment Guidelines
• High Blood Pressure – http://www.nhlbi.nih.gov
• Diabetes – http://www.diabetes.org
• High Cholesterol - http://www.nhlbi.nih.gov
• Asthma - http://www.nhlbi.nih.gov
• Obesity - http://www.nhlbi.nih.gov
• Chronic Heart Failure – http://www.acc.org
• Coronary Heart Disease - http://www.acc.org

degree of central nervous system side effects such as sedation or depression. Mr. Brown is receiving hydrochlorothiazide, a recommended first-line agent, in an acceptable dose. If blood pressure is not controlled with one first-line agent alone, the addition of another first-line agent should be considered in place of the clonidine patch.

Tailor Drug Therapy to the Individual

Treatment guidelines are important to enhancing therapeutic outcomes for the general population. However, guidelines are never so specific as to consider each and every individual encountered in daily practice. Tailoring therapy to an individual requires considering the patient's concomitant diseases, concomitant drugs, and wishes when developing a treatment plan. Mr. Brown is receiving two medications to lower blood pressure. However, he also has coronary heart disease as is evidenced by his prior myocardial infarction (heart attack). As a result, therapy with an angiotensin converting enzyme (ACE) inhibitor (e.g., enalapril or ramipril) and a beta-blocker (e.g., atenolol or metoprolol) is warranted. ACE inhibitors and beta-blockers are first-line therapy for hypertension and are recommended for patients with coronary heart disease, particularly those who have had a previous heart attack. Tailoring therapy in this patient could result in replacing clonidine with an ACE inhibitor or beta-blocker. The pharmacist should also encourage compliance with his cholesterol-lowering agent since Mr. Brown is at risk for another cardiovascular event, such as heart attack or stroke.

Tailoring therapy also takes into account the need to use some medications with caution. Mr. Brown was prescribed Naprosyn® for his arthritis pain. Naprosyn®, a nonsteroidal anti-inflammatory drug (NSAID), may worsen his gastric reflux and can increase blood pressure by increasing sodium and water retention by the kidneys. In addition, advancing age is a risk factor for gastrointestinal bleeding with NSAID therapy. If Mr. Brown's arthritis pain is due to osteoarthritis, a trial of acetaminophen (Tylenol®) is warranted. Mrs. Smith (Case II) has gastric distress and has been prescribed warfarin. It would be prudent to determine if the distress has been associated with any bleeding or erosions before treatment with warfarin. Tailoring therapy for Mrs. Smith would involve a great deal of discussion regarding drug-drug interactions. Bleeding effects of warfarin can be potentiated by Tagamet HB®, Advil®, Pepto-Bismol®, high doses of ascorbic acid and vitamin E, and a variety of natural medicines. These agents prevent the metabolism of warfarin or inhibit the ability of platelets to form a clot, thereby placing the patient on warfarin at greater risk for bleeding.

Conclusion

Older individuals can derive significant benefits from appropriate pharmacotherapy. In order to optimize the benefits of drug therapy and minimize the risk of adverse medication outcomes, careful assessment of risk and benefits of drug therapy must be performed. Agents with superior safety and efficacy proven in well-designed clinical trials should be utilized. Once appropriate medication therapy is implemented, pharmacists should monitor individuals to ensure that patients receive therapeutic benefits and do not endure drug-induced illness that might be inappropriately attributed to the aging process.

COUNSELING TIPS

- Encourage adherence to medications. Never assume that the patient is convinced that they need the medication. Explain the benefits of treatment.
- Supply adherence devices and regularly monitor adherence.
- Suggest strategies that reduce potential side effects. If a significant adverse drug reaction occurs, have the patient contact the prescriber.

MANAGEMENT OF COMMON GERIATRIC DISORDERS

Alzheimer's Disease

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In recent years, more successful treatments for Alzheimer's disease have been developed. Currently, four drugs have been approved to treat it, with many more in clinical trials. Alzheimer's disease, although not yet curable, is now more readily diagnosed and treatable.

Drug therapy for Alzheimer's disease is of great interest to patients, families, loved ones, and clinicians. Not surprisingly, individuals diagnosed with probable Alzheimer's disease and their caregivers are very interested in both approved and unapproved treatments. Many individuals like Thelma Young (Case III) take prescription, nonprescription, and herbal/alternative remedies concurrently. Alzheimer's disease offers the pharmacist an opportunity to act as a consultant to patients, caregivers, and other healthcare practitioners.

MYTHS & FACTS

MYTH: *Vitamin E improves memory.*

FACT: High doses of Vitamin E may reduce the time to nursing home placement in Alzheimer's disease, but do not appear to improve memory or cognition.

MYTH: *Alzheimer's disease can be diagnosed by imaging the brain.*

FACT: Various types of radiological imaging have improved the ability to diagnosis Alzheimer's disease by ruling out certain conditions, but today it is not possible to diagnosis it with reasonable certainty only by imaging.

MYTH: *Currently available drugs to treat Alzheimer's disease can cure the disease.*

FACT: Unfortunately there is no cure for Alzheimer's disease. Drugs may improve symptoms of the disease and appear to slow its progression.

What is Alzheimer's Disease?

Alzheimer's disease is a progressive neurological disease that results in extensive brain damage and impaired memory. It has a gradual onset and patients generally become aware that they are having difficulty remembering recent events, finding words, or performing tasks that were once routine. A condition called minimal cognitive impairment, characterized by mild memory impairment that has not yet reached a level of clinical significance, but is noticeable to the individual, is being studied to determine if people diagnosed with it eventually develop Alzheimer's disease. Several clinical drug trials, some using combinations of donepezil and vitamin E, are examining a possible role for drug therapy in minimal cognitive impairment.

As Alzheimer's disease progresses, patients experience changes in personality, increasing confusion, impaired judgment, and difficulty following simple directions. These changes take place at various rates in different patients, but are exemplified by a slow, steady decline. A rapid change in cognitive function strongly suggests a problem other than Alzheimer's disease. Hallucinations, delusions, Parkinson-like gait disturbances and/or seizures may appear in the later stages. Eventually the patient with severe Alzheimer's disease is unable to manage even basic physical functions. Death is due to secondary complications, usually an infection. Currently, the average life expectancy is about seven years from the time of diagnosis, with a range of two to twenty years.

Neurological damage caused by Alzheimer's disease is responsible for approximately 50 percent of reported dementias. A combination of Alzheimer's disease and vascular dementia (previously called multi-infarct dementia) and primary vascular dementia comprise another 25 percent. Dementia of the Lewy body type and frontotemporal dementia comprise perhaps another 15 percent. The remaining 10 percent includes Picks' disease, Parkinson's disease, Huntington's chorea, Creutzfeld-Jakob disease, and a new variant of Creutzfeld-Jakob disease commonly called mad cow disease. Thus, the term dementia does not necessarily mean the patient has Alzheimer's disease. Rather, it signifies a cluster of symptoms.

Increasingly sensitive diagnostic skills and advances in imaging and medical technology are enabling medical practitioners to identify specific dementia disorders that will improve and expand the options for treatment and research. A reversible

dementia is detected in 10–20 percent of suspected Alzheimer's disease cases. These are most often caused by electrolyte imbalances, thyroid disorders, trauma to the head (e.g., subdural hematoma), vitamin B_{12} deficiencies, psychiatric conditions (e.g., depression), medications, or substance abuse (e.g., alcoholism). Medications are the most common reversible cause.

What Happens to the Brain?

In Alzheimer's disease, plaques develop first in the areas of the brain used for memory and other cognitive functions. These plaques are primarily composed of beta-amyloid, which is a fragment of a protein derived from a larger protein called amyloid precursor protein. Beta-amyloid is intermingled with portions of neurons and with other cells, such as microglia (cells that surround and digest damaged cells or foreign substances, which cause inflammation) and astrocytes (cells that serve to support neurons.) It is still not clear whether amyloid plaques themselves cause Alzheimer's disease or whether they are a by-product of the disease process. Many researchers believe that the formation of amyloid plaques is the primary culprit.

Brains afflicted with Alzheimer's disease show numerous clusters of degenerated nerve endings and tangles of fibers in excess of those found in the normal aging brain. These findings, which assure the diagnosis, can only be confirmed after an autopsy. In recent years, we have learned that patients with Alzheimer's disease also suffer from a depletion of certain essential chemicals in the brain called neurotransmitters. Neurotransmitters, such as acetylcholine, serotonin, norepinephrine, and dopamine, are vital to facilitating communication between nerve cells. Acetylcholine is significantly reduced in the Alzheimer's disease patient's brain, leading to attempts to increase its concentration by either adding more acetylcholine or preventing its normal enzymatic destruction. Other neurotransmitters may play a role in modulating the activity of acetylcholine.

Who Is At Risk?

Over four million people in the United States have been diagnosed as having Alzheimer's disease. Approximately 1.6 million of these patients have severe deficits, requiring daily supervision or nursing home care. The prevalence (the number of individuals diagnosed as having Alzheimer's disease at any one time) in the 65 and older age group doubles every five years. In general, women over 75 years of age are at greatest risk for developing Alzheimer's disease. Genetics play a role in both younger and older adults, with most cases of Azheimer's disease occurring before the age of 60 displaying a significant genetic link. While Alzheimer's disease is not just a disease of the old, the vast majority of cases are identified in people over 65 years of age. Except in specific genetically-related disorders (e.g., Down's syndrome), Alzheimer's disease, if it does occur, generally emerges late in life, usually after 75 years of age.

Habits of lifelong learning, male gender, estrogen supplementation, and regular NSAID use may offer some degree of protection from developing Alzheimer's disease. Estrogen therapy does not appear to be an effective treatment for Alzheimer's disease. Nonsteroidal anti-inflammatory drugs (NSAIDs) have been suggested to reduce the risk of developing it, but this also remains to be proven. The pharmacist can tell Thelma Young and her husband (Case III), that as of yet, there is no evidence that ibuprofen improves memory. In fact, several clinical studies found NSAIDs are not effective to treat Alzheimer's disease, refuting an older study of indomethacin that suggested NSAIDs might be helpful. At present, the risks of NSAID-related side effects do not warrant recommending these drugs.

Caregivers

Families or other caregivers provide most of the care for patients with Alzheimer's disease and are usually responsible for medication management. Most recent estimates place the cost to the family at $18,000 per year for patients diagnosed with mild Alzheimer's disease and approximately $37,000 per year for those suffering from severe Alzheimer's disease. The toll on families and caregivers can be devastating, not only in financial cost, but personal costs as well. Caregivers display up to a 50 percent increased risk for depression and stress-related conditions.

An important role for pharmacists is counseling Alzheimer's disease patients and their caregivers regarding the safe and effective use of medications. When counseling, use short sentences, avoid complicated words, be clear, be brief, and break down tasks into simple, one-step instructions. Remember that Alzheimer's disease patients, especially early in the disease, may suffer from anxiety, depression, and irritability as well as confusion. The pharmacist should direct attention to the client (patient) as well as to the caregiver.

Drug Therapy

Over the years, numerous drugs and other agents have been used to treat senile dementia (i.e., improve memory and reduce confusion), including ergoloid mesylates

(Hydergine®), cyclandelate (Cyclospasmol®), papaverine (Pavabid®), niacin, choline hydrochloride, and lecithin. Although published research suggested many of these drugs should be effective in treating dementia, this was not generally observed in practice. Many of the early research trials used small numbers of patients, and frequently the study design was flawed. At this time, there appears to be little reason to prescribe any of these drugs for Alzheimer's disease.

Cholinesterase Inhibitors

Tacrine (Cognex®), donepezil (Aricept®), rivastigmine (Exelon®) and galantamine (Reminyl®) have been approved for the treatment of Alzheimer's disease. Their most prominent pharmacological action is to inhibit the degradation of acetylcholine in the brain. This is accomplished by inhibiting the action of acetylcholinesterase or butyrylcholinesterase, which are the primary naturally occurring enzymes that break down acetycholine. By preventing the destruction of acetylcholine, overall brain concentrations are increased.

To date there have been no head-to-head studies comparing the efficacy of these drugs. It is important to remember that a positive response to the cholinesterase inhibitors may not be reflected in a noticeable improvement, but rather in a temporary stabilization or reduction of specific symptoms. Clinical experience suggests one-third of patients will demonstrate an observable improvement, one-third will remain stable or decline more slowly, and in one-third there will be no observable improvement and they will continue to steadily decline.

It is important to counsel patients and caregivers about the appropriate use of these agents. If any of these agents, particularly rivastigmine, is discontinued for more than three days, the dosage titration should be restarted from the beginning. Patients taking cholinesterase inhibitors should be monitored closely when they have medical conditions that might be worsened by a cholinergic drug (e.g., asthma, gastrointestinal disorders, seizures, incontinence, muscle cramps). Drugs with anticholinergic activity should be avoided whenever possible.

Tacrine (tetrahydroaminoacridine, THA, Cognex®)

Tacrine's use in medicine dates from the 1940s. It was used for a variety of medical purposes including reversal of the delirium caused by anticholinergic drugs. Cognitive function improves in about 30 percent of patients taking tacrine in doses of at least 120 mg to 160 mg per day. Unfortunately, few people tolerate these doses. Given the frequent side effects, drug interactions, need for multiple daily doses, and required testing to avoid liver toxicity, tacrine has been replaced by newer, less problematic drugs. Tacrine served a useful purpose, however, by raising awareness that Alzheimer's disease could be treated.

Donepezil (Aricept®)

Donepezil, though modestly efficacious, represents a significant advance in the treatment of Alzheimer's disease. It is more active in the central nervous system and less so in peripheral tissues. There is good evidence that donepezil has a beneficial effect on cognition, although it has little impact on activities of daily living. It may delay the time to nursing home placement in Alzheimer's disease patients. As with other drugs in this group, gastrointestinal side effects (nausea, diarrhea, anorexia) are by far the most common adverse effects associated with donepezil. These can be minimized or avoided by increasing the dose slowly. Insomnia, usually described by patients as nightmares that awaken them, can occur. Switching the dose to the morning hours usually corrects this problem.

Given its relatively benign side effect profile and the similar costs of the 5-mg and 10-mg tablets, donepezil should be titrated to the maximum suggested dose of 10 mg per day when possible. The usual regimen is to start patients on 5 mg per day in the evening, allowing the patient/caregiver to change to a morning dose if insomnia occurs. The dosage should be increased to 10 mg per day after 4–6 weeks. A few patients will not tolerate the 5 mg per day dose and can be started at 2.5 mg per day. If so, the dose should be titrated up more slowly to the maximum dose tolerated. Dividing the dose into two daily dosages may enable patients who are encountering gastrointestinal side effects to reach a therapeutic dose.

Rivastigmine (Exelon®)

Rivastigmine, a carbamate derivative, is a long-acting, reversible, noncompetitive acetylcholinesterase inhibitor that acts on both cholinesterase and butyrylcholinesterase. In comparison, tacrine acts preferentially on butyrylcholinesterase, while donepezil inhibits acetylcholinesterase sites. The clinical importance of the different sites of action is not known. Even though it has a short half-life, rivastigmine has a rather long duration of action, which allows twice daily dosing.

A dose-related response has been identified with rivastigmine and a minimum dose of 6 mg/day is necessary for therapeutic effect. Some patients treated with doses of 6–12 mg/day experience substantial cognitive improvement. Side effects associated with rivastigmine are also dose related, with more rapid titration being associated with more adverse effects. Gastrointestinal side effects occur most commonly and include

nausea, vomiting, anorexia, and dyspepsia. Side effects are generally transient and mild to moderate in severity, unless the dose is increased too rapidly. Weight loss has been reported with rivastigmine therapy. In one clinical trial, 26 percent of women and 18 percent of men in the high-dose group experienced weight loss of 7 percent or more of their baseline body weight.

Rivastigmine is dosed twice daily, with food to reduce gastrointestinal side effects. Food reduces the peak blood level, but does not reduce the extent of absorption. Few drug interactions would be expected since rivastigmine exhibits minimal protein binding and is metabolized to only a small degree by cytochrome P450. Doses should be reduced in patients with hepatic or renal impairment, which is also true for tacrine, donepezil, and galantamine.

Galantamine (Reminyl®)

Galantamine was first isolated from the bulbs of the common snowdrop and several amaryllidaceae plants such as daffodils. It is a selective, competitive acetylcholinesterase inhibitor as well as a modulator of nicotinic receptors. This dual action may enhance the impact of acetylcholine; however, this remains to be proven. Recent clinical trials confirm galantamine's efficacy at doses of 16–24 mg/day, administered in divided doses. There are apparent benefits in cognitive, functional, and behavioral symptoms. It appears that galantamine, if titrated slowly, has tolerable side effects.

Gingko biloba

Gingko biloba is used in patients with Alzheimer's disease, both as a prescribed therapy and as a non-prescribed dietary supplement. Egb 761, an extract of gingko biloba, is the predominant form currently being investigated. While some studies have shown statistically significant benefits, these were not always apparent to clinicians. Previous studies generally used 120 mg daily in divided doses. Currently, doses of 240 mg/day of gingko biloba are being studied in a multi-site trial.

Gingko biloba has demonstrated a potent antioxidant effect and is known to possess antiplatelet activity. A possible interaction exists with other antiplatelet agents such as aspirin, clopidogrel, ticlopidine, or dipyridamole. It is prudent to advise patients that they may be at an increased risk for bleeding or bruising. Opinion differs regarding whether patients taking anticoagulants (e.g., warfarin) should also take gingko biloba. Several case reports have associated the combination with cerebral and intraocular hemorrhages. In one controlled trial, gingko biloba did not increase the anticoagulant effect in patients stabilized on warfarin. Patients taking both gingko biloba and warfarin should be monitored closely.

Behavior Problems Associated with Alzheimer's Disease

A significant number of patients diagnosed with Alzheimer's disease will experience behavioral problems. These include hallucinations (usually visual), delusions, paranoia, depression, aggressive behavior (both verbal and physical), inappropriate sexual behavior, restlessness/wandering, and screaming. It is not uncommon for the term "agitation" to be used to describe an aberrant behavior. However, it is important for the health care provider to note exactly what the behavior is, when it occurs, what may have provoked it, and the environment in which it occurred. Some problems like wandering, restlessness, poor grooming, aggressive behavior, and mild-to-moderate agitation are best managed by careful assessment and non-drug interventions. Non-drug interventions should generally be attempted prior to initiating drug treatment. Physical, psychological, pharmacological, and environmental factors should be assessed prior to selecting drug therapy to treat the behavior. Drugs are usually not the first choice for treatment. They rarely make the behavior disappear and when effective, may only reduce the behavior by 50 percent. A variety of drugs are being prescribed, with variable success, for psychiatric behavioral problems associated with Alzheimer's disease and other dementias. (See Table 1.) Hallucinations, paranoia, delusions, severe agitation with aggressive/combative features, and depression are more apt to respond to psychotherapeutic agents.

Case Discussion

Mrs. Young's (Case III) disturbing dreams may be the result of administering donepezil at bedtime, which is often done to spare the patient mild gastrointestinal problems that may occur when the drug is first started. Some individuals find dreams may be more vivid and not disturbing, some report no changes in their dreams, and some, as with Mrs. Young, may find the dreams disturbing. If so, donepezil should be given in the morning, which usually resolves the problem. Most OTC sleeping products contain antihistamines such as diphenhydramine or doxylamine, which have anticholinergic properties and should be avoided. If Mrs. Young's sleeping problem persists, she should be referred to her physician.

Mr. Young asks, "How fast will Aricept® work?" As noted

Table 1. Medications for Behavioral Symptoms Associated With Alzheimer's Disease		
Drug Class	Examples	Comments
Antidepressants	Fluoxetine Sertraline Citalopram Escitalopram	SSRIs are considered first-line therapy. Citalopram and sertraline may be effective in behavioral disturbances, even when depression is not present. Tricyclic antidepressants should be avoided.
Cholinesterase inhibitors	Donepezil Rivastigmine Galantamine	Case reports, uncontrolled and retrospective studies suggest possible role in management of behavior. May be drugs of choice for hallucinations in Lewy Body Type dementia.
Antipsychotics	Typical: Haloperidal Fluphenazine Atypical Antipsychotics: Clozapine Risperidone Olanzapine Quetiapine Ziprasidone	Side effects (tardive dyskinesia, extrapyramidal side effects, orthostatic hypotension) limit use. Clozapine rarely used, due to side effects. Risperidone 1mg usually effective; more side effects with 2 mg. Olanzepine 5 mg/day appears effective; 15 mg same as placebo. Risk of diabetes and some anticholinergic activity problematic. Quetiapine appears usesful in Lewy Body, Parkinson's with minimal EPS. Ziprasidone efficacy unknown, possible arrhythmias.
Antiseizure medications	Valproic acid Divalproex Carbamazepine	Mostly uncontrolled studies; appear more effective for aggression, impulse control, rare liver toxicity (adults) and thrombocytopenia. Possibly effective, but numerous drug interactions; side effects limit use.
Antianxiety drugs	Benzodiazepines Buspirone	Limit to short-term therapy for acute episodes. Choose intermediate-acting agents (lorazepam, oxazapam). Avoid long-acting agents (diazepam), except clonazepam may be useful. Side effects include increased risk of falls, impaired coordination, possible memory impairment. Lorazepam is not safer than other drugs in this class. Must be dosed consistently for 2 weeks to see benefit (not prn). Varying reports as to efficacy. Minimal side effects.

earlier, some individuals do not exhibit improvement on drugs like Aricept®. However, they do not decline as rapidly, which is considered a positive response. Mr. Young should be told to look for improved alertness, reduced apathy, and possible improvement in activities of daily living (ADLs), such as bathing, toileting, or dressing. Memory may or may not improve. Some prescribers will discontinue the cholinesterase inhibitor if improvement or stabilization cannot be identified after six months.

Neither NSAIDs (e.g., ibuprofen) nor vitamin E have demonstrated an ability to improve memory or cognition in Alzheimer's disease. NSAIDs may reduce the risk of developing Alzheimer's disease, but this remains to be proven. At the present time, NSAIDs should not be recommended for prevention or treatment of Alzheimer's disease, because the risk of adverse drug reactions (e.g., gastric ulcers, bleeding) outweighs potential benefits.

Conclusion

Approximately 10 percent of people over 65 years of age suffer from Alzheimer's disease, which increases to 47 percent in nursing home residents over 85 years of age. It is a progressive neurological disease that can burden both patients and family with emotional, financial, and social costs. Patients and families/caretakers have numerous questions regarding medications. Recent advances in drug therapy and conflicting information in both the professional and consumer media make it difficult for patients and their caregivers to make informed decisions. The pharmacist is an ideal person to answer their questions and provide advice.

COUNSELING TIPS

- Speak slowly and ask only one question at a time. If there is a need to repeat the question, repeat it exactly as first stated.
- When the patient is having difficulty expressing a thought or statement, help supply the words. Take a guess at the words, then ask if that is correct. Be patient.
- Do not openly disagree with the person. This may lead to agitation. Don't provide too much information at one time. Don't interrupt as Alzheimer's disease patients can lose concentration quickly. Remember, the patient's behavior is a result of the disease. These patients can't improve their behavior by trying harder. In fact, the frustration may make their behavior worse.
- Remain calm. Speak in a calm voice, low and well modulated. As with any verbal interaction, the feelings you express in your voice are as meaningful as the words.

Depression

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Depression is a potentially serious medical disorder that often causes significant impairment to daily functioning and quality of life. Despite the risk of increased mortality and morbidity, depression is often underdiagnosed in the elderly. When it is diagnosed, it is often undertreated. Depression represents a major economic burden to the U.S. health care system. Annual costs related to depression are reported to be over $50 billion, of which only 28 percent, in one analysis, were for medical treatment. The remaining 72 percent were attributable to morbidity and mortality associated with depression. Morbidity associated with a major depressive episode includes inability to manage daily living activities, decreased productivity and increased absence from work, longer stays for acute hospitalizations, prolonged rehabilitation, and worse health outcomes than for non-depressed persons. An increase in mortality is also associated with depression. The lifetime risk of death by suicide is 15 percent for patients with a history of major depression, as compared to less than 1 percent for the general population. The rate of suicide among older depressed patients, especially males, is almost twice that of the general population.

Major depression is defined as a loss of interest and/or pleasure or a depressed mood that lasts at least two weeks. Additionally, five or more of the following symptoms must be present: weight loss or gain, insomnia or hypersomnia, motor agitation or retardation, decreased energy, feelings of guilt, inability to concentrate, and thoughts of suicide. The lifetime prevalence of depression in the general U.S. population is reported to be 17 percent. The Epidemiological Catchment Area Study reported symptoms of depression occurred in 15 percent of community dwelling residents over the age of 65, a lower prevalence than in younger people. Higher prevalence rates (up to 42 percent) have been reported for elderly nursing home residents. Depression in elderly patients is associated with significant risk of mortality. A four-fold increase in mortality risk for depressed older adults compared to non-depressed controls has been reported. Furthermore, the presence of depression in a resident of a long-term care facil-

MYTHS & FACTS

MYTH: *Depression is a natural part of aging.*

FACT: Depression is a medical disorder of unknown cause that may be precipitated by environmental, physiological, and/or biochemical factors. These factors, while often present in older persons, are not necessarily associated with aging or the aging process.

MYTH: *Depression that results from loss (death of a loved one, loss of job) is a normal reaction to life adversity and should not be treated.*

FACT: For some, bereavement and loss may precipitate major depression. Marked functional impairment, feelings of worthlessness, suicidal ideation, and psychomotor retardation may indicate major depression. Treatment is appropriate, especially if these symptoms persist two months after the loss.

MYTH: *If response to an antidepressant is not evident 4-6 weeks after initiation of therapy in an older patient, another antidepressant drug should be substituted.*

FACT: Response to antidepressant drug therapy in older patients occurs later than in younger patients and treatment should be continued for at least 6 to 12 weeks.

ity increases risk of death in the first year following admission by almost 60 percent.

Depression is often inadequately diagnosed and treated in elderly persons. This occurs even though newer, presumably safer, antidepressant drugs have become available. Barriers to diagnosing depression in older adults include the perception by clinicians, patients, and caregivers that depression is a natural part of aging. Coexistence of depression with one or more chronic diseases and disabilities, including dementia and anxiety, may mask or make the diagnosis of depression in elderly persons difficult. Medication prescribed to treat concomitant medical or neurological conditions (e.g., hypertension, pain, Parkinson's disease, arthritis) may complicate diagnosis by causing or contributing to depression. (See Table 1.) There is also a tendency for older patients to under report psychiatric symptoms and focus instead on somatic symptoms when communicating with their medical care providers. Finally, older persons are more likely to experience losses (e.g., loss of a loved one, loss of home) and other stressors (e.g., financial difficulties) that may contribute to depression or cause depressive symptoms to be dismissed as a normal response to life adversity. However, depression in response to stressors such as bereavement and losing one's home are not necessarily consequences of adversity and should be treated. This is especially true if depressive symptoms persist two months following the loss.

In addition to underdiagnosis of depression in elderly patients, barriers to treatment include cost of therapy for many who subsist on fixed-incomes without prescription drug insurance. Another barrier to optimal therapy is lack of studies and data in depressed older adults, especially those in the "old-old" age group (over 85 years old). This necessitates extrapolation of treatment recommendations from experiences with younger patients. Heterogeneity in response to therapy further complicates treatment of depression in the elderly, and patients with late-onset depression (i.e., depression that first appears in old age rather than earlier ages and continuing into old age) may be more resistant to treatment. When medications are used to treat late-life depression, significant response generally takes longer to become evident, often requiring at least six to twelve weeks of therapy.

Table 1. Medications That May Cause or Contribute to Depression

• Carbidopa/levodopa
• Beta-blockers
• Clonidine
• Benzodiazepine
• Barbiturates
• Anticonvulsants
• H_2 antagonists
• Alcohol
• Corticosteroids
• Interferon
• Narcotics

Appropriate and effective treatment of depression in the elderly, just as in younger adults, can improve signs and symptoms of depression, enhance quality of life, reduce relapse and recurrence, decrease mortality especially with respect to suicide, and lower the cost of health care. Both biological therapy (defined as drug therapy and electroconvulsive therapy), and psychosocial therapy have been shown to be effective in the treatment of late-life depression. The following discussion will focus on drugs that have been used and shown to be effective in the treatment of depression in the elderly.

Drug Therapy

Antidepressants currently available in the United States are generally considered equally effective. Antidepressants are primarily chosen based on the prescribing preference of the health care provider, their formulary status, and their side effect profiles. The most commonly prescribed are discussed below.

Tricyclic Antidepressants

Tricyclic antidepressants (TCAs) were the mainstay of therapy prior to the introduction of the selective serotonin reuptake inhibitors (SSRIs) and other newer agents. Examples of TCAs are amitriptyline (Elavil®), nortriptyline (Pamelor® and Aventyl®), desipramine (Norpramin®), doxepin (Sinequan®), and imipramine (Tofranil®). The mechanism of action of TCAs includes activity with multiple neurotransmitters. They inhibit the reuptake of norepinephrine and serotonin and they also antagonize histamine, dopamine, and cholinergic receptors. The TCAs are effective for the treatment of depression, but burdened with side effects of special relevance to the elderly. Orthostatic hypotension is a serious complication of TCAs that may lead to falls. They may also delay cardiac conduction and exacerbate the risk of sudden death due to arrhythmia in persons with ischemic heart disease. Additionally, TCAs have anticholinergic side effects,

including constipation, dry mouth, urinary retention, and blurred vision. The latter two are of particular concern in men with benign prostatic hyperplasia and persons with certain types of glaucoma, respectively. Due to these bothersome and significant side effects, TCAs have fallen to second- or third-line therapy for the treatment of depression. When TCAs are considered for treatment of late-life depression, nortriptyline and desipramine are the preferred agents, because they have less anticholinergic activity.

Trazodone

Trazodone (Desyrel®) is a weak inhibitor of serotonin uptake and a norepinephrine antagonist, which causes orthostatic hypotension. Dizziness related to orthostatic hypotension and sedation caused by the drug may limit full therapeutic dosing in the elderly. Additionally, trazodone is associated with priapism (prolonged, persistent abnormal erections) that may, in rare cases, require medical intervention. Thus, trazodone is used primarily for its sedative effects at relatively low doses.

Selective Serotonin Reuptake Inhibitors (SSRIs)

The SSRIs are second-generation antidepressants that impact the serotonergic system in the central nervous system via the selective inhibition of the reuptake of serotonin. They provide a major improvement in antidepressant tolerability, because they are safer than TCAs in an overdose and are essentially free of cardiac and anticholinergic effects (although paroxetine does have some anticholinergic activity). However, these drugs also have significant side effects, including nausea, vomiting, headache, insomnia, weight loss, and a high rate of sexual dysfunction. Products currently available in the U.S. include fluoxetine (Prozac®), sertraline (Zoloft®), paroxetine (Paxil®), citalopram (Celexa®), and escitalopram (Lexapro®).

The SSRIs are all given as a single daily dose, in the morning or at bedtime. Fluoxetine has a long half-life and, therefore, may take up to six weeks to be completely eliminated from the body. They affect the cytochrome P450 hepatic enzyme system, which leads to potential drug-drug interactions. Fluoxetine and paroxetine have the greatest potential to inhibit the metabolism of other medications through their effect on this enzyme system. Sertraline, citalopram, and escitalopram are also metabolized by this enzyme system, but have much less impact on the metabolism of other drugs. Fluoxetine has been associated with elevated INRs[i] in persons previously stabilized on warfarin therapy. Additionally, all of the SSRIs have been associated with changes in platelet function and abnormal bleeding in individuals not taking anticoagulants.

Venlafaxine (Effexor®)

In addition to inhibiting serotonin reuptake, venlafaxine also inhibits norepinephrine reuptake at doses above 150 mg/day. At high doses, it also inhibits the reuptake of dopamine. Venlafaxine is effective; however, it requires multiple daily dosing. A sustained-release product, Effexor XR®, allows once daily dosing. At higher doses, venlafaxine causes a predictable elevation in blood pressure in nine percent of patients.

Mirtazapine (Remeron®)

Mirtazapine is an alpha-2 antagonist that leads to increased concentrations of central norepinephrine. Mirtazapine also has activity at the cholinergic and histamine-1 receptors, which explains its side effect profile. It is sedating, causes weight gain, and has several anticholinergic side effects similar to the TCAs. However, mirtazapine does not significantly affect cardiac conduction. The combined use of clonidine, an antihypertensive central alpha-2 agonist, and mirtazapine may lead to hypertensive urgency, which can result in stroke and/or death. Similar drug interactions have been reported with TCAs and clonidine.

Bupropion (Wellbutrin®)

Bupropion is thought to produce an antidepressant effect via the relatively weak inhibition of norepinephrine, serotonin, and dopamine reuptake. It is effective and well tolerated in the elderly. Bupropion has been studied in elders with significant cardiac disease and has been shown to be safe and effective. Its use is limited by a significant seizure risk; thus it is contraindicated in persons diagnosed with a seizure disorder. Doses must be limited to not more than 150 mg per dose and 450 mg per day (400 mg per day for the sustained-release product) to minimize seizure risk. Bupropion is also associated with agitation and insomnia; therefore, the last dose of the day should be given in the late afternoon. It has little or no impact on sexual function. Ritonavir, an antiviral medication used in the treatment of HIV/AIDS, inhibits the metabolism of bupropion, resulting in large increases in serum bupropion levels. Because of the increased risk of seizures, this combination should be used cautiously, if at all.

Nefazodone (Serzone®)

Nefazodone is structurally related to the first generation antidepressant trazodone. Its mechanism of action is weak inhibition of serotonin reuptake and weak antagonism of norepinephrine. There are limited data regarding the use of nefazodone in the elderly. Nefazodone, like trazodone, also causes sedation and dizziness, which may limit full therapeutic dosing in the elderly. It has been associated with significant liver toxicity leading to liver transplant or death. Although rare, the severity of this reaction warrants increased caution. Nefazodone should not be initiated in persons with underlying liver disease and patients taking the medication should be counseled to watch for the symptoms of liver dysfunction (jaundice, anorexia, gastrointestinal complaints, malaise, darkening of the urine) and to notify their healthcare provider immediately if any of these occur. Due to the risk of hepatotoxicity, nefazodone is considered -third or fourth-line therapy. Additionally, nefazodone inhibits the cytochrome P450 3A4 enzyme, resulting in its inhibition of the metabolism of several drugs (e.g., benzodiazepines, cyclosporine, statins).

St. John's Wort

No discussion of the treatment of depression today is complete without mention of St. John's Wort (*Hypericum perforatum*). This popular herbal product inhibits the reuptake of serotonin, norepinephrine, and dopamine. St. John's Wort has been beneficial in the short-term treatment of mild-to-moderate depression. However, it is not effective in the treatment of severe depression. St John's wort induces cytochrome P450 isoenzymes 3A4 and 2C9 and can significantly reduce plasma levels and activity of cyclosporine, warfarin, protease inhibitors, digoxin, and other drugs.

Pharmacotherapeutic Considerations

Product Selection

All of the antidepressant drugs currently marketed in this country are equally effective in the treatment of geriatric depression. However, not all patients will respond uniformly to all agents. Among the drug therapy options, the second-generation agents (SSRIs, venlafaxine, bupropion) have fewer undesirable effects in older patients (e.g., dry mouth, urinary retention, sedation) than first-generation agents (e.g., TCAs, trazodone). Some adverse effects, such as orthostatic hypotension, may be associated with both first- and second-generation agents. The potential for drug-drug interactions also exists for the first-generation tricyclic agents and some of the second-generation antidepressant drugs.

Dose and Duration of Therapy

The potential to undertreat the elderly with depression should not be overlooked. Pharmacokinetic studies for several antidepressants (e.g., nefazodone, citalopram, paroxetine, bupropion) demonstrate age-related decline in the elimination rates of these agents. This highlights the importance of starting with a low dose and titrating up slowly. Clinical trials indicate that standard doses of antidepressants are well tolerated in the elderly and all efficacy studies in the elderly have utilized standard target doses. Drug therapy should be reassessed on a routine basis for both efficacy and side effects. If

side effects emerge, dose reduction, slowing the rate of dose escalation, or changing to a different medication may be appropriate. Persons who fail to respond to one antidepressant may benefit from a trial of an alternative antidepressant within the same class or in a different class.

In general, older depressed patients take longer to demonstrate a response to drug therapy than younger patients. Twelve weeks of drug therapy may be necessary to see a response in some elderly patients. Older patients should be treated for a minimum of six to twelve weeks (instead of the usual four to six weeks) before a determination of therapeutic failure or decision to change to another treatment agent or modality is made.

Maintenance therapy in the pharmacological treatment of depression should extend for at least six months beyond the resolution of symptoms, because earlier discontinuation leads to high recurrence rates. Persons who have experienced more than one previous episode of depression may be candidates for life long therapy. The decision to continue or discontinue maintenance therapy must be weighed by the patient and healthcare provider, taking into account the impact on quality of life.

Serotonin Syndrome

Serotonin syndrome is a severe adverse reaction characterized by irritability, increased muscle tone, shivering, myoclonus (involuntary muscle twitching or spasms), and altered consciousness. Many of the antidepressants discussed above modify serotonin concentrations in the central nervous system as part of their proposed mechanism of action. These agents can induce rapid accumulation of serotonin in the central nervous system when used in combination (e.g., monoamine oxidase inhibitors with other antidepressants) or when co-administered with other serotonergic agents (e.g., selegeline [Eldepryl®], St. John's Wort, sumatriptan [Imitrex®], zolmitriptan [Zomig®]). The antidepressants most frequently linked with serotonin syndrome are monoamine oxidase inhibitors, SSRIs, and venlafaxine. If the reaction occurs, discontinue the offending agent and provide supportive medical care.

Case Discussions

Mrs. Smith (Case II) illustrates several points related to depression. First, her antidepressant is an SSRI, which is the drug class of choice for first-line therapy because of its minimal cardiac and anticholinergic side effects. However, fluoxetine (Prozac®) has been reported to increase the effect of warfarin (Coumadin®), increasing the risk of bleeding. Fluoxetine inhibits the enzyme (CYP 3A4) responsible for the metabolism of warfarin and also impairs platelet function. Both effects may lead to bleeding. Since she has already been stabilized on the antidepressant, her anticoagulation provider will likely adjust for this drug interaction. Choosing an alternative SSRI (e.g., sertraline or citalopram) is another option, but impractical. It takes five to six weeks for Prozac® to be eliminated from the body and a similar amount of time for the new agent to become effective. Finally, Mrs. Smith has selected an over-the-counter product, Cimetidine (Tagamet HB®), which may contribute to her symptoms of depression. A pharmacist, working in conjunction with her primary care provider, can optimize Mrs. Smith's pharmacotherapy.

Conclusion

Despite the serious consequences of decreased quality of life and increased risk of suicide, depression is underdiagnosed in the elderly. A number of barriers to the diagnosis of geriatric depression exist, the most insidious being the general perception that depression occurs as a natural part of aging. When diagnosed and appropriately managed, depression in the elderly is highly treatable. Although electroconvulsive and psychosocial therapy are effective, pharmacotherapy remains the cornerstone for treating depression in the elderly.

COUNSELING TIPS

- Advise elderly patients how and when to take their prescribed antidepressant.
- Be sure to rise slowly from a supine position when taking nortriptyline, doxepine, trazodone, or mirtazapine, to minimize orthostatic hypotension and dizziness.
- Sedating antidepressants, such as trazodone or nefazodone, are best taken at bedtime.
- Activating antidepressants, such as sertraline or bupropion, are best taken when the patient is normally awake.
- Discuss how long to take the drug. Response to therapy may not be seen for up to twelve weeks in older patients. Patients should continue the drug for at least that length of time, even if they feel they are not receiving benefit from it. Depending on the onset of symptoms and number of previous major depressive episodes, duration of therapy may vary.
- Caution patients against abrupt withdrawal of prescribed antidepressant therapy. This could produce symptoms similar to those of serotonin syndrome (e.g., agitation, insomnia, sweating, restlessness, seizures).

Osteoarthritis Pain

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Pain is the most common reason that patients visit their healthcare providers. Acute pain usually has a cause and usually resolves. Chronic pain, also referred to as persistent pain, is an individual's unpleasant sensory or emotional experience that continues for a prolonged period of time and may or may not be associated with a recognizable disease. Osteoarthritis, also called degenerative joint disease, probably accounts for more than two-thirds of pain complaints among older adults and, thus, is the focus of this article. Pain is a highly subjective, personal experience for which there are no objective tests. Persistent pain can impair a person's ability to perform daily activities and decreases quality of life. Elderly patients expect pain as they age; thus, they may be reluctant to complain or report it fearing an unfavorable medical evaluation and treatment side effects. Significant persistent pain may result in anxiety, depression, insomnia, difficulty concentrating, decreased ability to exercise, and inability to enjoy usual activities.

Older people are more likely to suffer from diseases that cause pain. An estimated 21 million Americans (women more commonly than men), most of whom are older than age 45, are affected with osteoarthritis. It is the most common form of arthritis in this country and is also one of the most expensive and debilitating diseases. It results in more than 7 million physician visits per year and the cost to the U.S. economy is nearly $65 billion per year in expenses, lost wages, and productivity. Osteoarthritis of the knee can be as debilitating as any cardiovascular disease, with the exception of stroke.

There are many risk factors for developing osteoarthritis. Age and obesity may lead to osteoarthritis of the knees and lower joints. People with joint injuries due to sports, accidents, or work activity may be at increased risk of developing osteoarthritis. Discomfort usually results from breakdown of cartilage, which is the part of the joint that provides a cushion between the ends of bones. As the cartilage erodes, the bones rub against each other causing pain and loss of movement. Osteoarthritis pain typically worsens with weight bearing activity and improves with rest. The most commonly involved joints include the knees, hips, feet, ankles, and the joints near the fingertips. Patients often experience morning stiffness, tenderness, bony enlargements, and/or limited joint motion of the affected area(s). Unlike rheumatoid arthritis, inflammation is usually mild and localized to the affected joint(s).

MYTHS & FACTS

MYTH: *Nonsteroidal anti-inflammatory medications are the safest and preferred medications to treat mild-to-moderate osteoarthritis pain in older adults.*

FACT: There is often little inflammation with osteoarthritis. Acetaminophen is the recommended first-line agent for mild-to-moderate arthritis pain.

MYTH: *Opioids should not be used for moderate-to-severe non-cancer pain in the elderly.*

FACT: Opioids are recommended for moderate-to-severe pain when other medications and non-pharmacologic interventions provide inadequate pain relief and the patient's quality of life is affected by the pain.

MYTH: *Elderly patients who take opioids for chronic non-cancer pain will become addicted in days to weeks.*

FACT: Patients taking opioids regularly for pain may become physically dependent, but addiction is rare. The pharmacist should be able to distinguish between physical dependence and addiction.

Treatment Strategies

There is no known cure for osteoarthritis. Treatment focuses on decreasing pain, improving joint mobility, and improving quality of life. Recommended treatment strategies include:

- Exercise to keep joints flexible and to improve muscle strength and mobility
- Analgesic or pain medications
- Heat or cold therapy for temporary pain relief
- Joint protection to prevent strain or stress
- Weight control to minimize extra stress on joints

Other non-pharmacologic treatment strategies include physical and occupational therapy (strengthening exercises and rest), assistive devices such as braces and footwear, traction to immobilize joints, and transcutaneous electrical nerve

stimulation to alleviate pain. Surgical treatment is considered when drug therapy is ineffective or function is severely impaired, before severe deformity develops.

Drug Therapy

Pharmacologic therapy should be combined with non-pharmacologic strategies to optimize pain management. Pharmacologic management usually involves the use of analgesic medications. Generally, acetaminophen is the first-step drug. Patients should expect pain relief, but it may not be realistic for them to expect to be completely pain free. Analgesic medications are generally as safe and effective in older adults as in younger patients. However, two patients rarely respond in the same way to medications, so therapy should be tailored to the individual. There may be health, dosing, and side effect variables to consider in older adults.

A fundamental principle of treating persistent pain, which applies to osteoarthritis, is to use pain medications on a regular schedule to provide continuous pain relief. Long-acting medications that only need to be taken once or twice daily may improve adherence to the regimen. The use of as-needed medications should be reserved for intermittent pain or exacerbations of pain. The goals of treatment should be to decrease the patient's pain and improve function, mood, and sleep. Older adults are more likely to experience the side effects of pain medications and they also appear to be more sensitive to their pain relieving effects, thus, a low starting dose is generally recommended. The exception is acetaminophen, which can be started at regular doses for moderate pain.

Acetaminophen

Acetaminophen (up to 4,000 mg daily in divided doses) is the drug of choice for mild-to-moderate arthritis pain. Patients who drink more than two alcoholic beverages a day or have liver disease should reduce the dose to a maximum of 2,500 mg per day. Tylenol Long Acting® (650 mg per tablet) dosed every eight hours may offer some individuals an easier regimen.

Non-acetylated Salicylates

Non-acetylated salicylates offer a viable alternative to acetaminophen or nonsteroidal anti-inflammatory medications. Salsalate (Disalcid®) 500 mg three or four times daily may be increased to 1,000 mg three or four times daily if necessary. Another product, choline/magnesium trisalicylate (Trilisate®), is available as a tablet or liquid, and should be taken in doses of 500 mg to 1,500 mg every 8 to 12 hours, up to a maximum dose of 5,500 mg per 24 hours. Nonacetylated salicylates have fewer gastrointestinal side effects and are less likely to impair kidney function, as compared to NSAIDs. Unlike aspirin and the NSAIDs, they do not affect platelet function. The non-acetylated salicylates are relatively safe and are less expensive alternatives to COX-2 NSAIDs.

Nonsteroidal Anti-inflammatory Drugs

Nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen and naproxen are commonly used for moderate-to-severe arthritis pain. Older adults seeking relief from osteoarthritis pain take an estimated 50 percent of all NSAIDs produced. All NSAIDs should be used cautiously in persons with hypertension or edema. Some patients may benefit from taking non-specific NSAIDs together with a medication to prevent GI bleeding (e.g., misoprostol or a proton pump inhibitor). NSAIDs should be used with caution in the elderly. High-dose, long-term NSAIDs use should be avoided and when used chronically, NSAIDs should be dosed on an as-needed rather than an around-the-clock basis. They should also be avoided in patients with a history of peptic ulcer disease or impaired renal function. Avoid the use of more than one NSAID at a time.

COX-2 Inhibitors

The selective cyclo-oxygenase (COX-2) inhibitors (celecoxib, rofecoxib) should be considered when NSAIDs are indicated in the elderly, because they have less potential for gastrointestinal side effects. The COX-2 NSAIDs have minimal effects on platelet aggregation, so if a patient is taking low dose aspirin for heart or stroke prevention, it should be continued. When COX-2 NSAIDs and aspirin are used together, there is probably a similar risk for GI bleeding as with non-selective NSAIDs. The American Geriatrics Society recommends non-acetylated salicylates as relatively safe and less expensive alternatives to COX-2 NSAIDs.

Tramadol

Tramadol (Ultram®), a centrally-acting analgesic, may be used alone or in combination with acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs). Tramadol should be started at low doses (50 mg every 4-6 hours) and increased slowly to minimize side effects such as drowsiness and nausea in the elderly. The maximum dose recommended in the elderly is 300 mg daily in divided doses, which should be decreased in the presence of kidney or liver disease.

Opioids[i]

Opioid medications such as oxycodone, morphine, hydrocodone, or other mu-receptor agonists, are recommended for moderate-to-severe arthritis pain for which other treatments do not provide substantial relief. Extensive experience

[i]Opioid refers to a pain medication class that is similar to or derived from morphine. This class is often referred to as "narcotic," but this is a legal term for controlled substances that are not specific to pain medications.

and evidence supports the use of long-acting opioids to improve patient adherence, minimize medication blood level peaks and valleys, and to minimize side effects when managing cancer pain. These advantages also appear to apply in the management of arthritis pain. Although the literature supports the use of opioid analgesics to treat moderate-to-severe chronic non-cancer pain, these drugs continue to be underused. Reluctance to prescribe or administer opioids (as well as patient and family reluctance to use them) may be unduly influenced by fear of addiction and side effects as well as social pressure to control illicit drug use. Although the true rate of addiction among chronic pain patients is not established, addictive behavior among elderly patients taking opioid drugs for medical reasons is reportedly low. The use of codeine and propoxyphene should be avoided because of their side effects and limited efficacy.

Glucosamine

Glucosamine sulfate is a synthetic version of a bodily substance that helps to make cartilage. The American Pain Society recommends that adults with osteoarthritis be encouraged to take 1,500 mg of oral glucosamine sulfate daily. A recent study compared 1,500 mg of oral glucosamine versus a placebo for three years in osteoarthritis patients. Glucosamine decreased pain and improved physical function by about 20-25 percent, as compared to the placebo. By X-ray examination, the cartilage remained stable in those patients taking glucosamine and shrank in the group taking a placebo, suggesting worsening of arthritis in the placebo group.

Chondroitin

Chondroitin sulfate, another dietary supplement, may stimulate production of cartilage and has been shown in a small number of trials to improve pain and function with daily use. The effects usually take weeks to months to occur. There are preparations containing both glucosamine and chondroitin, but no long-term studies have shown the combination to be superior to either agent alone.

Case Discussions

When counseling Mr. Brown (Case I), the pharmacist should ask about his arthritis pain and how often he takes his Naprosyn® If Mr. Brown is taking his Naprosyn® one or two times a day with good relief, he may be a candidate for acetaminophen. Since he is also taking Zantac®, he may have GI distress. Acetaminophen is preferred, because of the potential for GI bleed with NSAIDs. The COX-2 inhibitors may not have the advantage of a lower risk for GI bleed in Mr. Brown, because he takes low-dose aspirin for its anti-platelet effects. Low dose aspirin offsets any GI protective effect of the COX-2 inhibitors. If Mr. Brown is experiencing moderate-to-severe pain despite the use of a nonsteroidal analgesic or if he is experiencing GI distress from his NSAID, he could be a candidate for opioid therapy in combination with acetaminophen. Opioid therapy should be initiated with the lowest dose of a short-acting drug given on a scheduled basis. Often an initial dose at bedtime may be helpful with sleep and may allow the patient to sleep through any side effects. Mr. Brown should not be taking a long-acting benzodiazepine (e.g., diazepam) with the opioid.

If an opioid is initiated, Mr. Brown should also be asked about any history of constipation. He should be reminded to drink plenty of water and exercise as permitted by his physician. He may consider taking a stimulant laxative (e.g., senna, bisacodyl) and a stool softener to avoid or minimize opioid-induced constipation. If his fluid intake is adequate, bulk forming laxatives may be considered. Stool softeners alone are rarely, if ever, effective in managing opioid-induced constipa-

tion. Mr. Brown is also on the diuretic hydrochlorothiazide and a Catapres® patch, which can both also cause constipation.

Mrs. Smith (Case II), who is already taking a COX-2 inhibitor (Vioxx®), is purchasing Advil®. Because Advil® has effects on platelet aggregation and can affect bleeding time, it should not be taken with her Coumadin®. She, too, should be questioned about her pain relief from the Vioxx® and why she needs the Advil®. Acetaminophen is the preferred agent for treating mild-to-moderate pain. If her arthritis pain is not relieved by her Vioxx®, Mrs. Smith may also be a candidate for an opioid. She seems to be having some GI distress, because she plans to supplement her Prilosec® with OTC Tagamet® and Pepto-Bismol®. Use of a chronic opioid would decrease her risk for GI bleed and drug interactions. She should be monitored carefully, as an opioid could exacerbate depression.

Conclusion

The elderly may suffer from significant pain of different origins. Pain is not normal and should not be expected to occur with aging. Patients should be encouraged to discuss their pain with their primary care providers and the underlying causes should be treated if possible. There are a variety of medical interventions available to minimize the pain and disability caused by osteoarthritis, resulting in improved physical function and quality of life.

COUNSELING TIPS

- Encourage scheduled use of pain medications for osteoarthritis. One exception is nonsteroidal anti-inflammatory agents, which when taken, should be dosed on an as-needed basis.
- When an elderly patient is taking an NSAID, ask about a history of peptic ulcer, GI bleed, and stomach distress. Evaluate aspirin and other NSAID intake from nonprescription drugs.
- When a COX-2 NSAID is started for a patient's pain, ask the patient if he or she is to continue taking low dose aspirin to prevent cardiac events. Generally, the low dose aspirin should be continued since COX-2 inhibitors do not affect platelet aggregation.
- When a patient is started on an opioid, discuss the possibility of constipation. Patients do not usually become tolerant to this side effect. Recommend adequate fluid intake, appropriate exercise, and possibly a prophylactic stimulant laxative.

Diabetes

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Diabetes is a condition that affects the body's ability to produce or respond to insulin, a hormone that allows blood sugar (glucose) to enter the cells of the body and be used for energy. This results in a high blood glucose level. Over time, diabetes can be associated with serious complications, such as heart, eye, kidney, and nerve disease. Nearly 17 million Americans have diabetes, representing approximately six percent of the population. The majority of people with diabetes have type 2 diabetes (formerly called non-insulin dependent diabetes or adult-onset diabetes), whereas approximately 1 million people have type 1 diabetes (formerly called insulin-dependent diabetes or juvenile-onset diabetes). Approximately, one-third of people with type 2 diabetes are undiagnosed. As people get older, the prevalence of type 2 diabetes increases; over 20 percent of people age 65 or older and 18 percent of nursing home residents have diabetes. Diabetes costs the U.S. over $98 billion annually, with people age 65 or older accounting for two-thirds of these costs. The annual per capita expenditure for a person with diabetes is four-fold that of a person without diabetes. Table 1 lists risk factors for diabetes other than aging.

Recognizing Diabetes

Mrs. Smith (Case II) is experiencing symptoms consistent with diabetes. She complains of thirst, blurred vision, and increased urination during the night. Common symptoms of diabetes include frequent urination (polyuria), excessive thirst (polydipsia), extreme hunger (polyphagia), unusual weight loss, increased fatigue, blurry vision, and irritability.

While people with type 1 diabetes tend to develop these symptoms abruptly and severely prior to diagnosis, people with type 2 diabetes often develop them more gradually and less severely. As a result, people tend to attribute their symptoms to other causes. For example, the elderly may attribute vision problems, increased need to urinate, and fatigue with general signs of aging, and may not seek medical care. Also,

MYTHS & FACTS

MYTH: *Only people on insulin need to monitor their blood glucose.*

FACT: People with diabetes that monitor their blood glucose can better self-manage their diabetes. People taking an oral medication that can cause hypoglycemia (e.g., a sulfonylurea, repaglinide, and nateglinide) should self-monitor their blood glucose.

Table 1. Major Risk Factors for Developing Type 2 Diabetes

• Family history of diabetes (such as parents or siblings with diabetes)
• Being overweight
• Sedentary lifestyle
• Race/ethnicity (African-Americans, Hispanic-Americans, Native Americans, Asian- Americans, and Pacific Islanders)
• Previously-identified impaired fasting glucose or impaired glucose tolerance. The ADA recently starting using the term pre-diabetes, which is when a person has blood glucose levels higher than normal, but not yet high enough to be diagnosed as diabetes.
• Hypertension (≥140/90 mmHg)
• Dyslipidemia or cholesterol disorders (HDL-cholesterol ≤35 mg/dL and/or a triglyceride level ≥250 mg/dL)
• History of diabetes during pregnancy or delivery of a baby weighing more than nine pounds
• Polycystic ovary syndrome

Table 2. American Diabetes Association Glycemic Goals

Index	Normal	Goal	Additional Action Suggested
Premeal glucose (mg/dL)			
Blood	<100	80-120	<80 or >140
Plasma	<110	90-130	<90 or >150
Bedtime glucose (mg/dL)			
Blood	<110	100-140	<100 or >160
Plasma	<120	110-150	<110 or >180
A1C (%)	<6	<7	>8

Note: A1C is referenced to a non-diabetic range of 4-6 percent.

hyperglycemia may be less symptomatic in the elderly since the renal threshold for glycosuria (spilling of glucose into the urine) increases with age. Typically the renal threshold is an ambient blood glucose of 180 mg/dL. This can increase to over 270 mg/dL in the elderly, meaning one would not experience the symptom of increased urination until the blood glucose level reached levels greater than 270 mg/dL.

Treatment Goals for Diabetes

The overall treatment goals set forth by the American Diabetes Association (ADA) are categorized in Table 2. The ADA's Standards of Care appear in Table 3. Recently, the American Association of Clinical Endocrinologists released tighter goals than the ADA, recommending the A1C[i] to be <6.5 percent, fasting plasma glucose <110 mg/dL, and a 2-hour post-meal glucose of <140 mg/dL. Plasma glucose concentrations are 10-15 percent higher than blood glucose concentrations. Thus, it is important to know whether the glucose monitor being used by the patient reads out plasma or blood values in order to interpret the readings properly.

Metabolic goals must be individualized. For patients with advanced diabetes complications, life-limiting co-morbid illness, or cognitive or functional impairment, the ADA states it is reasonable to set higher target goals. Glycemic goals are the targets for the glucose levels and the A1C. The A1C reflects the average blood glucose over the past 2-3 months. An A1C of 6 percent reflects an average blood glucose of approximately 120mg/dL; 7 percent and 8 percent are 150mg/dL and 180mg/dL, respectively. Thus for each 1 percent increase in the A1C, the average blood glucose rises by approximately 30 mg/dL. If the A1C is greater than 8 percent, additional action is recommended by the ADA (i.e., modifying the treatment plan to improve the glycemic control).

Support for these glycemic goals came from the United Kingdom Prospective Diabetes Study (UKPDS), which assessed whether intensive treatment reduced the development of complications over a ten-year period. The people in the intensive group (sulfonylurea, metformin, or insulin) had an A1C 0.9 percent lower than the standard group (lifestyle interventions), which resulted in a 25 percent reduction in the microvascular complications of diabetes (i.e., eye and kidney disease). For every 1 percent reduction in the A1C there was a 35 percent reduction in developing microvascular complications. Although a reduction in the cardiovascular complications was observed (specifically a 16 percent reduction in the risk of heart attack and sudden death), it did not reach statistical significance.

While the UKPDS provided good evidence of the need for improved glycemic control, intensive treatment had disadvan-

Table 3. American Diabetes Association Standards of Care

Procedure	Frequency	Goal
A1C	2-4 times/year (twice a year if treatment goals are met; otherwise quarterly)	<7%
Lipids	yearly	LDL-C ≤100 mg/dl TG <150 mg/dl HDL-C ≥45 mg/dl in men HDL-C ≥55 mg/dl in women
Urine albumin	yearly	Negative (normal is < 30 mg albumin/gm creatinine)
Blood Pressure	each medical visit	<130/80 mm Hg
Dilated eye exam	yearly	no retinopathy
Influenza vaccine	yearly	no infection
Pneumococcal vaccine	at least once[1]	no infection
Foot examination	yearly (comprehensive); each medical visit (visual)	no ulcerations; those at risk should self-inspect feet daily
Dental exam	twice yearly	no periodontal disease
Self-Monitoring of Blood Glucose (SMBG)[2]	individualized	detect hypoglycemia; include in self-management program

[1] A one-time revaccination is recommended for people >64 years of age if previously vaccinated at age <65 years and administered more than 5 years ago.
[2] Medicare covers testing supplies (strips, lancets, meters) whether or not one uses insulin. A physician needs to prescribe the blood glucose testing supplies and document how often to test the BG on the prescription.

[i]Older names for A1C were glycosolated hemoglobin or hemoglobin A1C.

tages: more weight gain (~6 pounds) and hypoglycemic episodes (1.4 percent versus 0.7 percent). Also, the mean age of participants in the UKPDS was 54 years and none was over the age of 65. Thus, clinical trial data is still lacking for the elderly. In light of this, the ADA glycemic goals need to be tailored to the individual.

Treatment Options for Diabetes

The six classes of oral medications for type 2 diabetes are listed in Table 4. The first three, which stimulate insulin release from the pancreas, are referred to as insulin secretagogues.

While the available medications provide various treatment options, they have led to confusion among health care providers and patients about which one to start first and which combinations are rational. Many practitioners use a stepped-care approach to managing type 2 diabetes, as is done with hypertension.

Step 1. Lifestyle Changes: Diet, Exercise, and Management of Cardiovascular Risk Factors

Diet and exercise are essential components to managing diabetes. Even if a person requires medication, this step remains. A complete discussion of medical nutrition therapy is beyond the scope of this article. However, a few basic principles can be followed. It is important that a meal plan be tailored to the individual and is realistic for that person, taking into account cultural and socioeconomic factors. Initial referral to a dietitian, if possible, is extremely useful. Spacing of meals, particularly balancing and spreading carbohydrate intake throughout the day, is one simple strategy.

Carbohydrates are converted to glucose in the body. Therefore, it is not only the obvious sources of glucose (candy, cola, sweets) that increase the blood glucose, but the carbohydrates that one eats. A few examples of high carbohydrate foods are: potatoes, rice, tortillas, bread, pita bread, pasta, cereal, starchy vegetables (corn and green peas), fruit, and milk. Many people with type 2 diabetes are overweight. Even a moderate weight loss (e.g., 10-20 pounds) can reduce blood glucose levels significantly and improve blood pressure and cholesterol. While many weight-loss methods exist, one that reduces saturated fat intake and includes some type of regular physical activity (such as walking) is most often effective.

If a person smokes, she/he should be strongly advised to quit and be referred for tobacco cessation counseling. The ADA recommends people with diabetes who have heart disease, or those at risk for it, also take an enteric-coated aspirin daily (81-325 mg a day). People with diabetes at high risk for heart disease are those with a family history; smoke cigarettes; have hypertension, kidney disease, or a cholesterol disorder; are obese; and are over 30 years of age. Mr. Brown (Case I) has already had a heart attack, so he appropriately takes an aspirin daily to prevent another one from occurring.

Step 2. Single Oral Medication (Added to Diet and Exercise)

When diet and exercise are no longer sufficient to maintain glycemic goals, a single oral medication may be added. All oral type 2 medications are options. Metformin (Glucophage®) is often used in overweight patients, since it does not cause weight gain. Sulfonylureas, repaglinide (Prandin®), and nateglinide (Starlix®) can all cause weight gain. Since the thiazolidinediones require liver monitoring every other month for the first year, they are often reserved for combination therapy.

Table 4. Oral Agents for Type 2 Diabetes

Class	Drug(s)	Primary Mechanism of Action
Sulfonylureas	glyburide (Micronase®, DiaBeta®) glipizide (Glucotrol®) glimepiride (Amaryl®) tolazamide (Tolinase®) tolbutamide (Orinase®)	stimulation of insulin release from the pancreas
Meglitinides	repaglinide (Prandin®)	stimulation of insulin release from the pancreas
Amino-acid derivatives	nateglinide (Starlix®)	stimulation of insulin release from the pancreas
Biguanides	metformin (Glucophage®)	reduction of glucose output from the liver
Alpha-glucosidase inhibitors	acarbose (Precose®) miglitol (Glyset®)	delayed digestion and absorption of carbohydrates from the meal
Thiazolidinediones	pioglitazone (Actos®), rosiglitazone (Avandia®)	reduction of insulin resistance in the body

Step 3. Combination Oral Medications

When single oral therapy is no longer sufficient to achieve glycemic goals, a second medication can be added for additional blood glucose lowering. The key is to combine medications that work at different sites. Triple therapy may also be useful if two oral agents are inadequate.

Step 4. Oral Medication Therapy Plus Insulin

Over time, as type 2 diabetes naturally progresses, the pancreas produces less and less insulin. The UKPDS demonstrated that additional drug therapy was needed every four to six years, on average. Insulin can be added to oral therapy.

Step 5. Insulin Alone

Many people with type 2 diabetes are on insulin alone to control their diabetes. Some people who are on insulin alone were never tried on the newer oral agents such as metformin (Glucophage®) or a thiazolidinedione. In these cases the addition of oral medication may enhance glycemic control and reduce the daily insulin requirement.

Special Considerations in the Elderly

Kidney and Liver Function

When selecting a type 2 diabetes medication for an elderly person, the kidney and liver function need to be assessed. Certain sulfonylureas are preferred in the elderly because they are metabolized to compounds with negligible activity (e.g., glipizide, tolbutamide), have a shorter duration of action (e.g., tolbutamide) or have been studied in patients with kidney problems (e.g., glimepiride). Longer acting sulfonylureas or those with active metabolites (e.g., glyburide, chlorpropamide) should be avoided because of an increased risk of hypoglycemia. Because repaglinide (Prandin®) and nateglinide (Starlix®) have a very short duration of action and have been studied in patients with reduced kidney function, these may also be preferable.

Pioglitazone (Actos®) and rosiglitazone (Avandia®) may be used in patients with reduced kidney function, but not in those with liver problems. Acarbose (Precose®) and miglitol (Glyset®) should be avoided in patients with severe kidney impairment (serum creatinine >2.0 mg/dL). Severe kidney impairment can cause injected insulin to last longer, so people on insulin therapy may require a reduction in their insulin doses.

Metformin (Glucophage®) should not be used in patients with kidney or liver problems. It should also not be used if a person has congestive heart failure requiring medications or has an acidotic condition. Metformin (Glucophage®) is predominantly eliminated from the body by the kidneys, so reduced kidney function will result in its accumulation and increase the risk for lactic acidosis. Lactic acidosis, a very rare side effect (approximate incidence is 1/33,000), can be life threatening. Metformin (Glucophage®) should not be used in men or women with serum creatinine concentrations of ≥1.5 mg/dL or ≥1.4 mg/dL, respectively. In elderly patients, an estimate of creatinine clearance (using the Cockroft and Gault equation described in the previous article, Altered Drug Action With Aging) may be a better and earlier indicator of reduced kidney function. Metformin (Glucophage®) should be avoided in patients with a creatinine clearance <60 ml/min. It should also not be used in patients who are >80 years unless their creatinine clearance suggests that kidney function is not significantly impaired. Other predisposing factors for lactic acidosis include shock, acute heart attack, liver failure, surgery, severe infection, an illness that causes severe dehydration, and excessive alcohol ingestion.

Eating Habits

People who have irregular eating habits or skip meals are at increased risk for hypoglycemia if taking a sulfonylurea. A short-acting agent, such as tolbutamide, repaglinide (Prandin®) or nateglinide (Starlix®), is preferable in such patients who require an insulin secretagogue.

Hypoglycemia

The ability to self-monitor blood glucose (SMBG) is an important consideration in the selection of the pharmacologic regimen for an elderly person. If a regimen may cause hypoglycemia, a person should SMBG. Of the sulfonylureas, tolbutamide, glipizide, and glimepiride have been associated with lower incidences of hypoglycemia. Although metformin (Glucophage®) should not cause hypoglycemia when used alone, hypoglycemia can occur when it is combined with other medications.

Intensive therapy may increase the incidence of hypoglycemia, as demonstrated in the UKPDS. In the elderly, hypoglycemia (blood glucose <70 mg/dL) is of special concern, because, over time, some people may not recognize the symptoms of hypoglycemia. This can delay treatment of low sugar reaction (hypoglycemic episode). Thus, if a patient has hypoglycemia unawareness, their metabolic treatment goals may need to be liberalized taking this into account.

Adherence

People with diabetes often take many other medications, as in Mr. Brown's case. Therefore, treatment regimens that are easy to follow and suited to a person's lifestyle are important considerations. For example, metformin (Glucophage®) can be taken either two or three times daily with food. Mr. Brown could take metformin twice a day (e.g., 500 mg in the morning and 1000 mg at dinner), if he is able to tolerate a 1000 mg dose. Also, he admits that he occasionally forgets to take lovastatin at bedtime. To improve adherence, he could try taking it with his other medications, and then monitor the cholesterol to see if it is adversely affected.

Insulin Therapy Considerations

Patients with vision or dexterity problems can have difficulty handling the insulin vial/syringe and injecting insulin. Insulin syringes are available in 1/3 ml (holds 30 units), 1/2 ml (holds 50 units), and 1 ml (holds 100 units) sizes. For patients whose insulin doses are less than 30 units, use of the 1/3 ml syringe is preferable, because its markings and lines are much easier to read. For patients with dexterity problems, an insulin delivery device, such as a pen device, may allow for easier handling and administration of insulin. Syringe magnifiers may also be of value.

Conclusion

People with diabetes often do not just have diabetes. They may also have hypertension, a cholesterol disorder, kidney disease, and/or heart disease, and thus may take many medications. It is important to periodically assess the safety and effectiveness of all medications, especially in older persons.

COUNSELING TIPS

- Teach patients how to recognize symptoms of low blood sugar (hypoglycemia) These include rapid heartbeat, hunger, sweating, irritability, shakiness, dizziness, headache, confusion, and anxiety.
- If any of these symptoms occur, the patient should check his or her blood glucose. If it is below 70 mg/dL, take a fast-acting source of 15 grams of glucose*.
- Recheck the blood glucose in 15 minutes; if it is still below 70 mg/dL, take another 15 grams of glucose.
- Sources of glucose that contain fat (e.g., candy bar) do not act fast enough to treat low blood glucose, because the fat delays absorption.
- If the blood glucose remains below 70 mg/dL call the emergency medical system.
- All people who use insulin should have a glucagon emergency kit at home. A family member or caregiver should be trained on how to administer it in case the person becomes unconscious.
- Patients taking insulin or other medications that can cause hypoglycemia should be told to wear some form of medical identification indicating that they have diabetes. These products, such as a bracelet or pendant, provide vital medical information during an emergency.
- Patients taking metformin should be familiar with the symptoms of lactic acidosis, even though it rarely occurs. These include feeling very weak, tired or uncomfortable; unusual or unexpected stomach discomfort; trouble breathing; feeling dizzy, light-headed or cold; or suddenly developing a slow or irregular heartbeat. If any of these symptoms occur, they should stop taking metformin and call their physician.
- It is important to temporarily stop metformin when undergoing an x-ray procedure that necessitates an injection of a dye (contrast agent). Metformin should be stopped at the time of or before the procedure and not restarted until 48 hours after the procedure and after kidney function has been re-evaluated and found to be normal.

*Examples of 15 grams of fast-acting glucose include:

1 cup (8 oz) of skim milk
1/2 cup (4 oz) apple, orange, or grapefruit juice
1/3 cup grape or cranberry juice
1/2 cup regular (not diet) soda (e.g., colas)
1 tablespoon honey
3-4 glucose tablets
1 tube glucose gel

RESOURCES AND INFORMATION FOR THE PATIENT AND THE PHARMACIST

Geriatric Self Care

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People over the age of 65 consume one-third of all prescription and nonprescription medications. The average older adult takes five to six prescription medicines and three to four nonprescription products on a daily basis. The over-the-counter (OTC) market is continuously growing as prescription medications are converted to over-the-counter (nonprescription) status. The dietary supplement market (herbs, nutritional supplements) is growing as well. The practice of self-medicating has become confusing for many older adults. Reliance on the advice of a neighbor, friend, or family member is not uncommon. The pharmacist's knowledge of a person's prescription and nonprescription medication use can assist greatly in improving self-care.

Pharmacists can educate and counsel older adults on product selection. Before recommending an OTC product, ask the person about specific symptoms that are bothersome and when they began to occur. The pharmacist should also ask what makes these symptoms better or worse and what has the person already tried for relief. A thorough health and medication history is necessary in order to select an appropriate medication without creating drug-disease or drug-drug interactions. Patients must be told how quickly their symptoms will improve, what side effects to expect, and when to seek medical care if symptoms do not resolve. In some instances, direct referral to a physician may be indicated.

For most people, information on health management is best acquired through effective communication with physicians, nurses, and pharmacists. The patient should therefore be encouraged to bring all medicines, or at least a complete list of them, to their physician at each visit. They should write out any questions they have in advance to assure that nothing is overlooked. The community pharmacist is an ideal resource for information on side effects, interactions, and contraindications, for both prescription and nonprescription products.

Common Conditions For Which The Elderly Seek Self Care

Dry skin

Dry skin is common in the elderly. Skin thinning, reduced water retention in the stratum corneum, and decreased sebum production produce tight, rough skin. Common skin problems in the elderly include scaling, fissures, inflammation, and pruritus, which often accompany dryness. One treatment goal is to maintain skin hydration, which can be done by simply maintaining adequate water intake (eight 8-oz. glasses per day). Hot baths and detergent soaps, which remove natural oils and lead to additional skin drying, should be avoided. Warm baths every other day, mild soap, gently patting skin rather than vigorously drying, and applying an emollient or moisturizing lotion immediately following a bath or shower may also help.

Common brand names of moisturizing products include Vaseline®, Curel®, Eucerin®, and Keri®. They contain combinations of emollients (e.g., petrolatum, lanolin, cocoa butter), which promote water retention through occlusion, and humectants (e.g., glycerin, propylene glycol), which promote water retention through hydration. Other products such as U-lactin®, Lachydrin®, and Lacticare® contain keratin-softening agents such as urea, lactic acid, or allantoin.

MYTHS & FACTS

MYTH: *Because over-the-counter medicines don't require a prescription, they're not as strong.*

FACT: The ingredients in OTC medicines can be just as strong as prescription medications. Always tell your doctor about all prescription and nonprescription medications you're taking so that potentially dangerous side effects and interactions can be avoided. Some nonprescription medicines are not recommended in the elderly. Do not use them without medical advice.

MYTH: *Because herbs are natural, they are safe.*

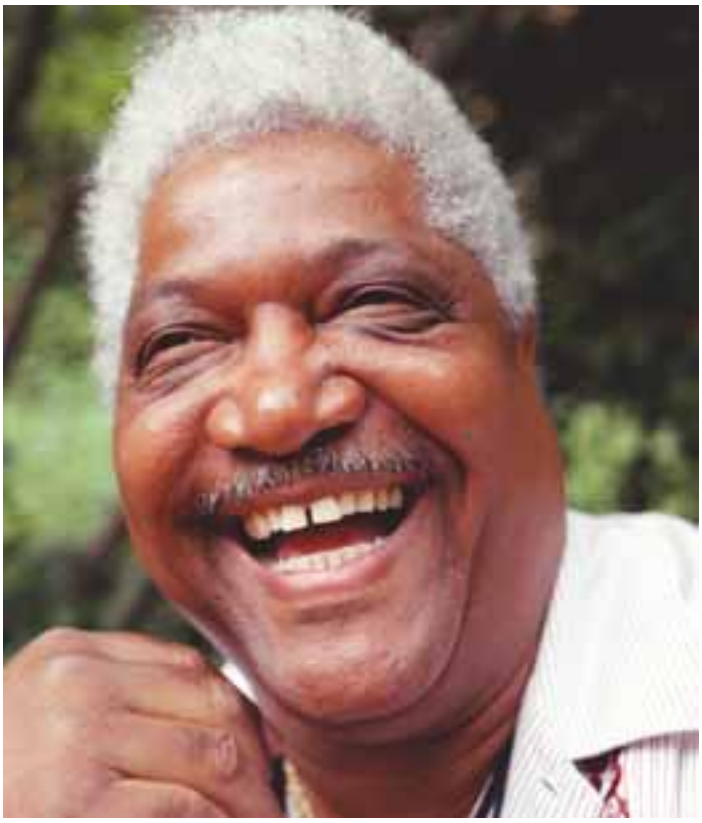
FACT: Just like traditional medicines, some herbs are safe and some are toxic. Many herbs have serious side effects and need to be monitored. They can also interact with traditional medicines.

MYTH: *I must buy expensive "natural vitamins" to get the best ones.*

FACT: Synthetic, cheaper vitamins and minerals are just as effective as the more expensive natural ones.

MYTH: *All vitamins are safe even at large doses.*

FACT: Fat soluble vitamins are not easily eliminated from the body. Large doses may lead to toxic reactions and can interact with certain prescription medicines.



Constipation

Among community-dwelling elders over the age of 65, approximately one-quarter of men and one-third of women suffer from chronic constipation. Many diseases commonly seen in the elderly, as well as some medications used to treat them, exacerbate the problem. Medications that cause constipation should be eliminated, if possible. Pharmacists can help identify such medicines and recommend less bothersome alternatives.

Management of constipation should begin with non-pharmacologic strategies. These include increasing dietary intake of fruits, vegetables, and grains high in fiber; drinking at least 8 glasses of liquid daily; and regular exercise. If unsuccessful, medications may be tried. Bulk-forming or fiber laxatives add enough bulk to the diet to regulate bowels and are safe and effective with chronic use. They usually take several days to produce a bowel movement and need to be continued on a daily basis to stay regular. Fiber laxatives must be taken with sufficient fluids, such as 1–2 eight-ounce glasses of water several times daily. Failure to do so may result in the exacerbation of constipation or even fecal impaction.

A stool softener, such as docusate, is another safe alternative for long-term use. It works by causing the stool to absorb more water, making it easier to evacuate. Like fiber laxatives, docusate takes about 72 hours to work and must be taken regularly. A combination of a fiber laxative and stool softener is safe, effective, and may be used chronically.

Other laxatives (e.g., stimulants, saline laxatives, lubricating agents) should be used on an as-needed basis only. Chronic use of stimulant laxatives like bisacodyl, castor oil, and milk of magnesia may lead to cramping, dehydration, and electrolyte imbalance. Frequent use of mineral oil is associated with malabsorption of fat-soluble vitamins. Although suppository or enema laxatives work very quickly, they can cause significant cramping and anal irritation and should only be used when other laxatives fail. Bowel evacuants (e.g., magnesium citrate, Fleet's Phospho Soda®) are available for over-the-counter use. However, they should not be used without a physician's advice, because unmonitored use can lead to severe dehydration in the elderly.

Urinary Incontinence

Urinary incontinence, defined as involuntary loss of urine or a sensation of urinary frequency or urgency, is predominately a problem of old age. Studies show that 56 percent of community-dwelling elderly and 80 percent of nursing home residents suffer from this disorder. The first step in treating it is to eliminate reversible causes. (See Table 1.) Non-pharmacologic approaches to management include timed or prompted voiding (i.e., bladder training) and Kegel exercises (20 minutes three times a day) to strengthen voluntary pelvic floor muscles, which improves periurethral structure support and bladder storage. If incontinence persists, prescription drug therapy may be indicated, which is beyond the scope of this article. The patient should be referred to his or her physician for thorough evaluation, which includes determining the underlying pathology.

Insomnia

Among healthy seniors, 12–25 percent report chronic insomnia. The incidence of insomnia appears to increase as the number of medical problems increases. Lifestyle changes, poor sleep habits and hygiene, anxiety, depression, dementia, age-associated reduction in deep sleep cycle, certain medical conditions (e.g., diabetes, pain, cardiac or respiratory disease), urinary incontinence, and medications can all contribute to insomnia in the elderly. Prolonged insomnia can result in daytime fatigue, impaired functioning, and reduced quality of life.

The most effective, long-term management of insomnia is non-pharmacologic. Although medications provide immediate relief from insomnia, non-pharmacologic measures can lead to permanent resolution of symptoms. Sleep hygiene measures include decreasing afternoon caffeine intake, exercising regularly before 6 pm, avoiding naps, establishing regular sleep hours, treating nighttime pain, addressing nocturia, and managing the bedroom environment (e.g., temperature, noise level). When drug therapy becomes neces-

sary, shorter-acting prescription drugs are preferred (e.g., zolpidem, zaleplon). Antihistamines commonly used in OTC sleep products (e.g., diphenhydramine, doxylamine) are associated with impairment of daytime functioning, even at low doses. They also have undesirable anticholinergic effects (e.g., delirium, confusion, disorientation).

Melatonin is a dietary supplement frequently used for sleep. Produced by the pineal gland, endogenous levels increase in the evening and peak during the normal hours of sleep. Older adults who suffer from insomnia appear to have lower levels of melatonin. Several small studies have shown that melatonin may be effective for sleep-onset insomnia (trouble falling asleep), but it has not been shown to be effective in sleep-maintenance insomnia (trouble staying asleep), which is common in the elderly. Side effects are generally mild and include headaches, daytime drowsiness, dizziness, fatigue, irritability, and stomach upset. Melatonin should not be taken concurrently with alcohol or other sleep aids, because the combination may cause dizziness and excessive sedation.

Weight Loss

Involuntary weight loss represents a serious health concern in the elderly. Malnutrition is reported to occur in 55 percent of nursing home residents and low body weight is a major risk

Table 1. Reversible Causes of Urinary Incontinence

Dietary causes	Medical conditions	Medications
Excess fluid intake More than 6 oz of fluid after 6:00 PM Caffeinated drinks Alcohol High sugar foods	Delirium Depression Restricted mobility Urinary tract infection Atrophic vaginitis Fecal impaction Polyuria due to poorly controlled diabetes, congestive heart failure	Acetylcholinesterase inhibitors Alpha agonists/antagonists ACE Inhibitors Anticholinergics Antihistamines Anti-Parkinson's drugs Diuretics Lithium Tricyclic antidepressants Antipsychotics Sedatives/hypnotics

Table 2. Medications Commonly Associated with Weight Loss

Drug name	Effect
SSRIs Bupropion	Reduced carbohydrate craving
Digoxin	GI side effects in 25 percent of patients; loss of appetite is often the first sign of toxicity
Metformin	GI side effects and increased insulin sensitivity
NSAIDs	Decreased appetite, possibly due to nausea and stomach upset
Theophylline, oral albuterol, pseudoephedrine	Stimulant effect, decreased appetite
Cholinergic drugs for Alzheimer's disease (e.g., donepezil, rivastigmine, galantamine)	GI side effects
Sedatives/hypnotics	Loss of appetite due to sedation
Cholestyramine	Nutrient malabsorption
Levodopa	Increased fat breakdown, altered taste
Cancer chemotherapy, gold therapy, phenytoin, potassium, doxycycline, alendronate, theophylline	Stomatitis, gingival hyperplasia, mucosal injury
Hydrochlorothiazide, captopril, enalapril, nifedipine, diltiazem, metformin, some inhaled or intranasal products	Changes in taste (bitter or metallic) or smell
Ma huang (ephedra), guarana	Stimulants, decreased appetite
Thyroid hormone	Decreased appetite, particularly if dose is excessive

factor for functional decline and mortality. Causes of involuntary weight loss include:

- Social—loss of dining companion, not wanting to cook for oneself
- Psychological—bereavement, depression, dementia
- Medical—malabsorption, gastrointestinal disease, infection, trouble swallowing, cancer
- Pharmacologic—drug induced weight loss
- Physiological—decreased food intake resulting from decline in physical activity and resting metabolic rate

Pharmacists should refer patients who report a rapid weight loss (e.g., 4 percent weight loss within a year) to their physicians, because this often signals an underlying medical cause. After ruling out medical and psychological causes, the medication regimen should be reviewed to ensure that these are not causing or contributing to weight loss. (See Table 2.)

Nonprescription Drugs

Nonprescription or over-the-counter (OTC) medicines have always been an important aspect of geriatric self-care. However, patients must be reminded that while only a limited number of ingredients are approved for over-the-counter use, thousands of brand name products are available and many contain combinations of identical medications. While some OTC drugs can be effective in managing symptoms safely, others can cause bothersome side effects. (See Table 3.) In some cases they create more problems than they treat, resulting in significant declines in health and functional ability. Therefore, patients selecting an over-the-counter medicine should be taught to look for specific drug names on the label, select a product that contains only those medicines needed for their particular symptoms, and ask a pharmacist for advice if they have any questions.

Dietary Supplements

One in three Americans uses a dietary supplement. However, consumers often lack accurate and objective medical information about the safety and efficacy of products before self-medicating.

The Dietary Supplement Health and Education Act (DSHEA) of 1994, amends the Federal Food Drug and Cosmetic Act pertaining to dietary supplements (defined as vitamins, minerals, herbs or other botanicals, amino acids, or other dietary supplements). This prevents manufacturers from claiming that herbs may be used

Table 3. OTC Ingredients That Can Cause Problems in the Elderly

Drug name	Indications	Side effects	Precautions
Pseudoephedrine	Nasal congestion	Nervousness, insomnia, agitation, decreased appetite, weight loss, increased blood pressure	Use cautiously in hypertension, cardiac disease, diabetes, or anxiety disorders.
Diphenhydramine Chlorpheniramine Brompheniramine	Allergies, runny nose, itchy eyes, itching, allergic rashes	Excessive sedation, dry mouth, constipation, urinary retention, tachycardia, confusion, mental status changes, delirium	Avoid in patients with dementia or BPH. Chlorpheniramine and brompheniramine may have milder side effects, but still bothersome.
Ibuprofen Naproxen Ketoprofen Aspirin	Arthritis, pain, fever reduction, inflammation, blood thinning (ASA)	Stomach upset, pain, ulcers, GI bleeding, acute kidney problems, water retention, increased blood pressure	Do not use without physician supervision. Always take with food. Can cause serious bleeding or acute kidney disease without warning. Increased risk of bleeding if taken with warfarin.
Bisacodyl senna	Stimulant laxatives for constipation	Related to purgative action	Not recommended as initial therapy; try bulk-forming product and docusate first. Use only as needed, for no more than 1 week at a time (except in patients on chronic narcotics). Chronic use can degrade colon function.
Magnesium citrate Sodium phosphate Magnesium hydroxide	Saline laxatives for constipation, bowel evacuation	Dehydration, weakness, fecal incontinence	Use only if clearly indicated. Unsupervised use can lead to severe dehydration, resulting in mental status changes, cardiac toxicity, and electrolyte imbalance.
Mineral oil	Lubricant laxative for constipation	Decreased absorption of fat-soluble vitamins, lipid pneumonia	Use only as needed; most problems are associated with chronic use.

to treat diseases such as high cholesterol, dementia, high blood pressure, anxiety, and depression. But it also limits the FDA's oversight. The manufacturers bear the responsibility for safety and effectiveness. The FDA is only allowed to remove products from the market after they have been proven to be hazardous.

Likewise, the FDA cannot impose the same strict manufacturing requirements on dietary supplements as it does on traditional pharmaceuticals. This results in batch-to-batch and manufacturer-to-manufacturer variation in concentrations and purity of ingredients. Chemical analysis of popular supplements used by the elderly, such as echinacea, ginkgo biloba, ginseng, St. John's wort, saw palmetto, melatonin, glucosamine, and chondroitin, have shown significant variations from labeled potency. Pharmacists can help inform consumers about safe use of these products. (See Tables 4 and 5.)

Vitamin and Minerals

Relatively little information is available on the vitamin and mineral requirements of older adults. The usual standards for assessing vitamin and mineral requirements are based on the recommended dietary allowance (RDA), which provides nutrient requirements for all age groups. Older adults fall into the

Table 4. Dietary Supplements Commonly Used by the Elderly

Herb or Supplement	Common Uses	Precautions
St. John's wort	Depression and anxiety	May cause GI distress, restlessness, sedation, headaches, confusion, and sun sensitivity. Drug interactions with many prescription medications.
Ginkgo biloba	Memory loss and to improve cognitive function; often used in Alzheimer's disease	Increases antiplatelet effects of NSAIDs and may increase risk of bleeding with warfarin. Should not be used 7–10 days pre- or postoperatively. Generally well tolerated, although rarely leads to mild GI upset, headache, anxiety, or insomnia.
Garlic	High cholesterol, although efficacy not established	May cause body odor, GI upset, decreased blood pressure. Potentiates antihypertensive medications and blood thinners. Should not be used 7–10 days pre- or postoperatively.
Ginseng	Performance enhancement and to increase energy, although efficacy not established	May cause insomnia, hypertension, and nervousness. Potentiates CNS stimulants and blood-thinning medications. Should not be used 7–10 days pre- or postoperatively.
Valerian root	Anxiety and insomnia	May cause daytime sedation, additive effects with other CNS drugs. Should not be used with other sedatives and hypnotics. Hepatotoxicity has been reported and one case of precipitating benzodiazepine withdrawal.
Melatonin	Insomnia and jet lag	May cause headaches, daytime drowsiness, dizziness, fatigue. Additive effects with other CNS drugs.
Glucosamine Chondroitin	Osteoarthritis	May cause mild GI effects. Avoid chondroitin from bovine sources.
Saw palmetto	Improved urinary flow in men with enlarged prostates	May cause headaches and GI upset.

Table 5. Potentially Ineffective or Dangerous Dietary Supplements

Herb or Supplement	Common Uses	Precautions
Zinc	Preventing or reducing the duration of a cold. Not proven effective	May cause nausea, vomiting, zinc toxicity (flu-like symptoms, CNS symptoms, fatigue, anemia). Doses used for colds far exceed RDA. Safety of large doses not established.
Kava	Anxiety, sedation	Taken alone or in combination with other sedatives or alcohol, may impair driving ability. Reports of serious liver toxicity requiring organ transplants.
Ma huang (Ephedra)	Weight loss. At low doses also used for bronchospasm, asthma, congestion	Causes rapid heartbeat, elevated blood pressure, CNS stimulation, anxiety, insomnia, agitation, and weight loss. Contraindicated in cardiac disease, diabetes, or hyperthyroidism.
Guarana	Weight loss, to enhance athletic performance, reduce fatigue	Contains caffeine, theophylline, theobromine, tannins, trace amounts of timbonine (fish poison). Tolerance, psychological dependence with chronic use. Withdrawal syndrome: headaches, irritability, fatigue. May cause painful urination, GI spasms, insomnia, nausea, vomiting, CNS excitation, diuresis, palpitations, arrhythmias, muscle spasms, tinnitus, headache, delirium, convulsions.
DHEA	Increased energy, sexual potency	Potentiates effects of estrogen, testosterone. May cause deep voice, facial hair, acne, breakthrough bleeding in women and breast or prostate enlargement in men. May increase risk of breast and prostate cancer.

"51 and over" group, which does not consider the variability in requirements for people in later years. The best source of vitamins and minerals is a well-balanced diet. However, since many seniors eat irregularly or have poor nutrition, a daily multiple vitamin that does not exceed the RDA may be beneficial.

Water-soluble Vitamins (Vitamins B and C)

Vitamin C is present in all citrus fruits, strawberries, kiwi, papaya, red peppers, broccoli, and fortified juices. The RDA is 75–90 mg/day. There is no evidence that vitamin C absorption or utilization is impaired in older adults. Complete absence of vitamin C from the diet (rarely seen in the United States) results in scurvy. More commonly, vitamin C deficiency is associated with poor wound healing, easy bruising, inflammation of the mucosa, and capillary fragility.

The optimal dose of vitamin C is uncertain. Researchers often advocate doses that exceed the RDA. It is thought that 140 mg per day is necessary to saturate tissues and may be desirable for its antioxidant properties. Other sources report no increase in bioavailability with doses above 400 mg. Vitamin C toxicity is rare; excess vitamin C is usually excreted, with the only side effect being discolored urine. Doses over 2 gm per day may contribute to diarrhea, nausea, stomach cramping, and kidney stones. There is little evidence that such doses prevent colds or cancer, or aid in wound healing.

Vitamin B_6 and B_{12} deficiencies are common in geriatrics and have been associated with anemia, impaired cognitive function, and cell-mediated immunity. Daily requirements do not substantially change with age. Vitamin B deficiency is sometimes due to poor gastric absorption. B vitamins are present in many foods, including rice, grains, meat, peas, beans, avocados, potatoes, milk, and fish. Many vitamin B-complex formulations are available on the market. Toxicity is rare.

Niacin (vitamin B_3) deficiency is rare in the elderly. The RDA for people over age 50 years is 13–15 mg/day. This amount is easily attainable through a balanced diet including grains, vegetables, and fish. Doses of 500–3,000 mg daily are used for lowering cholesterol. At these larger doses, niacin has been associated with flushing, itching, headache, fatigue, ulcers, elevations in uric acid and glucose concentrations, and liver toxicity. For this reason, patients should be discouraged from self-medicating with niacin to lower cholesterol.

Fat-soluble Vitamins (Vitamins A,D,E, and K)

Vitamin A is present in fish, butter, cream, eggs, milk, liver, carrots, and broccoli. The RDA is 800–1000 mcg daily. The risk of toxicity is greater than that of deficiency. Although vitamin A supplementation (as beta carotene) has been associated with a lower risk of some types of cancer, studies are controversial and long-term effects have not been explored. Large doses of vitamin A are associated with toxicity and include symptoms like nausea, vomiting, fatigue, malaise, and joint pain.

Vitamin D is necessary for adequate calcium absorption and maintaining strong bones. It is present in milk, eggs, and fish and may be obtained from sunlight, but daily intake is often inadequate. Deficiency is common in the geriatric population, particularly those who are homebound or institutionalized. The RDA is 200 IU daily, although larger doses (400–800 IU) are recommended for patients at risk for osteoporosis. Toxicity is associated with daily doses of 50,000–100,000 IU. Symptoms of toxicity include anorexia, nausea, weakness, aches and pains, joint stiffness, weight loss, constipation, hypertension, and renal failure.

Vitamin E is present in plant oil, margarine, green vegetables, and grains. The RDA is 12–15 IU daily. Deficiency is rare in older adults and is usually not a concern. Larger doses (400–800 IU) have been recommended for their antioxidant properties and for cancer prevention. Until recently, vitamin E was thought to reduce cardiovascular risk; however, two controlled trials (HOPE and GISSI) have cast doubt on that benefit.

Vitamin E 1000 IU twice a day is currently recommended for delaying progression of Alzheimer's disease, although no evidence exists to support its use in improving memory. Toxicity is rare, but large doses have an antiplatelet effect, reduce vitamin K levels, and increase the effect of warfarin.

Vitamin K aids in blood clotting. The only vitamin manufactured by bacteria in the gastrointestinal tract, it is also present in green leafy vegetables, dairy products, and fruits. The RDA is 65–80 mcg daily and the average diet contains 300–500 mcg/day. Vitamin K deficiency is usually associated with antibiotic or anticoagulant administration. Patients on warfarin should keep a diet constant in vitamin K to avoid fluctuations in their INRs.

Calcium

Calcium is necessary to maintain strong bones and prevent fractures. It is present in all milk products, broccoli, and fortified orange juice. The daily requirement for older adults is 1000–1500 mg/day of elemental calcium. Elderly patients often do not get enough calcium in the diet or through supplementation (e.g., an 8-oz. glass of milk contains only 300 mg of calcium). Most multivitamins, even those intended for older adults, do not contain sufficient amounts of calcium (e.g., 200–300 mg per dose). Additional calcium sources are usually needed and any calcium salt (e.g., calcium carbonate, citrate, or gluconate) may be used. Calcium carbonate and calcium citrate provide the most elemental calcium per dose. Calcium citrate may be better absorbed by older adults and those taking H_2 blockers or proton pump inhibitors. A typical elemental calcium regimen is 500 mg three times a day. Calcium supplementation is rarely associated with gas or bloating and there is no good evidence that it causes constipation.

Case Discussions

Mr. Brown (Case I) is taking diazepam for sleep, which is not recommended. His pharmacist should review good sleep hygiene with him to see whether any changes in his daily routine would help with his occasional insomnia. Following those adjustments, if medication is still necessary, he should ask his physician for something more appropriate. Mrs. Brown should make a list of all her over-the-counter medicines and herbs and bring it to her pharmacist, so that he or she can evaluate whether they are safe for her to take. Certain nonprescription medicines and herbs are not appropriate for older adults.

Because Mrs. Smith's (Case II) different medicines can potentially interact, she should choose one pharmacy, where a pharmacist can properly screen her drug regimen for drug interactions. Her warfarin interacts with many nonprescription medicines that she is planning to buy, including Tagamet HB®, Vitamin E (at doses greater than 1000 IU), Advil®, gingko biloba, and Pepto-Bismol®. She should be counseled to avoid taking these potentially dangerous combinations.

Other issues to consider discussing with her include the lack of an indication for vitamin E 1000 IU (she does not have Alzheimer's Disease) and lack of evidence that gingko improves memory in non-Alzheimer's disease patients. It is also important to find out why she is buying Tagamet HB® and Pepto-Bismol®. Both Vioxx® and Prozac® can cause stomach discomfort. If she is having stomach problems, her physician needs to be notified.

Mrs. Young's (Case III) OTC sleep aid likely contains diphenhydramine, which is not recommended in the elderly. It can cause excessive sedation, confusion, and other mental status changes, particularly in patients with dementia. If improving sleep hygiene does not help, her doctor should consider a short-acting sedative hypnotic. Vitamin E 1000 IU twice daily has been shown to slow down the progression of dementia in Alzheimer's disease and may be worth a try. It is not likely to cause any dangerous side effects and she may benefit from a trial. Taking Advil® for Alzheimer's disease is more controversial. The risk of bleeding from Advil® outweighs any benefits it may have; thus, it should not be recommended at this time.

Conclusion

Elderly patients, even those who can manage their own regimens adequately, often have many questions about their medications. Pharmacists are an ideal source of information and can counsel patients about their medications, educate them about the benefits and the potential dangers of self-medication, and screen their drug regimens for dangerous adverse reactions or drug interactions.

ADVICE TO PATIENTS WHEN SELF-MEDICATING

- When buying a new OTC product, ask your pharmacist whether it is safe for you.
- Tell your physician or pharmacist about all the nonprescription products you take. It is always a good idea to remind your physician what medicines you take, particularly if you are seeing more than one doctor.
- Read the label. Know what side effects to expect from each OTC product you take.
- Know how quickly you should see a response from an OTC medicine.
- Learn which medicine(s) you need for your symptoms and look for products containing only those ingredients.
- Learn which OTC medicines older adults should not use.
- Generic OTC products are just as effective as the more expensive brand names.
- Seek medical care if symptoms get worse or don't resolve.

Reimbursement and Access to Care

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Access to affordable prescription drug coverage is arguably the most critical healthcare issue facing older adults today. It is well documented that individuals 65 years of age and over consume a disproportionate amount of the healthcare services and dollars. They pay a larger out-of-pocket share of the cost than do their younger counterparts, particularly for prescription drugs. Total spending on prescription drugs was estimated to have been $90.6 billion in the United States in 1998. Older Americans comprise 13 percent of the population; yet they consume 34 percent of all prescription drugs and account for 42 percent of the drug expenditures. When accessing the healthcare system, including obtaining prescription drugs, reimbursement for services must be considered. This article will address the reimbursement options for prescription medications available to older adults and provide some practical strategies to aid pharmacists in minimizing out-of-pocket expenses for the elderly.

Prescription Drug Coverage for Seniors

With drug expenditures expected to increase at double-digit rates through 2007, older Americans, who have the greatest reliance on prescription drugs, do not have prescription drug coverage as part their basic Medicare benefit. Although Medicare has never provided an outpatient prescription drug benefit, it was estimated in 1996 that 69 percent of Medicare beneficiaries had some form of drug coverage from sources other than Medicare. The primary sources of drug coverage were a mix of employer–sponsored retiree benefits, Medicare+Choice managed care plans, Medigap plans, Medicaid, and veteran's benefits.

Employer-sponsored retiree benefits comprise the largest source of prescription drug coverage for the elderly. However, this benefit is on the decline as employers struggle to afford the rising premiums associated with providing care. Among firms of all sizes, the overall percentage of those offering retiree benefits dropped from 40 percent in 1994 to 28 percent in 1999.

The Medicare managed care plan, Medicare+Choice, provided some prescription drug coverage to 13 percent of Medicare beneficiaries in 1999. Medicare+Choice plans, however, have become a less reliable source of prescription drug coverage of late. They are not offered in every state and some health plans have stopped offering Medicare+Choice, while others have dropped or limited drug coverage because reimbursement from Medicare has been unable to keep pace with the rising cost of prescription drugs. Enrollees in these plans have also experienced shrinking benefits for a higher price tag. Examples of this shrinking benefit include annual spending limits placed on prescriptions, large co-pay differences between generic medications ($7-$10) and brand name medications ($30), drug benefits that only include generic drugs (i.e., brand name drugs are no longer covered) and the institution of a monthly premium.

Medigap insurance is another alternative for older adults. These insurance policies serve as supplemental coverage to the Medicare benefit. Of the ten Medigap policies available, only three offer prescription drug coverage. These three poli-

MYTHS & FACTS

MYTH: *Generic drugs are inferior to their brand name counterparts*

FACT: Generic drugs are regulated and rated by the FDA. If a generic drug has an "AB" rating it is therapeutically equivalent to the brand name medication

MYTH: *Patients with health insurance do not qualify for patient assistance programs through pharmaceutical industry*

FACT: Each pharmaceutical manufacturer has different eligibility criteria. Typically, a patient can have health insurance but the person may not qualify if he/she has a pharmacy benefit associated with the health insurance plan.

MYTH: *Because Medicare does not cover outpatient prescription drugs, most older Americans have no prescription drug coverage.*

FACT: Over 60 percent of older Americans have some form of prescription drug coverage either through Medigap plans, Medicare +Choice, Medicaid, and Veteran's Administration benefits.

cies provide roughly 8 percent of Medicare recipients with prescription drug coverage and each requires that the patient pay for the first $250 of their medication costs per year. After this $250 has been paid, the member must then pay for half of the cost of each prescription (i.e., a 50 percent co-pay). Prescription coverage is limited to $1,250 -$3,000 annually, depending on the plan. The amount that a senior would pay in monthly premiums to get this prescription coverage ranges from $1,900-$3,250 annually, making these options very expensive for most seniors.

Medicare beneficiaries who are low income and have limited resources may qualify for state Medicaid (e.g., Medi-Cal) to help them pay for expenses not covered by Medicare. Those eligible for both Medicare and Medicaid are called dual eligible beneficiaries. The Medicaid benefits available to dual eligible patients vary depending upon income and resources. For dual eligible patients, Medicaid supplements Medicare and provides coverage for additional services such as outpatient prescription drugs (usually at no cost to the patient), eyeglasses and hearing aids, as well as nursing facility care beyond the 100 days covered by Medicare.

Medicare patients who have served in the armed forces may be eligible for veteran benefits either through the Department of Veterans Affairs (VA) or TRICARE insurance. If veterans are enrolled in the VA system and are eligible for medical benefits, they are also entitled to a pharmacy benefit that may or may not require a co-payment for prescription medications. TRICARE is a regionally managed health care program for active duty and retired members of the uniformed services, their families, and survivors. When combined with Medicare, TRICARE serves as a supplement to Medicare and provides a prescription drug benefit. This benefit provides medications either for no co-payment or a small co-payment, depending upon where the prescription is filled.

For over one-third of the Medicare-eligible seniors without a prescription drug benefit, the escalating cost of drugs is particularly problematic. These individuals may be low-income but may have non-liquid assets that prevent them from qualifying for state Medicaid programs. The amount that these individuals spend on prescription drugs can consume a large portion of their income, thus leaving them with difficult choices as to what essentials they are going to do without.

Pharmacist Interventions

Regardless of practice setting, pharmacists are in a position to assist this vulnerable population. Most pharmacies are equipped with software for drug utilization review to detect duplicate therapy, drug interactions and allergies. Pharmacists are also able to evaluate drug regimens to determine suboptimal dosing and unnecessary drugs. Pharmacists have

immediate access to drug prices, formularies, third-party billing, therapeutic alternatives, and most importantly, the patients themselves. Along with therapeutic interventions, the opportunity for cost-saving interventions occurs each time the patient is counseled on appropriate medication use. Once the pharmacist has identified an opportunity for cost savings, it is important to engage the physician and the patient as team members to ensure the best outcome, both financially and therapeutically.

If the pharmacist determines that there are financial issues that may interfere with medication adherence, there are several strategies that can be employed to decrease the amount seniors are paying for prescription drugs (See Table 1).

Most pharmaceutical companies have a program that provides free or low cost brand name drugs to patients in need. These are sometimes referred to as indigent programs or patient assistance programs. Unfortunately, the programs can be confusing and difficult to use, as each company has different forms, eligibility criteria, renewal processes, and mechanisms for the patient to obtain medications. For these reasons many of the programs are underutilized. There are, however, several useful websites to assist patients and providers in obtaining this information (See Table 2).

Pharmaceutical manufacturers have recently introduced

new drug discount card programs that differ from their patient assistance programs. These discount card programs are intended for those patients whose income is above the levels necessary to qualify for patient assistance programs. Many of these applications do not require a physician's signature and medications are obtained through the patient's pharmacy. Each company's program differs in qualifications and discounts, but they too can provide savings to the patient on brand name medications. Before these programs and discount cards are considered, the pharmacist should review the patient's medication regimen, because expensive brand name medications can often be converted to generic equivalents or to other drug classes that have generics available.

California pharmacists have another cost-saving measure to offer Medicare patients. In 1999, SB 393 was passed in California, which enables Medicare recipients to obtain their prescription drugs at a cost no higher than the Medi-Cal price for those drugs. Subsequent legislation enacted in 2002 has made these provisions permanent. Medicare patients must present their Medicare card to the pharmacy to be eligible for the discount.

Table 1. Cost Saving Strategies

• Ensure that the patient has maximized their reimbursement potential.
• Maximize generic drug use.
• Consider lower cost brand name medications.
• Consider tablet spitting where appropriate.
• Utilize all available assistance programs – Pharmaceutical industry-sponsored patient assistance programs – Pharmaceutical industry-sponsored discount cards – Offer Medicare patients the Medi-Cal contracted price of the drug. (SB 393)
• Determine whether mail-order provides cost-savings
• Patients should periodically review all medications with the prescribing health care provider and ask, "Is this drug necessary to maintain my health?"

Case Discussions

Although Mr. Brown (Case I) is a retired accountant and his wife is a part-time teacher, their only health insurance is Medicare parts A and B, which do not include an outpatient prescription drug benefit. Therefore, the Browns pay for their entire drug bill out of their own budget. Although Mr. Brown is the only one that takes prescription medications, his wife's nonprescription and herbal medications factor into their drug bills. Mr. Brown's drug regimen is predominantly generic; yet, his monthly bill still remains relatively high at about $190/month. Several steps could be taken to decrease this amount. First, he has a brand-name antihypertensive medication that may be substituted with a generic, either by changing him to the tablet formulation of clonidine or by switching therapeutic classes to one that has generics, such as a beta-blocker. A beta-blocker may also be indicated for cardio-protection, because he had a heart attack several years ago. If the Catapres® is changed, the pharmacist must contact the physician for a new prescription.

The other strategy that may save Mr. Brown money is pill-splitting his cholesterol medication. Although Mevacor® recently became available generically, it may take months to years before the price falls significantly below the brand-name medication. If a medication comes in a higher strength that is twice the dose and if the price is less than double the lower

Table.2 Useful Patient Assistance Websites and Resources

http://www.benefitscheckup.org/	A free, easy-to-use service that identifies federal and state assistance programs for older Americans. BenefitsCheckUp was developed to address a concerning problem: millions of older adults are eligible for benefits, but not receiving them. Ranging from health coverage to supplemental income to help pay utility bills, there are millions of older adults who could benefit from a wide array of public programs if they knew about them and how to apply for them.
www.rxassist.org	This site is very useful. It contains information about the federal poverty level, detailed information on individual patient assistance programs (including eligibility, contact and processing information and forms that can be downloaded). This site also allows for easy searching for patient assistance programs by drug class, brand name, generic name and the company that manufactures the drug.
www.phrma.org	This site provides an annually updated patient assistance program directory and some useful links.
www.needymeds.com	This site is another catalog of available programs listed according to drug name and the manufacturer. It also has some useful references to several information resources that could be convenient to use. Overall it has a similar format to rxassist.org but it might be easier to navigate.
Rx Assist Plus	This is a useful patient-tracking device that interfaces with the Internet to quickly complete the appropriate patient assistance forms. It also has a tickler feature, which reminds the advocate to provide the patient with timely refills and re-enrollment into programs when the patient is due.

Table 3. Example of Pill-Splitting Cost Savings.			
Drug	Strength	Directions and Quantity	Cost/ month
Mevacor®	40mg	Take 1 tablet daily, #30	$124
Lipitor®	20mg	Take 1 tablet daily, #30	$101
Lipitor®	40mg	Take 1/2 tablet daily, #15	$52

strength, one can use a higher strength tablet and split it to obtain cost savings. Unfortunately, the price of Mevacor® doubles as the strength doubles. However, it may be worthwhile to switch to a lower cost brand-name drug that can be split in half for cost savings. For example, he could be switched to Lipitor® 20mg. The cost savings by switching brands and pill-splitting is illustrated in Table 3.

When considering pill-splitting as a cost-saving technique, the pharmacist must first determine if the formulation of the tablet allows for it and whether the tablet size and shape allow for even pill splitting. Second, the pharmacist must evaluate whether the patient understands the concept of pill-splitting and if he or she has the dexterity to do it. Once these factors have been taken into consideration, the pharmacist should recommend a pill-splitter and demonstrate its use. If the pharmacist is going to recommend a change in the strength of the medication in order to split tablets, the physician must be contacted for a new prescription. The total savings to Mr. Brown if both of these medication changes are made is approximately $100 per month.

Mrs. Smith (Case II) has no outpatient drug coverage and her income from Social Security and her pension total $1,100/month, or $13,200/year. Her monthly drug bill is $400. She does not qualify for Medicaid, but her income does qualify her for patient assistance programs for Vioxx® and Prilosec®. Her Prozac® and her Coumadin® have generic equivalents. After these switches are made and the patient and doctor agree to complete the paperwork necessary for patient assistance programs on a quarterly basis, her new monthly drug bill is $100.

Because her Coumadin® was changed to the generic equivalent it is important for the pharmacist to explain to the patient that she may require a blood test to check her INR after she has been on the generic warfarin for a week or 10 days. Inform the patient to contact her anticoagulation provider to let him or her know that she has switched to the generic version.

After discussion with her pharmacist, Mrs. Smith realizes that she is doubling up on some of her medications with non-prescription products that she purchases at the pharmacy. Some of these over-the-counter medications can interfere with her prescription medications. She agrees to stop taking the non-prescription medications, which results in further cost savings.

As a retired schoolteacher Mrs. Young (Case III) may have a retiree benefit and therefore may have prescription drug coverage for her new drug, Aricept®. Because the drug is a brand name medication, she will most likely pay a co-pay ranging between $10-$30/month. Although there are no generic equivalents available for this class of medications, one possible cost-savings strategy is to purchase it through her insurance company's mail-order pharmacy. Many insurance companies offer a mail-order service for prescriptions allowing patients to obtain a 90-day supply of medication for the equivalent of one or two monthly co-payments, which saves one to two co-payment amounts every 90 days. If the patient has a high co-pay, these savings can be substantial. Mail-order may be considered for those medications that the patient takes chronically. Explain to the patient that if they choose to use a mail-order pharmacy to be sure that the company provides a telephone number that allows them to talk to a pharmacist. It is also important to let the mail-order pharmacy know about all of the medications they take, even if they are not filled by the mail-order pharmacy so that the pharmacy can perform drug utilization review.

Conclusion

Unfortunately, until there is a Medicare outpatient prescription drug benefit, older adults are at risk for non-adherence due to the cost of prescription medications. The pharmacist can identify these non-adherence issues and help solve these problems as a member of the healthcare team and as an advocate for the patient.

COUNSELING TIPS

- Explain health care coverage and prescription drug benefits available to older adults.
- Ask patients if their prescription costs are an issue or if their benefit has changed.
- Look for signs of non-adherence (refill dates that are extended, patients not refilling medications and no substitutes are on file, patients only getting partial fills of medications, inquiries about OTC alternatives to prescription drugs, repeated inquiries for generic alternatives to brand name medications).
- Ask the patient what they are realistically able to budget for prescription medications and what their income level is to determine eligibility for assistance programs.

NATIONAL TELEPHONE NUMBERS AND WEB SITES FOR COMMUNITY-BASED SERVICES

Senior Centers and Aging Network Services

Administration on Aging	(202) 619-7501	
National Association of State Units of Aging	(202) 898-2578	

Continuum of Services

Eldercare Locater	(800) 677-1116	www.ageinfo.org/elderloc/elderlo.html

Specific Senior Services and Specific Diseases

ABA Commission of Legal Problems of the Elderly	(202) 662-8690	www.abanet.org
Assisted Living Federation of America	(703) 691-8100	www.alfa.org
National Academy of Elder Law Attorneys	(520) 881-4005	www.naela.org
National Alliance for the Mentally Ill	(800) 950-6264	www.nami.org
National Association of Home Care	(202) 547-7424	www.nahc.org
National Hospice Foundation	(800) 658-8898	www.nho.org
American Pain Society		www.ampainsoc.org
Alzheimer's Association	(800) 272-3900	www.alz.org
American Cancer Society	(800) 227-2345	www.cancer.org
American Diabetes Association	(800) 324-2383	www.diabetes.org
American Heart Association	(800) 242-8721	www.americanheart.org
American Parkinson's Disease Association	(800) 223-2732	www.the-health-pages.com/resources/apda
Arthritis Foundation	(800) 283-7800	www.arthritis.org

Drug Therapy Considerations in Older Adults

A Continuing Education Program for California Pharmacists

Universal Program #005-000-03-003-H01 • 3 Contact Hours (0.3 CEU)

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TEST QUESTIONS

1. Which of the following is an indicator of polymedicine?
   a. the use of two medications to treat hypertension
   b. an elderly patient who is taking seven medications
   c. the use of four or more medications on an as-needed basis
   d. the use of a prescription medication with no accompanying diagnosis

2. Which of the following factors is the most common cause of drug-induced hospitalization in the elderly?
   a. adverse drug reactions
   b. use of nonprescription medications
   c. dispensing of incorrect medications by pharmacists
   d. multiple prescribers, each prescribing independently

3. Older adults are more likely to be nonadherent with medication regimens than younger adults, because the elderly person:
   a. has impaired vision and hearing
   b. is unable to remember instructions
   c. takes more medications than younger patients
   d. refuses to follow proper instructions for taking prescriptions

4 Which of the following can change, altering the distribution of drugs in the elderly?
   a. total body water
   b. serum protein concentrations
   c. total body fat
   d. all of the above

5. Renal function decreases significantly with aging, which necessitates a dosage decrease for those agents that are renally eliminated.
   a. True
   b. False

6. Which of the following statements is false with respect to physiological changes in the elderly patient:
   a. total body weight generally declines
   b. a_1-acid glycoprotein concentrations increase
   c. serum albumin concentrations increase
   d. renal function progressively declines

7. Which of the following statements is true regarding drug action in the aged:
   a. patients may become more sensitive to certain medications
   b. patients may become less sensitive to certain medications
   c. dizziness, sedation and confusion are common side effects
   d. they are more prone to experience orthostatic hypotension
   e. all of the above

8. Medications with significant anticholinergic effects can worsen
   a. mental confusion
   b. urinary retention
   c. constipation
   d. all of the above

9. Nationally published treatment guidelines tailor therapy for each individual.
   a. True
   b. False

10. A patient with a history of a recent fall and complaints of difficulty with balance should be evaluated to see if which of the following agent(s) is (are) prescribed:
    a. diazepam
    b. ascorbic acid
    c. aspirin
    d. all of the above

11. The most frequently diagnosed dementia in the U.S. is:
    a. Lewy Body dementia
    b. Alzheimer's Disease
    c. frontotemporal dementia
    d. pseudodementia

12. Alzheimer's disease may be treated with:
    a. anticholinergic drugs
    b. cholinergic drugs
    c. antispasmodic drugs
    d. antidepressant drugs

13. Because elderly patients are more sensitive to drugs, response to antidepressant therapy occurs earlier (e.g., sooner than 4-6 weeks of drug therapy) than in younger patients.
    a. True
    b. False

14. The following are all reasonable choices for the treatment of depression in an elderly patient, except:
    a. paroxetine
    b. amitriptyline
    c. sertraline
    d. buproprion
    e. venlafaxine

15. Orthostatic hypotension is a significant side effect commonly associated with which of the following antidepressants:
    a. imipramine
    b. trazadone
    c. sertraline
    d. doxepin
    e. a, b, and c above
    f. a, b, and d above

16. Which of the following medication regimens should be recommended first line for moderate osteoarthritis pain?
    a. nonsteroidal given routinely
    b. nonsteroidal given on an as-needed basis
    c. acetaminophen given on as-needed basis
    d. acetaminophen given routinely
    e. a low dose opioid given routinely

17. Which of the following is not a diagnostic characteristic of osteoarthritis?
    a. bony enlargements
    b. severe inflammation
    c. decreased cartilage on x-ray
    d. morning stiffness

18. Opioids should be avoided in the treatment of moderate to severe osteoarthritis, because of their potential for addiction at therapeutic doses.
    a. True
    b. False

19. Of the following diabetes medications, which one is more likely to cause hypoglycemia?
    a. glyburide
    b. glipizide
    c. metformin
    d. rosiglitazone
    e. acarbose

20. If a person is on a diabetes regimen that can cause hypoglycemia, it is important for that person to self-monitor their blood glucose.
    a. True
    b. False

21. Diphenhydramine should be avoided in the elderly, because it can cause:
    a. excessive sedation and cognitive impairment
    b. dry mouth
    c. constipation
    d. all of the above

22. Which of the following vitamins can be toxic at high doses?
    a. vitamin B complex
    b. vitamin E
    c. vitamin A
    d. vitamin C

23. Medicare+Choice plans are offered in select states and counties and may offer prescription drug coverage as well as other benefits not covered by Medicare.
    a. True
    b. False

24. Pharmaceutical industry-sponsored patient assistance programs provide free brand name medications to all Medicare-eligible patients.
    a. True
    b. False

25. When counseling elderly patients about medications, the pharmacist should:
    a. discuss very detailed and extensive information about any possible adverse effect or drug interaction
    b. explain the information quickly to ensure that all medications are covered
    c. talk very loudly to be heard above the background noise in the pharmacy
    d. provide written information as a supplement to verbal instructions

HEALTH NOTES

Drug Therapy Consideration in Older Adults

This issue of HEALTH NOTES is a collaborative effort of the California State Board of Pharmacy and the School of Pharmacy, University of California, San Francisco

The UCSF School of Pharmacy
Center for Consumer Self Care
"Helping People Help Themselves"

The Center for Consumer Self Care is an emerging collaborative center whose mission is to ensure optimal and responsible use of medication and dietary supplements by individuals and the public at large. The Center will accomplish its mission through the following program cores: Consumer Education, Research, Professional Education and Public Policy.

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References for this issue of Health Notes are available for download from the board's website (www.pharmacy.ca.gov), or upon written request from the California State Board of Pharmacy. Copies of this issue may also be downloaded from the UCSF CPE website (pharmacy.ucsf.edu; click on Lifelong Learning, then Continuing Professional Education.)

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The Script

BE AWARE & TAKE CARE:
Talk to your pharmacist!

The Script

CALIFORNIA BOARD OF PHARMACY JULY 2011

Update on Resubmission of Pharmacists' Fingerprints before License Renewal

Pharmacist "Request for Live Scan Service" form is now online

The previous issue of *The Script* addressed new requirements of the California Code of Regulations section 1702, which requires all California-licensed pharmacists who have not previously submitted fingerprints to the Board or for whom an electronic record of their fingerprints does not exist, to be electronically fingerprinted for the Board of Pharmacy via Live Scan **before** applying for license renewal.

These requirements will principally affect pharmacists licensed in California before 2001, and ***the Board will notify those affected in a separate mailing at least 90 days before renewal.***

For renewal of Board–issued pharmacist licenses, section 1702 also specifies that as a condition of renewal, the pharmacist must:

- disclose on the renewal form any arrest or conviction since the pharmacist's last renewal;
- pay the actual cost of compliance with the submission of fingerprints (This is paid at the Live Scan site, not to the Board.); and
- retain proof of compliance for at least three years.

The Board now has the appropriate "Request for Live Scan Service" form for pharmacists online at *www.pharmacy.ca.gov/licensing/rph_license_renewal.shtml*. Please use this form if you are being fingerprinted for the first time or resubmitting prints. For fingerprinting, take this form to any Live Scan location. A list of locations may be found at *www.ag.ca.gov/fingerprints/publications/contact.php*.

Since Live Scan service is available only in California, out-of-state California licensees, who are notified that fingerprints are required, must have their prints inked onto fingerprint cards. The cards must be requested from *www.pharmacy.ca.gov/pharmacy/pubs_request.asp#fp_card*. Then send the newly fingerprinted cards to the Board, where they will be scanned into the Department of Justice's electronic fingerprint database.

Failure to comply with the above requirements will result in an application for renewal being considered incomplete.

Pharmacy and Wholesaler Self-Assessment Forms Newly Revised

The July 1 deadline for pharmacies and wholesalers to perform their biennial (every odd-numbered year) self-assessment has arrived. These reporting requirements are contained in Title 16, California Code of Regulations section 1715 (for pharmacies) and section 1784 (wholesalers). New requirements have been added to the self-assessment forms to confirm whether Board-licensed facilities are in compliance with section 4013 of the Business and Professions Code, which requires all Board-licensed facilities to have joined the Board's e-mail notification list by July 1, 2011. Additionally, that section requires a facility to join the list within 60 days of obtaining a license or at the time of license renewal and update its e-mail address with the Board within 30 days of a change in the facility's e-mail address.

Whether using the current form or new amended form, self-assessments must be completed by July 1, 2011

*See **Self-Assessment Forms**, Page 15*

In This Issue

Update on Resubmission of RPH Fingerprints .....Front Page
PHY and WLS Self-Assessment Forms Revised .....Front Page
President's Message .....Page 2
Medication Error Issues .....Page 3
Safeguards to Implement with 'High Alert' Medications Page 4
Prescription for Improving Patient Safety .....Page 5
FDA Drug Safety Communication .....Page 6
Reminder to Join the Board's Email Notification List...Page 6
Changes in Pharmacy Law for 2011 .....Page 7
Regulation Update .....Page 9
Dispensing Internet Prescriptions can be very costly .Page 11
Rx for Good Practice .....Page 14
Nonprescription Sale of Syringes in Pharmacies .....Page 17
What to Look for on Tamper-Resistant Rx Forms .....Page 20
Electronic Prescribing of Controlled Substances in CA Page 21
DEA Interim Final Rule on Electronic Prescribing .....Page 22
Changes to Prescription Data Submission to CURES ...Page 25
Changes to the CPJE Content Outline .....Page 25
Board Honors Pharmacists Registered for 50 Years ...Page 26
Changes in the Board .....Page 26
CE Hours Awarded by Board .....Page 27
Explanation of Disciplinary Terms .....Page 28
Disciplinary Actions .....Page 28

President's Message

By Stanley C. Weisser, R.Ph.
President, Board of Pharmacy

At the beginning of every year, new laws become effective. This issue of *The Script* contains a summary of many of the new laws for 2011.

One of this year's new regulations is particularly significant for pharmacy patients and for pharmacies themselves. California became the first state to adopt requirements for standardized, patient-centered prescription drug labels on all prescription medications dispensed to patients in California (California Code of Regulations section 1707.5). Prescription container labels are often the patient's primary source of information, so it was vitally important to ensure that this information is consistently presented, easy to read, and easily found on the label.

Now, six months after implementation, many California pharmacies are providing such patient-centered prescription labels on their containers, and I encourage those few who are not yet compliant to complete the transition to the new labels as soon as possible. The requirement took effect January 1, 2011, but the Board recognizes that some pharmacies may need a bit more time to become fully compliant. For the first few months of 2011, Board inspections have focused on compliance through education.

Another important component of section 1707.5 is the requirement for the pharmacy to provide interpretive services for patients with limited English skills. The Board believes that many pharmacies will provide such services by telephone. During development of the requirements of 1707.5, the origin of this particular requirement came from the pharmacy profession itself: the California Pharmacists Association, the California Retailers Association, and the National Association of Chain Drug Stores.

Because of the importance of section 1707.5 to the public, the Board thanks the many consumers and pharmacy professionals who worked so long on finalizing the section's requirements. Over the coming years, the Board will continue to review the requirements of this section.

The Board is currently working to develop new Notice to Consumer posters, advising patients of the new labeling requirements and availability of interpretive services. However, it is not the Board's intent to add two more posters; instead, the Board plans to redesign new posters after integrating the new information into the current posters.

Also, in this issue on pages 3 and 4 are updates on medication error statistics for complaints filed with the Board and closed during 2009/10, with case histories and fines information, and error-producing drug names.

If your pharmacy has not joined the Board's e-mail notification list, as required by Business and Professions Code section 4013, I strongly encourage you to do so at "Sign up for Receiving E-mail Alerts" on the Board's Web site. This is now the Board's primary way of keeping everyone apprised of law changes, emergency information, drug recalls, the newsletter's availability, Board meetings, and much more.

I also encourage everyone to attend a Board meeting when it is in your area. Attending these meetings will not only provide continuing education credit, but also introduce you to Board operations and procedures and help you to become aware of emerging pharmacy issues, both in California and in the nation. By understanding how all the policy-making is done, you will be better prepared to do your part in improving the profession and producing better health outcomes. Board meeting information is available on the Board's Web site.

One final reminder, patient consultation has been a California requirement since the early 1990's. Yet in many pharmacies, patient consultation is not given the appropriate priority. As President of the Board, I want to remind all pharmacists and pharmacies of the importance that the Board places on patient consultation. Patient consultation has many significant benefits, including its potential to minimize or avoid medication errors, to screen for drug interactions, and to ensure compliance with therapy. Patient consultation is a crucial part of the clinical role of the pharmacist. In support of this role, California law places a specific mandatory obligation on each pharmacist (outside of inpatient, inmate, or patient discharge settings) to perform a patient consultation whenever: a prescription drug has not been previously dispensed to the patient by the pharmacy; a prescription drug has not been previously dispensed to the patient by the pharmacy in the same dosage form, strength, or with the same written directions; the patient requests a consultation; or the pharmacist, in the exercise of professional judgment, deems it warranted. This obligation applies *to the pharmacist*. The pharmacist must initiate consultation *unless and until* the patient or patient's agent refuses. It shall not be considered sufficient compliance with this obligation for consultation screenings to be performed by staff or by use of check-off boxes.

Medication Error Issues

One of the Board's primary goals is to elevate the California pharmacist's awareness of how to prevent and eliminate medication errors. In future editions of *The Script*, the Board will feature articles on medication errors. These articles will include sample cases that the Board has recently investigated and the processes that leading experts recommend for error prevention.

During 2009 and 2010, the top medication errors investigated by the Board continue to be the wrong drug being dispensed, followed by labeling errors and dispensing drugs to the wrong patient.

Medication errors reported to the Board originate from a number of different processes. Dispensing the wrong drug occurs when the pharmacist dispenses a sound/look-alike drug instead of the prescribed drug and when the pharmacist misreads the prescriber's direction for use. Patients also are dispensed the wrong drug when the properly filled, labeled and checked medication is provided to another patient at the counter, a patient often with a similar name. The Board strongly advises pharmacies to ensure a second check by checking the patient's address or birth date.

Pharmacists are provided all sorts of information intended to be helpful in reducing dispensing errors, but often it is easier to understand how some of these errors occur, and more importantly, how to prevent them by reviewing actual case files. The cases outlined below are medication errors investigated by the Board.

Case 1. A pharmacist erroneously furnished a prescription for Provigil 200mg #4, labeled for James C., to Jennifer C. (Fine $500)

Case 2. A random audit in the will-call area of a pharmacy revealed that approximately half of the verified prescriptions contained medication that did not correspond to the printed information on the container. (Fine $500)

Case 3. A pharmacist dispensed Duragesic 100mcg/hr instead of Duragesic 25mcg/hr as ordered on the prescription. (Fine $750)

Case 4. A pharmacist dispensed warfarin 5mg with incorrect dosing instructions to take every 12 hours instead of every 24 hours. (Fine $1,500)

Case 5. A pharmacist dispensed to a patient Lovenox 80mg prefilled single dose syringes, but instructed the patient to use the same needle to inject himself daily for two days. (Fine $2,500)

Case 6. A hospital pharmacy dispensed Recombivax-HB 5mcg vials (Hepatitis B Vaccine) instead of the prescribed Engerix-B 10mcg (Hepatitis B Vaccine), requiring the 50 infants who received the wrong drug to be identified and reinoculated with the correct vaccine. (Fine $5,000)

The following charts reflect the type and percent of citations related to California prescription errors and look/sound-alike drug errors from July 1, 2009 to June 30, 2010.

MEDICATION ERROR DATA
All pharmacy settings July 1, 2009 – July 1, 2011

	Prescribed	Dispensed
Common Look-alike Sound-alike Errors	Aclaro	Aldara
	Biaxin	Robaxin
	Chlorzoxazone	Chlorothiazide
	Cyclophosphamide	Cyclosporine
	Elocan	Eletone
	Hydralazine	Hydroxyzine
	Kaopectate	Kayexalate
	Lamisil	Lamictal
	Lipitor	Lexapro
	Lorazepam	Alprazolam
	Oxycontin	Oxycodone
	Plavix	Protonix
	Protonix	Pravastatin
	Repliva	Reclipsen
	Risperdal	Requip
	Ritalin	Dilantin
	Seroquel	Serzone
	Sulfadiazine	Sulfasalazine
	Valium	Vicodin
	Zyrtec	Zyprexa

*See **Medication Error Issues**, Page 4*

NOTE: The Board of Pharmacy has begun developing short informational videos for consumers. The first of these videos, "Purchasing Drugs from the Internet" and "Avoiding Medication Errors" can be viewed at www.pharmacy.ca.gov.

Medication Error Issues

Continued from Page 3

PRESCRIPTION ERRORS DATA
All pharmacy settings July 1, 2009 – June 30, 2010

Medication Error Category	Number	Percent of Total Citations
Wrong Drug	215	34%
Wrong Strength	52	8%
Wrong Instructions	48	8%
Wrong Patient	80	13%
Wrong Medication Quantity	31	5%
Labeling Error	128	20%
Compounding/Preparation Error	3	.5%
Refill Errors (frequency, timeliness)	2	.5%
Other	67	11%
Total # Citations for errors (may have more than one category listed)	626	

The Institute for Safe Medication Practices (ISMP) is dedicated to medication error prevention and works directly with the pharmaceutical industry to prevent errors, providing the following information online:

"Sound/Look-Alike Drug Names"
***www.ismp.org/tools/confuseddrugnames.pdf*.**

ISMP also has a list of such drugs where "tall man" (upper case) letters have been used to draw attention to the dissimilarities of similar drugs and to help distinguish between them.

"Look-Alike Drug Name Sets with Recommended Tall Man Letters"
www.ismp.org/tools/tallmanletters.pdf.

"Error-Prone Abbreviations, Symbols, and Dose Designations"
***www.ismp.org/tools/errorproneabbreviations.pdf*.**

Safeguards to Implement with 'High Alert' Medications

This article was originally prepared by the Institute for Safe Medication Practices (ISMP) for the Oregon State Board of Pharmacy newsletter and is printed here with permission. ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. ISMP is a FDA Med-Watch partner. Call 1-800-FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at ***www.ismp.org****. ISMP address: 200 Lakeside Dr., Suite 200, Horsham, PA 19044. Phone 215/947-7797. E-mail:* ***ismpinfo@ismp.org****.*

While most medications have a large margin of safety, a small number of drugs have a high risk of causing injury when they are misused. ISMP calls these "high-alert medications" to draw attention to this characteristic so that all involved in their use will treat them with the care and respect that they require. Errors may or may not be more common with these drugs than with the use of any others; however, the consequences of the errors are more devastating. For this reason, special considerations are required. These medications often need to be packaged differently, stored differently, prescribed differently, and administered differently than others. Examples of high-alert medications in community pharmacy include warfarin, insulin,

See ***Safeguards****, Page 5*

Safeguards

Continued from Page 4

methotrexate, and fentanyl patches. Whenever possible, "forcing functions" — methods that make it impossible for the drug to be given in a potentially lethal manner — should be developed and instituted. Forcing functions are procedures that create a "hard stop" during a process to help ensure that important information is provided before proceeding. For example, a pharmacy computer system that prevents overriding selected high-alert messages without a notation (e.g., patient-specific indication must be entered if high-alert medication selected) is a forcing function.

An independent double-check of a high-alert medication is a procedure in which two pharmacists, alone and apart from each other, separately check each component of dispensing and verifying the high-alert medication, then compare results before giving it to the patient to self-administer. While technological solutions such as bar coding systems have great potential to detect human error, manual redundancies such as independent double checks still play an important role in error detection. Studies show that manual redundancies detect about 95% of errors. Independent double checks serve two purposes: to prevent a serious error from reaching a patient; and just as important, to bring attention to the systems that allow the introduction of human error. In retail pharmacies, with only one pharmacist per shift, the independent double check can be performed via a "will call" bag check or by another pharmacist at the beginning of the next shift. If the medication has been dispensed, serious harm can be avoided or mitigated if the error is discovered within one or two doses.

The following information must be verified during the double-check process:

Comparison to prescriber's order:

- Is this the prescribed drug?
- Is this the prescribed dose/strength/rate and route of administration?
- Is this the right patient (use two patient identifiers)?
- Is this the prescribed frequency?

Additional cognitive checks:

- Does the drug's indication correspond to the patient's diagnosis?
- Is this the right drug formulation?
- Are dose calculations correct?
- Is the dosing formula (e.g., mg/kg) used to derive the final dose correct?
- Is the prescribed dose/frequency/timing appropriate for this patient?
- Is the route of administration safe and proper for this patient?
- Has patient been educated on appropriate monitoring?

Prescription for Improving Patient Safety: Addressing Medication Errors

The following are recommendations that were provided by The Medication Errors Panel, established pursuant to California Senate Concurrent Resolution 49.

Communication Improvements, improving the quality and accuracy of communications between prescribers, pharmacists and patients.

1. Improve the legibility of handwritten prescriptions, and establish a deadline for prescribers and pharmacies to use electronic prescribing.
2. Require that the intended use of the medication be included on all prescriptions and require that the intended use be included on the medication label unless disapproved by the prescriber or patient.
3. Improve access to and awareness of language translation services by pharmacists at community pharmacies and encourage consumers to seek out pharmacists who speak their language and understand their cultural needs.
4. Promote development and use of medication packaging, dispensing systems, prescription container labels and written supplemental materials that effectively communicate to consumers accurate, easy-to-understand information about the risks and benefits of their medication, and how and where to obtain medication consultation from a pharmacist.

Consumer Education, increasing consumer awareness regarding the proper use—and dangers of misuse—of prescription and over-the-counter medications.

*See **Improving Patient Safety**, Page 16*

FDA Drug Safety Communication: Medication errors resulting from confusion between risperidone (Risperdal) and ropinirole (Requip)

On June 13, 2011, the FDA published a statement warning about potentially dangerous errors resulting when the drugs risperidone (generic for Risperdal) and ropinirole (generic for Requip) are confused. The agency received 226 reports of patients accidentally receiving one drug instead of the other, and five patients required hospitalization. One patient who died was given Risperdal instead of Requip for a month before the error was discovered and the correct medication given, but it is unclear whether the error was responsible for the death.

The FDA determined there are several causes of confusion between the two products: similarities of drug names; overlapping product characteristics; proximity in pharmacy stocking, and poor or illegible handwriting.

The FDA noted in the statement that:

- the brand and generic names of each drug are similar; that labeling and packaging on the drugs are similar; and that drug strengths, dosage forms, and dosing intervals may overlap;
- as a precaution, patients who take either drug should check the appearance and labeled name of the drug they receive at the pharmacy, and confirm with a pharmacist the drug's use to be sure the correct medication was dispensed;
- healthcare professionals should clearly print the name of the drug on a written prescription, and spell it out when phoning one in. They should also be sure to discuss the purpose of the treatment with the patient; and
- pharmacists should confirm with the patient which drug should be dispensed

The FDA also requested drug makers to provide differentiating characteristics for each drug—such as "tall man" lettering of generic names, like risperiDONE and rOPINIRole—and distinctive font size and type, layout, and coloring of packaging—as additional preventive measures against confusion.

Reminder to All Board-Licensed Facilities to Join the Board's E-mail Notification List — It's Mandatory (And individuals may want to join, too.)

If your facility is not yet on the Board's e-mail notification list, this is a reminder pursuant to Business and Professions Code section 4013, that all Board-licensed facilities were required to join the Board's e-mail notification list by July 1, 2011. New facilities must join within 60 days of obtaining a license or at the time of license renewal. Facilities are also required to update their e-mail address with the Board within 30 days of any e-mail address change.

Further, section 4013 was **amended** to allow an owner of two or more board-licensed facilities to subscribe to the Board's e-mail notification list if the owner maintains an electronic system within all of its licensed facilities that, upon receipt of an e-mail notification from the Board, immediately transmits that

notification to all of its licensed facilities. If the owner wishes to comply with the mandate by using such an electronic notice system, the owner must register the electronic notice system with the Board.

Additionally, the Board strongly encourages individual licensees to join the list, since it is now the primary means for disseminating important information from the Board.

To join the list:

- Go to the Board's Web site, ***http://www.pharmacy.ca.gov***
- On the left side of the screen, click on the circled letter image with the words, "Sign up to Receive E-mail Alerts."
- Scroll down the page and check the box next to "Board of Pharmacy – E-mail Notification List."
- Scroll down again and note that the "Subscribe" button is already selected.
- Enter your e-mail address, follow the remaining instruction, and we'll do the rest!

Note: If you or your facility joined the e-mail notification list prior to November 17, 2009, you will need to join again, due to the Board's upgrading of the software for collecting e-mail addresses.

Changes in Pharmacy Law for 2011

The Senate and Assembly bills listed in this article were enacted in 2010, and unless otherwise specified, took effect January 1, 2011. The new and amended Business and Professions Code (B&PC), Health and Safety Code (H&SC), and Government Code laws are paraphrased or summarized below, but for pertinent information that is not included in the summaries, you are strongly urged to review the exact language at ***www.pharmacy.ca.gov/laws_regs/new_laws.pdf***.

SB 1172 (Negrete McLeod), Chapter 517, Statutes of 2010

B&PC 315.2—Added to require the Board to order a board licensee to cease practice if the licensee tests positive for any substance that is prohibited under the terms of the licensee's probation or diversion program. A cease practice order under this section shall not constitute disciplinary action.

B&PC 315.4—Added to allow the Board to adopt regulations to order a licensee on probation or in a diversion program to cease practice for major violations and when the Board orders a licensee to undergo a clinical diagnostic evaluation. A cease practice order under this section shall not constitute disciplinary action.

SB 1489 (Committee on Business, Professions and Economic Development, Healing Arts) Chapter 653, Statutes of 2010

Board Licensed Facilities Required to Join Board's E-mail Notification List B&PC 4013—This section, requiring all board-licensed facilities to join the Board's e-mail notification list, was **amended** to allow an owner of two or more board-licensed facilities to subscribe to the Board's e-mail notification list if the owner maintains an electronic system within all of its licensed facilities that, upon receipt of an e-mail notification from the Board, immediately transmits that notification to all of its licensed facilities. If the owner wishes to comply with the mandate by using such an electronic notice system, the owner must register the electronic notice system with the Board by July 1, 2011 or within 60 days of initial licensure, whichever is later, and must update its e-mail address with the Board's e-mail notification list within 30 days of an e-mail address change.

Several sections, **B&PC 4017, 4028, 4037, 4052.3, 4059, 4119, 4127.1, 4169, and 4181** were **amended** to change the reference to "State Department of Health Services" to "State Department of Public Health."

Sections **4425** and **4426** were amended to change the reference to "State Department of Health Services" to "State Department of Health Care Services."

Standardized, Patient-Centered Prescription Labels; Requirements; Exceptions
B&PC 4076.5—Amended to allow the Board to exempt from its patient-centered prescription drug label regulations prescriptions dispensed to a patient in a health facility (as defined in section 1250 of the Health and Safety Code), if the prescriptions are administered by a licensed health care professional. The Board may also exempt prescription drug labels from the Board's standardized labeling requirements if all of the following apply:

- The drugs are dispensed by a JCAHO-accredited home infusion or specialty pharmacy;
- The patient receives health-professional-directed education prior to the beginning of therapy by a nurse or pharmacist;
- The patient receives weekly or more frequent followup contacts by a nurse or pharmacist;
- Care is provided under a formal plan of care based upon a physician and surgeon's orders; and
- Home infusion and specialty therapies include parenteral therapy or other forms of administration that require regular laboratory and patient monitoring.

Veterinary Food-Animal Drug Retailer License Required: Approved Designated Representative-in-Charge; Temporary License; Persons Authorized in Storage Area
B&PC 4196—Requires every veterinary food-animal drug retailer to be supervised or managed by a designated representative-in-charge, and subsection (d) was **amended** to require the Board's approval of every veterinary food-animal drug retailer's designated representative-in-charge. Subsection (e) was **added** to detail the procedures

*See **Changes in Pharmacy Law**, Page 8*

Changes in Pharmacy Law

Continued from Page 7

for obtaining Board-approval for proposed designated representatives-in-charge.

Multiple Failures of License Examination; Additional Education Requirements
B&PC 4200.1—Requires applicants who have failed both the North American Pharmacist Licensure Examination and the California Practice Standards and Jurisprudence Examination four times to obtain a minimum of 16 additional semester units of Board-approved pharmacy education within 12 months of the date of his or her application for reexamination. Existing language requiring data collection for the Joint Committee on Boards, Commissions, and Consumer Protection was deleted.

AB 1414 (Hill), Chapter 76, Statutes of 2010

Schedule II Controlled Substances
H&SC 11055—Amended to remove apomorphine from Schedule II.

AB 1659 (Huber), Chapter 666, Statutes of 2010

Sunset Review
Government Code 9147.7 Article 7.5, Chapter 1.5 of Part 1 of Division 2 of Title 2—Added to create the Joint Sunset Review Committee to identify and eliminate waste, duplication, and inefficiency in government agencies and to conduct a comprehensive analysis of every "eligible agency," as defined, to determine if the agency is still necessary and cost effective. This section defines an "eligible agency" as an entity of state government, however denominated, for which a date for repeal has been established by statute on or after January 1, 2011. This section also requires each eligible agency scheduled for repeal to submit a report to the committee containing specified information. The committee is required to take public testimony and evaluate the eligible agency prior to the date the agency is scheduled to be repealed, and requires that an eligible agency be eliminated unless the Legislature enacts a law to extend, consolidate, or reorganize the agency. This section specifies the composition of the committee, which will be appointed by the Senate Committee on Rules and the Speaker of the Assembly, and certain aspects of its operating procedure. Also see AB 2130.

AB 1701 (Chesbro), Chapter 667, Statutes of 2010

Furnishing of Hypodermic Needles and Syringes without Prescription
B&PC 4145—Amended to extend to December 31, 2018, the time period in which pharmacists can furnish or sell 10 or fewer hypodermic needles or syringes at any one time to a person 18 or older for human use without a prescription, if the pharmacist is registered with the Disease Prevention Demonstration Project.

AB 2104 (Hayashi), Chapter 374, Statutes of 2010

Executive Officer; Records; Revenue
B&PC 4003—Amended to require the Department of Consumer Affairs Director's approval of the hiring of a Board-appointed executive officer.

AB 2130 (Huber, Professions and Vocations), Chapter 670, Statutes of 2010

Sunset Review
Government Code 9148.52 and 9148.52—Is a partner bill with AB 1659 and is **amended** to abolish the Joint Committee on Boards, Commission, and Consumer Protection and establish the Joint Sunset Review Committee. The committee shall review all eligible agencies and report to the public and the Legislature whether the reviewed agency should be terminated or continued and whether the agency's functions should be revised or consolidated with those of another agency. The report shall include the committee's recommendations for improving the effectiveness and efficiency of the reviewed agency.

This bill also repealed section 101.1 of the Business and Professions Code, which authorized the Department of Consumer affairs to manage a board's regulatory program as a "bureau" if a board failed to pass legislative or "sunset" review.

AB 2699 (Bass), Chapter 270, Statutes of 2010

Sponsored Events; Requirements for Participation
B&PC 901—Added to define, for purposes of this section, (1) "board" as a healing arts board that is responsible for the licensure or regulation of health care practitioners; (2) "health care practitioner" as an individual who engages in acts that are subject to licensure and regulation; and (3) "sponsored event," as an event not to exceed 10 calendar days, sponsored by a nonprofit organization, administered by either a sponsoring entity or a local government, or both, through which health care is provided without compensation to the health care practitioner. Prior to providing services as part of a "sponsored event" and after the board adopts implementing regulations, the health care practitioner must obtain authorization from the board to participate in such sponsored events and meet all other requirements including a contract of liability insurance that covers specific entities and its participants.

Regulation Update

The following regulation changes to Division 17, Title 16 of the California Code of Regulations are in effect:

Pharmacist Renewal Requirements
1702—Added to require pharmacists who have not previously submitted fingerprints to the Board as a condition of licensure or for whom no electronic fingerprint record exists with the Department of Justice's criminal offender database, to submit electronic fingerprints to the Board by their license renewal date. The Board will notify affected licensees when implementation of the regulation begins. Effective 12/07/2010.

Patient-Centered Labels on Prescription Containers
1707.5—Added to specify requirements of a standardized patient-centered prescription drug label. Effective 01/1/2011.

Dishonest Conduct During Examination
1721—Amended to extend to three years the amount of time required before an individual, who has engaged in dishonest conduct during the pharmacist examination, can retake the examination. Effective 09/17/2010.

Confidentiality of Exam Questions
1723.1—Amended to direct that an applicant for a board-issued license, who removes exam information from the examination room or conveys exam information to others, will not be allowed to take the examination for three years, must surrender his or her intern license, and may not have a pharmacy technician license until eligible to take the examination. Effective 09/17/2010.

Compounding

Compounding Unapproved Drugs for Prescriber Office Use
1716.1—The provisions of this section are now included within other sections including 1735 and 1735.2. Effective 07/06/2010.

Record Requirements—Compounding for Future Use
1716.2—The provisions of this section are now included in 1735.3. Effective 07/06/2010.

Compounding in Licensed Pharmacies
1735—Added to define "compounding." Effective 07/06/2010.

Definitions Related to Compounding
1735.1—Added to define "integrity," "potency," "quality," and "strength." Effective 07/06/2010.

Compounding Limitations and Requirements
1735.2—Added to detail all aspects and requirements of compounding, including the compounding of products for future use, and for completing the pharmacy self-assessment section related to compounding and sterile injectable compounding. Effective 07/06/2010.

Recordkeeping of Compounded Drug Products
1735.3—Added to detail all record requirements for each compounded drug, for acquisition, storage, and destruction of products used in compounding, sources from which drug products to be used for compounding were obtained, and certificates for drug purity. These records must be maintained for at least three years. Effective 07/06/2010.

Labeling of Compounded Drug Products
1735.4—Added to require that the labeling of the product complies with Business and Professions Code 4076 and specifies that the labeling requirements for compounded drugs must include the generic name of the principal active ingredients as well as a statement that the product is compounded. This requirement will enable the consumer to identify any potential allergies to the ingredients used. Effective 07/06/2010.

Compounding Policies and Procedures
1735.5—Added to require a compounding pharmacy to maintain a written policies and procedures manual that includes a plan for recalling compounded products that have demonstrated potential for adverse effects, maintaining, storing, calibrating, cleaning and disinfecting equipment used in compounding, and methodology for determining compounded drug's expiration date. Effective 07/06/2010.

Compounding Facilities and Equipment
1735.6—Added to require written documentation regarding the compounding facility and the storage of the equipment in accordance with the manufacturer's specifications for the calibration of any equipment used to compound drug products that require calibration or adjustment. Such calibrations must be done prior to use, and calibration records must be retained in the pharmacy. Effective 07/06/2010.

Training of Compounding Staff
1735.7—Added to require written documentation that staff has had training to do accurate compounding and that there is ongoing competency evaluation of compounding staff. Effective 07/06/2010.

Compounding Quality Assurance
1735.8—Added to require a written quality assurance plan designed to ensure the integrity, potency, quality, and labeled strength of compounded drug products and a procedure for action if any compounded drug product is found to be below required minimum standards. Effective 07/06/2010.

*See **Regulation Update**, Page 10*

Regulation Update

Continued from Page 9

Sterile Injectable Compounding

Sterile Injectable Compounding; Compounding Area
1751—Added to direct that any pharmacy engaging in compounding sterile injectable drug products shall conform to the parameters and requirements of 1735 et seq., applicable to all compounding and to 1751 et seq., applicable solely to sterile injectable compounding. A pharmacy who compounds a sterile injectable product from one or more non-sterile ingredients shall comply with the environment requirements of Business and Professions Code (B&PC) 4127.7. Effective 07/06/2010.

Sterile Injectable Recordkeeping Requirements
1751.1—Amended to renumber 1751.3 to 1751.1 and to require pharmacies that compound sterile injectable products for future use and drug products compounded from one or more non-sterile ingredients to make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber. These records must be kept for three years in a readily retrievable form. Effective 07/06/2010.

Sterile Injectable Labeling Requirements
1751.2—Amended to add the labeling requirements of the B&PC 4076 and CCR 1735.4 to the existing requirements of this section. Effective 07/06/2010.

Sterile Injectable Policies and Procedures
1751.3—Amended to renumber 1751.02 to 1751.3 and to require any pharmacy engaged in compounding sterile injectable drug products to maintain a written policy and procedure manual that includes the elements required by 1735.5, disposal of infectious materials and/or materials containing cytotoxic residues, and pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards. Effective 07/06/2010.

Facility and Equipment Standards for Sterile Compounding from Non-Sterile Ingredients
1751.4—Amended to renumber 1751.01 to 1751.4 and to require pharmacies that prepare parenteral cytotoxic agents to do so with an annually certified laminar air flow hood in accordance with the National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry or manufacturer's specifications. The certification records must be retained for at least three years. Effective 07/06/2010.

Sterile Injectable Compounding Attire
1751.5—Amended to renumber 1751.4 to 1751.5. Effective 07/06/2010.

Training of Sterile Injectable Compounding Staff, Patient, and Caregiver
1751.6—Amended to renumber 1751.5 to 1751.6. Effective 07/06/2010.

Sterile Injectable Compounding Quality Assurance and Process Validation
1751.7—Amended to require any pharmacy engaged in compounding injectable drug products to maintain, as part of its written policies and procedures, a written quality assurance plan that also includes the elements required by 1735.8. Additionally, batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures. Effective 07/06/2010.

Sterile Injectable Compounding Reference Materials
1751.8—Amended to renumber 1751.9 to 1751.8 to require any pharmacy engaged in compounding sterile injectable drug products to have current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy. Effective 07/06/2010.

For complete information, please review the exact text of these regulatory changes at ***www.pharmacy.ca.gov/laws_regs/new_laws.pdf***.

Dispensing Internet prescriptions can be very costly on many levels!

On January 1, 2001, section 4067 of the Business and Professions Code became effective, permitting the Board to issue citations involving potential fines of up to $25,000 per violation for dispensing dangerous drugs or devices on the Internet without a prescription issued pursuant to a good faith prior examination of a human or animal. For a physician and surgeon, section 2242 states that prescribing, dispensing, or furnishing dangerous drugs or devices without an appropriate prior examination and a medical indication, constitutes unprofessional conduct. Section 2242.1(a) specifically prohibits any person or entity from prescribing, dispensing, or furnishing dangerous drugs or devices on the Internet for delivery to any person in this state, without an appropriate prior examination and medical indication.

The following information, defining the "appropriate prior examination" required for Internet prescribing, is found in Section 5.12 "Internet Prescribing," in a Medical Board of California publication, "Guide to the Laws Governing the Practice of Medicine."

> *Essential* ***components of proper prescribing include performing and documenting a physical examination that includes obtaining a legitimate medical history, engaging in sufficient dialogue to form a treatment opinion, determining the risks and benefits of the drug or treatment regimen, scheduling follow-up appointments to assess therapeutic outcome and maintaining an adequate and accurate medical record before prescribing any medication for the first time. Telephone interviews, Internet questionnaires or online consultations are not appropriate or acceptable by law, and fail to meet the minimum components of an appropriate prior examination since they cannot, with any certainty, provide enough information to make a verifiable diagnosis.***

The many consequences of dispensing dangerous drugs on the Internet without valid prescriptions could include, along with substantial fines and emotional devastation, the requirement for violators to write a letter for publication, advising fellow pharmacists of these consequences. Three such letters follow:

Open Letter to My Colleagues Licensed by the California Board of Pharmacy

I am ashamed to have to write this letter and admit my stupidity, actually my extreme short sightedness caused by greed induced by promises of quick easy money. And so little money. My shame is increased not only by the relatively small amount of money I was promised and paid but also because I have been a pharmacist licensed in and by this state for almost thirty (30) years and throughout those many years I had an unblemished professional record and prided myself in the belief that I had never violated any laws or regulations related to my profession or the distribution of controlled substances.

Then in late 2006 I was contacted over the telephone by a representative of a company proposing that I fill prescriptions that would be sent to my pharmacy over the internet and very unfortunately, I agreed to do so. I was promised, over the telephone, by a faceless, smooth talker: a net profit of $5.00 for each prescription I filled (they also promised to pay all shipping charges). When I was first contacted by that persistent, persuasive and reassuring representative of "an internet prescription company," he helped lead me to the conclusion that this would be an easy way to make a little extra money with a minimum of effort. That promise of easy, extra money partially blinded me to aspects of the arrangement that were illegal as well as professional misconduct.

I knew immediately that I would have to confirm that each of the prescribing parties was a physician licensed in the state in which the prescription was written and, if I could not confirm the doctor was licensed and had a valid DEA number, I could not and would not fill a prescription from that doctor. I soon realized that the prescriptions were from doctors all over the country; but in each case I was able to verify that the prescribing doctor was licensed with valid state and DEA numbers. Under those circumstances, based upon the fact that all of the prescribers were physicians, I thought at the time that it was alright to fill the prescriptions and all that was required of me was spending the time to fill the prescription and ship it. I also realized the drugs I was shipping were primarily controlled substances but I was receiving all of the appropriate prescription forms in order to comply with the law. I was also quickly and reliably paid $5.00 plus costs for each prescription dispensed.

Obviously, I did not give the proposal enough thought before I agreed and once I started receiving and filling prescriptions, I should have paid more attention to and thought more about all the information on the prescriptions. I was repeatedly receiving prescription from the same half dozen or so doctors who were prescribing mostly very strong (and controlled) painkillers to patients in areas, even states far away from the doctor's office and address. In hindsight, I should have noticed that geographical distance, questioned whether those doctors were really even seeing or communicating with these "patients" much less properly examining them before dispensing any drugs much less those types of drugs. I never directly confirmed that there were good faith prior examinations of the patients by the prescribing doctors before I dispensed the drugs.

Honestly, I did not notice the disparity or think of the possibility that there was not a professional examination and relationship between the prescribing doctor and recipient; but, again in hindsight, the nature of most of the drugs (painkillers)

See ***Dispensing Internet Prescriptions****, Page 12*

Dispensing Internet Prescriptions

Continued from Page 11

should also have alerted me to the potential impropriety. I was so busy, especially with all these additional prescriptions to fill (another warning signal I missed then but now see in hindsight) that I just kept working as fast as I could, never imagining that I was breaking not one but many very serious federal and state laws. Now I know I could have been charged with criminal felonies in both state and federal courts!

Thankfully a representative of one of the companies I buy my drugs from who had known me a long time and correctly did not believe I would knowingly distribute any prescription much less controlled substances illegally or improperly, warned me about dealing with such internet companies. I filled prescriptions over the internet for about four months. As soon as I was warned that what we had been doing might be illegal, I immediately stopped that practice, but by then we had already filled over 5,000 prescriptions all around the country, almost 500 in California and 90 percent of those prescriptions were for painkillers. As soon as I agreed to fill internet prescriptions for one of those companies, more contacted me with the same proposal and in those four months we dispensed prescriptions for five (5) of those internet companies, (Another warning I now see too late.)

I was eventually contacted by both the federal Drug Enforcement Administration (DEA) and the State Board of Pharmacy. Both instituted investigations and those investigations have resulted in me incurring significant fines both to the State Board and to the DEA and my license and that of my store being placed on probation. Those penalties are many times the money I made filling those internet prescriptions. My family has been hurt by my conduct both financially and emotionally and I would do anything to be able to go back and undo the decisions I made without adequate thought and consideration.

Believe it or not, my fines could have been much, much higher. Both the State of California and the Federal Government could have fined both me and my pharmacy $25,000 for every prescription dispensed by us in this fashion. In fact, the Board of Pharmacy sent both me and my pharmacy (since we have different licenses) formal written penalty demands for $11,700,000 each! Imagine my fear and that of my wife and others when we saw those documents!

The practice of filling prescriptions over the internet for patients previously unknown to my practice is dangerous to the patients and the profession. I have come to learn that in many cases the patients contacted physicians only through a website and that they never had any personal contact with the physician. A few form questions were answered on the website by the patient which resulted in the generation of the prescription by the physician which was relayed to me over the internet and filled by me and mailed to the patients in various states. I also never had any personal contact with the patient or the physician. Obviously the physicians should not be issuing prescriptions to persons unknown to them and I should not have been filling those prescriptions.

In hindsight I now can see the purpose of the law. Many potential drug abusers who are unable to obtain controlled substances through a legitimate physician relationship turn to the internet to continue the abusive practices. Filling of prescriptions in these circumstances makes the pharmacist at least an enabler if not more culpable than that. By filling internet prescriptions we are exposing people to unknown risks from drugs about which they have never realistically consulted a physician. Drug interactions are possible resulting in untold potential complications, including death. Further, my attorneys advise me that if injury occurs to a person to whom I supplied drugs over the internet that I could well be liable for their damages, and that is a liability I not certain my insurance would cover.

We are in the electronic age and more and more matters are being handled by e-mail and by internet communications. These forms of communication are fraught with danger for abuse and as pharmacists we all will have to be on guard to prevent misuse. The old adage to be careful if it seems too good to be true, is correct. Somebody, not me, was making a significant amount of money with this process and I was only an incidental part of it; however, without a pharmacist, the scheme cannot work. We must all be careful to screen prescriptions and the prescribers and err on the side of caution, not greed. The public relies more and more on us and we must step up and protect them as much as we can.

Sincerely,

Byung Sik Yuh
Nichols Hill Pharmacy

To Whom it May Concern

We, Patterson Family Pharmacy, were approached by a company named TeleMed to possibly fill prescriptions and mail them to their patients. We were given names of several pharmacies as references. We called and were able to verify their relationship with TeleMed. The contract that was offered to us ranged between $5 to $10 for each prescription plus the cost of each medication. We believed that each patient had a good faith exam prior with the MD which was stated on each prescription and signed by the MD.

The web portal that we had been given access to pertaining to the patient profiles was extensive. Each electronic health record varied from x-rays, prior MD consults, CT records and results, and prescription history.

One day we received a phone call from a pharmacy located somewhere in the Mid-West stating that what we were doing was possibly violating the law. I immediately searched and located a cell phone number for Inspector Joseph Wong, which

*See **Dispensing Internet Prescriptions**, Page 13*

Dispensing Internet Prescriptions

Continued from Page 12

was on a business card from a prior annual visit, and called Inspector Wong. Inspector Wong stated that if there were any questions as to the validity of what we were doing that it was his recommendation to cease our actions. We immediately stopped filling TeleMed prescriptions.

The untold stress and emotional rollercoaster that I have put my family, my true friend and business partner John Wong and myself have been tremendous. Western medical literature can support and corroborate the premise that emotional stress on an individual can and will have severe and ever reaching consequences. I have become a poor example. Something I did not wish to be. Diagnosed with hypertension, sleepless nights, and irritability are just a few of the outcomes that I have been handed. The financial strains will be felt for decades by my family. Ashamed, humiliated, and embarrassed. I just hope and believe that I will be able to restore my faith and integrity in a profession that I so passionately love.

Sincerely,

Tom Bragdon

To Whom it May Concern

We (the pharmacy) were approached to provide internet prescription service by a fax solicitation. We were contacted by the company and explained that we would be providing medications thru the mail from written orders from their physicians. We were put in touch with other pharmacies that were also providing this service as references. The enticement of providing these services was a dispensing fee between $5 and $10 per prescription.

I believed the patients had a good faith exam from the medical information that was provided in their profile. Detailed information was provided such as medical exams with x-ray information. For the given information, I did not doubt the validity of these patient's medical conditions.

I filled approximately 339 controlled prescriptions.

I ceased filling the internet prescriptions after we consulted with a state board investigator who told us if you don't think it is legal then stop. Once that was said, we ceased all processing of prescriptions.

I was never given any sales pitch to provide service for any other internet provider or to increase the number of prescriptions filled.

The fallout of this episode in my life is of emotional stress on me, financial hardship and a disgrace to my profession. I believed this to be a legal venture and thought we had researched this completely. This legal progress has caused me untold emotional pain. It has led to sleepless nights and irritability. It has drained finances that I would otherwise have, making myself conscience of all my expenses. It has also put a shame on my profession since I should have been up to date on the law and should have used better judgment on what I was doing. This also brings doubt in trust with the public and which I hope to reestablish by being the best pharmacist I can be.

Sincerely,

John Wong

Rx for Good Practice

Do you have a question that you would like to see addressed in the newsletter? If so, please e-mail them to ***Hope.Tamraz@dca.ca.gov***.

Q. What does the pharmacist do upon receiving a Schedule II prescription on which the prescriber has omitted the quantity or has written the wrong strength?

A. Section 1716, Title 16 of the California Code of Regulations (CCR) prohibits the pharmacist from deviating from the requirements of a prescription except upon the prior consent of the prescriber. Further, section 1761 does not permit a pharmacist to compound or dispense **any** (emphasis added) prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of such prescription, the pharmacist must contact the prescriber to obtain the information needed to validate the prescription.

Q. Is it true that pharmacists are required to provide Medication Guides with those medications with Black Box Warnings? And are they required to provide the Guides with refill prescriptions?

A. With many dispensed prescription medicines, the pharmacist is required to provide a "Medication Guide" that includes information to help the patient avoid possible adverse effects of the drug. Some Medication Guides contain a Black Box Warning—a more severe warning enclosed within a black frame—that advises consumers and prescribers that the drug may pose a serious or life-threatening risk for certain individuals. If the drug is one that requires a Medication Guide, it must be provided with both new and refill prescriptions whether or not it contains a Black Box Warning.

Q. Can an individual under 18 years of age pick up any controlled or non-controlled substance prescription for a parent or any another person? Some non-controlled prescription drugs may still have abuse potential.

A. Neither California nor federal law has age restrictions related to whom may pick up a controlled or non-controlled drug prescription at the pharmacy, and in such situations, you must use your professional judgment. However, be aware that section 4075 of the Business and Professions Code (B&PC) requires proof of identity from anyone picking up a prescription that was orally or electronically transmitted to the pharmacy.

Q If a physician prescribes MS Contin 30mg qty 60 1 bid, can the pharmacist call the physician and request to change the prescription to Kadian 30mg qty 60 1 bid without requesting a new prescription? And if the physician authorizes this change over the phone and the pharmacist documents the conversation with the physician for this change on the original prescription, is all pharmacy law fulfilled?

A. The answer to both questions is yes. After you have discussed changing the prescription with the prescriber and received permission to do so, the change can be made on the prescription, and no new prescription is required. The Board recommends documenting the discussion with the prescriber, including the receipt of consent, on the prescription. (CCR 1716 and B&PC 4073)

Q. Does a pharmacist need a separate license for compounding sterile injectable drug products?

A. No separate license is required for the pharmacist who compounds drugs, but a compounding license is required for the compounding pharmacy unless the pharmacy meets the accreditation requirements contained in B&PC 4127.1.

Q. If there is an error or omission on a CII prescription, can the pharmacist call the prescriber to orally change or add the necessary information onto the prescription? Or does the pharmacist have to send the prescription back to the physician to make the necessary changes, or write a new prescription?

A. Title 16, CCR 1716 and 1761, relating to deviating from the requirements of a prescription and errors/omissions on a prescription, do not address whether to send the prescription back to the physician for a new prescription in such instances. They do, however, require the pharmacist to obtain prior consent of the physician before making any change to the prescription. The Board recommends that the pharmacist note the conversation with the physician on the back of the prescription, and enter the changes on the front as one possible method of documentation.

*See **Rx for Good Practice**, Page 15*

Rx for Good Practice

Continued from Page 14

Q. If the prescriber fails to indicate the number of refills on a controlled substance prescription, does the pharmacist write in the number of refills on the prescription after consulting the prescriber?

A. Section 11162.1(a)(10) of the Health and Safety Code (H&SC) requires check boxes to be printed on the form so that the prescriber may indicate the number of refills ordered. If the number of refills is not noted, there is no requirement to contact the prescriber to determine whether refills were authorized, but the standard of practice would be for the pharmacist to assume none were ordered.

Q. Our pharmacy is often audited by billed insurance companies. Some of the audits go back as far as 2006, and the auditors take issue with the fact that some of the controlled substance prescriptions are not written on tamper-resistant prescription forms. At what point was it mandated that older prescription forms could no longer be accepted?

A. The requirements for tamper-resistant prescription forms (H&SC 11162.1, et seq.) became effective on September 18, 2004, as a result of urgency legislation, but there was no official cutoff date for accepting prescriptions written on the old forms. Because the Board wished to allow a reasonable amount of time for prescribers to contact a security-resistant prescription form printer and order the new forms, pharmacists were not disciplined for accepting the old forms for a brief time after January 1, 2005. Prescriptions written in 2006 should have been considered invalid.

Q. Is a non-controlled prescription void if it is written on a tamper-resistant form and the quantity box is not checked off?

A. No. Health and Safety Code section 11162.1 requires the quantity check-off boxes be printed on the security form. However, there is no requirement for the prescriber to check any of the boxes. Both B&PC 4040 and H&SC 11164 require the quantity be indicated on the prescription, but no requirement for the prescriber to use the check-off box.

Q. If a prescription is written for a quantity larger than the insurance will cover, can it be split into two prescriptions, with one being billed to the insurance company and the other being paid by cash?

A. Yes. There is no legal prohibition of this procedure.

Self-Assessment Forms

Continued from Page 1

Further, section 4013 has been amended to allow an owner of two or more facilities to subscribe to the Board's notification list with a single e-mail address—rather than having each facility subscribe with an individual e-mail address—if the owner maintains an electronic notice system that will immediately forward Board e-mail notifications to all the owner's facilities.

Currently, the Board has approved the specific changes to the self-assessment forms but has not completed the formal regulation adoption process to secure the amendments. To ensure the best assessment for our licensees, the Board would prefer that the draft (updated) forms be used, but the Board cannot require that the newer version be used until the formal regulation has been adopted.

Therefore, pharmacies and wholesalers have a choice in how they will comply with the July 1 deadline for self-assessment completion.

Pharmacies may use either:

1. The January 2010 version of the self-assessment form (current regulations) by accessing the following links:
   - Community Pharmacy & Hospital Outpatient Pharmacy: *http://www.pharmacy.ca.gov/forms/17m_13.pdf*
   - Hospital Pharmacy: *http://www.pharmacy.ca.gov/forms/17m_14.pdf*
   - Compounding: *http://www.pharmacy.ca.gov/forms/17m_39.pdf*

Wholesalers may use this link to the current self-assessment: *http://www.pharmacy.ca.gov/forms/17m_26.pdf*

*See **Self-Assessment Forms**, Page 16*

Self-Assessment Forms

Continued from Page 15

OR

2. Use the draft self-assessment form (which is not specifically required, but contains more up-to-date descriptions of pharmacy and wholesaler requirements).

Pharmacies

- Community Pharmacy & Hospital Outpatient Pharmacy: *http://www.pharmacy.ca.gov/forms/17m_13_draft.pdf*
- Hospital Pharmacy: *http://www.pharmacy.ca.gov/forms/17m_14_draft.pdf*
- Compounding: *http://www.pharmacy.ca.gov/forms/17m_39_draft.pdf*

Wholesalers may use this link to the self assessment: *http://www.pharmacy.ca.gov/forms/17m_26_draft.pdf*

During board inspections, the board will use its enforcement discretion to ensure that one of the self-assessments has been completed by July 1, 2011.

Improving Patient Safety

Continued from Page 5

5. Identify and disseminate information about best practices and effective methods for educating consumers about their role in reducing medication errors.
6. Establish an on-going public education campaign to prevent medication errors, targeting outpatients and persons in community settings.
7. Develop and implement strategies to increase the involvement of public and private sector entities in educating consumers about improving medication safety and effectiveness.

Pharmacy Standards and Incentives, focusing on information and medication consultations given by pharmacists to their patients as a means of educating consumers about drug safety.

8. Help ensure quality and consistency of medication consultation provided by pharmacists within and among pharmacies.
9. Establish standards for Medication Therapy Management (MTM) programs and create incentives for their implementation and ongoing use by pharmacists and other healthcare providers.

Training and Education for Healthcare Providers, focusing on various medication safety practices.

10. Create training requirements for pharmacists and other healthcare professionals that address medication safety practices and related programs, including medication consultation and medication therapy management programs.

Research, obtaining information about the incidence, nature, and frequency of medication errors in the community setting.

11. Establish and support efforts to collect data regarding the nature and prevalence of medication errors and prevention methods for reducing errors, especially focused on persons at high risk for medication errors and on community, ambulatory and outpatient settings.

Other, addressing the obstacles that pharmacists face in providing drug consultation to patients, encompassing a variety of factors such as manpower shortages and lack of payment systems to cover the time and expense associated with these tasks. Before additional duties can be imposed upon pharmacists in outpatient settings, these issues must be addressed:

12. Convene a panel of stakeholders to identify and propose specific actions and strategies to overcome barriers to qualified pharmacists being recognized and paid as health care providers.

Perhaps the most disturbing aspect of medication errors is that the tremendous human and financial costs are not the result of some serious disease, but rather well-intentioned efforts to treat or prevent illness. Those well-intentioned efforts must be matched by our continuing efforts to discover ways to prevent medication errors.

Nonprescription Sale of Syringes (NPSS) in Pharmacies

Information for Pharmacists and Frequently Asked Questions about the Disease Prevention Demonstration Project

The following information was prepared by the California Department of Public Health, Office of AIDS, who granted the Board permission to reprint.

In 2005, Senate Bill (SB) 1159 (Vasconcellos, Statutes of 2004) established the Disease Prevention Demonstration Project (DPDP), which allows California pharmacies to sell up to ten syringes to an adult without a prescription. The law changed pharmacy practice as a part of efforts across the state to prevent the spread of HIV, hepatitis, and other blood-borne diseases. The program has since been re-authorized by the Governor and legislature through the passage of Assembly Bill (AB) 1701 (Chesbro, Statutes of 2010). This bill continues the program with no changes except for the new sunset date of 2018. **All previously registered pharmacies may continue to sell syringes, and there is no need to re-register.**

The sharing of contaminated syringes is linked to 19 percent of all AIDS cases in California, and an estimated 5,000 new hepatitis C virus (HCV) infections each year are attributable to the sharing of injection equipment. Preventing the spread of disease through pharmacy access to sterile syringes has the potential to dramatically shift the trends in the HIV and HCV epidemics in California.

Currently in California, there are over 650 pharmacies in sixteen counties and four cities that are participating in the DPDP program. Research has found no evidence of negative effects, such as increased crime or syringe littler.

Pharmacist's Roles and Responsibilities

Pharmacists play an important and often unrecognized role in public health, as health educators and resources for their communities. As respected members of the medical profession, pharmacists have the ability to positively influence the health behaviors of their patients, and to influence public health policy. To date, sixteen counties and four cities have authorized a DPDP. Individual pharmacists and local pharmacy associations have been actively involved in the political process needed to secure authorization.

Pharmacies operating within those jurisdictions which have authorized a DPDP may participate in the program by contacting their local health department to register. Pharmacists located in jurisdictions that have not yet authorized a DPDP may contact their local health department to let them know of their interest in participating.

Participating pharmacies are required to:

- Register with their local health department and certify that they will provide the purchaser with written information or verbal counseling on all of the following:
  - how to access drug treatment;
  - how to access testing and treatment for HIV and HCV; and,
  - how to safely dispose of sharps waste;
- Store hypodermic needles and syringes so that they are available only to authorized personnel; and
- Provide for the safe disposal of hypodermic needles and syringes through one or more of the following options:
  - providing an on-site safe hypodermic needle and syringe collection and disposal program;
  - furnishing or making available for purchase mail-back sharps disposal containers that meet state and federal standards; and/or
  - furnishing or making available for purchase personal sharps disposal containers.

Pharmacists are no longer required to keep a logbook of non-prescription syringe sales, even for bulk sales of syringes to diabetic or other customers who normally present to the pharmacist with prescriptions.

Frequently Asked Questions

- **Why was this program started?**

  Prior to 2005, California was one of only five states that required a prescription for pharmacy syringe purchase. A significant body of scientific evidence indicates that improved syringe access reduces the rate of HIV transmission, without increasing rates of drug use, drug injection, or crime.[1] A study published in 2001 compared rates of HIV among injection drug users in 96 U.S. cities. Sixty cities did not require a prescription for the sale of syringes and 36 did require a prescription. There was no statistically significant difference in the prevalence of injection drug use between the two groups of cities. However, the rate of HIV among injection drug users was twice as high in the cities that prohibited sale of syringes (13.8 percent versus 6.7 percent).[2]

- **Are all pharmacies required to sell syringes without a prescription?**

  No. The DPDP allows, but does not require pharmacists to sell syringes without a prescription.

*See **NPSS in Pharmacies**, Page 18*

NPSS in Pharmacies

Continued from Page 17

- **Wasn't the program supposed to end in 2010?**

  AB 1701 (Chesbro, Statutes of 2010) extended the sunset date for the DPDP until 2018, but made no changes to the program.

- **Wasn't there another bill about nonprescription syringe sales?**

  Another bill introduced in 2010, SB 1029, would have concluded the DPDP and allowed pharmacies statewide to sell up to 30 syringes without a prescription, with no need for counties to authorize or pharmacies to register. This bill was vetoed by Governor Schwarzenegger. It has been reintroduced this session as SB 41 (Yee).

- **Do pharmacies that are already registered have to re-register?**

  Under current law, pharmacies already registered for the DPDP may continue to sell up to 10 syringes at a time to customers without a prescription. Neither counties nor pharmacies need to re-register for the program.

- **Does each pharmacist need to register with the county? Which pharmacy staff is allowed to sell syringes over the counter (OTC)?**

  The pharmacy itself is registered, not the pharmacist. Any pharmacy staff may sell syringes OTC.

- **Does pharmacy staff need to ask for identification from the customer?**

  No, identification is not required in order to purchase syringes.

- **Why isn't a log or record book required for OTC sales of syringes?**

  In 2005 the requirement that pharmacists keep a logbook of non-prescription syringe sales was eliminated from the Business and Professions Code, including the requirement that a log be kept for sales of up to 100 syringes to diabetic or other customers who normally present to the pharmacist with prescriptions.

  One of the goals of the law is to increase injection drug users' (IDUs) purchase of new, sterile syringes by making the purchase simple and non-threatening. By allowing syringe purchase without requiring the customer to give a name, or show i.d., customer privacy is protected.

- **Will children or teens be able to walk into drug stores and get syringes?**

  The DPDP allows only adults over the age of 18 to purchase and possess up to ten syringes without a prescription. Minors with a valid syringe prescription will be able to continue to use their prescriptions to obtain syringes.

- **How often can the same person buy syringes?**

  There are no restrictions on how many times a person may purchase syringes on a given day, week or month. However, the pharmacy may sell only 10 syringes at a time.

- **Is this program for IDUs only, or can anyone buy syringes OTC?**

  Anyone 18 years of age or older can purchase syringes OTC in participating pharmacies.

- **Will this attract criminals and crime to my pharmacy?**

  Among participating California pharmacies, there have been no reports of unruly or criminal behavior associated with pharmacy sale of syringes. In other states, where OTC sale of syringes is the norm, few problems have been reported.

- **Is my pharmacy required to develop the educational materials about drug treatment, HIV and HCV testing and treatment and proper syringe disposal?**

  Educational materials are developed and provided to pharmacies by your local health department.

- **Is my pharmacy required to collect used syringes?**

  The law requires participating pharmacies to provide for the safe disposal of hypodermic needles and syringes through at least **one of these options**: collecting syringes on site, making mail-back syringe disposal containers available for purchase, or making personal sharps disposal containers available for purchase. Some (few) counties may require syringe collection on site; however that is not the norm in California.

- **Won't increased access result in improperly discarded needles that could pose health and safety risks?**

  Research in other states has shown that programs similar to the DPDP have actually resulted in fewer improperly discarded syringes. When the possession of a syringe without a prescription is criminalized, people have a greater incentive to dispose of their syringes immediately after use to avoid being caught with them. When possession of

*See **NPSS in Pharmacies**, Page 19*

NPSS in Pharmacies

Continued from Page 18

syringes is not criminalized, IDUs may keep their syringes until they can be disposed of safely.

Under the provisions of the program, participating pharmacies are required to hand out information about proper syringe disposal with each syringe sale, and to sell or provide mail back containers, sharps containers, or onsite disposal of used syringes.

The legislation also imposes penalties for the improper disposal of syringes on a playground, beach, park or schoolyard.

- **Won't increased needle access "send the wrong message" or encourage drug use?**

  Several studies have examined this question, and found no evidence of increased initiation of drug use by young adults in areas which have expanded syringe access, either through OTC pharmacy sale of syringes or through syringe exchange programs. Seven major government-funded studies have concluded that improving access to sterile syringes does not lead to increased drug use.

- **Letting drug users buy syringes at pharmacies seems like a pretty radical concept. Do many people think this is a good idea?**

  Pharmacy sale of syringes is the norm in 46 states. The Centers for Disease Control and Prevention, the American Medical Association, the National Association of Boards of Pharmacy and many other state and national organizations also support increased syringe access through pharmacy sale without a prescription.

- **Aren't syringes available at needle exchanges already? Why should they also be available at drug stores?**

  Syringe exchange programs, which operate in select counties and provide sterile syringes in exchange for used, potentially contaminated ones, are a good way to reach some IDUs. But such programs are not available in all areas, and have limited hours of operation.

  Pharmacies are ideal sources of sterile injection equipment: they are located in most neighborhoods, open during convenient hours, and staffed by trained health-care professionals who can provide needed advice regarding disease prevention and safe disposal of syringes to all purchasers.

  These two approaches to syringe access are complementary, reaching different IDU populations with different needs. Both can serve as important conduits to health services, including drug treatment.

- **What size syringe should I sell?**

  Most customers will tell you what size needle and syringe they want. Generally, 1 cc or 3 cc syringes are adequate.

- **How do I register my pharmacy?**

  Contact the HIV prevention staff at your local health department. Additional assistance may be found by calling the California Department of Public Health, Office of AIDS at 916-449-5796.

An educational video on the DPDP can be found here: *http://www.vimeo.com/6634757*

More information about syringe access is available on the Office of AIDS web site *http://www.cdph.ca.gov/programs/aids/Pages/OASyringeAccess.aspx*

What to Look for on Tamper-Resistant Security Prescription Forms

On September 18, 2004, Health and Safety Code section 11162.1 was enacted, requiring the use of tamper-resistant prescription forms, which contain specific security features, for controlled substances. A year later, additional features were added to the security form requirements. To recognize counterfeit or invalid controlled substance prescriptions, pharmacists should familiarize themselves with the required security features of section 11162.1 below:

11162.1 Controlled Substance Prescription Form Requirements

(a) The prescription forms for controlled substances shall be printed with the following features:
  (1) A latent, repetitive "void" pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.
  (2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words "California Security Prescription."
  (3) A chemical void protection that prevents alteration by chemical washing.
  (4) A feature printed in thermochromic ink.
  (5) An area of opaque writing so that the writing disappears if the prescription is lightened.
  (6) A description of the security features included on each prescription form. **[*Ed. Note: The description may be printed anywhere on the form (e.g., in warning bands along the edges of the form's face or listed on the back of the form). The description should tell what and where the features are on the form and how to test them.*]**
  (7) (A) Six quantity check off boxes shall be printed on the form and the following quantities shall appear:
    1–24
    25–49
    50–74
    75–100
    101–150
    151 and over.
    (B) In conjunction with the quantity boxes, a space shall be provided to designate the units referenced in the quantity boxes when the drug is not in tablet or capsule form.
  (8) Prescription blanks shall contain a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."
  (9) The preprinted name, category of licensure, license number, federal controlled substance registration number of the prescribing practitioner.
  (10) Check boxes shall be printed on the form so that the prescriber may indicate the number of refills ordered.
  (11) The date of origin of the prescription.
  (12) A check box indicating the prescriber's order not to substitute.
  (13) An identifying number assigned to the approved security printer by the Department of Justice. [***Ed. Note: These forms must be printed by printing companies that have been approved by the Department of Justice/Bureau of Narcotic Enforcement and assigned a security printer (SP) number. The printer identifying number can be found anywhere on the form and will be seen as "SP" followed by a number. Absence of the number may indicate a fraudulent prescription form.***]
  (14) (A) A check box by the name of each prescriber when a prescription form lists multiple prescribers.
    (B) Each prescriber who signs the prescription form shall identify himself or herself as the prescriber by checking the box by his or her name.

(b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

(c) (1) A prescriber designated by a licensed health care facility, a clinic specified in Section 1200, or a clinic specified in subdivision (a) of Section 1206 that has 25 or more physicians or surgeons may order controlled substance prescription forms for use by prescribers when treating patients in that facility without the information required in paragraph (9) of subdivision (a) or paragraph (3) of this subdivision.
  (2) Forms ordered pursuant to this subdivision shall have the name, category of licensure, license number, and federal controlled substance registration number of the designated prescriber and the name, address, category of licensure, and license number of the licensed health care facility the clinic specified in Section 1200, or the clinic specified in subdivision (a) of Section 1206 that has 25 or more physicians or surgeons preprinted on the form.
  (3) Forms ordered pursuant to this section shall not be valid prescriptions without the name, category of licensure, license number, and federal controlled substance registration number of the prescriber on the form.
  (4) (A) Except as provided in subparagraph (B), the designated prescriber shall maintain a record of the prescribers to whom the controlled substance prescription forms are issued, that shall include the name, category of licensure, license number, federal controlled substance registration number, and quantity of controlled substance prescription forms issued to each

See ***What to Look for****, Page 37*

Electronic Prescribing of Controlled Substances in California

Please see more detailed information on this subject at "Transmission and Receipt of Electronic Controlled Substance Prescriptions," on the Board's Web site under "What's New."

Since at least 2001, California has allowed e-prescribing for controlled substances, excluding Schedule II, subject to "… if authorized by federal law and in accordance with regulations promulgated by the Drug Enforcement Administration." (Health and Safety Code 11164.5[a]). However, the DEA did not permit DEA registrants to e-prescribe controlled substances. Nevertheless, as prescribers, pharmacies, and payers increasingly turn to e-prescribing technology to increase efficiency and reduce expenses, the DEA has searched for ways to reconcile its e-prescribing regulations of controlled substances with those of individual states. Subsequently, the DEA published on June 27, 2008, a proposed rule to permit e-prescribing of controlled substances under specific, fairly detailed requirements. Comment period on the rulemaking closed in September 2008, and the Interim Final Rule (IFR) on e-prescribing of controlled substances became effective and was published in the Federal Register on June 1, 2010. What follows is a very brief summary of the rule.

The DEA's basic prescribing structure has remained consistent: whereas it has previously allowed controlled substances to be prescribed only by using (secure) paper prescriptions, the IFR will make it possible to prescribe Schedules II through V controlled substances by using electronic prescription applications (software systems), transmitted either directly or through intermediaries to pharmacies.

The new IFR requirements affect:

- The companies that develop, sell, and host electronic prescription software applications, electronic health record applications, and pharmacy applications;
- Any DEA-registered prescriber, including any mid-level practitioner who wants to sign and transmit controlled substance prescriptions electronically;
- Any DEA-registered pharmacy that wants to process electronic prescriptions for controlled substances;
- Software application providers must undergo third-party audit or certification to determine whether the application meets DEA's requirements;
- Prescribing practitioners must select application, submit to identity proofing, set access controls; and sign prescriptions; and
- Pharmacies must select software application, set access controls, process prescriptions, and archive prescriptions.

The requirements to participate in e-prescribing include, but are not limited to the following factors:

Identity Proofing: The IFR continues the requirement that practitioners be subject to identify proofing before they are issued authentication credentials (the password[s] and hard token or biometric that permits them to issue e-prescriptions).

Two Factor Authentication: Practitioners must be authenticated to the e-prescribing system by using two of the following three factors: knowledge-based (i.e., password), a hard token, (e.g., a security card that gives a user access to a computer system), and/or a biometric (e.g., scanned iris, fingerprint, etc.).

Creating and Signing E-Prescriptions: Controlled substance prescriptions are required to contain the same data elements as paper prescriptions, but the prescriber is only required to review the patient name, drug information, refill/fill information, and the prescriber's information on-screen before approving/signing the prescription. It will be possible to authorize multiple prescriptions for a single patient with one transaction.

Digital Signatures: The application will apply a digital signature to and archive the required controlled substance prescription information when the practitioner completes the two-factor authentication process (this is his or her way of "signing" the prescription). For those practitioners who have private keys for digital signatures (e.g., those practicing in federal facilities), the private key infrastructure may be used to digitally sign the prescription. The prescription need not be transmitted immediately, because it has been digitally signed (and therefore locked). The IFR also requires the pharmacy or the last intermediary before pharmacy receipt to digitally sign the prescription, and the pharmacy to archive the digitally signed record.

Recordkeeping: All records related to controlled substance e-prescriptions must be retained for two years.

Participation in the transmission and receipt of electronic prescriptions is not mandatory: it is voluntary. The regulations do not mandate that prescribers use only electronic prescribing for controlled substances, nor do they require pharmacies to accept electronic controlled substance prescriptions. Written prescriptions are still acceptable, as are oral prescriptions for Schedule III-V controlled substances. If used, electronic prescriptions for Schedule II-V controlled substances must meet DEA regulatory requirements.

DEA Interim Final Rule on Electronic Prescribing and Receiving Controlled Substance Prescriptions

Questions and Answers for Pharmacies
[as of 03/31/2010]

The questions and answers below are intended to summarize and provide general information for pharmacies regarding the Drug Enforcement Administration Interim Final Rule on electronic prescriptions for controlled substances.

Q. What is DEA's rule "Electronic Prescriptions for Controlled Substances?"

A. DEA's rule, "Electronic Prescriptions for Controlled Substances" revises DEA's regulations to provide practitioners with the option of writing prescriptions for controlled substances electronically. The regulations will also permit pharmacies to receive, dispense, and archive these electronic prescriptions. The rule was published in the Federal Register Wednesday, March 31, 2010 and became effective on June 1, 2010.

Q. Is the use of electronic prescriptions for controlled substances mandatory?

A. No, the new regulations do not mandate that practitioners prescribe controlled substances using only electronic prescriptions. Nor do they require pharmacies to accept electronic prescriptions for controlled substances for dispensing. Whether a practitioner or pharmacy uses electronic prescriptions for controlled substances is voluntary from DEA's perspective. Prescribing practitioners are still able to write, and manually sign, prescriptions for schedule II, III, IV, and V controlled substances and pharmacies are still able to dispense controlled substances based on those written prescriptions. Oral prescriptions remain valid for schedule III, IV, and V controlled substances. Electronic prescriptions for controlled substances are only permissible if the electronic prescription and the pharmacy application meet DEA's requirements. In addition, electronic prescriptions for controlled substances may be subject to state laws and regulations. If state requirements are more stringent than DEA's regulations, the state requirements would supersede any less stringent DEA provision.

Q. When can a pharmacy start processing electronic prescriptions for controlled substances?

A. A pharmacy will be able to process electronic controlled substance prescriptions only when the application the pharmacy is using to process prescriptions complies with the requirements in the interim final rule.

Q. What must a pharmacy application be able to do to process electronic controlled substance prescriptions?

A. The application requirements are detailed in 21 C.F.R. 1311.205. Generally, the application must be able to import, display, and store the required contents of a controlled substance prescription accurately and consistently. The application must be able to digitally sign and archive the controlled substance prescription or import and archive the record that the last intermediary digitally signed. The application must electronically accept and store all of the information that DEA requires to be annotated to document the dispensing of a prescription. The application must allow the pharmacy to limit access for the annotation, alteration (to the extent such alteration is permitted by DEA regulations), or deletion of controlled substance prescription information to specific individuals or roles. The application must have an internal audit trail that documents whenever a prescription is received, altered, annotated, or deleted. The application must conduct an internal audit that identifies any potential security problems daily and generate a report for review by the pharmacy if a problem is identified. Many of these requirements are standard functionalities for pharmacy applications.

Q. How will a pharmacy be able to determine that an application complies with DEA's rule?

A. The application provider must either hire a qualified third party to audit the application or have the application reviewed and certified by an approved certification body. The auditor or certification body will issue a report that states whether the application complies with DEA's requirements and whether there are any limitations on its use for controlled substance prescriptions. (A limited set of prescriptions require information that may need revision of the basic prescription standard before they can be reliably accommodated, such as hospital prescriptions issued to staff members with an identifying suffix.) The application provider must give a copy of the report to pharmacies that use or are considering use of the pharmacy application to allow them to determine whether the application is compliant with DEA's requirements.

Q. Until a pharmacy has received an audit/certification report from the pharmacy application provider indicating that the application meets DEA's requirements, how can the pharmacy application be used to process controlled substance prescriptions?

A. A pharmacy cannot process electronic prescriptions for controlled substances until its pharmacy application provider obtains a third party audit or certification review that determines that the application complies with DEA's requirements and the application provider gives the audit/certification report to the pharmacy. The pharmacy may continue to use its pharmacy application to store and process information from paper or oral controlled substances prescriptions it receives, but the paper records must be retained.

*See **DEA Interim Final Rule**, Page 23*

DEA Interim Final Rule

Continued from Page 22

Q. What is a pharmacy's responsibility if the pharmacy's application cannot accommodate special DEA requirements, such as extension data for institutional-based practitioners?

A. The audit report the pharmacy will receive from the pharmacy application provider will indicate if the application is capable of importing, displaying, and storing such information accurately and consistently. If the audit or certification report indicates that the pharmacy application cannot accurately and consistently import, store, and display this information, the pharmacy must not process electronic prescriptions for controlled substances that require such information. For example, until the audit or certification report indicates that the pharmacy application can import, display, and store both a hospital DEA number and the individual practitioner's extension number, the pharmacy must not accept electronic prescriptions that include only a hospital DEA registration. The pharmacy may, however, use the application to process other controlled substance prescriptions if the audit or certification report has found that the pharmacy application meets all other requirements.

Q. How does a pharmacy limit access to the pharmacy application?

A. The pharmacy application has to allow the pharmacy to set access controls. These controls may be set either by name or by role (e.g., pharmacist, pharmacy technician). The controls define who has permission to annotate, alter (where such alteration is permitted by DEA regulations), or delete controlled substance prescription information.

Transmission of Prescriptions to Pharmacies

Q. What is an intermediary?

A. An intermediary means any technology system that receives and transmits an electronic prescription between the practitioner and the pharmacy.

Q. If transmission of an electronic prescription fails, may the intermediary convert the electronic prescription to another form (e.g. facsimile) for transmission?

A. No, an electronic prescription must be transmitted from the practitioner to the pharmacy in its electronic form. If an intermediary cannot transmit the electronic data file of a controlled substance prescription to the pharmacy, the intermediary must notify the practitioner. Under such circumstances, if the prescription is for a schedule III, IV, or V controlled substance, the practitioner can print the prescription, manually sign it, and fax the prescription directly to the pharmacy. This prescription must indicate that it was originally transmitted to, and provide the name of, a specific pharmacy, the date and time of transmission, and the fact that the electronic transmission failed.

Q. What are the restrictions regarding alteration of a prescription during transmission?

A. The (DEA-required) contents of a prescription must not be altered during transmission between the practitioner and pharmacy. However, this requirement only applies to the content (not the electronic format used to transmit the prescription). This requirement applies to actions by intermediaries. It does not apply to changes that occur after receipt at the pharmacy. Changes made by the pharmacy are governed by the same laws and regulations that apply to paper prescriptions.

Q. What should a pharmacist do if he/she receives a paper or oral prescription that was originally transmitted electronically to the pharmacy?

A. The pharmacist must check the pharmacy records to ensure that the electronic version was not received and the prescription dispensed. If both prescriptions were received, the pharmacist must mark one as void. The pharmacy is responsible for verifying that the prescription was not received electronically and that no controlled substances were dispensed pursuant to the electronic prescription prior to filling the paper prescription. The paper prescription must comply with all DEA requirements for any paper prescription, including a manual signature.

Q. What should a pharmacist do if he/she receives a paper or oral prescription that indicates it was originally transmitted electronically to another pharmacy?

A. The pharmacist must check with the other pharmacy to determine whether the prescription was received and dispensed. If the pharmacy received the original electronic prescription, but had not dispensed the prescription, that pharmacy must mark the electronic version as void or canceled. If the pharmacy that received the original electronic prescription dispensed the prescription, the pharmacy with the paper version must not dispense the paper prescription and must mark the prescription as void.

Records

Q. What are the DEA requirements regarding the storage of electronic prescription records?

A. Once a prescription is created electronically, all records of the prescription must be retained electronically. As is the case with paper prescription records, electronic controlled substance prescription records must be kept for a minimum period of two years.

Q. Are electronic prescription records required to be backed-up, and if so, how often.

A. Yes, pharmacy application service providers must back up files daily. Also, although it is not required, DEA recommends as a best practice that pharmacies store their back-up copies at another location to prevent the loss of the records in the event of natural disasters, fires, or system failures.

*See **DEA Interim Final Rule**, Page 24*

DEA Interim Final Rule

Continued from Page 23

Reporting Security Incidents

Q. Is a person who administers logical access controls required to report security incidents?

A. Yes, the application is required to run an internal audit for potential security incidents daily and generate a report of any such incidents. If the application generates a report and, upon investigation, the person(s) designated to administer logical access controls for the pharmacy determine that the issuance or records of controlled substance prescriptions has been compromised or could have been compromised, it must be reported to the application provider and DEA within one business day. In general, the security incidents that should be reported are those that represent successful attacks on the application or other incidents in which someone gains unauthorized access.

Audits and Certification of Applications

Q. Who can conduct an audit or certify an application?

A. Application providers must obtain a third-party audit or certification to certify that each electronic prescription and pharmacy application to be used to sign, transmit, or process controlled substances prescriptions is in compliance with DEA regulations pertaining to electronic prescriptions for controlled substances.

- The application may undergo a WebTrust, SysTrust, or SAS 70 audit conducted by a person qualified to conduct such an audit.
- The application may undergo an audit conducted by a Certified Information System Auditor who performs compliance audits as a regular ongoing business activity.
- The application may have a certification organization whose certification has been approved by DEA verify and certify that the application meets DEA's requirements.

Q. When must a third-party audit or certification be conducted?

A. The third-party audit or certification must be conducted before the electronic prescription application is used to sign or transmit electronic prescriptions for controlled substances, or before the pharmacy application is used to process electronic prescriptions for controlled substances, respectively. Thereafter, a third-party audit or certification must be conducted whenever a functionality related to controlled substance prescription requirements is altered or every two years, whichever occurs first.

Q. To whom does the third-party audit/certification requirement apply?

A. The requirement for a third-party audit applies to the application provider, not to the individual practitioner, institutional practitioner, or pharmacy that uses the application. Unless an individual practitioner, institutional practitioner, or pharmacy has developed its own application, the practitioner or pharmacy is not subject to the requirement.

Changes to Controlled Substance Prescription Data Submission to CURES

Effective January 1, 2011, all controlled substance prescription data transmitted to CURES must be submitted to the new CURES data collection vendor, Atlantic Associates, Inc (AAI). Additionally, all data submissions must adhere to the American Society for Automation in Pharmacy (ASAP) standards, ASAP 2009 version 4.1 format. **All other data formats will be rejected**; however, AAI will continue to accept ASAP 2005 version 3.0 until July 31, 2011, to allow pharmacies time to gain compliance.

The notification to licensees and software vendors from the Department of Justice, dated December 9, 2010, includes many significant changes and important instructions to ensure data acceptance by the new vendor. Highlights include:

- ASAP 2009, version 4.1 data format; accepted methods of data transmission;
- Data validation process; emailed data acceptance and rejection notices, and required data correction and resubmission;
- How to resubmit a corrected file or record that was rejected by AAI;
- How to delete a record or correct an error found by the pharmacy;
- Proper entry of the DEA number for Medical Residents;
- Mandatory and optional data fields;
- Mandatory pharmacy license number field;
- Limitations on paper submissions;
- Rejections due to use of special characters; pipes (|) and carets (^);
- Reporting zero controlled substances dispensed (zero fills);
- Pharmacy's using third party software vendors to submit prescription data; the pharmacy is responsible for notifying of changes and verifying compliance; and
- Instructions to send email to AAI to request email notifications for data transmissions.

Please review the entire DOJ notification at http://www.pharmacy.ca.gov/licensing/cures_ltr.pdf.

For information regarding data transmission and/or format, please contact:

Atlantic Associates, Inc. (AAI)
Phone: (800) 539-3370
Email: *data@aainh.com*
Web site coming soon: *www.aainh.com*

If you have additional questions, please visit the Department of Justice Web site at *http://ag.ca.gov/bne/cures.php* or contact the CURES Program at (916) 319-9062.

Changes to the California Practice Standards and Jurisprudence Examination Content Outline and Verification of Out-of-State Intern Hours

CPJE Changes

On April 1, 2011, changes were made to the CPJE content outline. These changes, the first to be made in the outline since 2005, effected examinations taken on or after April 1, 2011.

The development of any examination program involving licensure begins with an occupational analysis, which identifies the tasks performed in a profession or a job and the knowledge, skills and abilities required to perform that job. The Board of Pharmacy completed its most recent job analysis, acquired from a survey of 3,000 California-residing pharmacists in 2010. The content of the new examination is based on the task statements and knowledge areas that the surveyed pharmacists determined to be critical to practice. Tasks that were included in the NAPLEX content outline were removed from the CPJE content outline, and the remaining tasks were incorporated into the new CPJE content outline. Both the current and the new CPJE content outline can be accessed at the Board's Web site (*www.pharmacy.ca.gov*) under "Applicants," then "Exam Information."

In February 2011, the Board sent updated eligibility letters to candidates eligible to take the CPJE and also notified eligible exam candidates who have not taken the CPJE of the upcoming change.

Verification of Out-of-State Intern Hours

Some states no longer validate or verify intern hours to another state. Consequently, if the applicant's state will not validate or verify intern hours to California, the Board now requires the applicant to submit proof of their 1,500 hours of intern experience on the California "Pharmacy Intern Hours Affidavit" (form 17A-29) as part of their licensure examination application. Form 17A-29 can be downloaded at: *www.pharmacy.ca.gov/forms/intern_hours_affidavit.pdf*.

Board honors pharmacists registered for at least 50 years

In an ongoing feature of *The Script*, the Board of Pharmacy pays tribute to those who have been registered California pharmacists on active status for at least 50 years. The Board recognizes these individuals and gratefully acknowledges their years of contribution to the pharmacy profession. These pharmacists may take great pride in being part of such an ancient and honorable profession for so long.

Kenneth O. Wedul

At the May 2011 meeting, President Stanley Weisser recognized RPh Kenneth O. Wedul and his wife Kathleen. Mr. Wedul graduated from North Dakota State University in 1956 and became a licensed pharmacist in California in 1961. He has owned ten stores in Orange County and is currently employed at Leisure World Pharmacy in Seal Beach. President Weisser presented Mr. Wedul with the Board's 50-year pin.

Arragg, Ronald G.	Ventura, CA
Asami, Richard K.	Fresno, CA
Barak, Morton	Petaluma, CA
Bates, John E.	Tustin, CA
Beeman, Jerry R.	Beaumont, CA
Bertelli, Daniel C.	Columbia, CA
Blank, Bruce L.	Palm Desert, CA
Braun, Bernard J.	Santa Barbara, CA
Budman, Allan	Fountain Valley, CA
Colucci, James R.	Oceanside, CA
Erskine, Paul R.	Fresno, CA
Goertzen, Edwin	Reedley, CA
Hardy, Donald T.	Arcata, CA
Hopkins, Marilyn L.	Dublin, CA
Kalman, Mervyn	Woodland Hills, CA
Kasen, David	Encino, CA
Latchford, Robert G.	Henderson, NV
Lefley, Richard W.	Corona, CA
Mallouf, Wayne D.	Oakhurst, CA
Martin, Charles	Los Banos, CA
McKinney, Forrest M. Jr.,	Desert Hot Springs, CA
Mihelic, Robert J.	Arroyo Grande, CA
Miller, Alan N.	Tamarac, FL
Miller, Samuel J.	Los Angeles, CA
Pearlman, Martin B.	Santa Monica, CA
Pritchett, William H.	Sun City, AZ
Roe, George R.	Snohomish, WA
Sowell, Arlene L.	Medford, OR
Wedul, Kenneth O.	Seal Beach, CA
Weiss, Martin D.	Palos Verdes Estates, CA
Williams, Donald H.	Bellvue, WA
Wong, Dennis W. K.	Torrance, CA
Wong, Donald R.	Isleton, CA
Ziebell, Russell J.	Novato, CA

Changes in the Board

New Member

The Board welcomes **Anil "Neil" Hiro Badlani** of Cerritos, who was appointed to the Board by Governor Arnold Schwarzegger, who also reappointed **Shirley Lee Wheat** of Irvine on January 1, 2011.

R.Ph. Badlani, a graduate of Bombay University, College of Pharmacy, has served as a pharmacist at the National Compounding Institute and as a research and development pharmacist for Healthspecialty Skin Care since 2006. Prior to that time, RPH Badlani worked as staff pharmacist and as pharmacy manager at American Drug Stores, Savon Drugs, and was a franchise owner of a General Nutrition Center. He is currently a member of the Prescription Compounding Centers of America, the International Academy of Compounding Pharmacists, and the California Pharmacists Association. R.Ph Badlani's term will expire on June 1, 2012.

Ms. Wheat's reappointment ensures her continued participation as a public member on the Board until June 1, 2014.

Departing Member

The Board membership of Kenneth H. Schell, Pharm.D., a member since July 2003, expired June 1, 2011. Dr. Schell was elected Vice President of the Board in September 2006 and President in April 2008. The Board appreciates and thanks him for his many contributions to California pharmacy practice.

Dr. Schell offered the following message to all Board licensees:

It has been a wonderful eight years, but all good things must make way for different good things. I was involved in numerous Board projects, but the most significant one was the Patient-Centered Label. I am also proud that we were able to get the E-Pedigree legislation passed. However, my best and most fond memory is working with the incredible Board staff and the Executive Officer who do tremendous work with great positive attitudes even though the conditions aren't always what we'd like them to be. In addition, I am proud to have served with fantastic Board members who were thoughtful, open, and most of all had the public's best interest at heart. I will forever remember this opportunity to serve the people of the state of California in such a positive way.

CE hours are awarded for attending one day of a Pharmacy Board or Committee meeting, or for becoming a Certified Geriatric Pharmacist

Continuing education (CE) hours are awarded to encourage pharmacists and pharmacy technicians to learn more about the issues and operation of the Board. These hours can be earned by:

- Attending one full day of a Board meeting per year (maximum of six hours of CE per year); or
- Attending a one-day committee meeting (two hours of CE for each of two different committee meetings—maximum of four hours per year); or
- Upon becoming certified by the Commission for Certification in Geriatric Pharmacy (three hours of CE).

Note: It is the pharmacy technician's responsibility to determine from the Pharmacy Technician Certification Board how many, if any, of the above hours are acceptable for recertification with that board.

Board of Pharmacy meetings are held at least four times per year: typically January, April, July and October. There are four committees that usually hold public meetings prior to each Board meeting:

- Enforcement Committee—Makes recommendations to the Board regarding oversight of all regulatory and enforcement activities for the improvement of consumer protection.
- Licensing Committee—Makes recommendations to the Board regarding the development of standards for the professional qualifications of licensees.
- Legislation and Regulation Committee—Advocates legislation and recommends regulations that advance the vision and mission of the Board to improve the health and safety of Californians.
- Communication and Public Education Committee—Prepares relevant information for the improvement of consumer awareness and licensee knowledge.

Attendance at these meetings provides an opportunity to participate in the development of policies that will guide the Board in its decision-making. Frequently, both statutory and regulatory texts are formulated at such meetings, modifications to current programs are developed, and evidence-based decisions are made.

Board or committee meetings are held in various locations throughout California to give the public and licensees the opportunity to attend. No reservations are needed: You simply arrive at the meeting location at the start of the meeting. For Board meetings, only one day is designated as eligible for CE: This is specified on the agenda. To obtain CE credit for attending committee meetings, attendees must arrive at the designated start of the meeting and register on the CE sign-in sheet.

The Board meeting dates and locations for 2011 are:

July 26-27	**Department of Consumer Affairs** **1625 N. Market Blvd** **1st Floor Public Hearing Room** **Sacramento, CA 95834** **(916) 574-7910**
October 19-20	**To be Determined**

Additional information regarding the dates, locations, and agendas for Board and committee meetings will be posted on the Board's Web site, ***www.pharmacy.ca.gov/about/meetings.htm,*** at least 10 days prior to each meeting. Also, about five days before each meeting, you may download meeting information packets that contain background information and action items that will be discussed during the meeting.

Explanation of Disciplinary Terms

Accusation Filed—an accusation is the document containing the charges and allegations of violations of the law filed when an agency is seeking to discipline a license.

Effective Date of Action—the date the disciplinary action goes into operation.

Revocation or Revoked—the license is revoked as a result of disciplinary action by the Board, and the licensee's right to practice or operate a Board-licensed entity is ended.

Revoked, Stayed—the license is revoked, but the revocation is postponed until the Board determines whether the licensee has failed to comply with specific probationary conditions, which may include suspension of the licensee's right to practice.

Stipulated Settlement—the board and a licensee mutually agree to settle a disciplinary case brought by the board by way of a settlement agreement.

Stayed—the revocation or suspension action is postponed, and operation or practice may continue so long as the licensee fully complies with any specified terms and conditions..

Probation—the licensee may continue to practice or operate a Board-licensed entity under specific terms and conditions for a specific period of time.

Voluntary Surrender—the licensee has agreed to surrender his or her license, and the right to practice or operate Board-licensed entity is ended. The board may agree to accept the surrender of a license through a "stipulation" or agreement.

Suspension—the licensee is prohibited from practicing or operating a Board-licensed entity for a specific period of time.

Suspension/Probation—the licensee is prohibited from practicing or operating a Board-licensed entity for a specific period of time, and the right to practice or operate is contingent upon meeting specific terms and conditions during the probationary period.

PC 23 Order Issued—the licensee is restricted from practicing or operating a Board-licensed entity by a court order that is issued under the provisions of Penal Code section 23.

Public Reprimand—resulting from a disciplinary action, the licensee is issued a letter of public reprimand.

Reinstatement of License—a previously revoked or suspended license is reinstated with or without specified terms and conditions.

Statement of Issues—a legal document that details the factual or legal bases for refusing to grant or issue a license.

Disciplinary Actions

The following licenses were disciplined through actions taken by the Board from July 2, 2010, to May 11, 2011. To view details of the probation terms and conditions of each case, go to the Board's Web site, ***www.pharmacy.ca.gov***, and from the "Quick Hits" menu, select "Enforcement Actions."

Pharmacist Licenses

Allen, William Andrew, RPH 54535, San Diego, CA—Case 3412
By Stipulated Settlement, license revoked, stayed, five years' probation subject to terms and conditions that include: cannot supervise any intern pharmacist; perform preceptor duties or be pharmacist-in-charge; practice must be supervised; and no ownership of any Board-licensed entity.
Decision effective 12/31/2010

Basilyan, Madlen, RPH 56808, Pasadena, CA—Case 3156
By Stipulated Settlement, license revoked, stayed, five years' probation subject to terms and conditions that include: suspended from practicing pharmacy for 15 days; cannot own any additional Board-approved premises, may be pharmacist-in-charge with a consultant; and must successfully complete an approved ethics course.
Decision effective 01/07/2011

Bell, Lawrence Steven, RPH 40966, Ventura, CA—Case 3177
By Stipulated Settlement, license revoked, stayed, three years' probation subject to terms and conditions that include: cannot supervise any intern pharmacist, perform preceptor duties or be pharmacist-in-charge; must successfully complete an approved ethics course; and must have worksite monitor.
Decision effective 08/05/2010

Bragdon, William Thomas, Jr., RPH 52585, Patterson, CA—Case 3626
By Stipulated Settlement, license revoked, stayed, five years' probation subject to terms and conditions that include but not limited to: may be pharmacist-in-charge with a consultant.
Decision effective 10/27/2010

Braun, Mark Howard, RPH 43806, Culver City, CA—Case 3233
By Stipulated Settlement, license revoked, stayed, five years' probation subject to terms and conditions that include: suspended from practicing pharmacy until deemed fit to practice, cannot supervise any intern pharmacist, perform preceptor duties or be pharmacist-in-charge, and must have supervised practice.
Decision effective 05/11/2011

*See **Disciplinary Actions**, Page 29*

Disciplinary Actions

Continued from Page 28

Brown, Michael Edward, RPH 37708, Chula Vista, CA—Case 3411
By Stipulated Settlement, license revoked, stayed, five years' probation subject to terms and conditions that include: 30 days' suspension; cannot supervise any intern pharmacist, perform preceptor duties or be pharmacist-in-charge; practice must be supervised; no ownership of any Board-licensed premises.
Decision effective 09/29/2010

Callahan, Edward III, RPH 26227, Playa Del Rey, CA—Case 3132
By Stipulated Settlement, Letter of Admonishment issued.
Decision effective 12/10/2010

Chan, Sharon Lee, Pharmacist Applicant, La Canada, CA—SI 3384
By Stipulated Settlement, when Pharmacist license is issued, it will be placed on four years' probation; cannot supervise any intern pharmacist, perform preceptor duties or be pharmacist-in-charge; practice must be supervised; no ownership of any Board-licensed premises; and must successfully complete an approved ethics course.
Decision effective 07/28/2010

Cho, Edric, RPH 38333, Grass Valley, CA—Case 3419
By Stipulated Settlement, license revoked, stayed, four years' probation subject to terms and conditions that include: 30 days' suspension; cannot supervise any intern pharmacist, perform preceptor duties or be pharmacist-in-charge; practice must be supervised; no ownership of any Board-licensed premises.
Decision effective 09/29/2010

Clark, Bruce Edward, RPH 30899, Fresno, CA—Case 3568
By Stipulated Settlement, license revoked, stayed, five years' probation subject to terms and conditions that include: cannot supervise any intern pharmacist, perform preceptor duties or be pharmacist-in-charge; must successfully complete an approved ethics course; and must have worksite monitor.
Decision effective 12/31/2010

Dash, Michelle Anne, RPH 42182, Porter Ranch, CA—Case 3537
By Default Decision, license revoked.
Decision effective 03/28/2011

Doan, Long Ngoc, RPH 50777, Tustin, CA—Case 3491
By Stipulated Settlement, license revoked, stayed, four years' probation subject to terms and conditions that include: 15 days suspended pharmacy practice; cannot supervise any intern pharmacist, perform preceptor duties or be pharmacist-in-charge; practice must be supervised; no ownership of any Board-licensed premises; and must successfully complete an approved ethics course.
Decision effective 08/25/2010

Eastland, Kerry Joe, RPH 61785, Riverside, CA—Case 3710
By Stipulated Settlement, license revoked, stayed, four years' probation subject to terms and conditions that include: suspended from practicing pharmacy for 60 days, cannot supervise any intern pharmacist, perform preceptor duties or be pharmacist-in-charge; no ownership of any Board-licensed entity, and must have supervised practice.
Decision effective 05/11/2011

Ferry, Brenna Ann, Pharmacist Applicant, Sacramento, CA—Case SI 3857
Statement of Issues has been withdrawn.
Decision effective 02/08/2011

Gaurano, Valerie Reyes, RPH 38852, Del Mar, CA—Case 3736
By Stipulated Settlement, license revoked, stayed, two years' probation subject to terms and conditions that include: cannot supervise any intern pharmacist, perform preceptor duties or be pharmacist-in-charge; and no ownership of any Board-licensed entity.
Decision effective 05/11/2011

Gill, Gurmukh Singh, RPH 51983, Hilmar, CA—Case 3230
By Stipulated Settlement, license revoked, stayed, five years' probation subject to terms and conditions that include: suspended from practicing pharmacy for 90 days, cannot own any Board-license entity and may be pharmacist-in-charge with a consultant.
Decision effective 03/28/2011

Glen, Michael Alexander, RPH 51983, Bellingham, WA—Case 3571
By Stipulated Settlement, license revoked, stayed, six years' probation subject to terms and conditions that include: practice must be supervised, cannot supervise any intern or be pharmacist-in-charge, suspended from practicing pharmacy for 90 days with credit given for time already served, and no ownership of any Board-licensed entity.
Decision effective 03/28/2011

Golka, Stephen James, RPH 32396, Sacramento, CA—Case 3341
By Stipulated Settlement, license revoked, stayed, five years' probation subject to terms and conditions that include: suspended from practicing pharmacy for 21 days and may be pharmacist-in-charge with a consultant.
Decision effective 01/07/2011

Hall, Robert Thomas, RPH 32860, Eureka, CA—Case 3699
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 02/05/2011

Hoerrner, Jennifer W., RPH 52366, Glen Allen, VA—Case 3575
By Default Decision, license revoked.
Decision effective 08/05/2010

Kim, Dianna M., RPH 54036, San Diego, CA—Case 3434
By Hearing Decision, license revoked.
Decision effective 04/27/2011

Krinsky, Oscar J., RPH 21664, Long Beach, CA—Case 37399
By Default Decision, license revoked.
Decision effective 04/15/2011

Klein, Jerry B., RPH 33188, Crescent City, CA—Case 3404
By Stipulated Settlement, license revoked, stayed, four years' probation subject to terms and conditions that include: can be pharmacist-in-charge with consultant; and no ownership of any Board-licensed premises.
Decision effective 11/18/2010

Koo, Anna K., RPH 42518, Torrance, CA—Case 3254
Accusation withdrawn as to Anna K. Koo.
Decision effective 12/03/2010

*See **Disciplinary Actions**, Page 30*

Disciplinary Actions

Continued from Page 29

Kung, Julie Shu-Hwa, RPH 49994,
Arcadia, CA—Case 3410
By Stipulated Settlement, license revoked, stayed, five years' probation subject to terms and conditions that include: 15 days' suspension from practicing; cannot supervise any intern pharmacist, perform preceptor duties or be pharmacist-in-charge; no ownership of any Board-licensed premises; and must successfully complete an approved ethics course.
Decision effective 02/17/2011

Lizarazo, Gustavo Adolpho,
RPH 59384,
Spring Valley, CA—Case 3367
By Hearing Decision, license revoked.
Decision effective 03/28/2011

Lloyd, Warren Christopher,
RPH 41161,
Long Beach, CA—Case 3596
By Stipulated Settlement, license revoked, stayed, five years' probation subject to terms and conditions that include: cannot supervise any intern pharmacist, perform preceptor duties or be pharmacist-in-charge; practice must be supervised; and no ownership of any Board-licensed premises.
Decision effective 10/27/2010

MacMullen, Gary, RPH 30639,
Rancho La Costa, CA—Case 3183
By Decision, license revoked, stayed, five years' probation subject to terms and conditions that include: 180 days' suspended pharmacy practice; cannot supervise any intern pharmacist or ancillary personnel, perform preceptor duties or be pharmacist-in-charge; and no ownership of any Board-licensed premises.
Decision effective 07/02/2010

Merkel, Donald Steven, RPH43281,
San Diego, CA—Cases 3306 and 3682
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 08/20/2010

Margolin, Steven Michael, RPH 36992,
Van Nuys, CA—Case 3618
By Hearing Decision, license revoked.
Decision effective 10/27/2010

Montoya, Richard D., RPH 41140,
Big Bear Lake, CA—Case 3379
By Stipulated Settlement, license revoked, stayed, five years' probation subject to terms and conditions that include: 45 days' suspended pharmacy practice; cannot supervise any intern pharmacist, perform preceptor duties or be pharmacist-in-charge; practice must be supervised; and no ownership of any Board-licensed premises.
Decision effective 09/29/2010

Neminov, Polina, RPH 50440,
Woodland Hills, CA—Case 3254
Accusation withdrawn as to Polina Neminov..
Decision effective 12/03/2010

Ozimy, Eric Duane, RPH 36956,
Stockton, CA—Case 3298
By Stipulated Settlement, license revoked, stayed, five years' probation subject to terms and conditions that include: 30 days' suspended pharmacy practice; cannot supervise any intern pharmacist, perform preceptor duties or be pharmacist-in-charge; and practice must be supervised.
Decision effective 11/18/2010

Parks, Tara Ann, RPH 58965, Fallbrook,
CA—Case 3704
By Stipulated Settlement, license revoked, stayed, five years' probation subject to terms and conditions that include: cannot supervise any intern pharmacist, perform preceptor duties or be pharmacist-in-charge, practice must be supervised, and must successfully complete an approved ethics course.
Decision effective 04/15/2011

Patel, Paragi, RPH 49421,
San Leandro, CA—Case 3515
By Stipulated Settlement, license revoked, stayed, three years' probation subject to terms and conditions that include: 30 days' suspended pharmacy practice; may be pharmacist-in-charge with a consultant; and cannot own any new Board-licensed premises.
Decision effective 02/17/2011

Payne, Robert John, RPH 26146,
Carmichael, CA—Case 3341
By Stipulated Settlement, license revoked, stayed, five years' probation subject to terms and conditions that include: suspended from practicing pharmacy for 60 days; cannot supervise any intern pharmacist, perform preceptor duties or be pharmacist-in-charge; cannot own any Board-licensed premises; and must successfully complete an approved ethics course.
Decision effective 01/07/2011

Phan, Hung Phi, RPH 45283,
Milpitas, CA—Case 3440
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 03/09/2011

Platt, Chris Eugene, RPH 41579,
Ojai, CA—Case 3364
By Stipulated Settlement, license revoked, stayed, four years' probation subject to terms and conditions that include: cannot supervise any intern pharmacist, perform preceptor duties or be pharmacist-in-charge; practice must be supervised; and cannot own any additional Board-approved premises.
Decision effective 01/07/2011

Puccinelli, John Michael, RPH 26552,
San Jose, CA—Case 3430
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 08/25/2010

Rodefshalom, Nima, RPH 55990,
Los Angeles, CA—Case 3330
By Stipulated Settlement, license revoked, stayed, two years' probation subject to terms and conditions that include: two years' probation; cannot supervise any intern pharmacist or serve as consultant to any Board-licensed premises; may function as pharmacist-in-charge if she retains an independent consultant; must compete 10 hours of remedial education; and no new ownership of any Board-licensed premises.
Decision effective 07/28/2010

Sardinas, Jose Ramon, RPH 27061,
Manhattan Beach, CA—Case 3584
By Hearing Decision, license revoked, stayed, three years' probation subject to terms and conditions that include: 30 days suspended pharmacy practice; cannot supervise any intern pharmacist, perform preceptor duties or be pharmacist-in-charge.
Decision effective 03/09/2011

*See **Disciplinary Actions**, Page 31*

Disciplinary Actions

Continued from Page 30

Sawai, Myles Y., RPH 41279, Orange, CA—Case 3733
By Stipulated Settlement, license revoked.
Decision effective 05/11/2011

Shibley, Norman Bruce, RPH 39528, Lancaster, CA—Case 3370
By Stipulated Settlement, license revoked, stayed, six years' probation subject to terms and conditions that include: nine months suspended pharmacy practice; cannot supervise any intern pharmacist, perform preceptor duties or be pharmacist-in-charge; practice must be supervised; and no ownership of any Board-licensed premises.
Decision 03/28/2011

Simpson, Thomas Russell III, RPH 26687, Stockton, CA—Case 3478
By Stipulated Settlement, license revoked, stayed, four years' probation subject to terms and conditions that include: cannot supervise any intern pharmacist, perform preceptor duties or be pharmacist-in-charge, no ownership of any Board-license entity, and practice must be supervised.
Decision effective 05/11/2011

Strom, Carter R., RPH 36629, Moreno Valley, CA—Case 3393
By Stipulated Settlement, license revoked, stayed, five years' probation subject to terms and conditions that include: 18 days suspended pharmacy practice; cannot supervise any intern pharmacist, perform preceptor duties or be pharmacist-in-charge; practice must be supervised; no ownership of any Board-licensed premises; and must successfully complete an approved ethics course.
Decision effective 08/25/2010

Tomlin, Stuart Blake, RPH 42645, Stockton, CA—Case 3681
By Stipulated Settlement, license revoked, stayed, five years' probation subject to terms and conditions that include: suspended from practicing pharmacy for seven days; cannot supervise any intern pharmacist, perform preceptor duties or be pharmacist-in-charge; practice must be supervised; no ownership of any Board-licensed entity; and must successfully complete an approved ethics course.
Decision effective 12/31/2010

White, Michael Francis, RPH 28654, Solvang, CA—Case 3547
By Stipulated Settlement, license revoked, stayed, four years' probation subject to terms and conditions that include: cannot supervise any intern pharmacist, perform preceptor duties or be pharmacist-in-charge, no ownership of any Board-licensed entity, and practice must be supervised.
Decision effective 05/11/2011

Wong, John F., RPH 52583, Patterson, CA—Case 3626
By Stipulated Settlement, license revoked, stayed, five years' probation subject to terms and conditions that include: cannot supervise any intern pharmacist, perform preceptor duties or be pharmacist-in-charge.
Decision effective 10/27/2010

Woods-Munoz, Donna, RPH 50357, Kingsburg, CA—Case 3296
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 11/18/2010

Yee, Michelle, RPH 53971, San Francisco, CA—Case 3602
By Default Decision, license revoked.
Decision effective 05/11/2011

Yuh, Byung Sik, RPH 36896, Burlingame, CA—Case 3737
By Stipulated Settlement, license revoked, stayed, five years' probation subject to terms and conditions that include but are not limited to: can be pharmacist-in-charge with a consultant.
Decision effective 01/07/2011

Pharmacist Technicians, Intern, and Exemptee

Alonso, Cristina, TCH 56096, Chatsworth, CA—Case 3390
By Default Decision, license revoked.
Decision effective 08/05/2010

Anderson, Adrienne, TCH 49864, Chico, CA—Case 3700
By Stipulated Settlement, license revoked, stayed, five years' probation subject to terms and conditions that include: suspended from practicing for three days, passing the Pharmacy Technician Certification Board examination, no ownership of any Board-licensed entity, and must have worksite monitor.
Decision effective 04/15/2011

Asaro, Andrew Albert, TCH 56928, Spring Valley, CA—Case 3800
By Default Decision, license revoked.
Decision effective 05/11/2011

Avalos, Albert, TCH 69538, La Puente, CA—Case 3490
By Default Decision, license revoked.
Decision effective 12/10/2010

Avalos, Donna Leigh, TCH 54402, San Jacinto, CA—Case 3337
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 08/25/2010

Bain, Nicholas Peter, TCH 80186, Yucaipa, CA—Case SI 3451
By Hearing Decision, the application for license is granted, Upon satisfaction of all statutory and regulatory requirements for issuance of a license, a license shall be issued. License will be immediately revoked, stayed, placed on two years' probation, and must pass the Pharmacy Technician Certification Board examination.
Decision effective 05/16/2011

Barragan, Miguel Angel, TCH 79627, South El Monte, CA—Case 3400
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 12/31/2010

Bendele, Donald E., III, TCH 50148, Denair, CA—Case 2973
By Default Decision, license revoked.
Decision effective 08/06/2010

Berghouse, Angela, TCH 51956, Ramona, CA—Case 3597
By Default Decision, license revoked.
Decision effective 01/21/2011

Bernal, Rita, TCH 54691, Fresno, CA—Case 3524
By Default Decision, license revoked.
Decision effective 04/15/2011

Blackmon, Jessica Ann, TCH 63102, Lake Elsinore, CA—Case 3805
By Default Decision, license revoked.
Decision effective 05/11/2011

Bounthapanya, Sysavath Jimmy, TCH 68660, San Jose, CA—Case 3706
By Stipulated Surrender, license was voluntarily surrendered.
Decision effective 02/17/2011

*See **Disciplinary Actions**, Page 32*

Disciplinary Actions

Continued from Page 31

Breen, Richard Max, TCH 87605, Cathedral City, CA—Case 3743
By Stipulated Settlement, license revoked.
Decision effective 03/28/2011

Bruns, Ingret, TCH 49154, Pinole, CA—Case 3600
By Stipulated Settlement, license revoked, stayed, five years' probation. The terms and conditions of probation include passing the Pharmacy Technician Certification Board examination, no ownership of any Board-licensed entity, and needs a worksite monitor.
Effective 04/15/2011

Bryant, Linda Sami, TCH 44259, Ontario, CA—Case 3621
By Default Decision, license revoked.
Decision effective 10/03/2010

Bryant, Tommari, TCH 72272, Lancaster, CA—Case 3366
By Default Decision, license revoked.
Decision effective 08/05/2010

Canchola, Yvonne M., TCH 51226, Palm Springs, CA—Case 3598
By Default Decision, license revoked.
Decision effective 01/07/2011

Cantero, David Donny, TCH 10551, Santa Maria, CA—Case 3616
By Hearing Decision, license revoked.
Decision effective 05/11/2011

Cauley, Krista R., TCH 30909, Grass Valley, CA—Case 3292
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 12/31/2010

Chacon, Ronald, TCH 80432, Daly City, CA—Case 3782
By Default Decision, license revoked.
Decision effective 05/11/2011

Chau, Loan Ngoc, TCH 54960, Newark, CA—Case 3574
By Default Decision, license revoked.
Decision effective 10/27/2010

Chavez, Reina, TCH 65722, Sacramento, CA—Case 3277
By Stipulated Settlement, license revoked.
Decision effective 11/18/2010

Chavez, Roger Anthony, TCH 63325, Hayward, CA—Case 3540
By Proposed Decision, license revoked.
Decision effective 02/17/2011

Chavez, Walter Joaquin, TCH 35962, Arleta, CA—Case 3635
By Default Decision, license revoked.
Decision effective 03/28/2011

Collins, Heidi Sue, TCH 64864, Dana Point, CA—Case 3734
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 01/07/2011

Conner, Deborah, TCH 23357, Santee, CA—Case 3581
By Default Decision, license revoked.
Decision effective 08/05/2010

Cuayu, Wayne Buencamino, TCH 77398, Hayward, CA—Case 3658
By Stipulated Decision, license was voluntarily surrendered.
Decision effective 05/11/2011

Dalou, Christopher, TCH 85056, Moreno Valley, CA—Case 3426
By Default Decision, license revoked.
Decision effective 08/05/2010

Davis, Melissa Carmel. TCH 21218, Saugus, CA—Case 3260
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 03/28/2011

Davis, Tanya Sherita, TCH 45240, Los Angeles, CA—Case 3667
By Default Decision, license revoked.
Decision effective 01/19/2011

Davis, Tracey Lynne, TCH 13104, Santa Rosa, CA—Case 3666
By Default Decision, license revoked.
Decision effective 05/11/2011

Dayao, Jan Perry, TCH 64006, San Francisco, CA—Case 3549
By Default Decision, license revoked.
Decision effective 10/27/2010

Devoe, Miranda Vanessa, TCH 33767, Fremont, CA—Case 3614
By Default Decision, license revoked.
Decision effective 05/11/2011

Diaz, Dante Santos, TCH 26083, West Hollywood, CA—Case 3744
By Default Decision, license revoked.
Decision effective 01/19/2011

Diaz, Morgan Leigh, TCH 72220, Denver, CO—Case 3632
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 03/09/11

Dicaro, Tammy Lynn, TCH 64715, Moss Landing, CA—Case 3363
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 07/23/2010

Dorosky, Lisa Marie, TCH 63119, Seal Beach, CA—Case 3721
By Stipulated Settlement, license was voluntarily surrendered.
Decisiion effective 11/18/10

Dorsey, Kamau, TCH 64637, Perris, CA—Case 3683
By Default Decision, license revoked.
Decision effective 12/17/2010

Downey, Clara Diane, TCH 3748, Oceanside, CA—Case 3730
By Default Decision, license revoked.
Decision effective 11/18/10

Eaves, Denise Christine, TCH 50501, Highland, CA—Case 3815
By Default Decision, license revoked.
Decision effective 04/15/2011

Facciani, Tammy Jane, TCH 49496, Clovis, CA—Case 3680
By Default Decision, license revoked.
Decision effective 01/19/2011

Fame, Precious, TCH 38982, Pittsburg, CA—Case 3473
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 08/25/2010

Farmer, Phyllis Ann, TCH 53610, Truckee, CA—Case 3558
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 08/05/2010

Fernandez, Stephanie Rae, TCH 75828, Hayward, CA—Case 3551
By Default Decision, license revoked.
Decision effective 10/27/2010

Fofana, Mohamed Lamine, TCH 72507, Oakland, CA—Case 3483
By Stipulated Settlement, license revoked.
Decision effective 12/31/2010

Freitas, Jolene Antonette, TCH 40919, Fremont, CA—Case 3807
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 05/11/2011

Gabriel, Jena Castillo, TCH 54611, Oceanside, CA—Case 3578
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 11/18/2010

*See **Disciplinary Actions**, Page 33*

Disciplinary Actions

Continued from Page 32

Gamond, Jonathan Allen, TCH 38235, Lakewood, CA—Case 3503
By Default Decision license revoked.
Decision effective 03/28/2011

Garcia, Anjelica Marie, TCH 74274, Redlands, CA—Case 3247
By Hearing Decision, license revoked.
Decision effective 10/27/2010

Garibaldi, Rita Jeanine, TCH 48059, Vacaville, CA—Case 3605
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 04/15/2011

Gearing, Lola Yvette Cooks, Pharmacy Technician Applicant, Fontana, CA—Case SI 3197
By Default Decision, the application was denied.
Decision effective 01/07/2011

Geralde, Errol R., TCH 68671, La Mirada, CA—Case 3494
By Default Decision, license revoked.
Decision effective 05/11/2011

Glaser, Andrew Christopher, TCH 67216, Winton, CA—Case 3620
By Default Decision, license revoked.
Decision effective 10/03/2010

Godinez, Christina Marie, TCH 86747, Hollister, CA—Case 3545
By Default Decision, license revoked.
Decision effective 10/27/2010

Gonzalez, Carmen, TCH 36174, Sun City, CA—Case3459
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 11/18/10

Gonzales, Jason P., TCH 30137, Chula Vista, CA—Case 3548
By Stipulated Settlement, license revoked, stayed, five years' probation subject to terms and conditions that include: must have worksite monitor and pass the pharmacy technician certification exam.
Decision effective 08/25/2010

Gonzales, Jeremy Rubin, TCH 59768, Norwalk, CA—Case 3417
By Default Decision, license revoked.
Decision effective 03/09/2011

Guerrero, Mayra Leticia, TCH 68342, Los Angles, CA—Case 3376
By Stipulated Settlement, license revoked, stayed, five years' probation subject to terms and conditions that include: must pass the pharmacy technician certification examination; no ownership of a Board-licensed entity; and must have worksite monitor.
Decision effective 12/10/2010

Gutierrez, Frank Anthony, TCH 64204, Oakhurst, CA—Case 3579
By Hearing Decision, license revoked, stayed, three years' probation. The terms and conditions of probation include passing the Pharmacy Technician Certification Board examination.
Decision effective 05/11/2011

Gutierrez, Raul, TCH 14159, Perris, CA—Case 4018
By Hearing Decision, license reinstated, revoked, stayed, five years' probation subject to all terms and conditions which include having a worksite monitor.
Decision effective 02/18/2011

Gwin, Gary Patrick, TCH 92152, Sacramento, CA—Case 3748
By Default Decision, license revoked.
Decision effective 04/15/2011

Halstead, Jason Matthew, TCH 80317, Chino, CA—Case 3264
By Default Decision, license revoked.
Decision effective 08/25/2010

Hannesyan, Petros, TCH 68925, Burbank, CA—Case 3538
By Default Decision, license revoked.
Decision effective 04/15/2011

Hanson, Heidi Joy, TCH 86214, Calabasas, CA—Case 3529
By Default Decision, license revoked.
Decision effective 01/19/2011

Hardy, Denise Lavon, TCH 80089, Aliso Viejo, CA—Case 3724
By Default Decision, license revoked.
Decision effective 01/07/2011

Hawes, Jason, TCH 95258, Torrance, CA—Case SI 3760
By Stipulated Settlement, the application for pharmacy technician is granted. Upon satisfaction of all statutory and regulatory requirements, a license shall be issued. The license will be immediately revoked, stayed, placed on three years' probation. The terms and conditions of probation include: passing the Pharmacy Technician Certification Board examination, no ownership of any Board-licensed entity, and must have worksite monitor.
Decision effective 04/15/2011

Higgins, Desiree, TCH 83979, Antelope, CA—Case 3542
Accusation withdrawn as to Desiree Higgins.
Decision effective 01/10/2011

Ho, Loan T., TCH 56090, Riverside, CA—Case 3475
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 08/25/2010

Houston, Shelise, TCH 31260, Inglewood, CA—Case 3742
By Default Decision, license revoked.
Decision effective 01/19/2011

Houston, Tajza Monet-Maxine, TCH 83930, Berkeley, CA—Case 3638
By Default Decision, license revoked.
Decision effective 05/11/2011

Hunt, Patti Lynn, TCH 2936, El Cajon, CA—Case 3592
By Default Decision, license revoked.
Decision effective 10/27/2010

Jacob, Katherine Hirning, TCH 39354, Stockton, CA—3864
By Default Decision, license revoked.
Decision effective 04/15/2011

Jacobs-Blake, Mandy, TCH 41556, Chico, CA—Case 3878
By Default Decision, license revoked.
Decision effective 05/11/2011

James, Briggett D., TCH 61760, Sacramento, CA—Case 3603
By Default Decision, license revoked.
Decision effective 04/15/2011

Johnson, Deanna May, TCH 87674, Biggs, CA—Case 3599
By Default Decision, license revoked.
Decision effective 01/07/2011

Johnson, Raquel Lenora, TCH 37600, Los Angeles, CA—Case 3372
By Default Decision, license revoked.
Decision effective 03/28/2011

Juarros, Robert Anthony, TCH 39870, Elk Grove, CA—Case 3913
By Default Decision, license revoked.
Decision effective 05/11/2011

Junio, James Alfred, TCH 64371, Anaheim, CA—Case 3010
By Default Decision, license revoked.
Decision effective 01/07/2011

Jurado, Jaime, TCH 59073, Sun Valley, CA—Case 3688
By Default Decision, license revoked.
Decision effective 01/19/2011

*See **Disciplinary Actions**, Page 34*

Disciplinary Actions

Continued from Page 33

Kamel. Anthony J., TCH 62157, Irvine, CA—Case 3690
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 09/29/2010

Khairzada, Abdullah, TCH 66070, Hayward, CA—Case 3629
By Default Decision, license revoked.
Decision effective 03/28/2011

Kokorian, Jessica Cecilia, TCH 44692, Torrance, CA—Case 3580
By Default Decision, license revoked.
Decision effective 11/18/2010

Kumar, Naresh, TCH 49281, Tracy, CA—Case 3669
By Default Decision, license revoked.
Decision effective 10/03/2010

LaPerle, Leslie Marie, Pharmacy Technician Applicant, Concord, CA—Case SI 3513
Statement of Issues has been withdrawn.
Effective 01/19/2011

Lazaro, Emily Maria, TCH 33870, Lompoc, CA—Case 3498
By Default Decision, license revoked.
Decision effective 01/19/2011

Le, Bobby Hoang Quang, TCH 48785, West Covina, CA—Case 3768
By Stipulated Settlement, license revoked, stayed, five years' probation subject to terms and conditions that include: passing the Pharmacy Technician Certification Board examination and no ownership of any Board-licensed entity.
Decision effective 03/28/2011

Leyva, Francisco J., TCH 38071, Sacramento, CA—Case 3650
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 05/11/2011

Locke, Brandon Carlisle, TCH 77299, Bakersfield, CA—Case 3646
By Default Decision, license revoked.
Decision effective 01/19/2011

Lookman, Samantha, TCH 77115, Yorba Linda, CA—Case 3518
By Default Decision, license revoked.
Decision effective 08/05/2010

Lopez, Filimon M., TCH 35419, Laguna Niguel, CA—Case 3314
By Stipulated Settlement, license revoked, stayed, five years' probation subject to terms and conditions that include: 60 days' suspension; must pass the pharmacy technician certification examination; no ownership of a Board-licensed entity; and must have worksite monitor.
Decision effective 02/17/2011

Loveless, Andrew M., TCH 80976, Redding, CA—Case 3540
By Proposed Decision, license revoked.
Decision effective 02/17/2011

Lue, Donald, TCH 57402, San Francisco, CA—Case 3553
By Default Decision, license revoked.
Decision effective 12/10/2010

Madry, Taren Danette, TCH 88082, San Diego, CA—Case 3566
By Default Decision, license revoked.
Decision effective 08/25/2010

Magana, Maria, TCH 23065 and INT 18877, San Mateo, CA—Case 3611
By Stipulated Settlement, licenses revoked, stayed, placed on probation for five years. The terms and conditions of probation include no ownership of any Board-licensed entity.
Decision effective 04/15/2011

Maluto, Charriza C., TCH 47630, Hayward, CA—Case 3436
By Default Decision, license revoked.
Decision effective 03/28/2011

Marseilles, Crystal, TCH 48067, Idyllwild, CA—Case 3474
By Default Decision, license revoked.
Decision effective 03/28/2011

Martinez, John J., TCH 14084, Fresno, CA—Case 3327
By Proposed Decision, license revoked.
Decision effective 10/27/2010

Matthias, Tyree Michael, TCH 73611, Los Angeles, CA—Case 3861
By Default Decision, license revoked.
Decision effective 05/11/2011

Maxie, Lori, TCH 21460, Los Angeles, CA—Case 3555
By Default Decision, license revoked.
Decision effective 03/28/2011

Medeiros, Heidi L., TCH 25025, Martinez, CA—Case 3837
By Default Decision, license revoked.
Decision effective05/11/2011

Mendoza, Julie Marie, TCH 24030, San Jose, CA—Case 3712
By Stipulated Settlement, license revoked, stayed, three years' probation subject to terms and conditions that include: passing the Pharmacy Technician Certification Board examination, no ownership of any Board-licensed entity, and needs a worksite monitor.
Decision effective 03/28/2011

Menendez, Amada A., TCH 43329, Novato, CA—Case 3500
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 11/18/2010

Mitosinka, Michael Joseph, TCH 80095, El Centro, CA—Case 3577
By Default Decision, license revoked.
Decision effective 04/15/2011

Mojarro, Araceli, TCH 34970, Temecula, CA—Case 3495
By Hearing Decision, license revoked.
Decision effective 04/15/2011

Mojica, Ferdinand Mendez, TCH 58422, San Francisco, CA—Case 3455
By Stipulated Settlement, license revoked, stayed, two years' probation subject to terms and conditions that include: passing the pharmacy technician certification exam and no ownership of any Board-licensed premises.
Decision effective 11/18/2010

Morrissey, Lourdes, TCH 32807, North Hills, CA—Case 3401
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 09/29/2010

Munoz, Edgardo Ernesto, TCH 72067, Aptos, CA—Case 3793
By Default Decision, license revoked.
Decision effective 04/15/2011

Nalbandbashian,Tama Gilda, TCH 67784, North Hills, CA—Case 3392
By Default Decision, license revoked.
Decision effective 11/18/2010

Nardini, Kelsie Teran, TCH 41156, Hanford, CA—Case 3522
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 03/09/2011

Nelson-Coats, Rhonda Lee, TCH 51846, Mariposa, CA—Case 3085
By Proposed Decision, license revoked, stayed, five years' probation subject to terms and conditions that include: 60 days suspension;

*See **Disciplinary Actions**, Page 35*

Disciplinary Actions

Continued from Page 34

must pass the pharmacy technician certification examination; no ownership of a Board-licensed entity; and must have worksite monitor.
Decision effective 02/17/2011

Nguyen, Hoai Nam, TCH 64936, Rancho Cucamonga, CA—Case 3590
By Default Decision, license revoked.
Decision effective 08/25/2010

Nguyen, Tung Thanh, TCH 54215, Stockton, CA—Case 3665
By Default Decision, license revoked.
Decision effective 08/25/2010

Nunez, Jesse, TCH 74636, Los Angeles, CA—Case 3355
By Default Decision, license revoked.
Decision effective 04/15/2011

O'Brien, Meghan Hanora, Pharmacy Technician Applicant, El Paso, TX—Case SI 3466
By Default Decision, application denied.
Decision effective 03/28/2011

Owen, Jana Richelle, TCH 14407, Redding, CA—Case 3608
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 08/05/2010

Padda, Ravinder, TCH 51508, Tracy, CA—Case 3644
By Hearing Decision, license revoked.
Decision effective 05/11/2011

Padua, Armando Daniel, TCH 76317, West Covina, CA—Case 3559
By Default Decision, license revoked.
Decision effective 03/28/2011

Palazot, Carl Robert, TCH 37328, San Diego, CA—Case 3504
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 04/15/2011

Papageorge, Nicholas Andrew, TCH 48940, Nipomo, CA—Case 3397
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 05/11/2011

Pascua, Marissa, TCH 45411, Chula Vista, CA—Case 3595
By Stipulated Settlement, license revoked, stayed, two years' probation subject to terms and conditions that include: must pass the pharmacy technician certification examination; cannot own any Board-licensed premises; and must have worksite monitor.
Decision effective 01/07/2011

Patel, Nikin, TCH 78009, Long Beach, CA—Case 3758
By Default Decision, license revoked.
Decision effective 04/15/2011

Payne, Kenneth J., TCH 61842, Redding, CA—Case 3570
By Default Decision, license revoked.
Decision effective 05/11/2011

Pena, Mark Joseph, TCH 77759, San Diego, CA—Case 3310
By Decision, license revoked.
Decision effective 07/23/2010

Perro, Milynn Joy, TCH 46183, Scotts Valley, CA—Case 3541
By Default Decision, license revoked.
Decision effective 11/18/2010

Porrini, David, TCH 84158, Riverside, CA—Case 3636
By Default Decision, license revoked.
Decision effective 10/03/2010

Ramirez, Jose A., TCH 65747, San Diego, CA—Case 3546
By Stipulated Settlement, license revoked, stayed, three years' probation subject to terms and conditions that include: must pass the pharmacy technician certification examination; no ownership of a Board-licensed entity; and must have worksite monitor.
Decision effective 02/17/2011

Ramos, Elisajoy Espiritu, TCH 83365, Poway, CA—Case 3332
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 8/25/2010

Ramos, Jose Juan, TCH 38837, Glendale, CA—Case 3657
By Default Decision, license revoked.
Decision effective 01/19/2011

Rayos, Steven, TCH 40025, Bellflower, CA—Case 3338
By Stipulated Settlement, license revoked, stayed, three years' probation subject to terms and conditions that include: passing the pharmacy technician certification exam; no ownership of any Board-licensed premises; and must have worksite monitor.
Decision effective 11/18/2010

Reese, Pricilla, TCH 12265, Harbor City, CA—Case 3664
By Stipulated Settlement, license revoked, stayed, three years' probation subject to terms and conditions that include: passing the pharmacy technician certification exam; and no ownership of any Board-licensed premises.
Decision effective 01/07/2011

Rendon, Lizette, TCH 110862, Sultana, CA—Case SI 3535
By Hearing Decision, application is granted, and upon satisfaction of all statutory and regulatory requirements for issuance of a license, a license shall be issued, revoked, stayed, and placed on three years' probation. The terms and conditions of probation include passing the Pharmacy Technician Certification Board examination, no ownership of a Board-licensed entity, and must have worksite monitor.
Decision effective 03/09/2011

Rhodes, Kenneth Charles, TCH 14881, Northridge, CA—Case 3573
By Default Decision, license revoked.
Decision effective 12/10/2010

Rini, Corin, TCH 30033, Thousand Oaks, CA—Case 3375
By Stipulated Settlement, license revoked, stayed, four years' probation subject to terms and conditions that include but are not limited to: passing the pharmacy technician certification exam; no ownership of any Board-licensed premises; and must have worksite monitor.
Decision effective 01/07/2011

Robinson, Gregory Julian, TCH 75222, Concord, CA—Case 3649
By Default Decision, license revoked.
Decision effective 02/17/2011

Rodriguez, Alfredo, TCH 66606, Compton, CA—Case 3528
By Default Decision, license revoked.
Decision effective 03/28/2011

Romero, Cecilia Delores, TCH 44069, Poteet, TX—Case 3334
By Default Decision, license revoked.
Decision effective 12/8/2010

Saba, Tymour Farah, TCH 72030, Dana Point, CA—Case 3764
By Default Decision, license revoked.
Decision effective 01/19/2011

Saenz, Jose Perucho, TCH 49120, Chula Vista, CA—Case 3735
By Default Decision, license revoked.
Decision effective 01/19/2011

*See **Disciplinary Actions**, Page 36*

Disciplinary Actions

Continued from Page 35

Sandoval, Denise Rene, TCH 91445, Modesto, CA—Case 3691
By Default Decision, license revoked. Decision effective 11/18/2010

Sandoval, Johana, TCH 50785, Richmond, CA—Case 3588
By Default Decision, license revoked. Decision effective 05/11/2011

Sapida, Michelle Charlene, TCH 91564, Vallejo, CA—Case 3679
By Default Decision, license revoked. Decision effective 05/11/2011

Satele, Carolyn T., TCH 35566, La Mesa, CA—Case 3731
By Default Decision, license revoked. Decision effective 01/19/2011

Saucedo, Margarie, TCH 40762, Buena Park, CA—Case 3717
By Default Decision, license revoked. Decision effective 08/25/2010

Scheepers, AnMarie, TCH 90857, Redding, CA—Case 3775
By Default Decision, license revoked. Decision effective 04/15/2011

Schneider, Brandi Renee, TCH 50527, Gardena, CA—Case 3365
By Default Decision, license revoked. Decision effective 08/05/2010

Schreiber, Maria Carmen, TCH 12067, Huntington Beach, CA—Case 3565
By Default Decision, license revoked. Decision effective 12/10/2010

Serratos, Leonard E., TCH 60575, San Bernardino, CA—Case 3394
By Default Decision, license revoked. Decision effective 08/05/2010

Seulean, Cornelius, TCH 22736, Riverside, CA—Case 3418
By Hearing Decision, licensed revoked.
Decision effective 03/09/2011

Sierra, Charlene A., TCH 39666, Fresno, CA—Case 3299
By Decision, license revoked. Effective 01/07/2011

Silva, Danna Michelle, TCH 8898, Milpitas, CA—Case 3838
By Default Decision, license revoked. Decision effective 04/15/2011

Singh, Ajaypal, TCH 85115, Anaheim, CA—Case 3613
By Default Decision, license revoked. Decision effective 01/07/2011

Singh, Dilpreet, TCH 43779, Grand Terrace, CA—Case 3415
By Default Decision, license revoked. Effective 05/25/2011.

Slevin, Paul Thomas, TCH 92205, Auburn, CA—Case SI 3718
By Stipulated Settlement, the application for license is granted. Upon satisfaction of all statutory and regulatory requirements for issuance of a license, a license shall be issued. License will be immediately revoked, stayed, and placed on four years' probation. Terms and conditions of probation include passing the Pharmacy Technician Certification Board examination, no ownership of any Board-licensed entity, and must have worksite monitor.
Decision effective 05/11/2011

Smith, Joel Robert, TCH 46392, Yucaipa, CA—Case 3290
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 07/23/2010

Smith, Mary K., TCH 60321, Marin City, CA—Case 3439
By Default Decision, license revoked. Decision effective 08/05/2010

Sosa, Joe Luis, TCH 32591, Hanford, CA—Case 3615
By Default Decision, license revoked. Decision effective 08/05/2010

Spanos, Nicholas Hercules, III, TCH 10499, Lodi, CA—Case 3288
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 11/18/2010

Ter-Grigoryan, Kevin, TCH 84200, Altadena, CA—Case 3637
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 05/11/2011

Thomas, Karen Anissa, TCH 39656, Lancaster, CA—Case 3352
By Decision, license revoked. Decision effective 12/17/2010

Thrift, James Robert, TCH 74800, Fullerton, CA—Case 3634
By Default Decision, license revoked. Decision effective 01/19/2011

Topete, Tomas, TCH 5914, San Diego, CA—Case 3476
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 11/18/2010

Tran Ai Quoc, TCH 76153, Fountain Valley, CA—Case 3703
By Default Decision, license revoked. Decision effective 11/18/2010

Tubbs, Nicole, TCH 80903, Oceanside, CA—Case 3556
By Default Decision, license revoked. Decision effective 05/11/2011

Urquidi, Gianna Frances, TCH 45225, Rosemead, CA—Case 3321
By Default Decision, license revoked. Decision effective 08/20/2010

Valles, Rudy, TCH 92099, Moreno Valley, CA—Case SI 3829
By Stipulated Settlement, the application for license is granted. Upon satisfaction of all statutory and regulatory requirements for issuance of a license, a license shall be issued. License will be immediately revoked, stayed, and placed on two years' probation. Terms and conditions of probation include passing the Pharmacy Technician Certification Board examination, and no ownership of any Board-licensed entity.
Decision effective 05/11/2011

Varela, Javier M., TCH 61270, Desert Shores, CA—Case 3486
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 08/05/2010

Vu, Kim N., TCH 45621, Garden Grove, CA—Case 3425
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 08/25/2010

Ward, Kalynda Dale, TCH 50138, Antioch, CA—Case 3670
By Default Decision, license revoked. Decision effective 01/19/2011

Webb, Paul F. Jr., TCH 53679, Sacramento, CA—Case 3647
By Hearing Decision, license revoked.
Decision effective 05/11/2011

Wheeler, Wilbur Lon, TCH 41397, Sacramento, CA—Case 3827
By Default Decision, license revoked. Decision effective 05/11/2011

White, Cathy Lois, TCH 15916, Twain Harte, CA—Case 3501
By Decision, license revoked. Decision effective 12/31/2010

White, Derrick W., TCH 56617, Los Angeles, CA—Case 3368
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 01/07/2011

*See **Disciplinary Actions**, Page 37*

Disciplinary Actions

Continued from Page 36

Wright, Lisa Ann, TCH 39223,
Lake Arrowhead, CA—Case 3534
By Default Decision, license revoked.
Decision effective 08/05/2010

Zhu, Xiu Ming, TCH 82173,
San Francisco, CA—Case 3564
By Default Decision, license revoked.
Decision effective 02/17/2011

Zorrilla, George, TCH 47312,
Vallejo, CA—Case 3562
By Default Decision, license revoked.
Decision effective 12/17/2010

Exemptee

Musgrave, Theresa, EXC 16709,
San Luis Obispo, CA—Case 3651
By Stipulated Settlement, license revoked, stayed, two years' probation subject to terms and conditions including continuing to be a designated-representative-in- charge with current employer.
Decision effective 03/28/2011

Site Licenses (Pharmacies and Wholesaler)

CT International, WLS 3575,
San Luis Obispo, CA—Case 3651
By Stipulation Settlement, license revoked, stayed, two years' probation subject to terms and conditions that include: must retain independent consultant and no additional ownership of any Board-licensed entity.
Decision effective 03/28/2011

Cali Pharmacy, PHY 43882,
San Jose, CA—Case 3440
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 03/09/2011

College Pharmacy,
NRP 1034 and NSC 99550,
Colorado Springs, CO—Case SI 3445
By Stipulated Settlement, license revoked, stayed, seven years' probation, subject to all terms and conditions of probation.
Decision effective 11/1/2010

County of Sacramento Primary Care,
PHE 46273,
Sacramento, CA—Case 3341
By Stipulated Settlement, five years' probation subject to terms and conditions that include but are not limited to: must retain a consultant.
Decision effective 01/07/2011

Dairyland Pharmacy, PHY 39285,
Hilmar, CA—Case 3230
By Stipulated Settlement, license revoked, stayed, five years' probation subject to all terms and conditions.
Decision effective 03/28/2011

Elmhurst Pharmacy, PHY 45683,
Oakland, CA—Case 3515
By Stipulated Settlement, license revoked, stayed, three years' probation subject to terms and conditions.
Decision effective 02/17/2011

Emerson Pharmacy, PHY 48754,
Los Angeles, CA—Case 3330
By Stipulated Settlement, license revoked, stayed, three years' probation subject to all terms and conditions.
Decision effective 07/28/2010

First Care Pharmacy, PHY 47361,
Los Angeles, CA—Case 3132
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 12/10/2010

Garos Pharmacy, PHY 47485, Pasadena, CA—Case 3156
By Stipulated Settlement, license revoked, stayed, five years' probation subject to all terms and conditions.
Decision effective 01/07/2011

Nichols Hill Prescription Pharmacy, PHY 46970, Oakland, CA—Case 3737
By Stipulated Settlement, license revoked, stayed, five years' probation subject to all terms and conditions.
Decision effective 01/07/2011

Patterson Family Pharmacy,
PHY 47152, Patterson, CA—Case 3626
By Stipulated Settlement, license revoked, stayed, five years' probation subject to all terms and conditions.
Decision effective 10/27/2010

Savco Generic Drugs, PHY 32506,
San Jose, CA—Case 3430
By Stipulated Settlement, license was voluntarily surrendered.
Decision effective 08/25/2010

Target Store No. T-227, PHY 44113,
West Hills, CA—Case 3377
By Stipulated Settlement, license revoked, stayed, five years' probation subject to all term and conditions.
Decision effective 03/28/2011

What to Look for

Continued from Page 20

prescriber. The record shall be maintained in the health facility for three years.

(B) Forms ordered pursuant to this subdivision that are printed by a computerized prescription generation system shall not be subject to subparagraph (A) or paragraph (7) of subdivision (a). Forms printed pursuant to this subdivision that are printed by a computerized prescription generation system may contain the prescriber's name, category of professional licensure, license number, federal controlled substance registration number, and the date of the prescription.

(d) This section shall become operative on July 1, 2004.

If the form does not contain all the required security features, it may indicate that it was not printed by a Department of Justice-approved printer. ***Forms that do not contain the required security printer (SP) approval ID number and/or security features should be reported to the California Security Prescription Printer Program at (916) 319-9035.***

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Attachment C:

E-Prescribing of Controlled Substances Guidelines for Pharmacies and Prescribers

California State Board of Pharmacy and Medical Board of California

Transmission and Receipt of Electronic Controlled Substance Prescriptions

Pursuant to DEA Interim Final Rule (IFR): Electronic Prescriptions for Controlled Substances

21 CFR Parts 1300, 1304, 1306, and 1311 (Fed. Reg. 16236-16319 (March 31, 2010)) **Effective June 1, 2010**

Deputy Attorney General Joshua A. Room and Deputy Attorney General Kerry Weisel
May 2011

The following is merely a summary and/or paraphrasing of the law as reflected in the IFR, and/or a compilation of opinion(s) on the interpretation of the IFR. It does not constitute an official opinion of, nor is it sanctioned by, the Attorney General, the California State Board of Pharmacy, or the Medical Board of California. This is not a binding statement of pertinent law. It is a summary, and is not intended to be comprehensive. It is offered as a guideline and a compilation of references to the appropriate sections of the IFR. Any person(s) wishing to understand the IFR are encouraged to review the regulation(s) themselves, and/or to consult an attorney.

Who is affected: Prescribers; pharmacies; application providers. To participate, each category must:

Prescribers	Pharmacies	Application Providers
Select application and ensure it meets DEA requirements	Select application and ensure it meets DEA requirements	Evaluate application(s) and/or reprogram as necessary
Apply for identity proofing	Set access controls	Undergo third-party audit or certification of software
Set access controls	Process prescriptions	Make audit/certification report available to users/possible users
Sign (and archive) prescriptions	Archive prescriptions	

Participation is voluntary.[1] The regulations do not mandate that prescribers use only electronic prescribing for controlled substances, nor do they require pharmacies to accept electronic controlled substance prescriptions.[2] Written prescriptions are still acceptable, as are oral prescriptions for Schedule III-V controlled substances. If used, electronic prescriptions for Schedule II-V controlled substances must meet DEA regulatory requirements.

Audit and Selection of Software Application(s)

Before being used to create, sign, transmit, or process controlled substance prescriptions, electronic prescribing applications or pharmacy applications (stand-alone or integrated Electronic Medical Record (EMR) types) must have a third-party audit of the application certifying that it meets the requirements of the DEA regulations. The **application provider** must secure an audit from (1) a person/entity qualified to conduct a SysTrust, WebTrust, or SAS 70 audit; (2) a Certified Information System Auditor that performs compliance audits; or (3) a

[1] There are various incentives for electronic prescribing and use of electronic medical records (EMR), most notably those contained in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), and the Health Information Technology for Economic and Clinical Health (HITECH) Act, a component of the American Recovery and Reinvestment Act of 2009 (ARRA). These federal laws include incentive payments under Medicare for prescribers who reach certain e-prescribing and/or EMR thresholds. Prescribers may receive incentive payments on their billings of up to 2% in 2009 and 2010, 1% in 2011 and 2012, and 0.5% in 2013; they may be hit with penalties of 1% in 2012, 1.5% in 2013, and 2% in 2014 and beyond, for failure to meet these e-prescribing/EMR thresholds.

[2] Beginning January 1, 2012, Medicare Part D prescriptions can no longer be sent to a pharmacy by computer-generated fax. As of this date, prescriptions must be (a) transmitted electronically, (b) handed to the patient in hardcopy form, or (c) manually faxed to the pharmacy. As of October 1, 2008, the Centers for Medicare and Medicaid Services (CMS) required all written Medicaid prescriptions be written on a tamper-resistant prescription blank. Electronic prescriptions are excluded from this requirement (and are acceptable).

certifying organization whose certification process has been approved by the DEA.[3] (21 CFR § 1311.300.)

The auditor issues a report and/or certification to the application provider. The application provider must keep that report and/or certification for two years, and make it available to any prescriber or pharmacy that uses the application or is considering using the application. (21 CFR § 1311.300(f).) May be on provider's website.

Prescribers and pharmacies must review audit/certification report prior to using application to confirm that it performs the appropriate functions successfully. (21 CFR §§ 1311.102(d), (e), 1311.200(a), (b).) A prescription created using an application that does not meet requirements is invalid. (21 CFR § 1311.100(d).)

Furthermore, both prescribers and pharmacies have an **ongoing responsibility** to immediately cease using an application (and ensure that any designated agents also cease using the application) if: any required function of the application is disabled or appears to be functioning improperly; the application provider notifies them that a third-party audit or certification report indicates that the application no longer meets DEA requirements; or the application provider reports that the application is non-compliant. (21 CFR §§ 1311.102, 1311.200, 1311.300.)

The requirements for an electronic prescription application are quite specific. (21 CFR § 1311.120.)

Identity Proofing of Prescribers (Practitioners)[4]

Identity proofing is the process by which a prescriber is uniquely identified, so that only that prescriber has the access necessary to authorize and sign electronic prescriptions using a software application. Identity proofing of prescriber must be done by an approved credential service provider (CSP) or certification authority (CA) [for digital certificates]. Remote identity proofing is permissible. (21 CFR § 1311.105.) Prescribers should consult with their selected application provider to determine which identity proofing organization to work with.

Institutional prescribers can undergo identity proofing using the third-party method described above, or identity proofing can be conducted in-house by their institution(s). (21 CFR § 1311.110.)

Once identity is verified, the prescriber is issued a two-factor authentication credential. (21 CFR § 1311.105.) The two factors must be two of the following: (1) Something the prescriber knows, such as a password or PIN; (2) A hard token separate from the computer being accessed (meeting at least FIPS 140-2 Security Level 1); or (3) A biometric, such as a fingerprint or iris scan, meeting DEA criteria. (21 CFR. §§ 1311.115, 1311.116.)

Two-factor credentials will be used for (1) approving access controls, and (2) signing electronic prescriptions. (21 CFR § 1311.120.) They must always be in the exclusive control of the prescriber. (21 CFR § 1311.102.)

Access Controls – For Both Prescribers and Pharmacies

[3] A follow-up audit/certification must be conducted whenever functionality related to controlled substance prescription requirements is altered, or every two years, whichever comes first. (21 CFR § 1311.300(a)(2), (e)(2).)
[4] "Practitioner" is used throughout the regulations where we might use "prescriber." We use prescriber exclusively in this document.

Access controls relate to software-based specifications and restrictions that ensure that only those individuals authorized to sign prescriptions are allowed to do so, and only those persons authorized to enter information regarding dispensing, or to annotate or alter or delete prescription information, are allowed to do so.

At the prescriber level, in each registered location there must be at least two individuals designated to manage access control to the application. One of these has to be the registered prescriber who has obtained two-factor authentication credentials. (21 CFR § 1311.125.) These access controls are required to limit the permission to sign controlled substance prescriptions to persons whose DEA registration is current and in good standing, and whose state authorization(s) to prescribe are current and in good standing,. (21 CFR § 1311.125(b).) There is also a two-person management requirement in an institutional setting. (21 CFR § 1311.130.)

Prescriber software application must be capable of setting logical access controls to limit permissions for both the indication that a prescription is ready for signing, and the electronic signature on the prescription, as well as for changes to the access controls themselves. (21 CFR § 1311.120(b).) The software must revoke permission to sign controlled substance prescriptions on the date that any of the following is discovered: A hard token or any other authentication factor is lost, stolen or compromised; DEA registration expires without renewal; DEA registration is terminated, revoked, or suspended; or the prescriber is no longer authorized to use the software (e.g., when the prescriber leaves the practice or institution). (21 CFR §§ 1311.125(d), 1311.130(d).)

At the pharmacy level, logical access controls in the pharmacy application must be set so that only the person(s) authorized to enter information regarding dispensing of controlled substance prescriptions and/or to annotate or alter or delete records of prescriptions, are permitted to do so. (21 CFR §§ 1311.200(e), 1311.205(b)(1), (2).)

Signature and Transmission of Prescription(s) by Prescribers

A prescriber or prescriber's agent may prepare one or more prescriptions for review and signature by prescriber. (21 CFR § 1311.135(a).) A prescriber may access a list of prescriptions for a single patient, and sign one, some, or all of them at once. (21 CFR § 1311.140(a)(1).) The screen must display, for each prescription: the date of issuance; full patient name; drug name; dosage strength and form; quantity prescribed; directions for use; refills authorized (for Schedule III-V drugs); earliest fill date, if applicable (see 21 CFR § 1306.12(b)); and the name, address, and DEA registration number of the prescriber. (21 CFR § 1311.140(a)(1), 1311.120(b)(9).) The same screen must also display the following statement: "By completing the two-factor authentication protocol at this time, you are legally signing the prescription(s) and authorizing the transmission of the above information to the pharmacy for dispensing. The two-factor authentication protocol may only be completed by the practitioner whose name and DEA registration number appear above." (21 CFR § 1311.140(a)(3).)

Only the prescriber may indicate those prescriptions that are ready to be signed and, while the screen displays the prescription information and the warning statement, only the prescriber may be prompted to complete, and may complete, the two-factor authentication protocol. Completion of the two-factor authentication protocol by the prescriber is a legal signature pursuant to 21 CFR § 1306.05. (21 CFR § 1311.140(a)(2), (4), (5).) Multiple prescriptions for the same patient can be signed by one application of the two-factor authentication protocol; no separate keystroke is required to acknowledge the warning or to sign the prescription. (21 CFR § 1311.140.)

Upon completion of the two-step authentication protocol, one of two things must happen: either the application digitally signs (i.e., locks) and electronically archives the required information (21 CFR § 1311.140(a)(6)), and designates the prescription eligible for transmission; or, if the prescriber has a digital certificate (see 21 CFR § 1311.105), the application applies the prescriber's private key to digitally sign and electronically archive the required data (21 CFR § 1311.145) before designating the prescription for transmission. If the latter, digital certificate methodology is applied, the prescription may be transmitted to a pharmacy without digital signature, and a digital signature is not required, so long as the application first checks the certificate revocation list of the prescriber's issuing certificate authority (CA) prior to transmission. (21 CFR § 1311.145(e), (f), (g).)

The prescription must be transmitted as soon as possible after signature. (21 CFR § 1311.170(a).) It must stay in electronic form all the way from the prescriber to the pharmacy (including through intermediaries); at no time may it be converted to another form (e.g., facsimile). (21 CFR § 1311.170(f).) Likewise, the application must restrict printing of electronic prescriptions for controlled substances. The application must not allow electronic transmission of a prescription that has already been printed. (21 CFR § 1311.170(d).) A prescription may be printed **after** its electronic transmission only under two circumstances: (a) where the prescriber is notified by an intermediary or pharmacy that an electronic prescription was not delivered, in which case the prescriber must be sure that any paper (or oral) prescription issued as a replacement indicates that the prescription was previously transmitted electronically, to a particular pharmacy, and that transmission failed; or (b) where a prescriber prints a copy of an electronically-transmitted prescription (or a list of a patient's prescriptions), and the copy or list is clearly labeled "Copy only – not valid for dispensing." (21 CFR § 1311.170(c).) Data from prescription(s) may also be electronically transferred to (electronic) medical records. (21 CFR § 1311.170(c).)

It is no longer required that the prescription be transmitted immediately. The DEA has expressly acknowledged that prescribers "may prefer to sign prescriptions before office staff add pharmacy or insurance information." (General Questions and Answers [as of 03/31/2010], www.deadiversion.usdoj.gov/ecomm/e_rx/faq/faq.htm.) In other words, a (reasonable) delay between signature and transmission is permissible, and it is also acceptable for additions or changes to be made to items in the information being electronically transmitted that are not part of the prescription information required by DEA regulations under 21 CFR Part 1306. However, the contents of the prescription required by Part 1306 must not be altered either following signature or during transmission, not by the prescriber, prescriber's staff, or intermediaries. (21 CFR § 1311.170(e).) The data may be converted to be readable in or by different softwares and so forth, but Part 1306 data may not be changed. (*Ibid*.)

Receipt and Processing of Prescription(s) by Pharmacies

The pharmacy application must be certified by the third-party auditor to, among other things: import, store, and display the information required for prescriptions; import, store, and display an indication of signing transmitted by the prescriber; import, store, and display the number of refills; and import, store, and verify the prescriber's digital signature, where applicable. (21 CFR § 1311.200(a)(1), (2), (3), (4).) The second and the fourth of these listed requirements are particularly important to a pharmacy's proper verification of transmitted prescriptions.

Namely, when a pharmacy receives a transmitted electronic prescription, it must either: (a) have been digitally signed by the last intermediary that sends the prescription record to the pharmacy, in which case the digitally signed record must be archived upon receipt (21 CFR §§

1311.205(b)(3), 1311.210(b)(1)); (b) have been signed digitally using the prescriber's digital certificate, in which case the pharmacy application must verify the digital signature as provided in FIPS 186-3, check the validity of the digital certificate against the certificate revocation list of the issuing certificate authority (CA), and archive the digitally signed record as well as an indication that it was verified upon receipt (21 CFR § 1311.210(c)); or (c) be digitally signed (as per 21 CFR § 1311.205(b)(4)) and archived by the pharmacy upon receipt (21 CFR §§ 1311.205(b)(3), 1311.210(a)(2).) Pharmacists are (still) permitted to annotate an electronic prescription in the same way they would a paper prescription, except that the annotations must be made and retained electronically. (21 CFR § 1311.200(f).) The IFR also permits transfers between pharmacies of electronic prescription information for Schedule III-V controlled substances for refill(s) on a "one-time basis only," so long as the transfer is communicated directly between two licensed pharmacists, and appropriate notations are added to the prescription record at both the transferring and receiving pharmacy. Pharmacies that electronically share a real-time, online database may (also) transfer up to the maximum refills permitted by law and the prescriber's authorization. (21 CFR § 1306.25(a), (b).)

When a pharmacist receives a paper or oral prescription that indicates that it was previously transmitted to that pharmacy electronically, the pharmacist must check the pharmacy's records to ensure that the electronic version of the prescription was not received and (already) dispensed. If both versions were received, the pharmacist must mark one as void. (21 CFR § 1311.200(g).) When a pharmacist receives a paper or oral prescription that indicates that it was previously electronically transmitted to a different pharmacy, the pharmacist must check with the other pharmacy to determine whether the prescription was (already) received and dispensed. If the electronic transmission version was already received and dispensed, the subsequent paper (or oral) prescription must be marked as void. If the electronic transmission version has not yet been dispensed, that version must be marked as void and the paper (or oral) prescription may be dispensed. (21 CFR § 1311.200(h).)

Archiving of Prescription(s) Recordkeeping by Prescribers and Pharmacies

As has been indicated above, the prescribing application is required to archive the prescription at the time that it is signed, and the pharmacy application is required to archive the prescription at the time it is received (so that the two archived versions can later be compared to ensure there has been no alteration of prescription contents required by Part 1306). (21 CFR §§ 1311.140(a)(6), 1311.145, 1311.205(b).) In addition to storing the data required by Part 1306 and by 21 CFR § 1311.205, pharmacy applications must be capable of sorting/retrieving controlled substance prescriptions by prescriber name, patient name, drug name, and date dispensed. (21 CFR § 1311.205(b)(11), (12).) The records must be secure, maintained electronically, backed up daily, and able to be read or downloaded into human-readable format. (21 CFR §§ 1311.205(b)(17), (18), 1311.305.)

The prescriber's electronic prescription application must generate a log of all controlled substance prescriptions issued by the prescriber during the previous calendar month and must provide that log to the prescriber no later than seven calendar days after month's end. (21 CFR § 1311.120(b)(27)(i).) In addition, the application must be capable of generating a log of all controlled substance prescriptions issued by the prescriber during a time period specified by the prescriber, upon request; it must be able to search back for at least the previous two years. (21 CFR § 1311.120(b)(27)(ii).) Any logs that are generated must be archived, human-readable, and sortable by patient name, drug name, and issuance date. (21 CFR § 1311.120(b)(27)(iii), (iv), (v).)

Audit Trails and Other Requirements

The regulations specify various events and incidents for which both prescriber and pharmacy applications must maintain an audit trail (i.e., a secure activity log that can be used to retrace those events/incidents). An "audit trail" is defined as "a record showing who has accessed an information technology application and what operations the user performed during a given period." (21 CFR § 1300.03.)

For prescribers, the application must track, among other things, the creation, alteration, indication of readiness for signing, signing, transmission, or deletion of an electronic controlled substance prescription, as well as any notification of a failed transmission. (21 CFR § 1311.120(b)(23).) For pharmacies, the application must track, among other things, all receipts, annotations, alterations, and deletions of controlled substance prescriptions. (21 CFR § 1311.205(b)(13)(i).) For both prescribers and pharmacies, the application(s) must track: the setting of, or changes to, access controls (21 CFR §§ 1311.120(b)(23)(ii), 1311.205(b)(13)(ii)); as well as other events that the application provider establishes as "auditable events," which are typically security incidents (21 CFR §§ 1311.120(b)(23)(iv), 1311.205(b)(13)(iii), 1311.150(a), 1311.215(a).)

In addition, both types of applications must conduct daily internal audits to determine whether any "auditable events" (security incidents) have occurred on that day. (21 CFR §§ 1311.150, 1311.215.) This may be an automated function that generates a report for the prescriber or pharmacist to review. If the prescriber or pharmacist reviewing the report determines that a security incident has in fact occurred, that incident must be reported to the application provider and to the DEA within one day. (21 CFR §§ 1311.150(c), 1311.215(c).)

Relationship Between DEA Regulation(s) and California Law

The IFR packet issued by the DEA contains the following statement: "This rulemaking does not preempt or modify any provision of State law; nor does it impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws." (VII. Required Analyses, G. Executive Order 13132, Fed Reg. 16304.) The DEA has also been explicit in the FAQs on its website that "electronic prescriptions for controlled substances may be subject to state laws and regulations," and that "[i]f state requirements are more stringent than DEA's regulations, the state requirements would supersede any less stringent DEA provision." (Interim Final Rule with Request for Comment, Questions and Answers for Pharmacies [as of 03/31/2010], www.deadiversion.usdoj.gov/ecomm/e_rx/faq/pharmacies.htm.) Thus, any conflicting state laws (e.g., about five states prohibit controlled substance electronic prescriptions altogether, and a further twenty or so do not permit electronic prescribing of Schedule II drugs) are apparently permitted to control. The IFR is also explicit that the two-year retention period prescribed by the IFR does not preempt any longer retention period required by state (or other federal) law or regulation. (21 CFR § 1311.205(b).)

As to this last point, because the requirement in California is that all records of manufacture, sale, acquisition, or disposition, and/or all prescription records, be maintained and kept available for inspection for three years (Bus. & Prof. Code, §§ 4081, 4333; Cal. Code Regs., tit. 16, § 1717), the three-year retention period applies. (See also Health & Saf. Code, §§ 11159, 11159.1 [seven year retention for chart orders].) California standards for transfers of electronic prescriptions between pharmacies also control. (Cal. Code Regs., tit. 16, § 1717.)

In general, however, California is one of the most "e-prescribing-friendly" states, and state law does not set up any obstacles to electronic prescribing of controlled substances (or dangerous

drugs). California law (Bus. & Prof. Code, § 4040, Health & Saf. Code, § 11027) defines "prescription" to include "electronic transmission." And California requirements for electronic transmission of prescriptions (Cal. Code Regs., tit. 16, §1717.4) do not materially increase the burden for electronic prescribing over the DEA requirements.[5] California law even specifically permits electronically transmitted prescriptions to be stored only in electronic form (i.e., they do not have to be printed/reduced to writing) so long as that storage is tamper-proof. (Bus. & Prof. Code, §4070.)

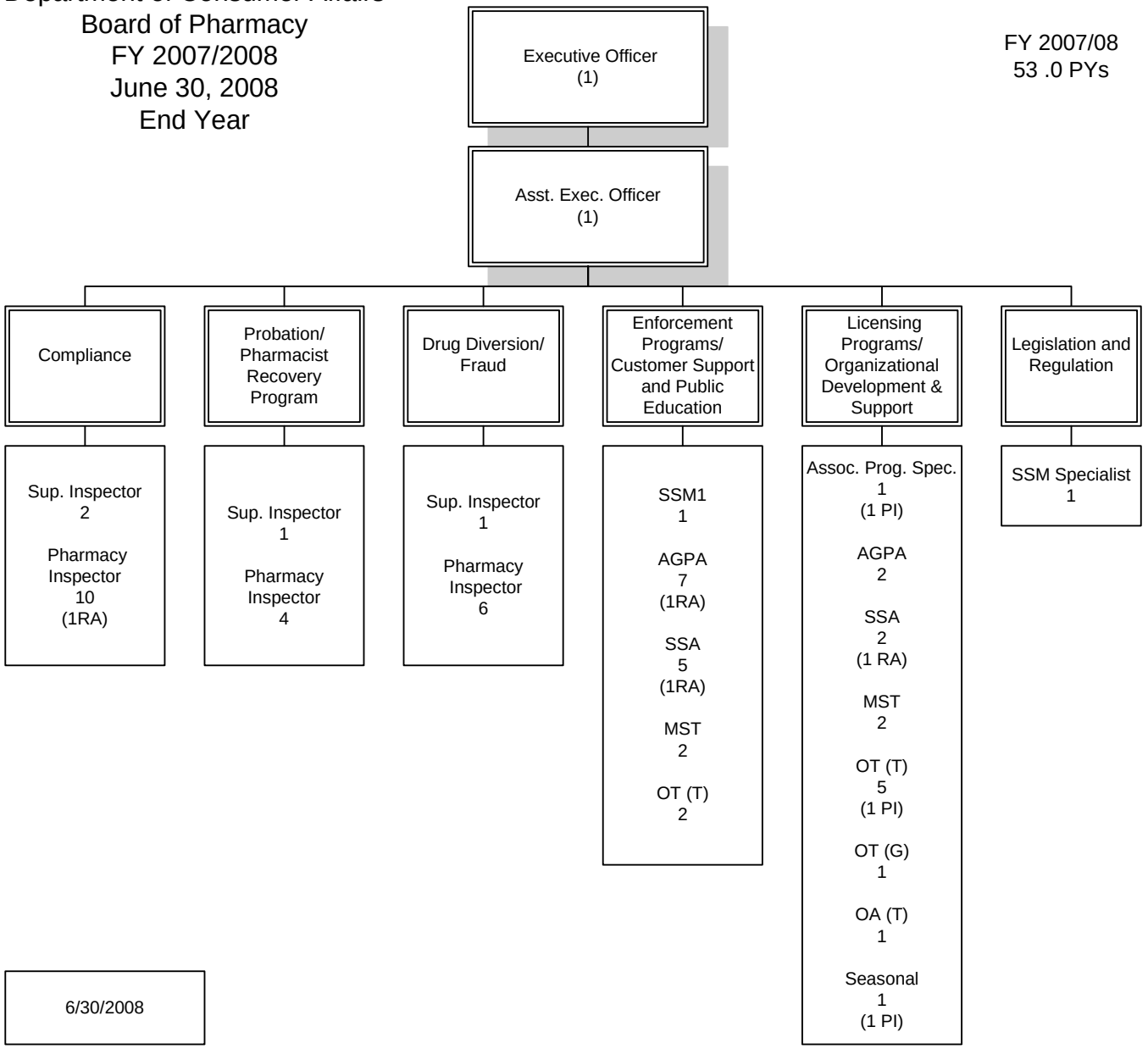
[5] Under California law, an electronically transmitted prescription shall include, in addition to the name and address of the prescriber, a prescriber telephone number, the date of transmission, and the identity of the recipient. (Cal. Code Regs., tit. 16, § 1717.4(c), (d).)

Attachment D:

Organizational Charts

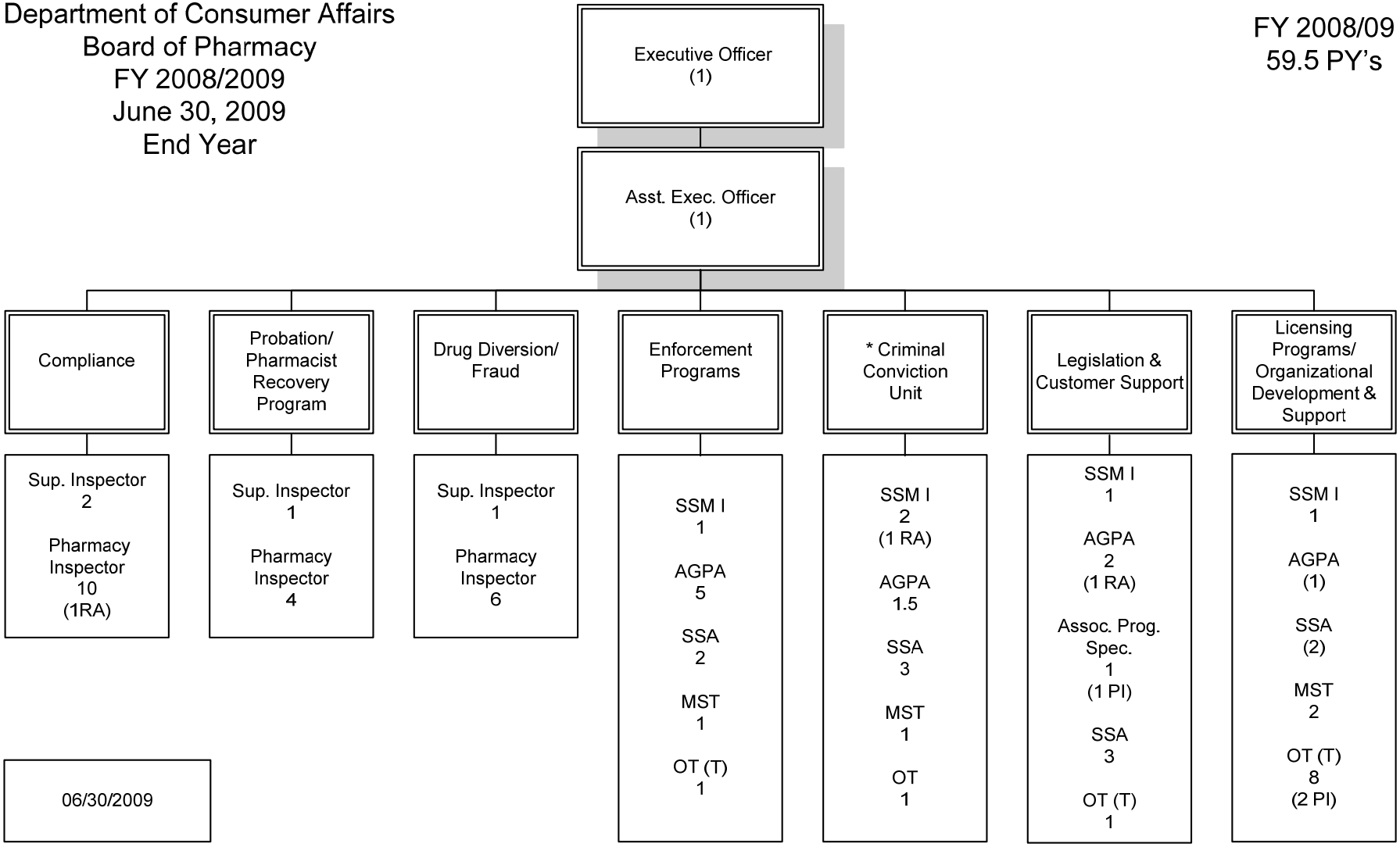
Department of Consumer Affairs
Board of Pharmacy
FY 2007/2008
June 30, 2008
End Year

FY 2007/08
53 .0 PYs



Department of Consumer Affairs
Board of Pharmacy
FY 2008/2009
June 30, 2009
End Year

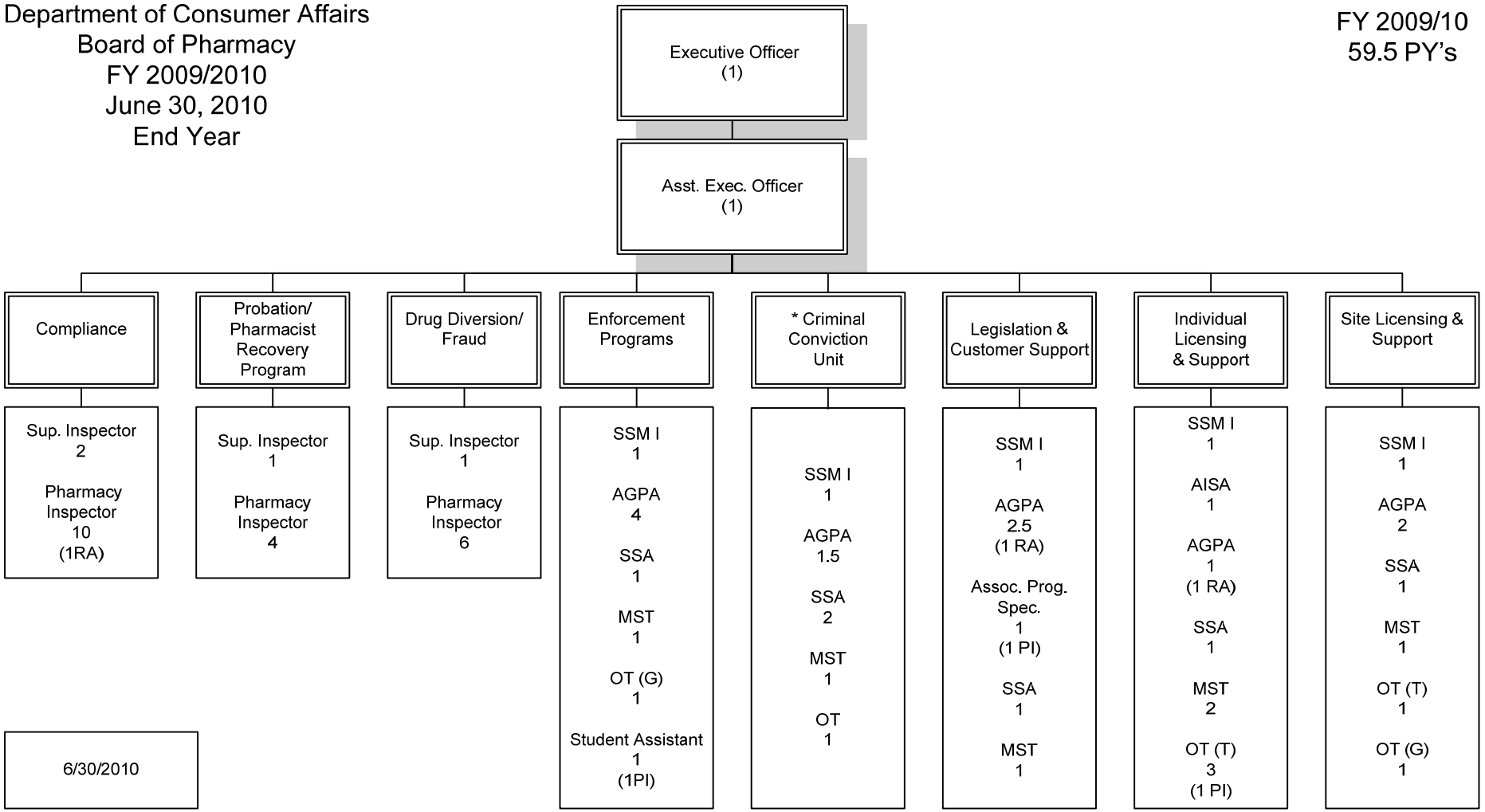
FY 2008/09
59.5 PY's



* Criminal Conviction Unit established July 1, 2009. Board established unit in advance of budget augmentation.

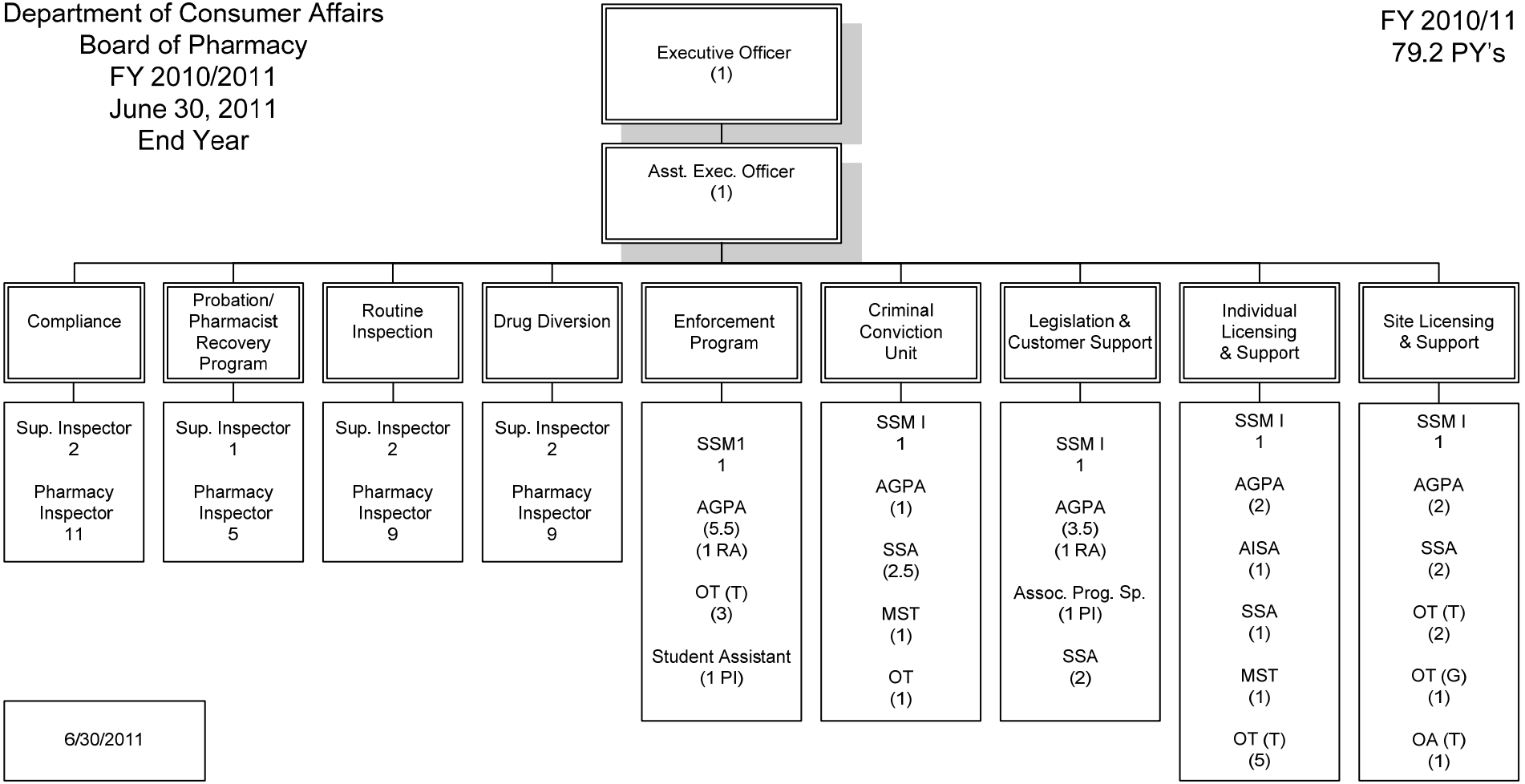
Department of Consumer Affairs
Board of Pharmacy
FY 2009/2010
June 30, 2010
End Year

FY 2009/10
59.5 PY's



Department of Consumer Affairs
Board of Pharmacy
FY 2010/2011
June 30, 2011
End Year

FY 2010/11
79.2 PY's



6/30/2011

Attachment E:

Records Retention Schedule

ITEM #	CUBIC FEET *	CA STATE ARCHIVES USE ONLY	TITLE AND DESCRIPTION OF RECORDS (*Double spaces between items*)	MEDIA	VITAL	RETENTION				PRA (Exempt) & IPA	REMARKS
						OFFICE	DEPT.	SRC	TOTAL		
(37)	(38)	(39)	(40)	(41)	(42)	(43)	(44)	(45)	(46)	(47)	(48)
											Records Retention Schedule Key: **P**=Paper documents/files **E**=Electronic documents/files (ex. Word, Excel, PDF documents saved on the G drive or other applicable drive) **M**=TEALE/ATS/BREEZE database records **Note:** If there are duplicate copies of documents or "working copies" of documents saved on the G drive, make sure to destroy these records no later than the time that the paper copy of the record is destroyed.
			INDIVIDUAL LICENSING APPLICATIONS (INDIVIDUALS PENDING LICENSURE)								**Some of the information included in the files are: applicants, correspondence, transcripts, intern affidavits, exam scores, live scan documents, and personal information. The files contain confidential information and are subject to confidential destruction. Pending licensing applications are not public information.**
1	19		Pharmacist Examination Applicant: Active	P		Active			Active	XI	The file is active until the application is considered withdrawn/abandoned due to deficiencies, exam failure, not reapplying after exam failure, not paying appropriate fees, etc.
2	0		Pharmacist Examination Applicant: Active	M		Active			Active	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
3	4		Pharmacist Examination Applicant: Deficient files that are considered abandoned/withdrawn	P		1 yr			1 yr	XI	Destroy the file 1 year after the applicant has been notified that the application has been withdrawn or the application is considered abandoned.
4	0		Pharmacist Examination Applicant: Deficient files that are considered abandoned/withdrawn	M		5 yrs			5 yrs	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
5	4		Pharmacist Examination Applicant: Applicant failed exam(s), but did not reapply for the exam(s) and application is considered abandoned/withdrawn	P		1 yrs			1 yrs	XI	Applicant failed either the CPJE, NAPLEX or both examinations and did not reapply for the examination(s). Destroy the file 1 year after the applicant has been notified that the application has been withdrawn or the application is considered abandoned.

ITEM # (37)	CUBIC FEET * (38)	CA STATE ARCHIVES USE ONLY (39)	TITLE AND DESCRIPTION OF RECORDS (*Double spaces between items*) (40)	MEDIA (41)	VITAL (42)	RETENTION OFFICE (43)	RETENTION DEPT. (44)	RETENTION SRC (45)	RETENTION TOTAL (46)	PRA (Exempt) & IPA (47)	REMARKS (48)
6	0		Pharmacist Examination Applicant: Applicant failed exam(s), but did not reapply for the exam(s) and application is considered abandoned/withdrawn	M		5 yrs			5 yrs	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
7	1		Pharmacist Examination Applicant: Applicant failed the exam 4 times and the application is considered abandoned/withdrawn	P		5 yrs		10 yrs	15 yrs	XI	Application must satisfy additional education requirements before being eligible to reapply pursuant to B&P Code 4200.1. Destroy the file 3 years after the applicant has been notified of the 4 time failure.
8	0		Pharmacist Examination Applicant: Applicant failed the exam 4 times and the application is considered abandoned/withdrawn	M		15 yrs			15 yrs	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
9	0		Pharmacist Examination Score Data: NAPLEX	E		5 yrs			5 yrs	XI	NAPLEX score data is received electronically and saved on the G drive as well as transferred to ATS or BREEZE (once BREEZE is implemented). The exam data that is saved on the G drive is destroyed after 5 years.
10	0		Pharmacist Examination Score Data: CPJE	E		5 yrs			5 yrs	XI	CPJE score data is received electronically and saved on the G drive as well as transferred to ATS of BREEZE (once BREEZE is implemented. The exam data that is saved on the G drive is destroyed after 5 years.
11	2		Candidate Examination Results Data	P		Active +10 yrs			Active +10 yrs	XI	Raw candidate examination data from the pharmacist licensure examination, specific to the old paper and pencil format. The last data set is from the June 2003 examination administration.
12	1		Pharmacist Examination Applicant: Passed exams and the initial license fee was paid, but outstanding deficiencies remain/exist	P		Active			Active	XI	The application is active until the pharmacist license is issued or the application is withdrawn/abandoned. There may still be deficiencies, even if the licensing fee is paid. If the deficiencies are never meet, follow the withdrawn/abandoned destruction time period.
13	1		Pharmacist Examination Applicant: Passed exam and no initial license fee was paid	P		1 yr			1 yr	XI	If the applicant fails to pay the required fee within 1 year after the notification of eligibility for pharmacist license, considered the license abandoned pursuant to CCR 1706.2(c). Destroy the file 1 year after notification of abandonment/withdrawal.

ITEM # (37)	CUBIC FEET * (38)	CA STATE ARCHIVES USE ONLY (39)	TITLE AND DESCRIPTION OF RECORDS (*Double spaces between items*) (40)	MEDIA (41)	VITAL (42)	RETENTION OFFICE (43)	RETENTION DEPT. (44)	RETENTION SRC (45)	RETENTION TOTAL (46)	PRA (Exempt) & IPA (47)	REMARKS (48)
14	0		Pharmacist Examination Applicant: Passed exam and no initial license fee was paid	M		5 yrs			5 yrs	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
15	1		Pharmacist Examination Applicant: Eligible, but does not take examination	P		1 yr			1 yr	XI	If the applicant does not take the exam within 1 year after the notification of eligibility for pharmacist exam, considered the file abandoned pursuant to CCR 1706.2(d). Destroy the file 1 year after notification of abandonment/withdrawal.
16	0		Pharmacist Examination Applicant: Eligible, but does not take examination	M		5 yrs			5 yrs	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
17	1		Intern Pharmacist Applicant: Active	P		Active			Active	XI	The file is active until intern permit is issued, abandoned or withdrawn.
18	0		Intern Pharmacist Applicant: Active	M		Active			Active	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
19	3		Intern Pharmacist Applicant: Abandoned/Withdrawn	P		1 yrs			1 yrs	XI	The application is considered withdrawn/abandoned if the applicant does not satisfy the requirements for an intern permit within 1 year after notification of deficiencies, pursuant to CCR 1706.2 (e). Destroy the file 1 year after it is considered withdrawn/abandoned.
20	0		Intern Pharmacist Applicant: Abandoned/Withdrawn	M		5 yrs			5 yrs	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
21	7		Pharmacy Technician Applicant: Active	P		Active			Active	XI	The file is active until the license is issued, or the applicant fails to satisfy deficiencies within 60 days of notification, and the application is deemed withdrawn/abandoned. Destroy the file 1 year after it is considered withdrawn/abandoned.
22	0		Pharmacy Technician Applicant: Active	M		Active			Active	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
23	6		Pharmacy Technician Applicant: Abandoned/Withdrawn	P		1 yr			1 yr	XI	If the applicant fails to satisfy licensing requirements within 60 days after notification of deficiencies, the file is considered abandoned pursuant to CCR 1706.2 (b). Destroy the file 1 year after it is considered withdrawn/abandoned.

ITEM # (37)	CUBIC FEET * (38)	CA STATE ARCHIVES USE ONLY (39)	TITLE AND DESCRIPTION OF RECORDS (*Double spaces between items*) (40)	MEDIA (41)	VITAL (42)	RETENTION OFFICE (43)	RETENTION DEPT. (44)	RETENTION SRC (45)	RETENTION TOTAL (46)	PRA (Exempt) & IPA (47)	REMARKS (48)
24	0		Pharmacy Technician Applicant: Abandoned/Withdrawn	M		5 yr			5 yr	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
25	1		Designated Representative Applicant: Active	P		Active			Active	XI	The file is active until license is issued, fails to satisfy deficiencies within 60 days of notification, or is deemed withdrawn.
26	0		Designated Representative Applicant: Active	M		Active			Active	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
27	1		Designated Representative Applicant: Abandoned/Withdrawn	P		1 yr			1 yr	XI	If the applicant fails to satisfy licensing requirements within 60 days after notification of deficiencies, the file is considered abandoned pursuant to CCR 1706.2 (b). Destroy the file 1 year after it is considered withdrawn/abandoned.
28	0		Designated Representative Applicant: Abandoned/Withdrawn	M		5 yrs			5 yrs	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
			SITE LICENSE APPLICATIONS (SITES PENDING LICENSURE)								**Some of the information included in the files are: applications, correspondence, live scans, confidential financial documents, corporate/ownership information, lease information, personal information, PIC and Designated Representative documents etc. The files contain confidential information and are subject to confidential destruction. Check with legal to determine if the pending application information is subject to public disclosure (depending on ownership type, etc.)**
29	2		Pharmacy License Applicant: Active	P		Active			Active	XI	The file is active until license is issued, applicant fails to satisfy deficiencies, and the application is withdrawn/abandoned.
30	0		Pharmacy License Applicant: Active	M		Active			Active	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
31	1		Pharmacy License Applicant: Abandoned/Withdrawn	P		1 yr			1 yr	XI	If the applicant fails to satisfy licensing requirements within 60 days of notification of deficiencies pursuant to CCR 1706.2(a), the application is considered withdrawn/abandoned. Destroy the file 1 year after it is considered withdrawn/abandoned.

ITEM # (37)	CUBIC FEET * (38)	CA STATE ARCHIVES USE ONLY (39)	TITLE AND DESCRIPTION OF RECORDS (*Double spaces between items*) (40)	MEDIA (41)	VITAL (42)	RETENTION OFFICE (43)	RETENTION DEPT. (44)	RETENTION SRC (45)	RETENTION TOTAL (46)	PRA (Exempt) & IPA (47)	REMARKS (48)
32	0		Pharmacy License Applicant: Abandoned/Withdrawn	M		5 yr			5 yr	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
33	1		Non-Resident Pharmacy License Applicant: Active	P		Active			Active	XI	The file is active until license is issued, applicant fails to satisfy deficiencies, and the application is withdrawn/abandoned.
34	0		Non-Resident Pharmacy License Applicant: Active	M		Active			Active	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
35	1		Non-Resident Pharmacy License Applicant: Abandoned/Withdrawn	P		1 yr			1 yr	XI	If the applicant fails to satisfy licensing requirements within 60 days of notification of deficiencies pursuant to CCR 1706.2(a), the application is considered withdrawn/abandoned. Destroy the file 1 year after it is considered withdrawn/abandoned.
36	0		Non-Resident Pharmacy License Applicant: Abandoned/Withdrawn	M		5 yr			5 yr	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
37	1		Non-Resident Pharmacy Licensed Sterile Compounding License Applicant: Active	P		Active			Active	XI	The file is active until license is issued, applicant fails to satisfy deficiencies, and the application is withdrawn/abandoned.
38	0		Non-Resident Pharmacy Licensed Sterile Compounding License Applicant: Active	M		Active			Active	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
39	1		Non-Resident Pharmacy Licensed Sterile Compounding License Applicant: Abandoned/Withdrawn	P		1 yr			1 yr	XI	If the applicant fails to satisfy licensing requirements within 60 days of notification of deficiencies pursuant to CCR 1706.2(a), the application is considered withdrawn/abandoned. Destroy the file 1 year after it is considered withdrawn/abandoned.
40	0		Non-Resident Pharmacy Licensed Sterile Compounding License Applicant: Abandoned/Withdrawn	M		5 yrs			5 yrs	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)

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41	1		Resident Licensed Sterile Compounding License Applicant: Active	P		Active			Active	XI	The file is active until license is issued, applicant fails to satisfy deficiencies, and the application is withdrawn/abandoned.
42	0		Resident Licensed Sterile Compounding License Applicant: Active	M		Active			Active	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
43	1		Resident Licensed Sterile Compounding License Applicant: Abandoned/Withdrawn	P		1 yr			1 yr	XI	If the applicant fails to satisfy licensing requirements within 60 days of notification of deficiencies pursuant to CCR 1706.2(a), the application is considered withdrawn/abandoned. Destroy the file 1 year after it is considered withdrawn/abandoned.
44	0		Resident Licensed Sterile Compounding License Applicant: Abandoned/Withdrawn	M		5 yrs			5 yrs	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
45	1		Licensed Correctional Facility Applicant: Active	P		Active			Active	XI	The file is active until license is issued, applicant fails to satisfy deficiencies, and the application is withdrawn/abandoned.
46	0		Licensed Correctional Facility Applicant: Active	M		Active			Active	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
47	1		Licensed Correctional Facility Applicant: Abandoned/Withdrawn	P		1 yr			1yr	XI	If the applicant fails to satisfy licensing requirements within 60 days of notification of deficiencies pursuant to CCR 1706.2(a), the application is considered withdrawn/abandoned. Destroy the file 1 year after it is considered withdrawn/abandoned.
48	0		Licensed Correctional Facility Applicant: Abandoned/Withdrawn	M		5 yr			5 yr	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
49	1		Clinic Permit Applicant: Active	P		Active			Active	XI	The file is active until license is issued, applicant fails to satisfy deficiencies, and the application is withdrawn/abandoned.
50	0		Clinic Permit Applicant: Active	M		Active			Active	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)

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51	1		Clinic Permit Applicant: Abandoned/Withdrawn	P		1 yr			1 yr	XI	If the applicant fails to satisfy licensing requirements within 60 days of notification of deficiencies pursuant to CCR 1706.2(a), the application is considered withdrawn/abandoned. Destroy the file 1 year after it is considered withdrawn/abandoned.
52	0		Clinic Permit Applicant: Abandoned/Withdrawn	M		5 yr			5 yr	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
53	1		Drug Room Applicant: Active	P		Active			Active	XI	The file is active until license is issued, applicant fails to satisfy deficiencies, and the application is withdrawn/abandoned.
54	0		Drug Room Applicant: Active	M		Active			Active	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
55	1		Drug Room Applicant: Abandoned/Withdrawn	P		1 yr			1 yr	XI	If the applicant fails to satisfy licensing requirements within 60 days of notification of deficiencies pursuant to CCR 1706.2(a), the application is considered withdrawn/abandoned. Destroy the file 1 year after it is considered withdrawn/abandoned.
56	0		Drug Room Applicant: Abandoned/Withdrawn	M		5 yr			5 yr	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
57	1		Wholesaler or Out of State Wholesaler: Active	P		Active			Active	XI	The file is active until license is issued, applicant fails to satisfy deficiencies, and the application is withdrawn/abandoned.
58	0		Wholesaler or Out of State Wholesaler: Active	M		Active			Active	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
59	2		Wholesaler or Out of State Wholesaler: Abandoned/Withdrawn	P		1 yr			1 yr	XI	If the applicant fails to satisfy licensing requirements within 60 days of notification of deficiencies pursuant to CCR 1706.2(a), the application is considered withdrawn/abandoned. Destroy the file 1 year after it is considered withdrawn/abandoned.

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60	0		Wholesaler or Out of State Wholesaler: Abandoned/Withdrawn	M		5 yr			5 yr	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
61	1		Hospital Pharmacy Applicant: Active	P		Active			Active	XI	The file is active until license is issued, applicant fails to satisfy deficiencies, and the application is withdrawn/abandoned.
62	0		Hospital Pharmacy Applicant: Active	M		Active			Active	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
63	1		Hospital Pharmacy Applicant: Abandoned/Withdrawn	P		1 yr			1 yr	XI	If the applicant fails to satisfy licensing requirements within 60 days of notification of deficiencies pursuant to CCR 1706.2(a), the application is considered withdrawn/abandoned. Destroy the file 1 year after it is considered withdrawn/abandoned.
64	0		Hospital Pharmacy Applicant: Abandoned/Withdrawn	M		5 yr			5 yr	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
65	1		Veterinary Food-Animal Drug Retailer Applicant: Active	P		Active			Active	XI	The file is active until license is issued, applicant fails to satisfy deficiencies, and the application is withdrawn/abandoned.
66	0		Veterinary Food-Animal Drug Retailer Applicant: Active	M		Active			Active	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
67	1		Veterinary Food-Animal Drug Retailer Applicant: Abandoned/Withdrawn	P		1 yr			1 yr	XI	If the applicant fails to satisfy licensing requirements within 60 days of notification of deficiencies pursuant to CCR 1706.2(a), the application is considered withdrawn/abandoned. Destroy the file 1 year after it is considered withdrawn/abandoned.
68	0		Veterinary Food-Animal Drug Retailer Applicant: Abandoned/Withdrawn	M		5 yr			5 yr	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)

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69	1		Hypodermic Applicant: Active	P		Active			Active	XI	The file is active until license is issued, applicant fails to satisfy deficiencies, and the application is withdrawn/abandoned.
70	0		Hypodermic Applicant: Active	M		Active			Active	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
71	1		Hypodermic Applicant: Abandoned/Withdrawn	P		1 yr			1 yr	XI	If the applicant fails to satisfy licensing requirements within 60 days of notification of deficiencies pursuant to CCR 1706.2(a), the application is considered withdrawn/abandoned. Destroy the file 1 year after it is considered withdrawn/abandoned.
72	0		Hypodermic Applicant: Abandoned/Withdrawn	M		5 yrs			5 yrs	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
73	1		Bond Application for Wholesaler and Out of State Wholesaler Surety Bond: Active	P		Active			Active	XI	Refer to B&P Code sections 4162 and 4162.5 for information on surety bonds.
74	0		Bond Application for Wholesaler and Out of State Wholesaler Surety Bond: Active	M		Active			Active	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
75	1		Bond Application for Wholesaler and Out of State Wholesaler Surety Bond: Abandoned/Withdrawn	P		1 yr			1 yr	XI	If the application is abandoned/withdrawn, destroy the file 1 year after it is considered abandoned/withdrawn.
76	0		Bond Application for Wholesaler and Out of State Wholesaler Surety Bond: Abandoned/Withdrawn	M		5 yrs			5 yrs	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)

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			INDIVIDUAL LICENSING FILES **(RPH, TCH, INT, EXC, EXV)**								**Some of the information included in the files are: applicants, correspondence, transcripts, intern affidavits, exam scores, live scan information, and personal information. The files contain confidential information and are subject to confidential destruction. Some of information contained in the files are exempt from public disclosure (personal information, transcripts, live scan info, exam scores, etc.) but some information is publically disclosable (redacted licensing applications, intern hours information, correspondence, etc.).**
77	590		Pharmacist License (RPH) File: Active	P		Active			Active	XI	The file is considered active until license is cancelled for non-payment of renewal fees, canceled by request, revoked, or retired.
78	0		Pharmacist License (RPH) File: Active	M		Active			Active	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
79	4		Pharmacist License (RPH) File: Deceased	P		1 yr			1 yr	XI	File destroyed 1 year after notification of the date of death.
80	0		Pharmacist License (RPH) File: Deceased	M		10 yr			10 yr	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
81	12		Pharmacist License (RPH) File: Cancelled Non-Payment of Renewal	P		1 yr		1 yr	2 yr	XI	If a pharmacist license is not renewed within three years from the expiration date, the license will be canceled (pursuant to section 4402 of the Business and Professions Code). Any pharmacist who wishes to resume practice in California after having his or her license cancelled for non-payment of the renewal fees will be required to take and pass the licensure examination.
82	0		Pharmacist License (RPH) File: Cancelled Non-Payment of Renewal	M		10 yr			10 yr	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
83	3		Pharmacist License (RPH) File: Cancelled/Retired per licensee	P		1 yr		1 yr	2 yr	XI	License is cancelled or retired pursuant to the request of the licensee.
84	0		Pharmacist License (RPH) File: Cancelled/Retired per licensee	M		10 yr			10 yr	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)

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85	2		Pharmacist License (RPH) File: Revoked Because of Disciplinary Action	P		1 yr		19 yrs	20 yrs	XI	If a license is revoked because of disciplinary action, keep the file for the same time frame that that disciplinary action case file is maintained.
86	0		Pharmacist License (RPH) File: Revoked Because of Disciplinary Action	M		20 yrs			20 yrs	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
87	359		Pharmacy Technician (TCH) File: Active	P		Active			Active	XI	Active until deceased, canceled for non-payment of renewal fees, or canceled by request.
88	0		Pharmacy Technician (TCH) File: Active	M		Active			Active	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
89	1		Pharmacy Technician (TCH) File: Deceased	P		1 yr			1 yr	XI	Destroy the file 1 year after the notification of the date of death.
90	0		Pharmacy Technician (TCH) File: Deceased	M		10 yr			10 yr	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
91	20		Pharmacy Technician (TCH) File: Canceled Non-Payment of Renewal	P		1 yr		1 yr	2 yr	XI	A pharmacy technician registration may be cancelled 60 days after the expiration date. If a technician registration is cancelled, it may not be renewed. Returning to work as a technician in California will require the submission of a new application with the appropriate fees and meeting the current requirements. See B&P Code section 4402(e).
92	0		Pharmacy Technician (TCH) File: Canceled Non-Payment of Renewal	M		10 yr			10 yr	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
93	3		Pharmacy Technician (TCH) File: Canceled by Request/Retired	P		1 yr		1 yr	2 yr	XI	If the license is cancelled upon the request of the licensee, destroy the file after 2 years. Returning to work as a technician in California will require the submission of a new application with the appropriate fees and meeting the current requirements.
94	0		Pharmacy Technician (TCH) File: Canceled by Request/Retired	M		10 yr			10 yr	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)

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95	2		Pharmacy Technician (TCH) File: Revoked Because of Disciplinary Action	P		1 yr		19 yrs	20 yrs	XI	If a license is revoked because of disciplinary action, keep the file for the same time frame that that disciplinary action case file is maintained.
96	0		Pharmacy Technician (TCH) File: Revoked Because of Disciplinary Action	M		20 yrs			20 yrs	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
97	25		Intern Pharmacist (INT) File: Active	P		Active			Active	XI	See B&P Code section 4208 for information on the Intern Pharmacist License.
98	0		Intern Pharmacist (INT) File: Active	M		Active			Active	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
99	10		Intern Pharmacist (INT) File: Expired/Cancelled (and never applied for pharmacist license)	P		2 yrs			2 yrs	XI	See B&P Code section 4208 for information on the Intern Pharmacist License. If the license expired/was cancelled, and the individual never applied for a pharmacist license, destroy the file two years after the license cancellation.
100	0		Intern Pharmacist (INT) File: Expired/Cancelled (and never applied for pharmacist license)	M		10 yrs			10 yrs	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
101	1		Intern Pharmacist (INT) File: Revoked Because of Disciplinary Action	P		1 yr		19 yrs	20 yrs	XI	If a license is revoked because of disciplinary action, keep the file for the same time frame that that disciplinary action case file is maintained.
102	0		Intern Pharmacist (INT) File: Revoked Because of Disciplinary Action	M		20 yrs			20 yrs	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
103	17		Designated Representative (EXC) or (EXV): Active	P		Active			Active	XI	Active until deceased, canceled for non-payment of renewal fees, or canceled by request
104	0		Designated Representative (EXC) or (EXV): Active	M		Active			Active	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
105	3		Designated Representative (EXC) or (EXV): Cancelled Non-Payment of Renewal Fees	P		1 yr		1 yr	2 yrs	XI	Pursuant to B&P Code section 4402(e), the license may be cancelled if the license is not renewed within 60 days after the expiration date. Submission of a new application is required for licensure.

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106	0		Designated Representative (EXC) or (EXV): Cancelled Non-Payment of Renewal Fees	M		10 yrs			10 yrs	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
107	1		Designated Representative (EXC) or (EXV): Canceled by Request	P		1 yr		1 yr	2yr	XI	If the license is cancelled upon the request of the licensee, destroy the file after 2 years.
108	0		Designated Representative (EXC) or (EXV): Canceled by Request	M		10 yrs			10 yrs	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
109	1		Designated Representative (EXC) or (EXV): Deceased	P		1 yr			1 yr	XI	File destroyed 1 year after notification of date of death.
110	0		Designated Representative (EXC) or (EXV): Deceased	M		10 yrs			10 yrs	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
111	1		Designated Representative (EXC) or (EXV): Revoked Because of Disciplinary	P		1 yr		19 yrs	20 yrs	XI	If a license is revoked because of disciplinary action, keep the file for the same time frame that that disciplinary action case file is maintained.
112	0		Designated Representative (EXC) or (EXV): Revoked Because of Disciplinary	M		20 yrs			20 yrs	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
			SITE LICENSING FILES **(PHY, PHE, CLN, CLE, NRP, HSP, HPE, WLS, WLE, OSD, DRM, DRE, LCF, NSC, LSC, LSE, VET, HYP, HYE)**								**Some of the information included in the files are: applications, correspondence live scans, confidential financial documents, corporate/ownership information, lease information, personal information, PIC and Designated Representative documents etc. The files contain confidential information and are subject to confidential destruction. Some documents are exempt from public disclosure (financial information, live scan documents, personal information, etc.) but some information is subject to public disclosure (redacted applications, PIC, EXC and ownership information, correspondence etc.)**
113	217		Pharmacy License (PHY) or (PHE) File: Active	P		Active			Active	XI	The file is active until the license is canceled due to change of ownership, Discontinuance of Business (DOB), or canceled for non-payment of renewal fees.

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114	0		Pharmacy License (PHY) or (PHE) File: Active	M		Active			Active	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
115	20		Pharmacy License (PHY) or (PHE) File: Canceled	P		1 yr		4 yrs	5 yrs	XI	The file is active until the license is canceled due to change of ownership, Discontinuance of Business (DOB), or canceled for non-payment of renewal fees.
116	0		Pharmacy License (PHY) or (PHE) File: Canceled	M		10 yrs			10 yrs	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
117	3		Pharmacy License (PHY) or (PHE) File: Revoked Because of Disciplinary Action	P		1 yr		19 yrs	20 yrs	XI	If a license is revoked because of disciplinary action, keep the file for the same time frame that that disciplinary action case file is maintained.
118	0		Pharmacy License (PHY) or (PHE) File: Revoked Because of Disciplinary Action	M		20 yrs			20 yrs	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
119	30		Clinic Permit (CLN) or (CLE) File: Active	P		Active			Active	XI	The file is active until the license is canceled due to change of ownership, Discontinuance of Business (DOB), or canceled for non-payment of renewal fees.
120	0		Clinic Permit (CLN) or (CLE) File: Active	M		Active			Active	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
121	4		Clinic Permit (CLN) or (CLE) File: Cancelled	P		1 yr		4 yr	5 yr	XI	The file is active until the license is canceled due to change of ownership, Discontinuance of Business (DOB), or canceled for non-payment of renewal fees.
122	0		Clinic Permit (CLN) or (CLE) File: Cancelled	M		10 yrs			10 yrs	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
123	1		Clinic Permit (CLN) or (CLE) File: Revoked Because of Disciplinary Action	P		1 yr		19 yrs	20 yrs	XI	If a license is revoked because of disciplinary action, keep the file for the same time frame that that disciplinary action case file is kept.
124	0		Clinic Permit (CLN) or (CLE) File: Revoked Because of Disciplinary Action	M		20 yrs			20 yrs	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)

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125	37		Non-Resident Pharmacy (NRP) File: Active	P		Active			Active	XI	The file is active until the license is canceled due to change of ownership, Discontinuance of Business (DOB), or canceled for non-payment of renewal fees.
126	0		Non-Resident Pharmacy (NRP) File: Active	M		Active			Active	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
127	2		Non-Resident Pharmacy (NRP) File: Canceled	P		1 yr		4 yr	5 yr	XI	The file is active until the license is canceled due to change of ownership, Discontinuance of Business (DOB), or canceled for non-payment of renewal fees.
128	0		Non-Resident Pharmacy (NRP) File: Canceled	M		10 yrs			10 yrs	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
129	1		Non-Resident Pharmacy (NRP) File: Revoked Because of Disciplinary Action	P		1 yr		19 yrs	20 yrs	XI	If a license is revoked because of disciplinary action, keep the file for the same time frame that that disciplinary action case file is maintained.
130	0		Non-Resident Pharmacy (NRP) File: Revoked Because of Disciplinary Action	M		20 yrs			20 yrs	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
131	20		Hospital Pharmacy License (HSP) or HPE) File: Active	P		Active			Active	XI	The file is active until the license is canceled due to change of ownership, Discontinuance of Business (DOB), or canceled for non-payment of renewal fees.
132	0		Hospital Pharmacy License (HSP) or HPE) File: Active	M		Active			Active	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
133	1		Hospital Pharmacy License (HSP) or HPE) File: Canceled	P		1 yr		4 yr	5 yr	XI	The file is active until the license is canceled due to change of ownership, Discontinuance of Business (DOB), or canceled for non-payment of renewal fees.
134	0		Hospital Pharmacy License (HSP) or HPE) File: Canceled	M		10 yrs			10 yrs	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
135	1		Hospital Pharmacy License (HSP) or HPE) File: Revoked Because of Disciplinary Action	P		1 yr		19 yrs	20 yrs	XI	If a license is revoked because of disciplinary action, keep the file for the same time frame that that disciplinary action case file is maintained.

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136	0		Hospital Pharmacy License (HSP) or HPE) File: Revoked Because of Disciplinary Action	M		20 yrs			20 yrs	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
137	52		Wholesale (WLS) or (WLE) and Out of State Wholesale License (OSD) File: Active	P		Active			Active	XI	The file is active until the license is canceled due to change of ownership, Discontinuance of Business (DOB), or canceled for non-payment of renewal fees.
138	0		Wholesale (WLS) or (WLE) and Out of State Wholesale License (OSD) File: Active	M		Active			Active	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
139	4		Wholesale (WLS) or (WLE) and Out of State Wholesale License (OSD) File: Canceled	P		1 yr		4 yr	5 yr	XI	The file is active until the license is canceled due to change of ownership, Discontinuance of Business (DOB), or canceled for non-payment of renewal fees.
140	0		Wholesale (WLS) or (WLE) and Out of State Wholesale License (OSD) File: Canceled	M		10 yr			10 yr	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
141	1		Wholesale (WLS) or (WLE) and Out of State Wholesale License (OSD) File: Revoked Because of Disciplinary Action	P		1 yr		19 yrs	20 yrs	XI	If a license is revoked because of disciplinary action, keep the file for the same time frame that that disciplinary action case file is maintained.
142	0		Wholesale (WLS) or (WLE) and Out of State Wholesale License (OSD) File: Revoked Because of Disciplinary Action	M		20 yrs			20 yrs	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
143	1		Drug Room License (DRM) or (DRE) File: Active	P		Active			Active	XI	The file is active until the license is canceled due to change of ownership, Discontinuance of Business (DOB), or canceled for non-payment of renewal fees.
144	0		Drug Room License (DRM) or (DRE) File: Active	M		Active			Active	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
145	1		Drug Room License (DRM) or (DRE) File: Canceled	P		1 yr		4 yr	5 yr	XI	The file is active until the license is canceled due to change of ownership, Discontinuance of Business (DOB), or canceled for non-payment of renewal fees.

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146	0		Drug Room License (DRM) or (DRE) File: Canceled	M		10 yrs			10 yrs	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
147	1		Drug Room License (DRM) or (DRE) File: Revoked Because of Disciplinary Action	P		1 yr		19 yrs	20 yrs	XI	If a license is revoked because of disciplinary action, keep the file for the same time frame that that disciplinary action case file is maintained.
148	0		Drug Room License (DRM) or (DRE) File: Revoked Because of Disciplinary Action	M		20 yrs			20 yrs	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
149	1		Licensed Correctional Facility License (LCF) File: Active	P		Active			Active	XI	The file is active until the license is canceled due to change of ownership, Discontinuance of Business (DOB), or canceled for non-payment of renewal fees
150	0		Licensed Correctional Facility License (LCF) File: Active	M		Active			Active	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
151	1		Licensed Correctional Facility License (LCF) File: Canceled	P		1 yr		4 yr	5 yr	XI	The file is active until the license is canceled due to change of ownership, Discontinuance of Business (DOB), or canceled for non-payment of renewal fees.
152	0		Licensed Correctional Facility License (LCF) File: Canceled	M		10 yrs			10 yrs	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
153	1		Licensed Correctional Facility License (LCF) File: Revoked Because of Disciplinary Active	P		1 yr		19 yrs	20 yrs	XI	If a license is revoked because of disciplinary action, keep the file for the same time frame that that disciplinary action case file is maintained.
154	0		Licensed Correctional Facility License (LCF) File: Revoked Because of Disciplinary Active	M		20 yrs			20 yrs	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
155	1		Sterile Compounding Pharmacy License (LSC) or (LSE) File: Active	P		Active			Active	XI	The file is active until the license is canceled due to change of ownership, Discontinuance of Business (DOB), or canceled for non-payment of renewal fees.

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156	0		Sterile Compounding Pharmacy License (LSC) or (LSE) File: Active	M		Active			Active	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
157	1		Sterile Compounding Pharmacy License (LSC) or (LSE) File: Canceled	P		1 yr		4 yr	5 yr	XI	The file is active until the license is canceled due to change of ownership, Discontinuance of Business (DOB), or canceled for non-payment of renewal fees.
158	0		Sterile Compounding Pharmacy License (LSC) or (LSE) File: Canceled	M		10 yrs			10 yrs	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
159	1		Sterile Compounding Pharmacy License (LSC) or (LSE) File: Revoked Because of Disciplinary Action	P		1 yr		19 yrs	20 yrs	XI	If a license is revoked because of disciplinary action, keep the file for the same time frame that that disciplinary action case file is maintained.
160	0		Sterile Compounding Pharmacy License (LSC) or (LSE) File: Revoked Because of Disciplinary Action	M		20 yrs			20 yrs	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
161	1		Non Resident Pharmacy Sterile Compounding License (NSC) File: Active	P		Active			Active	XI	The file is active until the license is canceled due to change of ownership, Discontinuance of Business (DOB), or canceled for non-payment of renewal fees.
162	0		Non Resident Pharmacy Sterile Compounding License (NSC) File: Active	M		Active			Active	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
163	1		Non-Resident Pharmacy Sterile Compounding License (NSC) File: Canceled	P		1 yr		4 yr	5 yr	XI	The file is active until the license is canceled due to change of ownership, Discontinuance of Business (DOB), or canceled for non-payment of renewal fees.
164	0		Non-Resident Pharmacy Sterile Compounding License (NSC) File: Canceled	M		10 yrs			10 yrs	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
165	1		Non-Resident Pharmacy Sterile Compounding License (NSC) File: Revoked Because of Disciplinary Action	P		1 yr		19 yrs	20 yrs	XI	If a license is revoked because of disciplinary action, keep the file for the same time frame that that disciplinary action case file is maintained.

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166	0		Non-Resident Pharmacy Sterile Compounding License (NSC) File: Revoked Because of Disciplinary Action	M		20 yrs			20 yrs	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
167	1		Veterinary Food-Animal Drug Retailer License (VET) File: Active	P		Active			Active	XI	The file is active until the license is canceled due to change of ownership, Discontinuance of Business (DOB), or canceled for non-payment of renewal fees.
168	0		Veterinary Food-Animal Drug Retailer License (VET) File: Active	M		Active			Active	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
169	1		Veterinary Food-Animal Drug Retailer License (VET) File: Canceled	P		1 yr		4yrs	5 yrs	XI	The file is active until the license is canceled due to change of ownership, Discontinuance of Business (DOB), or canceled for non-payment of renewal fees.
170	0		Veterinary Food-Animal Drug Retailer License (VET) File: Canceled	M		10 yrs			10 yrs	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
171	1		Veterinary Food-Animal Drug Retailer License (VET) File: Revoked Because of Disciplinary Action	P		1 yr	19 yrs		20 yrs	XI	If a license is revoked because of disciplinary action, keep the file for the same time frame that that disciplinary action case file is maintained.
172	0		Veterinary Food-Animal Drug Retailer License (VET) File: Revoked Because of Disciplinary Action	M		20 yrs			20 yrs	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
173	1		Hypodermic License (HYP) or (HYE) File: Active	P		Active			Active	XI	The file is active until the license is canceled due to change of ownership, Discontinuance of Business (DOB), or canceled for non-payment of renewal fees.
174	0		Hypodermic License (HYP) or (HYE) File: Active	M		Active			Active	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
175	1		Hypodermic License (HYP) or (HYE) File: Canceled	P		1 yr		4 yr	5 yr	XI	The file is active until the license is canceled due to change of ownership, Discontinuance of Business (DOB), or canceled for non-payment of renewal fees.

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176	0		Hypodermic License (HYP) or (HYE) File: Canceled	M		10 yr			10 yr	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
177	1		Hypodermic License (HYP) or (HYE) File: Revoked Because of Disciplinary Action	P		1 yr		19 yrs	20 yrs	XI	If a license is revoked because of disciplinary action, keep the file for the same time frame that that disciplinary action case file is maintained.
178	0		Hypodermic License (HYP) or (HYE) File: Revoked Because of Disciplinary Action	M		20 yrs			20 yrs	XI	Licensing information located on CAS or BREEZE database (once BREEZE is implemented)
179	6		Bond File Wholesaler and Out of State Wholesaler Surety Bond: Active	P		Active			Active	XI	Refer to B&P Code sections 4162 and 4162.5 for information on surety bonds.
180	0		Bond File: Wholesaler and Out of State Wholesaler Surety Bond: Active	M		Active			Active	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
181	1		Bond File: Wholesaler and Out of State Wholesaler Surety Bond: Canceled	P		1 yr		4 yrs	5 yrs	XI	Destroy the file 5 years after the last associated wholesaler (if there are multiple wholesaler under the same bond) is cancelled.
182	0		Bond File: Wholesaler and Out of State Wholesaler Surety Bond: Canceled	M		10 yrs			10 yrs	XI	Applicant information located in the ATS or BREEZE database (once BREEZE is implemented)
			ENFORCEMENT FILES (PERTAINING TO ENFOREMENT AND CRIMINAL CONVICTION UNIT FILES)								**Enforcement case files contain some of the following documents/information, and are subject to confidential destruction: patient records, complainant information, inspection reports, investigative documents, correspondence etc. Board investigations are exempt from public disclosure pursuant to Government Code section 6254(f) and patient and complainant information is also exempt from disclosure; however, Citation and Fines, Letters of Admonishment, and the Board's Accusations and Decisions in disciplinary action cases, are public documents.**
183	30		Complaint Investigation Files (CI): Open	P/E		Active			Active	X	Investigation files are considered active until the investigation and/or review has been completed. Investigations are exempt from public disclosure pursuant to Government Code section 6254(f).

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184	0		Electronic Investigation Files (CI): Open	M		Active			Active	X	Enforcement information located on CAS or BREEZE database (once BREEZE is implemented)
185	20		Complaint Investigation Files (CI): Closed Investigation that did not reveal a violation of pharmacy law	P/E		90 days			90 days	X	A case in which the review and/or investigation of the complaint did not reveal a violation of pharmacy law, was closed insufficient evidence, no violation, or no jurisdiction. Destroy the file 90 days after the closure letter is sent to the complainant or the 90 days after the case is closed (whichever is sooner). **Note:** Destroy the corresponding docs saved on the G drive (or applicable drive) no later than the time in which the paper files are destroyed.
186	0		Electronic Investigation Files (CI): Closed Investigation that did not reveal a violation of pharmacy law	M		1 yr			1 yr	X	Enforcement information located on CAS or BREEZE database (once BREEZE is implemented)
187	40		Investigation Files (CI): Closed Investigation confirmed violation of pharmacy law, but no administrative or disciplinary action taken (also including investigations that are closed with a 4301 letter)	P/E		1 yr		2 yr	3 yr	X	The investigation confirmed a violation of Pharmacy Law, but no administrative or disciplinary action was taken against the licensee. **Note:** Destroy the corresponding docs saved on the G drive (or applicable drive) no later than the time in which the paper files are destroyed. SRC time frame does not relate to electronic files.
188	0		Electronic Investigation Files (CI): Closed Investigation confirmed violation of pharmacy law, but no administrative or disciplinary action taken (also including investigations that are closed with a 4301 letter)	M		7 yrs			7 yrs	X	Enforcement information located on CAS or BREEZE database (once BREEZE is implemented)
189	10		Application Investigation Files (AP): Open	P/E		Active			Active	X	The file is active until the investigation and/or review is complete, and the application is either approved, denied or withdrawn. **Note:** Destroy the corresponding docs saved on the G drive (or applicable drive) no later than the time in which the paper files are destroyed.
190	0		Electronic Application Investigation Files (AP): Open	M		Active			Active	X	Enforcement information located on CAS or BREEZE database (once BREEZE is implemented)

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191	15		Application Investigation Files (AP): Closed (Approved or Withdrawn)	P/E		1 yr		2 yr	3 yr	X	The file is active until the investigation and/or review is complete, and the application is either approved or withdrawn. **Note:** Destroy the corresponding docs saved on the G drive (or applicable drive) no later than the time in which the paper files are destroyed. SRC time frame does not relate to electronic files.
192	5		Application Investigation Files (AP): Closed (Denied)	P/E		1 yr		4 yrs	5 yrs		The file is active until the investigation and/or review is complete, and the application is denied. **Note:** Destroy the corresponding docs saved on the G drive (or applicable drive) no later than the time in which the paper files are destroyed. SRC time frame does not relate to electronic files.
193	0		Electronic Application Investigation Files (AP): Closed (Approved, Withdrawn or Denied)	M		7 yrs			7 yrs	X	Enforcement information located on CAS or BREEZE database (once BREEZE is implemented)
194	5		Electronic Site Inspection Reports	P/E		3 yrs			3 yrs		Inspection reports are maintained in the file cabinet in the office and saved in the Access Database. Destroy any inspection information saved on the G drive/Access Database or CAS or BREEZE database (once BREEZE is implemented)
195	0		Site Inspection Reports	M		3 yrs			3 yrs		Enforcement information located on CAS or BREEZE database (once BREEZE is implemented)
196	1		Orders of Correction	P/E		3 yrs			3 yrs	X	Destroy the corresponding documents saved on the G drive (or any applicable drive) at the same time that the paper files are destroyed. See B & P Code section 4083(g) regarding the conditions in which an Order of Correction would be considered a public document.
197	0		Orders of Correction	M		3 yrs			3 yrs	X	Enforcement information located on CAS or BREEZE database (once BREEZE is implemented)

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198	2		Drug Enforcement Agency (DEA) 106 Reports: Reports submitted by licensees to report drug loss	P/E		3 yr			3 yr	XI	Drug Loss reporting is required under CCR 1715.6. The paper copy of the document is scanned and electronically stored on the G drive. This category refers to DEA 106 reports that did not result in an investigation. DEA 106 reports that resulted in an investigation are located in the corresponding investigation file. **Note:** Destroy the corresponding docs saved on the G drive (or applicable drive) no later than the time in which the paper files are destroyed.
199	0		Controlled Substance Utilization Review and Evaluation System (CURES) Reports	P/E		3 yrs			3 yrs	X	Controlled Substance Utilization Review and Evaluation System (CURES) reports are generated and stored on the H and/or C drive.
			ENFORCEMENT ADMINISTRATIVE CASE FILES (CITATION AND FINES, LETTERS OF ADMONISHMENT)								**Citation and Fine and Letters of Admonishment (LOA) case files contain some the following information, and are subject to confidential destruction: patient records, complainant information, correspondence, investigative documents, the Citation or LOA that was issued, etc. Citation and Fines and LOA's are public documents; however, the Board's investigation is exempt from disclosure pursuant to Government Code section 6254(f). Patient and complainant information is also exempt from disclosure.**
200	50		Letter of Admonishment (LOA) Cases: Investigative cases which resulted in the issuance of a Letter of Admonishment	P/E		1 yr		2 yr	3 yr	X	Destroy the LOA paper file and the corresponding documents saved on the G drive (Word, Excel and/or Access files containing copies of the LOA, related correspondence and investigation) 3 years after the closure of the case. **Note:** Destroy the corresponding docs saved on the G drive (or applicable drive) no later than the time in which the paper files are destroyed. SRC time frame does not relate to electronic files.
201	0		Letter of Admonishment (LOA) Cases: Investigative cases which resulted in the issuance of a Letter of Admonishment	M		7 yr			7 yr	X	Enforcement information located on CAS or BREEZE database (once BREEZE is implemented)

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202	50		Citation and Fine Cases Investigative Cases which resulted in the issuance of a citation and/or fine	P/E		1 yr		4 yr	5 yr	X	Destroy the Citation and Fine paper file and the corresponding documents saved on the G drive (Word, Excel and/or Access files containing copies of the LOA, related correspondence and investigation) 5 years after the closure of the case. **Note:** Destroy the corresponding docs saved on the G drive (or applicable drive) no later than the time in which the paper files are destroyed. SRC time frame does not relate to electronic files.
203	0		Electronic Citation and Fine Cases Investigative Cases which resulted in the issuance of a citation and/or fine	M		7 yrs			7 yrs	X	Enforcement information located on CAS or BREEZE database (once BREEZE is implemented)
			ATTORNEY GENERAL DISCIPLINARY ACTION CASES								**Disciplinary Action case files contain some of the following information/documents and are subject to confidential destruction: patient records, complainant information, and investigative documents, documents subject to attorney client privilege, correspondence, Accusation and Decisions, etc. The Board's Accusations and Decisions are public documents; however, the Board's investigation is exempt from public disclosure pursuant to Government Code section 6254(f). Patient, complainant information, and communications with the AG's office are also exempt from disclosure.**
204	30		Administrative Case File: Pending (Accusations, Statements of Issues, Petitions to Revoke Probations and the Decision)	P/E		Active			Active	X	The file includes investigation report(s), inspection reports, exhibits, correspondence, work product from the Attorney General office, the accusation(s), etc. The case is considered active until the decision is effective.
205	0		Administrative Case File: Pending (Accusations, Statements of Issues, Petitions to Revoke Probations and the Decision)	M		Active			Active	X	Enforcement information located on CAS or BREEZE database (once BREEZE is implemented), and any other databases that are maintained.

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206	52		Administrative Case File: Closed (Accusations, Statements of Issues, Petitions to Revoke Probations and the Decision)	P/E		1 yrs		19 yrs	20 yrs	X	Administrative file includes, investigative report, exhibits, accusation, and final decision, attorney/client privileged correspondence Accusation and final decision are subject to public disclosure. **Note:** Destroy the corresponding docs saved on the G drive (or applicable drive) no later than the time in which the paper files are destroyed. SRC time frame does not relate to electronic files.
207	0		Administrative Case Closed	M		50 yrs			50 yrs	X	Enforcement information located on CAS or BREEZE database (once BREEZE is implemented), and the Access Database.
208	11		Probation Files: Active (Includes quarterly reports, work site inspections, fees paid, correspondence, etc.)	P/E/ M		Active			Active	X	The file is active until probation is terminated/completed.
209	8		Probation Files: Closed (Includes quarterly reports, work site inspections, fees paid, correspondence, etc.)	P/E/ M		2 yrs		5 yrs	7 yrs	X	Destroy 5 years after probation is considered successfully terminated/completed. If probation is violated and another AC case is opened (Petition to Revoked Probation), the probation file would be retained/merged with the new AC case file. **Note:** Destroy the corresponding docs saved on the G drive (or applicable drive) no later than the time in which the paper files are destroyed. SRC time frame does not relate to electronic files.
210	8		Pharmacist Recovery Program (PRP)Files: Open	P/E/ M		Active			Active	X	The files contain confidential reports, correspondence, etc. regarding the licensee's chemical dependency treatment program & rehabilitation, including medical & mental health evaluations. See B&P code section 4372.
211	4		Pharmacist Recovery Program (PRP) Files: Closed	P/E/ M		2 yrs		5 yrs	7 yrs	X	Destroy the file 5 years after the case is closed. **Note:** Destroy the corresponding docs saved on the G drive (or applicable drive) no later than the time in which the paper files are destroyed. SRC time frame does not relate to electronic files.

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212	0		Probation Database-Access Database	E		7 yrs			7 yrs	X	Destroy record 5 years after probation is considered terminated/completed.
213	21		Library of Board Administrative Actions Accusations and Decisions documents	P/E		50 yrs			50 yrs		Copies of Administrative Case accusations and final decisions maintained in binders in the board office and/or in a PDF format on the G drive
214	0		Evidence Logs	M		Active			Active	X	Access database used to check in pharmaceutical evidence and document location for board investigations. Includes confidential information. Destroy the information in the evidence logs in accordance with the corresponding records destruction time frame, depending on the type of case that it is.
215	10		Evidence for closed Administrative/Investigative Files paper documents, drugs – Location: Sacramento and Van Nuys Office (no other records at Van Nuys)	P		90 days			90 days	X	Destroy evidence 90 days following case closure and the expiration of appeal provisions. Contains confidential patient information.
216	1		Petition Files: Active (Ex. Petition for Reduction of Penalty, Petition for Early Termination of Probation, Petition for Reinstatement)	P/E		Active			Active	X	The file is considered active until the petition has been granted or denied.
217	0		Petition Files: Active (Ex. Petition for Reduction of Penalty, Petition for Early Termination of Probation, Petition for Reinstatement)	M		Active			Active	X	Enforcement information located on CAS or BREEZE database (once BREEZE is implemented), and the Access Database.
218	5		Petition Files: Closed (Ex. Petition for Reduction of Penalty, Petition for Early Termination of Probation, Petition for Reinstatement)	P/E		10 yrs			10 yrs	X	Destroy the file 10 years after the case is closed. **Note:** Destroy the corresponding docs saved on the G drive (or applicable drive) no later than the time in which the paper files are destroyed. SRC time frame does not relate to electronic files.

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219	0		Petition Files: Closed (Ex. Petition for Reduction of Penalty, Petition for Early Termination of Probation, Petition for Reinstatement)	M		10 yrs			10 yrs	X	Enforcement information located on CAS or BREEZE database (once BREEZE is implemented), and the Access Database.
			RECORDS REQUESTS								**All requests and responsive documents are subject to confidential destruction since requestors often include confidential information (SSN's and DOB's etc.) on the requests.**
220	6		Request for Information (PRA/IPA requests)	P/E		2 yr			2 yr	X	Requests for information/documents pursuant to the California Public Records Act (PRA) and/or Information Practices Act (IPA). Destroy the paper copies and correspondence and related documents saved on the G drive
221	0		Request for Information (RFI Log)	M		3 yr			3 yr	X	The RFI is an Access database with a log of the records requests received by the Board. Civil Code 1798.27 requires that an Information Practices Act (IPA) log be kept for 3 years.
222	5		Subpoenas and Courts Orders	P/E		2 yr			2 yr	X	Subpoenas and Court Orders for documents and/or witness appearance
223	5		License Verifications	P/E		2 yr			2 yr		License verification requests
224	1		Law Questions (Answered by a Board Inspector in Writing)	P/E		1 yr			1yr		Pharmacy law questions responded to in writing by a Board Inspector.
			ADMINISTRATIVE FILES								**All Board administrative files are subject to confidential destruction**
225	14		Chronological Copies of Correspondence	P/E		5 yrs			5 yrs	X	The files contain correspondence received by the Board, including the reply.
226	12		General Subject Files	P/E		5 yrs			5 yrs	X	
227	8		Employee Files	P		Active +1			Active +1	X	The file contains the employee's personal information. The file is active until the employee is no longer employed by the Board of Pharmacy.

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228	9		Recruitment Records	P		2 yrs			2 yrs		HR related records
229	6		Travel Expense Claims	P/E		4 yr			4 yr	X	The file contains employee and Board member personal information.
230	5		Board Member files	P		Active +5			Active +5	X	The file contains appointment information, and personal information including attendance information. The file is active until the Board member leaves the Board of Pharmacy.
231	26		California Code of Regulation Files	P		Active			Active	XI	The file includes official rulemaking file and background material. The Board is mandated to keep the file indefinitely.
232	14		Board Meeting Minutes	P		2 yrs		8 yrs	10 yrs		Minutes of the Board's public meetings
233	0		Board Meeting Minutes	E		25 yrs			25 yrs		Board meeting minutes located on the Board of Pharmacy website, and saved in a PDF and/or Word format.
234	6		Board Meeting Materials	P/E		5 yrs		5 yrs	10 yrs		Meeting agendas and materials in paper, PDF and/or Word format and located on the Board's website SRC time frame does not relate to electronic files.
235	14		Board Strategic Committee Files	P/E		5 yrs		5 yrs	10 yrs		Committee meeting agendas, minutes and materials, in paper, PDF and/or Word format and located on the Board's website SRC time frame does not relate to electronic files.
236	12		Legislative Files	P		Active+ 4 yrs			Active + 4 yrs	XI	The file is active until the end of the session. Destroy the file 4 years after the end of the session
237	6		Contracts Current F/Y	P/E		Active			Active	X	
238	5		Contracts Prior F/Y	P/E		3 yrs		2 yrs	5 yrs	X	SRC time frame does not relate to electronic files.
239	6		Budget Files Current F/Y	P/E		Active			Active	X	

ITEM # (37)	CUBIC FEET * (38)	CA STATE ARCHIVES USE ONLY (39)	TITLE AND DESCRIPTION OF RECORDS (*Double spaces between items*) (40)	MEDIA (41)	VITAL (42)	RETENTION				PRA (Exempt) & IPA (47)	REMARKS (48)
						OFFICE (43)	DEPT. (44)	SRC (45)	TOTAL (46)		
240	19		Budget Files Prior F/Y	P/E		5 yrs			5 yrs	X	Maintain the file for 5 years of until audited
			PUBLICATIONS								
241	12		Board Produced Publications	P		Active +2 yrs			Active +2 yr	XI	Includes law book, board newsletter, consumer brochures, health notes, etc.
242	0		Board Produced Publications	E		Active +5 yrs			Active +5 yrs		Electronic copies of publications
243	1		California Pharmacy Law Book	P/E		Active +25 yrs			Active +25 yrs		Refers to the California Pharmacy Law Book maintained in book form and in electronic form
			CASHIERING/ACCOUNTING								
244	15		Renewal Applications: Reflects Cashiering Receipt Number & Amount Paid	P		1yr		4 yr	5 yr	X	Or until audited whichever occurs first
245	1		Miscellaneous Receipts	P		1yr		4 yr	5 yr	X	Or until audited whichever occurs first
246	1		Returned Payment Notices	P		1yr		4 yr	5 yr	X	Or until audited whichever occurs first
247	1		Report of Collections	P		1yr		4 yr	5 yr	X	Or until audited whichever occurs first
248	2		Cashiering Logs	P		1yr		4 yr	5 yr	X	Or until audited whichever occurs first
249	2		Refund Requests	P		1yr		4 yr	5 yr	X	Or until audited whichever occurs first

ITEM # (37)	CUBIC FEET * (38)	CA STATE ARCHIVES USE ONLY (39)	TITLE AND DESCRIPTION OF RECORDS (*Double spaces between items*) (40)	MEDIA (41)	VITAL (42)	RETENTION OFFICE (43)	RETENTION DEPT. (44)	RETENTION SRC (45)	RETENTION TOTAL (46)	PRA (Exempt) & IPA (47)	REMARKS (48)
250	4		License Print Registers	P		1yr		4 yr	5 yr	X	Or until audited whichever occurs first
251	5		Renewal Update Control Reports (Exception Reports)	P		1yr		4 yr	5 yr	X	Or until audited whichever occurs first
			RECORDS MANAGEMENT								
252	1		Record Retention Schedule Approval Request and Record Retention Schedule (STD 73)	P		25 yrs			25 yrs		Retain the old Records Retention Schedules for reference purposes
253	2		Records Transfer List (STD 71) and Other records documenting destroyed records	P		25 yrs			25 yrs		Retain the Records Transfer Lists for reference purposes
254	1		Records Inventory Worksheet (STD 70)	P		Active			Active		Retain as active until next inventory
255	1		State Records Center Reference Request (STD 76) (Request to retrieve records)	P		Active			Active		Retain as active until request for referral or retrieval is complete
256	1		Authorization For Records Destruction (computer printout)	P		25 yrs			25 yrs		Retain the Authorization for Records Destruction documents for reference purposes
			RECORD ITEMS WHICH HAVE BEEN DISCONTINUED FROM THE PREVIOUS SCHEDULE								
			#2--PLEATS (Examination Tracking Database)								The Board no longer uses the PLEATS database. Currently the Board used ATS and will use BREEZE, once it is implemented.