

Memorandum

To: Board Members

Date: April 11, 2003

From: Organizational Development Committee

For Action

Subject: Action Items and Report on the Meeting of April 10, 2003

The Organizational Development Committee met on April 10, 2003, in a teleconferenced meeting. Minutes of this meeting are provided in this tab section as Attachment A (following the numbered attachments referenced below).

Issue 1:

Final Recommendations of the Board of Pharmacy by the Joint Legislative Sunset Review Committee and the Department of Consumer Affairs.

Background: On Wednesday, April 2, the Joint Legislative Sunset Review Committee (JLSRC) held its hearing on its staff recommendations for the board. Incorporated into these recommendations were draft recommendations of the Department of Consumer Affairs (they were draft recommendations because the Administration had not yet approved them). During the hearing, Board President Jones stated that he concurred the recommendations of the JLSRC.

On Monday April 7, the Joint Legislative Sunset Review Committee voted 5-0 to adopt the recommendations of the JLSRC staff. The recommendations arising from the sunset review are an aggregate of recommendations of the Department of Consumers and the JLSRC. The recommendations are:

1. The licensing and regulation of the pharmacy profession should be continued and a board structure should be maintained.
2. Add two public members to the board.
3. Make all committee meetings of the board public meetings.
4. The board should adopt the NAPLEX.
5. Modify the citation and fine program to exclude the involvement of board members and delegate to the executive officer the authority to issue citations and fines.
6. The board should not require all its investigators to be pharmacists.
7. The board should use the department's online consumer complaint form.

8. The board should expand its consumer outreach and education, and work with the department to develop additional materials.
9. The board should establish a reliable method of communicating and surveying those who have filed complaints, and revise its survey instrument to provide meaningful data.
10. The board should work with the department's Office of Privacy Protection on ensuring patient privacy.

Also, as observations:

- The board is implementing the recommendations of its Pharmacy Manpower Task Force.
- The board has expanded its consumer complaint disclosure policy.

Recommendations specific to the JLSRC:

11. Support the board's proposal to revise registration and program requirements for pharmacy technicians – specifically:
 - a) accept PTCB certification
 - b) accept the associate degree in pharmacy technology and eliminate the other associate degrees
 - c) revise the specificity of the theoretical and practical requirements of the training curriculum
 - d) accept graduation from a school of pharmacy, and
 - e) eliminate the equivalent experience provision for the clerk typist and hospital pharmacy technician.
12. The board should continue to ensure that pharmacists offer oral consultations on new prescriptions. Consumers should not be charged a separate fee for such consultations.

Legislation to implement some of these proposals (extension of the board's sunset review date for four years, use of NAPLEX, flexibility for hiring inspectors who are not pharmacists, addition of two public board members and changes to the pharmacy technician program) will be introduced in the JSLRC's proposed legislation. This legislation will be heard before the Senate Business and Professions Committee on May 5, 2003.

Attachment 1 is the JSLRC's final recommendation report on the Board of Pharmacy.

In November 2002, the board had its Sunset Report reviewed during a hearing by the JSLRC. There were five initial recommendations/proposals from this review:

1. Add two public members to the board.
2. Define "actively engaged" as provided for in the Business and Professions Code specification of the composition of the board's professional members.
3. Make all committee meetings public meetings.
4. Modify board regulations so that the executive officer issues citations and fines.
5. Use staff other than exclusively pharmacist inspectors to investigate and inspect licensees.

Attachment 2 contains the Legislative Counsel's opinion of what constitutes "actively engaged" within the meaning of Business and Professions Code section 4001 regarding

the appointment of professional members to the board. The opinion concludes that “actively engaged’ in this instance means the performance of one or more functions for which an active pharmacist license is required.” And that actively engaged means “holding a pharmacist license issued by the California State Board of Pharmacy other than an inactive or retired pharmacist license and performing an activity on a full-time or part-time basis that requires an active pharmacist license.”

Issue 2:

Findings of the Operational Audit of the Board by the Department of Consumer Affairs, Internal Audits Office.

Background: The Department of Consumer Affairs’ Internal Audits Office released the report of its operational audit of the board in late March 2003. This audit started October 1, 2002, and was completed in February 2003. The audit looked at the board’s internal controls, compliance with all state requirements, the licensing of pharmacists and technicians, enforcement matters and cashiering. (The department typically audits every agency undergoing sunset review.)

The findings and recommendations for the board arising from this operational audit are:

1. The loan of \$6 million from the Pharmacy Board Contingency Fund to the State’s General Fund will negatively impact on the board’s future operations if not repaid in a timely manner.
2. Although the board’s evidence room access controls are adequate, management could strengthen inventory controls and safety awareness.
3. The board’s licensing activities are adequate but could benefit from improvements.
4. The board’s enforcement program allows it to address consumer complaints, but continued improvements are needed to strengthen its operations.

A copy of the audit report is provided as Attachment 3.

Progress reports to the department on the board’s actions to incorporate these changes will be prepared every six months. Copies of these status reports will be shared with the board.

Issue 3:

Mandatory Ethics Training for Board Members and Designated Staff must be completed in 2003

Background: The committee notes that it is again time for all board members and designated staff to take state-mandated ethics training. This training must be completed during 2003. Attachment 4 contains information about the requirements and options for taking the training. There are approximately 50,000 individuals who must take this course.

The training can be taken online or in a group setting. The committee recommends that board members take this training individually, from the Web site (<http://caag.state.ca.us/ethics/index.htm>) or via a CD-ROM.

Issue 4:

Continuing Education for Pharmacists Attending this Board Meeting

Background: The board has agreed to award 6 units of continuing education credit to pharmacists who attend the full business day of a board meeting. This CE can be earned once a year, but cannot be earned by board members or board staff. This opportunity was published in the March 2003 *The Script*, and a notice has been placed on the listing for board meetings on the board's Web site.

The board is awarding CE starting at this Board Meeting. Attachment 5 displays the information posted on the board's Web site. The designated day of the board meeting on which pharmacists may earn CE will be stated on the board's Web site and on the meeting agenda.

Issue 5:

Budget Update for 2002/03 and 2003/04

The state is facing a huge budget deficit now estimated as \$35 billion.

A number of additional cost containment controls have been placed on state agencies besides hiring freezes and the elimination of vacant positions:

- In the 2002/03 budget, the board lost four positions and \$185,000 in associated funding for these positions.
- In February 2003, the board learned that any out-of-state travel would not likely be approved, allowing the board to redirect about \$20,000 to the board's AG program line item
- Also in February, all agencies were required to cut their in-state travel budgets by 35 percent (in the case of the board, this is \$52,100)
- All training requests, contracts and purchases now undergo additional review by the department as a means to reduce expenses, and approval is significantly harder to attain

On April 1, the Administration directed all agencies to cut their personnel services budgets by 10 percent for 2003/04, and to prepare a list of surplus employees to lay off. This will amount to a \$353,000 reduction for the board, the elimination of all vacant positions and the elimination of overtime and board member honoraria. However, we should not have to lay off any staff; although we will have to continue to redirect work and stop performing some functions in order to complete the most important tasks.

Transfer of Board's Reserve and Proposed Fee Increases

The board "loaned" \$6 million from its fund to the state's General Fund this budget year. This has left the board with a looming deficit of its own at the beginning of 2004/05 which will grow to at least a \$2.7 million deficit (or 4.2 months of expenditures) by June 30, 2005.

The Internal Audits Office of the department noted in its audit report on the board, that the board's fiscal condition will require repayment of the loan to begin late in 2003/04. During the sunset review hearings in early April, the department repeated that repayment of a general fund loan will occur before any agency has to increase fees (this was not in response to the board's budget, but that of another departmental entity). The board is working with the department and the Department of Finance to assure repayment of the loan before the board has a deficit.

Meanwhile, the department recalculated its budget assumptions that indicate that the board would not repayment of the loan until late in 2003/04 (about this time next year).

2002/03 Budget Reductions:

The board's final budget for last year (2001/02) was \$7,514,523

The board's initial budget for 2002/03 (Sept. 2002 when the state's budget was enacted) was \$7,481,000

The board's revised 2002/03 budget (Dec. 2002) was reduced to \$7,386,597 (due to the loss of funding for four positions eliminated by the Administration because the positions were vacant).

Budget Change Augmentations for 2002/03

At the last meeting, staff indicated a need to seek a deficiency augmentation for this fiscal year to continue access to legal services from the AG's Office. As of February 1, the board had spent \$587,520 for AG services. Estimates continue to confirm that the board will spend \$1 million for AG services this year, or \$230,000 more than the budgeted amount.

During development of the augmentation request, the board determined that it could redirect \$230,000 from several unfilled positions for several months, out of state travel and from printing as a result of reducing our the number of newsletters and *Health Notes* published (which also reduced our postage expenses). These redirections eliminated the need for the deficiency request. However, AG spending has been capped at \$1 million because the board will not be able to redirect additional money to this line item.

Budget Change Augmentations for 2003/04 and 2004/05

Seeking any augmentation requests in this fiscal climate will not likely be successful. However, the board needs to acknowledge its need for most necessary augmentations:

1. The board will continue to have problems with funding in its AG budget next year. The board has spent \$1 million the last three years for AG services, and to reduce the budget to the amount allocated (\$777,000) would result in a 25 percent reduction from prior years' spending. This year, the board withdrew some aging AG cases and reduced the number of AG cases referred as cost containment strategies required by the board's budget condition, and still the budget will be \$1 million. Nevertheless, the importance of the AG services to the board's consumer protection mandate require that a BCP be prepared to augment funding to historical levels of spending.
2. Additionally, the board will need to do a job analysis in 2004 for the pharmacist exam or if NAPLEX is approved, for the CA specific portion of the exam. The costs for this will be approximately \$25,000.

Issue 6:

Personnel Update

Background: A full personnel update is provided as Attachment 6

1. Promotions:
The board has promoted Joan Coyne and Dennis Ming into the two new supervising inspector positions created/reclassified this year.
 - Dr. Coyne has been with the board eight years and will oversee the Pharmacists Recovery Program and Probation Program.
 - Dr. Ming has been with the board three years and will oversee the Compounding Pharmacy Licensure Program.
2. Resignations:
Lynnee Ritchie resigned from her receptionist position in February.
3. Vacancies:
 - Two inspectors (one new position for compounding, the other from the promotion of Dennis Ming)
 - One staff analyst (enforcement)
 - One associate analyst (licensing of sites)
 - One office technician (licensing of sites)
 - One office technician (receptionist)
4. 10 per reduction for 2003/04 in Personnel Expenses:
By eliminating all these positions, the board will be able to reduce its annual personnel expenses to \$330,000 – all but \$23,000 of the \$253,000 the board must target for elimination.
5. Inspector interviews were conducted in March to compile a new list of pharmacists interested in working for the board as inspectors

6. Labor-Management Task Force held its second meeting to deal with inspector issues

Issue 7:

Future Meeting Dates

Background: The committee has identified the following as proposed meeting dates for 2004 (the dates for 2003 have already been established).

Are these dates acceptable to the board?

2003 Meeting Dates: Currently scheduled:

- April 29-30, Sacramento
- July 21-22, San Diego
- October 29-30, San Francisco

2004 Meeting Dates: Proposed (all dates are Wednesdays and Thursdays):

- January 21-22, Orange County (CPhA will hold its annual meeting at the end of January and beginning of February)
- April 21-22, Sacramento
- July 21-22, San Diego
- October 20-21, San Francisco (CSHP will hold its Seminar either the first week in November or earlier in October – in Long Beach or Palm Springs)

Issue 8:

Revised Strategic Goals and Objectives for 2003/04. The committee's restructured goals, objectives and tasks are listed in Attachment 7. The board needs to review and approve the committee's goals

Attachment 1

FINAL RECOMMENDATIONS FOR THE BOARD OF PHARMACY

RECOMMENDATIONS OF THE JOINT SUNSET REVIEW COMMITTEE AND THE DEPARTMENT OF CONSUMER AFFAIRS

ISSUE #1. (CONTINUE REGULATION OF THE PROFESSION AND THE BOARD?)
Should the licensing and regulation of pharmacy profession be continued, and be regulated by an independent board rather than by a bureau under the Department?

Recommendation #1: *The Joint Committee and the Department recommend the continued regulation of the pharmacy profession and that a board structure be maintained.*

Comments: Consumers rely upon the oversight provided by the Pharmacy Board to ensure prescription of pharmaceutical drugs (including controlled substances) and devices are responsibly distributed and dispensed by individuals and business establishments holding licenses in good standing. The board structure has proven to be an effective regulatory mechanism for doing this.

ISSUE #2. (CHANGE BOARD COMPOSITION?) **The Board currently consists of 11 members: seven professional members and four public members. This composition provides for a super majority of professional members. Almost all health related consumer boards have no more than a simple majority of professional members.**

Recommendation #2: *The Joint Committee and the Department recommend that two public members be added to the composition of the Board to expand public representation.*

Comments: This recommendation was first raised by a number of witnesses at the Department's public hearing. Currently, the board composition results in a super majority of professional members on the board. Given the broad impact the board has on the lives of consumers, the majority of whom regularly interact with a pharmacy or a pharmacist, it is important to ensure that the consuming public has a significant role in board decision-making.

The Department believes that public participation on regulatory boards ensures balanced approach to decision-making and enhances public protection. In recent years, public members have been added to the Accountancy, Contractors, Podiatry, Psychology, Respiratory Care, and Veterinary Medical Boards through the sunset review legislative process. Two additional board members would not substantially increase operational costs.

ISSUE #3. (BOARD MEETINGS OPEN TO THE PUBLIC?) Should all board committee meetings be publicly noticed and open to the public?

Recommendation #3: *The Joint Committee and the Department recommend that all committee meetings be publicly noticed and open to the public.*

Comments: This year, the Department has made a cross-cutting recommendation that all board committee meetings should be open to the public. Committees often develop significant policy recommendations for the board to consider and adopt. As such, consumers and industry stakeholders should have the opportunity to observe and provide comments and feedback on the committee's deliberations. This practice has been particularly common at the Board of Pharmacy, and the Department strongly urges it be changed to allow for greater public participation.

ISSUE #4. (ADOPT NATIONAL EXAMINATION?) Should the Board adopt the North American Pharmacist Licensure Exam (NAPLEX)?

Recommendation #4: *The Joint Committee and the Department recommend that the Board adopt the NAPLEX.*

Comments: According to the Board, and witnesses who provided comments at the Department's sunset hearings, California is experiencing a shortage of pharmacists. Many of the same witnesses testified that adoption of the national exam would help to alleviate the shortage by increasing the pool of pharmacists available to work in California. The Board's longstanding policy of declining to accept the national exam has made it more difficult for pharmacists to begin work in California and has hindered efforts to address the pharmacist shortage.

The Department is particularly concerned about pharmacist shortages in rural and underserved areas. During our recent efforts to assist Assembly Member Strom-Martin to meet the demand for state licensed pharmacists on the Hoopa Tribal Reservation in northern California, we learned of the difficulty in securing licensed pharmacists in that area of the state. In spite of impressive recruitment efforts, the Tribal Council was unable to attract California pharmacists and was effectively prohibited from hiring interested pharmacists who had passed the national exam.

It is important to note that California is the only state that does not currently recognize the NAPLEX exam. The Department's Office of Examination Resources has determined that the NAPLEX exam is equivalent to California's exam, so there is no risk of lowering the skill level practiced in California. When national exams are utilized, California typically prepares a supplemental exam that tests applicants for knowledge of applicable state laws, and often results in reduced exam administration costs.

ISSUE #5. (MODIFY CITE AND FINE PROCESS?) Should the Board change its cite and fine process to allow the Executive Officer to issue citations and fines and to exclude the involvement of board members?

Recommendation #5: *The Joint Committee and the Department recommend that the Board modify its cite and fine process to exclude the involvement of board members.*

Comments: The Department recommends that the Board revise their cite and fine process to allow the Executive Officer or designee to issue citations and fines to a pharmacist or pharmacy, continuing education violations, unlicensed activity, failure of a pharmacy to designate a pharmacist-in-charge or file a discontinuance of business.

The Board has adopted a policy of involving board members in the citation and fine issuance process. This is a staff function, not a function for board members and creates an inherent conflict for board members who are called upon later to adjudicate disciplinary actions. Further, this practice is inconsistent with the practices of other Department regulatory programs in which the Executive Officer has the authority to issue citation and fines. At the Department's public hearings, extensive testimony was provided about the conflict that is created by having board members participate in this process. The Department recommends this practice be discontinued and the Executive Officer be authorized to issue citations and fines.

ISSUE #6. (REMOVE MANDATE THAT INVESTIGATORS BE PHARMACISTS?) Should the Board be given the option of hiring investigators who are not licensed pharmacists?

Recommendation #6: *The Joint Committee and the Department recommend that investigators should not be required to be licensed pharmacists.*

Comments: The Board should have the option of hiring licensed pharmacists inspectors or other state investigators. Other boards (e.g. Medical, Dental, Psychology, Registered Nursing and others) do not mandate that only individuals licensed within their regulatory profession perform investigation or inspection of suspected violations. In lieu of the licensed professions, the boards and bureaus utilize professionally trained investigators and expert consultants or witnesses as required. The use of professionally trained investigators would reduce the excessive timelines for Pharmacy Board investigations. Additionally, this would result in personnel cost savings to the Board. The Board has indicated in the past that it is difficult to recruit and hire licensed pharmacists for enforcement activities because of the salary levels.

ISSUE #7. (UTILIZE DCA ONLINE COMPLAINT FORM?) Should the Board use the Department's consumer complaint form?

Recommendation #7: *The Joint Committee and the Department recommend that the Board utilize the Department's online consumer complaint form.*

Comments: In 2002, the Department launched a universal consumer complaint form that allows consumers to complete and submit a complaint online. The use of the online complaint form was offered to all boards and bureaus. At this time, the Board of Pharmacy is not utilizing the Department form. Given the resource limitations and the delay in the processing of complaints, the Board should adopt the Department's online complaint form to receive initial information from consumers. Follow-up communications can be employed to gather additional information from the consumer if necessary to pursue investigation of the complaint.

ISSUE #8. (EXPAND CONSUMER OUTREACH AND EDUCATION?) Should the Board expand consumer outreach and utilize DCA's Consumer Education Division?

Recommendation #8: *The Joint Committee and the Department recommend that the Board expand consumer outreach and education.*

Comments: The services provided by pharmacists touch upon the lives of practically every California consumer on a regular basis. The Department recommends that Board of Pharmacy review their current consumer education and outreach efforts to determine if they may be expanded. The Department has previously recommended that the Board consult with the Department's Consumer Education Division (CED) to enhance public education. While the Board has noted a lack of resources to increase public outreach, we would note that assistance from CED is a service available to the Board at no additional cost.

ISSUE #9. (IS BOARD'S COMPLAINT SURVEY INSTRUMENT AND PROCESS ADEQUATE?) Should the Board establish make revisions to its complaint survey instrument and process?

Recommendation #9: *The Joint Committee and the Department recommend that the Board immediately establish a reliable method of communicating with consumers who have filed complaints, and revise a written survey instrument that can provide meaningful data.*

Comments: It is not possible to truly assess the Board of Pharmacy's level of consumer satisfaction or adequacy of consumer complaint handling processes because the Board is inexplicably unable to provide data on the number of surveys distributed. Without that fundamental information, the information provided is meaningless.

The Department recommends that the Board immediately establish a reliable method of communicating with consumers who have filed complaints, and revise a written survey instrument that can provide meaningful data. The Department notes, for instance, that while the Board indicates it asks consumers to rank the level of service received, there is no such information provided on the survey summary provided.

The Department is concerned by the Board's indication that it intends to conduct phone surveys to assess consumer satisfaction. Absent careful training and supervision, phone surveys are often

not reliable. The Committee may recall the unreliable phone survey results that were presented by the Cemetery and Funeral Bureau during its recent sunset review. Additionally, the utilization of telephone staff for this purpose is probably not the most effective utilization of current staff resources. The Board has indicated to the Department in recent months its inability to receive and respond to phone calls regarding license application status. Given that situation, it is unclear how the Board would provide phone staff support for conducting surveys.

The Board should revise its consumer complaint survey instrument, working collaboratively with the Department, to include more questions how the Board can improve their complaint process. To increase consumer response, the Board should make a practice of immediately forwarding the survey to complainants upon closure of their case. The Department makes a similar recommendation relative to the Board of Registered Nursing (BRN) and the Board of Licensed Vocational Nurses and Psychiatric Technicians (BVNPT).

ISSUE #10. (ENSURE PATIENT PRIVACY?) Should the Board collaborate with the DCA Office of Privacy Protection to ensure patient privacy?

Recommendation #10: *The Joint Committee and the Department recommend that the Board work with the Department's Office of Privacy Protection on ensuring patient privacy.*

Comments: The Pharmacy Board should collaborate with the Department's Office of Privacy Protection in distributing the Office's consumer informational materials on health privacy. The Board should seek to make the materials available in pharmacies. As the new federal health privacy rule to implement the Health Insurance Portability and Access Act (HIPAA) takes effect this year, it is more critical than ever that patients become aware of their right to protect their privacy. The Office of Privacy Protection is preparing new materials that inform California consumers on their rights under state and federal law. The Board can significantly enhance the knowledge of consumers throughout California by helping to distribute this information through its licensee and outreach network.

ISSUE #11. (REVISE PHARMACY TECHNICIAN REGISTRATION AND PROGRAM REQUIREMENTS?) The Board has proposed statutory and regulatory changes would include, among other things, certification by the Pharmacy Technician Certification Board (PTCB) as a qualifying method to becoming a pharmacy technician.

Recommendation #11: *The Joint Committee supports the Board's proposal to revise registration and program requirements for pharmacy technicians.*

Comments: The original technician registration and program requirements have been in place for over 10 years. Although there have been some program modifications such as technician trainees, a ratio increase for the second pharmacist in the community setting, and mandatory registration of all pharmacy technicians, there has not been a major review or update of the program.

Based on the recommendations of the Pharmacy Manpower Task Force and others, the Board is proposing the following revisions to the pharmacy technician registration and program requirements: 1) accept PTCB certification; 2) accept the associate degree in pharmacy technology and eliminate the other associate degrees; 3) revise the specificity of the theoretical and practical requirements of the training curriculum; 4) accept graduation from a school of pharmacy; and 5) eliminate the “equivalent experience” provision for the clerk-typist and hospital pharmacy technician.

ISSUE #12. (PATIENTS CHARGED FOR ORAL CONSULTATIONS?) There is evidence that patients are being charged for oral consultations on new prescriptions.

Recommendation #12: *The Joint Committee recommends that the Board should continue to ensure that pharmacists offer oral consultations on new prescriptions. Further, the Joint Committee believes that consumers should not be charged a separate fee for such consultations.*

Comments: Pharmacists are required to offer oral consultations on all new prescriptions. There is evidence that patients are being charged for these consultations. Draft text approved by the Board’s Public Education and Communications Committee for the revised Consumer Alert poster originally included language referring to no-charge consultations but that statement was not included in the final version of the poster.

RECOMMENDATIONS FOR ALL BOARDS UNDER THE DEPARTMENT (“CROSSCUTTING RECOMMENDATIONS”)

RECOMMENDATIONS OF THE JOINT SUNSET REVIEW COMMITTEE AND THE DEPARTMENT OF CONSUMER AFFAIRS

The DCA has identified several “cross-cutting” issues affecting all boards and the Department’s consumer protection mission, including:

- Open Committee Meetings
- Meaningful Strategic Planning
- Increased Fine Amounts for Citations
- Discharge of Cost Recovery Orders

ISSUE #1. (BOARD MEETINGS OPEN TO THE PUBLIC?) Should the Bagley-Keene Open Meetings Act be amended to require that all DCA board meetings be noticed and open to the public?

Recommendation #1: *The Joint Committee and the Department recommend that the Bagley-Keene Open Meetings Act be amended to require that all DCA board committee meetings be noticed and open to the public.*

Comments: Committees are often convened by boards to consider particular issues in depth and committee recommendations are reported back to the full board. While this is an efficient method of addressing issues that are before the board, these meetings are often held outside of public view. Under the Bagley-Keene Open Meetings Act, meetings must only be publicly noticed if three board members or more are participating. As a result, some boards appoint only two members to serve on committees to avoid triggering the public notice requirement. This prevents the public from participating in or observing committee deliberations and decision making.

ISSUE #2. (UPDATE STRATEGIC PLAN ANNUALLY?) Should all boards update their strategic plan annually with board member participation?

Recommendation #2: *In order to maximize the strategic planning process, the Joint Committee and the Department recommend that boards update their strategic plan annually and require board member participation.*

Comments: It has come to the Department’s attention that some boards do not update their strategic plans on an annual basis in a meaningful way and in some instances, board members do not participate in the strategic planning process, relying on staff to provide them with a plan. It is a primary duty of

the board to set policy priorities and to direct staff – not the other way around. The purpose of strategic planning is for board staff, working collaboratively with board members to identify priorities and specific plans for the coming year. DCA believes its boards would be more successful if they engaged energetically in strategic planning.

ISSUE #3. (INCREASE CITE AND FINE LIMIT?) Should the cite and fine limit be increased to \$5000?

Recommendation #3: *The Joint Committee and the Department recommend that the citation and fine limit in Business and Professions Code Section 125.9 be increased to \$5000.*

Comments: The current cap for citations and fines issues by the Department’s regulatory programs is \$2,500. This cap has not been increased for over fifteen years. As a result, many licensees perceive fines as a cost of doing business rather than a penalty or deterrent, as they are intended to be.

ISSUE #4. (COST RECOVERY DISCHARGED IN BANKRUPTCY PROCEEDINGS?) Should steps be taken to prevent cost recovery from being discharged in bankruptcy proceedings?

Recommendation #4: *The Joint Committee and the Department believe that cost recovery orders should not be discharged in bankruptcy proceedings. Further, the Joint Committee and the Department recognize the need for clarification to prevent cost recovery from being discharged in bankruptcy proceedings.*

Comments: Cost recovery orders should not be discharged in a personal bankruptcy. The Department of Justice has successfully argued that “costs” are an element of the discipline sanction imposed on a licensee, so cost recovery orders are therefore considered to be penalties, not reimbursements. Clarification is needed to avoid the time and expense of repeatedly arguing this matter in federal bankruptcy courts.

Attachment 2

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March 19, 2003

Honorable Liz Figueroa
4061 State Capitol

MEMBER QUALIFICATIONS FOR THE CALIFORNIA STATE BOARD OF PHARMACY - #1972

Dear Senator Figueroa:

QUESTION

What is the meaning of the phrase "actively engaged in the practice of pharmacy," as used in subdivision (c) of Section 4001 of the Business and Professions Code?

OPINION

The phrase "actively engaged in the practice of pharmacy," as used in subdivision (c) of Section 4001 of the Business and Professions Code, means holding a pharmacist license issued by the California State Board of Pharmacy other than an inactive or retired pharmacist license and performing an activity on a full-time or part-time basis that requires an active pharmacist license.

ANALYSIS

Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code¹ sets forth the Pharmacy Law (Sec. 4000). Section 4001 establishes the California State Board of Pharmacy (hereafter the board) within the Department of Consumer

¹ All further section references are to the Business and Professions Code, unless otherwise indicated.

Affairs for the administration and enforcement of the Pharmacy Law. That section reads as follows:

"4001. (a) There is in the Department of Consumer Affairs a California State Board of Pharmacy in which the administration and enforcement of this chapter is vested. The board consists of 11 members.

"(b) The Governor shall appoint seven competent pharmacists, residing in different parts of the state, to serve as members of the board. The Governor shall appoint two public members and the Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member who shall not be a licensee of the board, any other board under this division, or any board referred to in Section 1000 or 3600.

"(c) At least five of the seven pharmacist appointees to the board shall be pharmacists who are actively engaged in the practice of pharmacy. Additionally, the membership of the board shall include at least one pharmacist representative from each of the following practice settings: an acute care hospital, a community pharmacy, and a long-term health care or skilled nursing facility.

"(d) Members of the board shall be appointed for a term of four years. No person shall serve as a member of the board for more than two consecutive terms. Each member shall hold office until the appointment and qualification of his or her successor or until one year shall have elapsed since the expiration of the term for which the member was appointed, whichever first occurs. Vacancies occurring shall be filled by appointment for the unexpired term.

"(e) Each member of the board shall receive a per diem and expenses as provided in Section 103.

"(f) In accordance with Sections 101.1 and 473.1, this section shall become inoperative on July 1, 2004, and, as of January 1, 2005, is repealed, unless a later enacted statute, that becomes effective on or before January 1, 2005, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473)." (Emphasis added.)

Thus, the Governor is required to appoint seven competent pharmacists to the board, and at least five of those seven pharmacist appointees are required to be "actively engaged in the practice of pharmacy." This particular phrase is not defined by the Pharmacy Law.

Rules of construction require that statutory terms be construed in accordance with the usual, ordinary import of the language employed, in harmony with the overall legislative scheme (*IT Corp. v. Solano County Bd. of Supervisors* (1991) 1 Cal.4th 81, 98). The Pharmacy Law identifies activities for which a license as a pharmacist is required. For example, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense any dangerous

drug or device,² or to dispense or compound any prescription of a medical practitioner unless he or she is a pharmacist, unless otherwise provided in the Pharmacy Law (Sec. 4051). In addition, a pharmacist is authorized to (1) furnish a reasonable quantity of compounded medication to a prescriber for office use by the prescriber, (2) transmit a valid prescription to another pharmacist, (3) administer, orally or topically, drugs and biologicals pursuant to a prescriber's order, (4) order or perform routine drug therapy-related patient assessment procedures, order drug-therapy-related laboratory tests, administer drugs and biologicals by injection pursuant to a prescriber's order, initiate or adjust the drug regimen of a patient pursuant to an order or authorization by the patient's prescriber, provided these functions are performed in specified settings in accordance with designated policies, procedures, or protocols, (5) manufacture, measure, fit to the patient, or sell and repair, dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices, (6) provide consultation to patients and professional information, advice, or consultation to other health care professionals, and (7) initiate emergency contraception drug therapy in accordance with designated procedures or protocols (Sec. 4052). Besides these functions, a pharmacist is additionally authorized to perform skin puncture associated with certain procedures, repackage a previously dispensed drug, furnish topical medications to physical therapists and optometrists, and furnish electroneuromyographic needles or hypodermic needles to physical therapists certified to use them in kinesiological electromyographic testing (Secs. 4052.1, 4052.7, and subds. (e) and (f), Sec. 4059). Further, any person who is not a pharmacist who takes charge of or acts as manager of any pharmacy or who compounds or dispenses a prescription or furnishes dangerous drugs is guilty of a misdemeanor, except as otherwise provided in the Pharmacy Law (Sec. 4329). The regulations of the board further regulate the practice of pharmacy (see, for example, 16 Cal. Code Regs. 1793.1).

Because a pharmacist is required to have an active pharmacist license issued by the board to perform the activities described in the preceding paragraph, we think those activities necessarily constitute the practice of pharmacy. Besides an active pharmacist license issued by the board pursuant to Section 4200,³ the board is required to issue an inactive pharmacist license⁴ (Sec. 700 and following) and a retired pharmacist license⁵ (Sec. 4200.5) to persons

² A dangerous drug or a dangerous device generally is one that may be dispensed by prescription only (Sec. 4022).

³ Section 4200 requires the board to license as a pharmacist, and issue a certificate to, an applicant who meets age, educational, practical experience, and examination requirements set forth in that section.

⁴ Each healing arts board referred to in Division 2, including the board, is required to issue, upon application and payment of the normal renewal fee, an inactive license or certificate to a person holding a current active license or certificate issued by that board (Sec. 701).

⁵ The board is required to issue upon application and payment of a specified fee, a retired license to a pharmacist who was previously licensed by the board (Sec. 4200.5)

meeting specified criteria. The provisions describing the inactive license provide that it is intended for a person who is not "actively engaged in the practice of his or her profession," to maintain licensure in a nonpracticing status (Sec. 700). Furthermore, persons holding an inactive license as well as those persons holding a retired pharmacist license issued by the board are expressly prohibited from performing any of the functions for which an active pharmacist's license is required (Sec. 702 and subd. (b), Sec. 4200.5).

Thus, we think the phrase at issue here refers to a pharmacist who currently holds an active license that allows the holder to perform the activities constituting the practice of pharmacy. Because the phrase specifies the active engagement in that practice, performing one or more of the activities constituting the practice of pharmacy identified above (see pp. 2-3) is, in our view, necessarily required in order to give effect to the entirety of this phrase, as mandated by statutory construction rules (*Lambert Steel Co. v. Heller Financial, Inc.* (1993) 16 Cal.App.4th 1034, 1040). In a related context, it has been held that the holding of a license without performing the functions for which that license is required ordinarily does not constitute active engagement in a profession (see *Flaherty v. State Bar* (1940) 16 Cal.2d 483, 484, 487). Consequently, we think "actively engaged" in this instance means the performance of one or more functions for which an active pharmacist license is required. It seems reasonable that this qualification is specified in order to assure that a pharmacist board member has knowledge of the current problems and issues in pharmacy practice.

While neither Section 4001 nor any other provision of the Pharmacy Law requires full-time practice as a pharmacist in order to be actively engaged in the profession, we necessarily think it requires performing on a full-time or part-time basis one or more activities for which an active pharmacist license is required.⁵

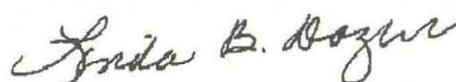
⁵ On March 17, 2003, we were informed by Patricia Harris, executive director of the board, that the board has taken no position as to the meaning of the phrase "actively engaged in the practice of pharmacy," as used in subdivision (c) of Section 4001.

Honorable Ltz Figueroa — Request #1972 — Page 5

Accordingly, it is our opinion that the phrase "actively engaged in the practice of pharmacy," as used in subdivision (c) of Section 4001 of the Business and Professions Code, means holding a pharmacist license issued by the California State Board of Pharmacy other than an inactive or retired pharmacist license and performing an activity on a full-time or part-time basis that requires an active pharmacist license.

Very truly yours,

Diane F. Boyer-Vine
Legislative Counsel



By
Linda B. Dozier
Deputy Legislative Counsel

LBD:dsc

Attachment 3

Operational Audit of

The California Board of Pharmacy

March 2003

Audit No. 2002-103



Consumer
Affairs
Internal Audit Office



The Great Seal



Internal Audit Office
400 R Street, Suite 2000
Sacramento CA 95814 (916) 322-6340



March 17, 2003

Denise Brown, Chief Deputy Director
Department of Consumer Affairs
400 R Street, Suite 3000
Sacramento, CA 95814

Subject: Operational Audit Report – California Board of Pharmacy

Transmitted herewith is an audit report of the California Board of Pharmacy (Board). The audit focused on the Board's strategic planning process and many of its core business operations. Within its enforcement program, we followed-up on several deficiencies noted by the Bureau of State Audits (BSA) in its April 2001 Report titled "Investigation of Improper Activities by State Employees: July 2000 through January 2001." We also reviewed selected financial and statistical data included in the Board's September 2002 Sunset Report to the Joint Legislative Sunset Review Committee (JLSRC).

Our audit revealed that the Board generally fulfilled its regulatory responsibility by demonstrating compliance with many applicable laws and regulations. We also noted that the Board's strategic planning process followed guidelines established by the Department of Consumer Affairs. Furthermore, the Board was able to materially support selected financial and statistical data included in its September 2002 Sunset Report. While we found that many of its regulatory responsibilities were generally fulfilled, we did identify several areas that need to be addressed to improve the Board's operations and ensure further compliance with laws and regulations.

We have included our specific findings and recommendations in the report. As outlined in its response, the Board agreed with our findings and plans to continue with its corrective actions to improve its operations. We plan to follow-up on the implementation of the corrective actions at 180- and 360- days from the report date.

We would like to thank the Board's management and staff for their cooperation during the audit. If you need further information, please call me at 327-6443.

Sincerely,
Original Signed by Steve Castillo
Steve Castillo, Chief
Internal Audit Office

Enclosure

cc: Patricia F. Harris, Executive Officer, California Board of Pharmacy
Kristy Wiese, Deputy Director, Legislative & Regulatory Review Division, DCA

TABLE OF CONTENTS

Report Summary	1
Background	8
Scope, Objectives and Methodology	8

Findings and Recommendations

1. The loan of \$6 million from the Pharmacy Board Contingency Fund to the State's General Fund will negatively impact on the Board's future operations if not repaid in a timely manner.	9
2. Although the Board's evidence room access controls are adequate, management could strengthen inventory controls and safety awareness.	11
3. The Board's licensing activities are adequate but could benefit from improvements.	14
4. The Board's enforcement program allows it to address consumer complaints, but continued improvements are needed to strengthen its operations.	17

Other Pertinent Information

1. Selected Financial and Statistical data from the September 2002 Report to the Joint Legislative Sunset Review Committee was materially supported by adequate documentation.	22
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ATTACHMENT I – Board's Response to the Draft Report

**California Board of Pharmacy
Operational Audit
March 2003**

The audit focused on the Board's strategic planning process and many of its core business operations.

The Department of Consumer Affairs' (Department) Internal Audit Office completed an operational audit of the California Board of Pharmacy (Board). The audit focused on the Board's strategic planning process and many of its core business operations. Within its enforcement program, we followed-up on several deficiencies noted by the Bureau of State Audits (BSA) in its April 2001 Report titled "Investigation of Improper Activities by State Employees: July 2000 through January 2001." We also reviewed selected financial and statistical data included in the Board's September 2002 Sunset Report to the Joint Legislative Sunset Review Committee (JLSRC).

The Board has statutory authority for licensing and regulating 12 major regulatory programs. The Board regulates over 75,000 licensees, encompassing both individuals and businesses that ship, store and dispense prescription drugs and devices to the State's health care providers and patients. With an appropriated fiscal year 2002-03 budget of \$7.3 million, the Board utilizes 48.5 authorized positions to carry out its responsibilities, including: issuing and renewing licenses; overseeing the examination and application processes; responding to various complaints; performing inspections and investigations; disciplining violators; and providing consumer information to the public.

In reviewing the Board's operations, we interviewed key personnel, tested key functions, documents and procedures. We compared operations to applicable laws, regulations and guidelines, as we deemed necessary. We conducted our audit in accordance with the *Standards for the Professional Practice of Internal Auditing*. Our audit compliance test period was from July 1, 2001, through June 30, 2002. The last day of audit fieldwork was February 7, 2003.

Our audit revealed that the Board generally fulfilled its regulatory responsibility by demonstrating compliance with many applicable laws and regulations.

Our audit revealed that the Board generally fulfilled its regulatory responsibility by demonstrating compliance with many applicable laws and regulations. We also noted that the Board's strategic planning process followed guidelines established by the Department. Furthermore, the Board was able to materially support selected financial and statistical data

included in its September 2002 Sunset Report. While we found that many of its regulatory responsibilities were generally fulfilled, we did identify several areas that need to be addressed to improve the Board's operations and ensure further compliance with laws and regulations. The following are the results of our audit:

The Board's strategic planning process followed the Department's guidelines.

We noted that the Board's fiscal year 2002-03 Strategic Plan (Plan) documented key elements of a strategic planning process as recommended by the Department. The Plan contained goals and objectives relating to the Board's core business activities. We verified that the Board members annually review and modify the Plan as necessary. The Board informed us that it monitors and tracks the progress of achieving its strategic goals and objectives. Consequently, we concluded that the Plan complies with the Department's recommended strategic planning process.

The Board has adequate controls over its cashiering process.

During our audit, we reviewed the Board's cashiering process and found that the Board has developed and implemented detailed policies and procedures for the receipt, processing, and deposit of funds received by the Board. Furthermore, Board staff followed proper recording and reconciliation procedures.

The loan of \$6 million from the Pharmacy Board Contingency Fund to the State's General Fund will negatively impact the Board's future operations if not repaid in a timely manner.

The Board has projected that future expenditures will exceed future revenues, and without repayment of the loan in a timely manner, the Board will deplete its Fund during fiscal year 2003-04, causing a negative reserve of approximately \$275,173 as of June 30, 2004.

The enactment of the 2002-03 Budget Act (AB 425) required the Board to loan \$6 million from its Contingency Fund (Fund) to the State's General Fund in August 2002. AB 425 states, "it is the intent of the Legislature that repayment be made so as to ensure that the programs supported by this fund are not adversely affected by the loan through reduction in services or through increased fees." The loan was made from the Fund's prior balance of \$10.8 million as of June 30, 2002. The Board has projected that future expenditures will exceed future revenues, and without repayment of the loan in a timely manner, the Board will deplete its Fund during fiscal year 2003-04, causing a negative reserve of

approximately \$275,173 as of June 30, 2004. By the end of fiscal year 2003-04, the Board may be faced with significant operational cuts if the loan is not repaid in a timely manner.

We recommend that the Board work with the Department of Finance to obtain repayment of the \$6 million loan in a timely manner to advert increased fees and/or reduction of services.

Although the Board's access controls to the evidence rooms are adequate, management could strengthen inventory controls and safety awareness.

The Board stores pharmaceutical evidence gathered during investigations in evidence rooms located in Southern and Northern California offices. Management has developed and implemented formal policies and procedures for the intake, documentation, storage, and security of the gathered evidence. Based on our review, we determined that the Board adequately controls the access to stored evidence; however, the Board needs to improve its inventory control procedures and safety awareness.

We noted the Board has not taken a physical inventory of the evidence rooms within the past 18 months. In addition, we were informed that the Board has not been able to destroy evidence marked for destruction because it has been unable to hire a contractor that will perform witness verified destruction. The accumulation of extensive amounts of pharmaceuticals poses safety hazards in the event of a fire or flood. We observed that the Board has not properly identified and marked potentially hazardous materials, which informs employees and emergency workers of the related risks and how to deal with the items during an emergency. **We recommend that the Board perform regular documented inventory counts of the evidence room contents. Additionally, the Board needs to take steps to properly dispose of evidence marked for destruction. The Board should also implement a process to identify the potential hazards associated with currently stored evidence and post appropriate warning signs on its premises.**

The Board's licensing activities are adequate but could benefit from improvements.

Our audit of the current licensing process noted that the Board has a system in place to ensure that applicants requesting

The accumulation of extensive amounts of pharmaceuticals poses safety hazards in the event of a fire or flood.

licensure meet the applicable laws and regulations prior to granting licensure. Based on our sample of 30 randomly selected pharmacist and pharmacy technician applicant files received in fiscal year 2001-02, we noted that files contained the required documentation validating licensure, were generally approved or denied within appropriate time periods, and were issued only to qualified applicants. While the Board has demonstrated compliance with many licensing laws and regulations, we did note a few areas that could benefit from improvement.

We found that the Board's current applicant tracking systems does not allow the monitoring of applicable internal and regulated processing times for several license categories.

Our audit revealed that the Board is not always notifying the applicants in the required time frame regarding the completeness of their applications. Next, we found that the Board's current applicant tracking systems does not allow the monitoring of applicable internal and regulated processing times for several license categories. We also noted that the Board had not obtained the required Criminal Offender Record Information (CORI) employee statement forms as of January 8, 2003. Subsequently, the Board obtained the required forms. **We recommend that the Board acknowledge applications and communicate deficiencies within the time frames required by the applicable laws and regulations. Additionally, the Board should implement an applicant tracking system that will allow it to adequately monitor processing time frames to ensure that it meets internal and regulated time requirements.**

The Board's enforcement program allows it to address consumer complaints, but continued improvements are needed to strengthen its operations.

We also determined that the Board has made substantial progress in addressing issues raised by the BSA in their April 2001 Report titled "Investigation of Improper Activities by State Employees: July 2000 through January 2001."

The audit revealed that the Board has a structured complaint process in place to address consumer complaints. The Board has developed processing timelines that are comparable to similar regulatory agencies. Staff generally monitors workflow and production activities. We also determined that the Board has made substantial progress in addressing issues raised by the BSA in their April 2001 Report titled "Investigation of Improper Activities by State Employees: July 2000 through January 2001."

The BSA report concluded that the Board had gross inefficiency in processing consumer complaints. The report stated that the time the Board allowed itself for resolving complaints was

excessive when compared to the time frames mandated by law or regulations for other consumer protection agencies. Also, the Board had experienced long delays in complaint processing. The BSA included backlog statistics and average processing times for complaints included in fiscal year 1999-00. The report also noted that the Board's process for prioritizing complaints did little to ensure that complaints involving potential consumer injury received immediate action. Finally, BSA reported that the Board had been unable to retain sufficient staff in its investigations unit to resolve consumer complaints efficiently.

During our audit, we verified that the Board has established various time frames for its major steps involved from complaint receipt through final action by the Board. We compared these time frames with two pharmacy regulatory agencies from other states as well as other regulatory boards within California. Based on our analysis, we determined that the Board's overall and individual processing time goals are comparable to the two pharmacy agencies and other regulatory boards.

The Board has also been successful in significantly reducing the amount of processing time it takes to complete its in-house investigations but has only made minimal progress in reducing processing times for the cases referred to the AG.

In recent years after the BSA report, the Board filled its vacant inspector positions. As a result, the Board has been successful in significantly reducing the amount of processing time it takes to complete its in-house investigations but has only made minimal progress in reducing processing times for the cases referred to the Office of the Attorney General (AG). For all in-house investigations closed in fiscal year 2001-02, we verified that approximately 66 percent were completed within 90 days, and 95 percent were completed within 180 days. The average processing time for investigations was 83 days in fiscal year 2001-02, compared to an average of 404 days in fiscal year 1999-00, a reduction of 321 days. However, the Board has not achieved the same success for investigations referred to the AG.

For fiscal year 2001-02, the number of days the Board needs to review and refer cases to the AG is exceeding its established processing time goal. The Board established a goal of 30 days for its supervising inspectors to review cases and refer them to the executive officer recommending referrals to the AG. We verified that in fiscal year 2001-02, the Board took an average of 181 days to refer investigations to the AG. The Board management acknowledged that it has been unable to meet its time frames because of two supervising inspector staff vacancies.

For cases forwarded to the AG, the Board established a processing time goal of 365 for the AG to complete its work and determine appropriate disciplinary actions. We verified that the AG is taking an average of 583 days to file formal charges to conclusion of disciplinary cases. In fiscal year 1999-00, similar cases took an average of 611 days, only a reduction of 28 days. Board management is aware of the delays but is limited in controlling the timely completion of cases referred to the AG. Given that the Board's goal is to complete these cases in one year, we concluded that these type of cases are still experiencing lengthy delays.

We also followed-up on the Board's priority system for complaints. We noted that the Board has a reasonable process for assigning and monitoring complaints to ensure the most critical complaints are addressed first. While we found that the Board had made progress in recent years, our compliance testing also identified that the Board was not always meeting its initial notification to complainants within 10 days and inaccurate information was inputted into Consumer Affairs System (CAS) for many of the case files reviewed. **We recommend that the Board continue efforts to reduce its complaint processing times, provide initial notification to complainants within 10 days from receipt of complaints, and ensure accurate dates are entered into the CAS.**

We have provided further detailed results for several of these issues under the Findings and Recommendations section of this report.

Other Pertinent Information

Selected Financial and Statistical data from the September 2002 Report to the Joint Legislative Sunset Review Committee was materially supported by adequate documentation.

As part of our audit, we verified the reasonableness of selected financial and statistical data from the September 2002 Report that was submitted to the JLSRC. We judgmentally selected data from the report and traced the selected information to underlying documentation. We concluded that the reported figures were materially supported by adequate documentation. However, we also noted that total revenues, as reported by the Board did not agree with final total revenues reported in the Department's

year-end 2001-02 financial reports. We found that the variance was due to definition and timing differences between the Board analysis and the Department's final accounting and budgeting analysis. The selected data is included under the Other Pertinent Information Section of this report.

BOARD'S RESPONSE:

The Board agreed with our audit findings and plans to continue with its corrective actions to improve its operations. For specific corrective actions, please refer to the Board's Response included in this report as ATTACHMENT I.

BACKGROUND

The California Board of Pharmacy (Board) is one of several semiautonomous regulatory boards under the Department of Consumer Affairs (Department). The Board consists of seven professional members and four public members. Under Business and Professions Code (BPC) and the California Code of Regulations (CCR), the Board is granted authority to regulate the pharmacy profession, which includes 12 major regulatory programs. The Board regulates over 75,000 licensees, encompassing both individuals and businesses that ship, store and dispense prescription drugs and devices to the State's health care providers and patients.

The Board regulates over 75,000 licensees, encompassing both individuals and businesses that ship, store and dispense prescription drugs and devices to the State's health care providers and patients.

With an appropriated fiscal year 2002-03 budget of \$7.3 million, the Board utilizes 48.5 authorized positions to carry out its responsibilities, including: issuing and renewing licenses; overseeing the examination and application processes; responding to various complaints; performing inspections and investigations; disciplining violators; and providing consumer information to the public.

OBJECTIVES, SCOPE AND METHODOLOGY

The audit was performed in accordance with the *Standards for the Professional Practice of Internal Auditing*. The audit objectives were to determine whether the Board has:

- Established performance goals and measures to monitor its operations;
- Established policies and procedures to guide staff in consistent handling of its operational activities; and
- Complied with applicable laws and regulations.

The audit methodology was limited to interviewing pertinent personnel, reviewing policies and procedures and performing compliance testing as deemed necessary. The scope included compliance testing from July 1, 2001, through June 30, 2002. Our last day of fieldwork was February 7, 2003.

FINDINGS AND RECOMMENDATIONS

FINDING 1

The loan of \$6 million from the Pharmacy Board Contingency Fund to the State's General Fund will negatively impact the Board's future operations if not repaid in a timely manner.

The enactment of the 2002-03 Budget Act (AB 425) required the Board to loan \$6 million from its Contingency Fund (Fund) to the State's General Fund in August 2002. AB 425 states, "it is the intent of the Legislature that repayment be made so as to ensure that the programs supported by this fund are not adversely affected by the loan through reduction in services or through increased fees." The loan was made from the Fund's prior balance of \$10.8 million as of June 30, 2002. The Board has projected that future expenditures will exceed future revenues, and without repayment of the loan in a timely manner, the Board will deplete its Fund during fiscal year 2003-04, causing a negative reserve of approximately \$275,173 as of June 30, 2004.

To determine if the remaining Fund reserves will adequately support the Board's operational needs, we evaluated the current licensing fee revenues, 2002-03 Governor's Budget, and management budget reports.

To determine if the remaining Fund reserves will adequately support the Board's operational needs, we evaluated the current licensing fee revenues, 2002-03 Governor's Budget, and management budget reports. Additionally we met with the Board's executive management team. Based on actual historical financial and operational data, it appears that the Board's operating expenses have remained relatively consistent during the past three years. Using past, current and projected Board data, we analyzed the impact that operating income or losses would have on the Fund balance.

Based on the current licensing fee structure, the Board has projected fiscal year 2002-03 expenses to exceed revenues by \$2.3 million. The shortage will cause the Fund balance to decrease to \$2.5 million by June 30, 2003. Board management has further projected that expenditures will exceed revenues by an estimated \$2.75 million during fiscal year 2003-04. Based on the estimated projections, the Fund would be depleted by the end of fiscal year 2003-04. By the end of fiscal year 2003-04, the Board may be faced with significant operational cuts if the loan is not repaid in a timely manner.

RECOMMENDATIONS:

We recommend that the Board work with the Department of Finance to obtain repayment of the \$6 million loan in a timely manner to avert increased fees and/or reduction of services.

BOARD'S RESPONSE:

The Board agreed with our finding. For specific corrective actions, refer to ATTACHMENT I.

FINDING 2***Although the Board's evidence room access controls are adequate, management could strengthen inventory controls and safety awareness.***

The Board stores pharmaceutical evidence gathered during investigations in evidence rooms located in Southern and Northern California offices. Management has developed and implemented formal policies and procedures for the intake, documentation, storage, and security of the gathered evidence. Based on our review, we determined that the Board adequately controls the access to stored evidence; however, the Board needs to improve its inventory control procedures and safety awareness.

To evaluate the adequacy of the Board's evidence room operations, we reviewed the Board's policies and procedures, met with the evidence custodian and observed the layout of the northern evidence room. We also contacted outside agencies to obtain information regarding the labeling of hazardous material and the appropriate safety measures in case of fires, floods or other emergency situations involving the evidence rooms.

The Board's policies and procedures establish adequate controls to ensure the evidence stored in the evidence rooms is restricted to authorized personnel only.

The Board's policies and procedures establish adequate controls to ensure the evidence stored in the evidence rooms is restricted to authorized personnel only. The evidence custodian and an alternative custodian control the access to the evidence rooms. The custodians maintain the only keys to the evidence rooms and the location of the computer, which stores the evidence inventory control logs. The evidence rooms are also secured by card-key access. We observed the northern evidence room and verified that the access controls were in place to adequately secure the evidence room.

The Board's policies also require proper inventory controls and evidence destruction procedures. During our review in these areas, we noted that the Board has not consistently followed its procedures. The Board's policy requires that staff perform an annual physical inventory of the evidence rooms. We found that the Board has not performed an inventory of the contents in the northern evidence room in the past 18 months. We also found that the evidence marked for destruction has not been destroyed within the past year.

Established Board policy requires that a supervising inspector conduct annual inventories of the evidence rooms. Management

informed us that the Board has been experiencing a significant amount of work since it has only two supervising inspectors to oversee its 20 inspectors. As a result, the inventory control procedures were placed at a lower priority than processing complaints, investigations, and supervision of the inspection staff. Additionally, management felt that there could be a conflict of interest for a supervising inspector to perform an inventory of his/her own gathered evidence. The lack of a regular physical inventory could limit the Board's ability to identify missing or misplaced evidence in a timely manner.

Our audit also showed that there was a significant amount of evidence marked for destruction being stored in the evidence rooms. According to Board management, its contract for witnessed destruction services has expired, and the Board has been unable to properly destroy the evidence it no longer needs for investigative or prosecutorial purposes. The Federal Department of Transportation (DOT) has jurisdiction over the storage and transportation of potentially hazardous chemicals and gasses. In complying with DOT standards, an entity storing potentially hazardous chemicals and/or gasses is required to maintain information on the potential hazardous reactions to fire, flood and mixing with other agents. In addition, appropriate hazardous warnings need to be displayed on the premises.

The Board does not have knowledge of the chemical makeup of its stored pharmaceuticals or the potential hazardous reactions to fire, floods and mixing with other chemicals. Board policies do not require staff to maintain a listing of the chemical makeup of the pharmaceutical evidence stored within the evidence rooms, nor are appropriate warnings posted. In addition, staff does not have knowledge of the potential hazard that may exist in the case of a fire or flood. Without sufficient information on the stored pharmaceuticals, the Board cannot post appropriate warnings, which would reduce the risk of potential hazardous exposure to its staff.

RECOMMENDATIONS:

We recommend that the Board perform regular physical inventory counts of the evidence room contents. The Board also needs to take steps to properly dispose of evidence marked for destruction. Finally, the Board should implement a process to identify the potential hazards associated with currently stored evidence and post appropriate warnings on its premises.

BOARD'S RESPONSE:

The Board agreed with our finding. For specific corrective actions, refer to ATTACHMENT I.

FINDING 3***The Board's licensing activities are adequate but could benefit from improvements.***

Our audit of the current licensing process showed that the Board has a system in place to ensure that applicants requesting licensure meet the applicable laws and regulations prior to granting licensure. Based on sampled applicant files, we noted that files contained the required documentation validating licensure, were generally approved or denied within appropriate time periods, and were issued only to qualified applicants. While the Board has demonstrated compliance with many licensing laws and regulations, we did note a few areas that could benefit from improvement.

The Board regulates 12 license categories that include both personal and business licenses. Applicable BPC and CCR, as well as the Board's established policies and procedures, provide rules and regulations for its licensing operations. To determine compliance with the criteria, we performed detailed testing on 30 randomly selected pharmacist and pharmacy technician applicant files received in fiscal year 2001-02. We reviewed the files to determine if there was evidence to support compliance with general eligibility requirements, applicable processing times were being met, and whether proper handling of the Criminal Offender Record Information (CORI) occurred.

The results of our audit revealed that the Board has adequate controls in place to fulfill its licensing responsibilities and satisfactorily comply with applicable laws and regulations. In addition, a quality control process exists to provide added assurance that policies and procedures are consistently followed and approved by management. However, the Board could benefit from operational improvements in the following areas:

- Non-compliance to applicant notification requirements
- Limited applicant tracking systems
- Incomplete CORI employee statement forms

The CCR requires the Board to notify applicants in writing within established time cycles, whether the applications are complete or deficient, and to identify what is needed to correct the deficiencies. The Board's existing policies and procedures do not require licensing staff to give receipt notification unless the applicant submits a self-addressed paid postcard with the application. Our compliance testing revealed that none of the 15

The results of our audit revealed that the Board has adequate controls in place to fulfill its licensing responsibilities and satisfactorily comply with applicable laws and regulations.

pharmacy technician files reviewed met the required 30-day acknowledgement. Ten files did not contain evidence that an acknowledgement was made and five files exceeded the required applicant notification timeframe. One file took 96 days to issue a deficiency letter. When acknowledgements are not made, and deficiencies not communicated in a timely manner, licensure may be delayed.

We also noted that the Board does not have a centralized applicant tracking system for all of its license types. Instead, the Board uses different piecemeal systems to track and conduct its licensing operation. During our review, we noted that for several license categories, the various tracking systems do not allow the Board to monitor compliance with its internal processing time goals and regulated timelines. For example, pharmacist, intern, and exemptee application information are only available through the Receipt of Collection (RC) logs, which is primarily used for cashiering purposes. The RC log captures various cashiering information, but does not record application, examination and licensing processing data. The RC logs are also maintained as hardcopy files only and may not provide Board staff flexibility for monitoring, tracking, and reporting purposes.

Other license types are logged in the Consumer Affairs System (CAS), with a “pending” status until ready for licensure. Once the application status is changed from “pending” to “issued”, the Board is limited in its ability to monitor compliance with established processing times. Neither of these two tracking systems is able to provide all actual processing times to determine compliance with regulated and internally established timelines.

We also evaluated the Board’s CORI procedures and concluded that the Board uses appropriate CORI access, storage, handling, dissemination, and destruction procedures. The Board also has established written policies and procedures to provide staff guidance. However, as of January 8, 2003, the Board did not have signed employee statement forms on file in accordance with the Department of Justice (DOJ) and departmental requirements. Subsequently, the Board obtained the required forms.

RECOMMENDATION:

We recommend that the Board acknowledge applications and communicate deficiencies within the time frames required by the applicable laws and regulations. Additionally, the Board should implement an applicant tracking system that will allow it to adequately monitor processing time frames to ensure that it meets internal and regulated time requirements.

BOARD'S RESPONSE:

The Board agreed with our finding. For specific corrective actions, refer to ATTACHMENT I.

FINDING 4***The Board's enforcement program allows it to address consumer complaints, but continued improvements are needed to strengthen its operations.***

The audit revealed that the Board has a structured complaint process in place to address consumer complaints. The Board has developed processing timelines that are comparable to similar regulatory agencies. Staff generally monitors workflow and production activities. We also determined that the Board has made substantial progress in addressing issues raised by the Bureau of State Audits (BSA) in their April 2001 Report titled "Investigation of Improper Activities by State Employees." However, the results of our compliance testing also revealed that improvements are still needed to address processing delays, untimely initial notification to complainants, and inaccurate initial complaint received dates entered in CAS.

The Board has authority to revoke, suspend, or place on probation any license if the licensee has violated provisions of the applicable laws and regulations.

The Board has authority to revoke, suspend, or place on probation any license if the licensee has violated provisions of the applicable laws and regulations. In order to enforce its responsibility to protect consumers, the Board maintains its own enforcement and investigative staff. The Board also uses the services of the Office of the Attorney General (AG) and the Office of Administrative Hearings (OAH). Additionally, the Board has established internal policies and procedures to guide its staff while performing enforcement activities. Time frames for enforcement processes have also been established to measure the efficiency of the time required to address consumer complaints.

To determine compliance with applicable laws, regulations, policies and procedures, we performed detailed testing on 20 randomly selected investigation case files that were closed in fiscal year 2001-02. We ascertained whether the sampled files contained appropriate documentation, were processed within the established timelines, accurate information was inputted into the CAS, and appropriate reviews were performed. We also followed-up on issues identified by the BSA during its investigation.

On April 3, 2001, the BSA issued its Report titled "Investigation of Improper Activities by State Employees: July 2000 through January 2001." Chapter 4 reported that the Board had gross inefficiency in processing consumer complaints. The report stated that the time the Board allowed itself for resolving

Finding 4

complaints, up to 290 days, was excessive when compared to the time frames mandated by law or regulations for other consumer protection agencies. Also, the Board had experienced long delays in complaint processing. The BSA included backlog statistics and average processing times for complaints included in fiscal year 1999-00. The BSA also noted that the Board's process for prioritizing complaints did little to ensure that complaints involving potential consumer injury received immediate attention. Finally, BSA reported that the Board had been unable to retain sufficient staff in its investigations unit to resolve consumer complaints efficiently.

Our audit results noted that the Board has an extensive training program for its inspectors. Also, the Board holds quarterly meetings to discuss various topics including: training, inspectors' workloads and productivity statistics. We also noted that the Board has updated policy and procedural manuals that guide staff in performing complaint and enforcement activities. We verified that the Board has filled many of its vacant inspector positions since the BSA Report in April 2001. Consequently, the Board has been able to address many of the issues noted in the past.

During our audit, we verified that the Board has established various time frames for its major steps involved from complaint receipt through final action by the Board. For example, the Board staff should complete a simple investigation within 90 days of receipt. A complex investigation may take 180 days. Other time frames were established for investigations requiring further disciplinary actions and referrals to the AG and OAH. As part of our audit, we compared these time frames with two pharmacy regulatory agencies from other states as well as other regulatory boards within California. Based on our analysis, we determined that the Board's overall and individual processing time goals are comparable to the two pharmacy agencies and other regulatory boards.

In recent years, the Board has been successful in significantly reducing the amount of processing time it takes to complete its in-house investigations but has only made minimal progress in reducing processing times for cases referred to the AG.

In recent years, the Board has been successful in significantly reducing the amount of processing time it takes to complete its in-house investigations but has only made minimal progress in reducing processing times for cases referred to the AG. For all in-house investigations closed in fiscal year 2001-02, we verified that 66 percent were completed within 90 days, and 95 percent were completed within 180 days. The average processing time for investigations was 83 days in fiscal year 2001-02, compared to an average of 404 days in fiscal year 1999-00, a reduction of

Finding 4

321 days. However, the Board has not achieved the same success for cases referred to the AG.

For fiscal year 2001-02, the number of days the Board needs to review and refer cases to the AG is exceeding its established processing time goal. The Board established a goal of 30 days for its supervising inspectors to review cases and refer them to the executive officer recommending referrals to the AG. We verified that in fiscal year 2001-02, the Board took an average of 181 days to refer investigations to the AG. The Board management acknowledged that it has been unable to meet its time frames because of two supervising inspector staff vacancies.

For cases forwarded to the AG, the Board established a processing time goal of 365 for the AG to complete its work and determine appropriate disciplinary actions. AG is taking an average of 583 days to file formal charges to conclusion of disciplinary cases. In fiscal year 1999-00, similar cases took an average of 611 days, only a reduction of 28 days. Board management is aware of the delays but is limited in controlling the timely completion of cases referred to the AG. Given that the Board's goal is to complete these cases in one year, we concluded that these type of cases are still experiencing lengthy delays.

Given that the Board's goal is to complete these cases in one year, we concluded that these type of cases are still experiencing lengthy delays.

We also followed-up on the Board's priority system for complaints. We noted that the Board has a reasonable process for assigning and monitoring complaints to ensure the most critical complaints are addressed first. Board management believes that the more critical complaints will not necessarily be resolved quicker than less critical ones. The higher priority cases are usually more complicated, require more investigative research, and generally are referred to the AG and OAH. As a result, these cases may actually take longer than the lower priority cases. Further, management informed us that it meets monthly with its enforcement and investigative staff to track progress on complaint processing and reassigns complaints as necessary to ensure all appropriate resources are allocated to completing priority complaints. While we found that the Board had made progress in recent years, our compliance testing also identified two additional areas needing operational improvements.

The following areas need to be addressed by the Board to strengthen its processes:

- Acknowledgement letters were not always sent in a timely manner; and
- Inaccurate information was inputted into CAS for many of the case files.

The Board did not always meet the 10-day complaint acknowledgement requirement. The BPC requires that the Board provide the complainant, within ten days from receiving the complaint, an acknowledgement as to the initial action taken. Of the detailed files tested, we found that the Board did not send timely 10-day acknowledgement letters to nine of 11, or 82 percent of complainants requiring a response. We found that one reason for the untimely acknowledgements was due to initial delays in opening complaint files. For example, we found that 14 of the 20 files we tested had been delayed at the initial processing stage. Untimely responses to a consumer complaint increases the risk of consumer dissatisfaction with the Board's complaint process.

Another area needing improvement is the inaccurate input of the complaints' received dates into CAS.

Another area needing improvement is the inaccurate input of the complaints' received dates into CAS. Our review showed that the complaint open dates in the CAS did not agree with the receipt dates stamped on 14 of the 20 files reviewed. We found that Board staff used the CAS data entry dates as the initial case open dates, rather than the dates the complaints were actually received by the Board. For example, we noted that the difference between the actual received dates and the CAS-entry dates ranged from 8 to 34 days. By using the data entry dates as the case open dates, the processing times for complaint handling are understated. Incorrect complaint open dates impacts management's ability to adequately monitor the Board's compliance with processing time goals.

RECOMMENDATION:

The Board should take necessary steps to continue reducing its complaint processing times, provide initial notification to complainants within 10 days from receipt of complaints, and ensure accurate dates are entered into the CAS.

BOARD'S RESPONSE:

The Board agreed with our finding. For specific corrective actions, refer to ATTACHMENT I.

OTHER PERTINENT INFORMATION

No. 1

Selected Financial and Statistical data from the September 2002 Report to the Joint Legislative Sunset Review Committee was material supported by adequate documentation.

As part of our audit, we verified the reasonableness of selected financial and statistical data from the September 2002 Report that was submitted to the Joint Legislative Sunset Review Committee. We judgmentally selected data from the report and traced the selected information to underlying documentation. We concluded that the reported figures below were material supported by adequate documentation. However, we also noted that total revenues, as reported by the Board did not agree with final total revenues reported in the Department's year-end 2001-02 financial reports. We found that the variance of \$198,000 was due to definitional and timing differences between the Board analysis and the Department's final accounting and budgeting analysis.

	Reported	Audited	Variance
Financial (in thousands)			
Total Revenues	\$5,756	\$5,558	\$198
Total Expenditures	7,115	7,115	-
Expenditures by Program			
Enforcement	4,611 (63%)	4,611	-
Exam	465 (6%)	465	-
Licensing	834 (14%)	834	-
Administration	1,008 (14%)	1,008	-
Diversion	198 (3%)	198	-
Statistical Data			
Licenses Issued	8,261	8,261	-
Renewals Processed	33,721	33,721	-
Complaints Closed	1,905	1,905	-
Investigations Completed	548	548	-
Within # of Days:			
90 days	359	359	-
180 days	161	161	-
1 year	23	23	-
2 years	3	3	-
3 years	1	1	-
> 3 years	1	1	-
Disciplinary Actions	182	182	-
Average Processing Days:			
Investigations	83	83	-
Referral to AG	181	181	-
Pre-Accusation (AG)	188	188	-
<u>Post-Accusation (AG)</u>	<u>395</u>	<u>395</u>	-
Total Average Processing Days	847	847	-



ATTACHMENT I

Board's Response to the Draft Report



California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814-6237
Phone (916) 445-5014
Fax (916) 327-6308
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

March 14, 2003

Steve Castillo, Chief
Internal Audit Office
Department of Consumer Affairs
400 R Street
Sacramento, CA 95814

Re: Operational Audit of the California Board of Pharmacy

Dear Mr. Castillo:

This letter is the California Board of Pharmacy's (Board) response to the March 2003 draft Operational Audit (Audit No. 2002-103) prepared by your office. Thank you for the opportunity to comment. This report will be provided to the Board at its April meeting; however, Board President John Jones has approved the Board's responses.

FINDING 1

The loan of \$6 million from the Pharmacy Board Contingency Fund to the State's General Fund will negatively impact the Board's future operations if not repaid in a timely manner.

RECOMMENDATION:

The Internal Audits Office recommends that the Board work with the Department of Finance to obtain repayment of the \$6 million loan in a timely manner to advert increased fees and/or reduction of services.

BOARD'S RESPONSE:

The Board agrees with this recommendation and is working with the Department's Budget Office to obtain timely repayment of the loan from the Department of Finance.

FINDING 2

Although the Board's evidence room access controls are adequate, management could strengthen inventory controls and safety awareness.

RECOMMENDATION:

The Internal Audits Office recommends that the Board perform regular physical inventory counts of the evidence room contents. The Board also needs to take steps to properly dispose of evidence marked for destruction. Finally, the Board should implement a process to identify potential hazards associated with currently stored evidence and post appropriate warnings on its premises.

BOARD'S RESPONSE:

The Board will implement this recommendation. The Board's objective is to ensure that the secured evidence areas are inventoried annually. At the last inventory 18 months ago, the Board took the necessary steps to inventory stored evidence and did destroy all designated evidence approved for destruction. Since that time the Board has been unable to destroy, as the Board requires a California contractor who can perform witness verified *incineration* of pharmaceutical evidence. The vendor that held the previous destruction contract no longer has a California facility that provides incineration services.

The Board is working to locate a California vendor that can provide the evidence destruction services that the board requires. Due to the stringent environmental requirements for certification to provide incineration services in California, the Board may not be able to locate a California vendor for its evidence destruction contract. In that case, the Board is researching the possibility of contracting with an out-of-state vendor who can provide incineration services and still ensure the chain-of-custody required for handling evidence.

The Board has obtained from the Office of Environmental Health Hazard Assessment's (OEHHA) the Governor's list of chemicals known to cause cancer or reproductive toxicity. This list will be compared to the evidence inventory to properly identify potentially hazardous materials. After determination of toxicity of stored evidence, the Board will change currently posted warnings to comply with Title 22, Division 2 § 12601 and with § 25249.6 of the Safe Drinking Water And Toxic Enforcement Act Of 1986. These signs will be clearly posted for viewing by employees and emergency personnel. In addition, the Board will add itself to OEHHA's notification list for periodic updates of the Governor's list.

FINDING 3

The Board's licensing activities are adequate but could benefit from improvements.

RECOMMENDATION:

The Internal Audit Office recommends that the Board acknowledge applications and communicate deficiencies within the time frames required by applicable laws and regulations. Additionally, the Board should implement an applicant tracking system that will allow it to adequately monitor processing time frames to ensure that it meets internal and regulated time requirements.

BOARD'S RESPONSE:

The Board agrees with this recommendation. The Board desires an integrated applicant tracking system that can monitor processing times for all of its 12 licensing programs. Such a system would eliminate weekly and monthly tallies of workload status now provided to managers. Such an integrated application tracking system will be a part of the proposed Professional Licensing and Enforcement Management System (PLEMS) that is being developed by the Department of Consumer Affairs – Office of Information Systems. The Board is scheduled for PLEMS implementation in 2006.

However, due to an increasing number of pharmacy technician applications, staff vacancies and the subsequent loss of positions, the Board has had difficulty meeting the established timeframes for the application notification requirements for pharmacy technicians. The Board strives to process applications and either issues a pharmacy technician license or a deficiency notice to the applicant. However, the Board typically does not issue a deficiency notice if it is only waiting for fingerprint clearances and this is the only reason for the delay in issuing a license. The Board also encourages applicants to send a self-addressed postcard in with their application, which the board mails when the application is received. Through management's ongoing monitoring of the application process, concerted efforts are continuously being made to redirect existing staff to assist with the processing of technician applications. At the time of this response, the Board is processing pharmacy technician applications within one week of receipt. Moreover, the Board is sponsoring legislation to update the registration requirements for pharmacy technicians that will have an added effect of improving the application process.

Meanwhile the Board will continue to use its existing tools to monitor workflow. While the Board has its own applicant tracking modules it has developed using the CAS "pending" status code and uses the Report of Collections for researching matters, the Board also uses Excel spreadsheets for the site and exemptee licensing programs to monitor and track workload. The Board also has an applicant-tracking module it developed for the pharmacist licensure candidates. Other licensing workload, for example the pharmacy technician and intern applications are monitored through weekly desk assessments which include the number of

applications to be processed and the date of the oldest applications.

FINDING 4

The Board's enforcement program allows it to address consumer complaints, but continued improvements are needed to strengthen its operations.

RECOMMENDATION:

The Board should take necessary steps to continue reducing its complaint processing times, provide initial notification to complainants within 10 days from receipt of complaints, and ensure accurate dates are entered into CAS.

BOARD'S RESPONSE:

The Board agrees with this recommendation.

The Board continually strives to improve its processing times through an on-going case review process of tracking, monitoring, assessing and prioritizing pending complaint investigations and appreciates this acknowledgement in the audit report.

As identified in its Sunset Report, the Board was aware that a principal source of delay for its complaint processing time has been when completed investigation reports have been awaiting review by one of the Board's two supervising inspectors. Because of positions gained through the budget change proposal process effective this year, the Board recently hired (March 1, 2003) two more supervising inspectors and the Board will now significantly reduce the supervisory review time of completed investigation reports. In addition, the board has implemented a system to identify investigations that require referral to the Attorney General's Office that alerts the supervising inspectors to prioritize review of these investigations. It is these cases, which take the longest to complete although they represented only 7 percent of all cases closed by the Board in 2001/02.

The Board has provided initial notification to complainants within 10 days of the receipt of a complaint. However, in 2001, the Board lost a key clerical position in its Complaint Unit due to the state-hiring freeze. As a result, the board has been experiencing some periodic delays in meeting the 10-day notification requirement. Furthermore, the one remaining clerical staff in the Complaint Unit has had to absorb workload created by the loss of a second clerical position in another unit.

Steve Castillo
March 14, 2003
Page Five

To ensure that the consumer complaints are acknowledged timely, Board staff is separating consumer complaints for immediate processing because the Board receives complaints from a variety of sources. This will ensure that the Board will acknowledge receipt of all consumer complaints within 10 days. Also, the Board has modified how it tracks the age of complaints to make certain it uses the date a complaint is received as the initial action date of a complaint. Board staff have been trained to assure that the receipt date of the complaint is captured, which is done by manually overriding the initiation date established automatically by the CAS system.

I trust that this information is responsive to the findings identified in the Operational Audit Report. The Board will be providing the 180-day and 360 day feedback to your office on the Board's implementation of its corrective action as outlined above.

I appreciate the courtesy and cooperation that you and your staff provided to us during the audit process. If you need additional information or have questions, please call me at 445-5014 (ext. 4004).

Sincerely,

Original signed by Patricia F. Harris
Patricia F. Harris
Executive Officer

cc: Denise Brown, Chief Deputy Director
Kristy Wiese, Deputy Director, Legislative & Regulatory Review Division
California State Board of Pharmacy

Attachment 4



STATE OF CALIFORNIA
OFFICE OF THE ATTORNEY GENERAL
BILL LOCKYER
ATTORNEY GENERAL

PETER SIGGINS
Chief Deputy Attorney General
Legal Affairs

March 26, 2003

To: All Client Agencies
State of California

Via Facsimile

Re: Personnel Management Letter from DPA - Ethics Training

Dear Client:

Your agency has recently received a Personnel Management Letter ("PML") from Nora Cheek of the Department of Personnel Administration regarding ethics training. New legislation requires that all state officials and employees who must file Statements of Economic Interests (Form 700) also must complete ethics orientation training in 2003. The PML lays out several methods in which agencies may satisfy their statutory duty to provide this training at least semiannually. (See Gov. Code §11146.1.)

One method utilizes a core ethics training course prepared by the Attorney General's Office in conjunction with the Fair Political Practices Commission. (See Gov. Code §§ 11146.1 and 11146.4(c).) An interactive version of this training course is available on the public website of the Attorney General's Office and may be found at: <http://caag.state.ca.us/ethics/index.htm>. You may also provide group training utilizing a CD-ROM version of this interactive web-based course.

Because there are between 40,000 and 50,000 state officials and employees who must complete this training during 2003, we have urged that training be spread out over the calendar year to prevent overloading our web server. The PML provides a schedule.

However, we are also aware that not all computers are capable of accessing and running the web-based course. In that circumstance, we encourage you to consider using the CD-ROM version for group training. Group training also facilitates presenting other ethics material (unique to your agency) that may be required by the law. (See Gov. Code §11146.1.) This includes – at a minimum – your agency's Incompatible Activities Statement, along with any agency-specific ethics statutes and regulations.

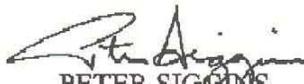
All Client Agencies

March 26, 2003

Page 2

To assist your agency's training staff in preparing to present group training utilizing the CD-ROM version, we are offering a training session for trainers. Please advise Deputy Attorney General Bob Leidigh via e-mail at robert.leidigh@doj.ca.gov, if your agency is interested in participating in this training. Please provide the name(s) of your training staff, their telephone numbers and e-mail addresses to facilitate scheduling.

Sincerely,



PETER SIGONS

Chief Deputy Attorney General
Legal Affairs

Attachment 5

Obtain Six hours of CE for attending one full day of a Pharmacy Board meeting

Continuing education hours may be earned by pharmacists who wish to learn more about the issues and operations of the board by attending a board meeting. A pharmacist may acquire six CE hours once a year by attending one full day of the board's quarterly meetings. (Board members are not eligible for this CE.) A pharmacist must attend the full business day session (this is designated) of the board meeting to earn the continuing education credit; no partial credit will be given.

Board meetings are held at different sites throughout the state to give the public and as many licensees as possible the opportunity to attend board meetings; all interested parties are encouraged to attend.

Additional information regarding sites and agendas will be posted on the Board's Web site approximately 10 days prior to meetings, or you may contact the board at (916) 445-5014, Ext. 4006.

Board meeting dates and sites for 2003 are:

April 29 and 30 (Board meeting)

Designated Business Day for Earning CE: April 29 Only

Department of Consumer Affairs
400 R Street, 1st Floor Hearing Room
Sacramento, CA 95814

July 21-22, 2003

San Diego (Specific site to be determined)

October 29-30, 2003

San Francisco/Bay Area (Specific site to be determined)

Earning CE from Attending Board of Pharmacy Meetings

Questions and Answers

Q: Will CE certificates be distributed following the meeting?

A: Certificates will be mailed to the licensee within 30 days of the board meeting.

Q: Does a pharmacist have to be present throughout the full meeting day to earn CE credit?

A: Yes. You will be required to sign in and sign out.

Q: Will certificates be issued for less than 6 hours?

A: No.

Q: Will credit be given for attendance at more than one meeting during a calendar year?

A: No. Only 6 hours will be awarded per year calendar year to any pharmacist.

Q: Can more than 6 hours of board meeting attendance be used towards fulfilling the CE requirement if attendance is in 2 calendar years?

A: Yes, as long as the hours were earned in 2 different calendar years, at least one year apart.

Q: Will the Board provide duplicate certificates to those who lose the original?

A: Yes

Attachment 6

Memorandum

To: Board Members

Date: April 12, 2003

From: Organizational Development Committee

Subject: Personnel Update

The board has promoted two inspectors to supervising inspector positions, new positions obtained/reclassified this year by the board.

- Dennis Ming has been appointed the supervising inspector in charge of the new compounding pharmacy program. Dr. Ming has been with the board three years, and he is currently developing a training program for inspectors and a self-inspection form for compounding pharmacies.
- Joan Coyne has been appointed the supervising inspector over the Pharmacists Recovery Program and the board's probationer program. Dr. Coyne has been the lead inspector over this team in the past, and her promotion to supervisor will enable her to fully assume all duties necessary to oversee these statewide programs. Dr. Coyne has been with the board eight years. Dr. Coyne's new position was a reclassification approved during the budget process to upgrade one inspector position to that of a supervising inspector.

Over the next few months, the board's executive staff will work to redefine the duties of the supervising inspectors and the workflow within the enforcement and licensing units to reflect the much needed additional supervisors, and the establishment of the compounding program.

In March 2003, Supervising Inspectors Ratcliff and Nurse spent a full week interviewing the 40 applicants who are interested in becoming board inspectors.

Board Receptionist Lynee Ritchie resigned from the board in early February. Ms. Ritchie had been with the board for more than five years, and started working as a seasonal employee in the enforcement unit.

The board has the following vacancies:

- Two inspectors (one new position for compounding, the other from the promotion of Dennis Ming)
- One staff analyst (enforcement)
- One associate analyst (licensing of sites, created by the retirement of Sandi Moeckly at the beginning of 2003)
- One office technician (licensing of sites, created by the promotion of Sue Lynn Yee for licensing compounding pharmacies)
- One office technician (receptionist)

To fill these positions, the board needs freeze exemptions, which have been rarely approved for most departmental agencies. Freeze exemptions were submitted last month to hire two new inspectors.

MEANWHILE: On April 1, the Governor's Office directed all departments to prepare a layoff list of employees that would account for 10 percent of each agency's personnel services costs (the directive is attached). In the case of the board, this would be \$353,000 annually. As the details of this layoff process are released in the future, this may preclude the board from filling the inspector positions even if freeze waivers are approved.

Other:

On February 28, Assistant Executive Officer Herold and Supervising Inspector Ratcliff participated in the second Labor/Management Meeting with the union representing board inspectors. The contract for the state requires that the board and the union convene meetings to discuss workload and management issues of concern (to the union). Two board inspectors are participating for the union (they are union stewards) as is one pharmacist from the Department of Mental Health. The next meeting is tentatively scheduled for July.

The items discussed were:

1. The daily activity program, an automated program used by inspectors to capture data necessary for cost recovery and workload, will be modified to reduce the complexity of the recording categories and allow facilitated review by the inspector before submitting data.
2. Data describing hours by team will be compiled and discussed at the next meeting.
3. The board will ask inspectors for requests for needed equipment
4. Training will be provided to inspectors so they can learn how to access the board's Web site.
5. The "team concept" will be discussed at the next Enforcement Team Meeting.
6. The number of inspections assigned each month (32) versus the number inspectors want (23).

Attachment 7

Attachment A
Minutes of the Organizational
Development Committee

April 10, 2004

and the new budget restrictions released by the Administration. Mr. Tilley added that the focus of the board's efforts should be more on education and less on enforcement.

Update on the Board's Strategic Goals 2002/03

The committee noted the department's progress in developing a new computer system for all entities in the department. A consultant working with each board and bureau has developed parameters for the Professional Licensing and Enforcement Management Systems (PLEMS). The department is currently seeking approval of a feasibility study report for the entire system from the Department of Finance.

The committee reviewed a copy of the summary overview for project. If approved, the new system will cost at least \$20 million. The board's share will be \$550,000 and board implementation will be in the last phase, currently set for 2007-08.

Chairperson Gubbins commented that earlier in April the department held a regulation hearing to amend the list of departmental officials and staff who must file annual conflict of interest statements with the Fair Political Practices Commission. The board's inspectors have been added to the list of filers, fulfilling a strategic objective of the board for the last three years.

Status Upon on the Board's Sunset Review

Ms. Harris stated that on Wednesday, April 2, the Joint Legislative Sunset Review Committee (JLSRC) held its hearing on its staff recommendations for the board. Incorporated into these recommendations were draft recommendations of the Department of Consumer Affairs (they were draft recommendations because the Administration had not yet approved them). During the hearing, Board President Jones stated that he concurred the recommendations of the JLSRC. On Monday April 7, the Joint Legislative Sunset Review Committee voted 5-0 to adopt the recommendations.

Meanwhile, the Department of Consumer Affairs' Internal Audits Office also released its report of its operational audit of the board in late March. This audit started October 1, 2002, and was completed in February 2003. The audit looked at the board's internal controls, compliance with all state requirements, the licensing of pharmacists and technicians, enforcement matters and cashiering. The department typically audits every agency undergoing sunset review.

The recommendations for the board arising from the sunset review are:

Informal Recommendations of the Joint Legislative Sunset Review Committee (November 2002):

1. Add two public members to the board.

2. Define "actively engaged" as provided for in the Business and Professions Code specification of the composition of the board's professional members.
3. Make all committee meetings public meetings.
4. Modify board regulations so that the executive officer issues citations and fines.
5. Use staff other than exclusively pharmacist inspectors to investigate and inspect licensees.

Findings of the Department of Consumer Affairs' Internal Audit Office (March 2003):

1. The loan of \$6 million from the Pharmacy Board Contingency Fund to the State's General Fund will negatively impact on the board's future operations if not repaid in a timely manner.
2. Although the board's evidence room access controls are adequate, management could strengthen inventory controls and safety awareness.
3. The board's licensing activities are adequate but could benefit from improvements.
4. The board's enforcement program allows it to address consumer complaints, but continued improvements are needed to strengthen its operations.

Draft Recommendations of the Department of Consumer Affairs (March 2003)

1. The licensing and regulation of the pharmacy profession should be continued and a board structure should be maintained.
2. Add two public members to the board.
3. Make all committee meetings of the board be public meetings.
4. The board should adopt the NAPLEX.
5. Modify the citation and fine program to exclude the involvement of board members and delegate to the executive officer the authority to issue citations and fines.
6. The board should not require all its investigators to be pharmacists.
7. The board should use the department's online consumer complaint form.
8. The board should expand its consumer outreach and education, and work with the department to develop additional materials.
9. The board should establish a reliable method of communicating and surveying those who have filed complaints, and revise its survey instrument to provide meaningful data.
10. The board should work with the department's Office of Privacy Protection on ensuring patient privacy.

Also, as observations:

11. The board is implementing the recommendations of its Pharmacy Manpower Task Force.
12. The board has expanded its consumer complaint disclosure policy.

Recommendations of the Staff of the Joint Legislative Sunset Review Committee (April 2003):

1. Items 1-10 above, plus:
 11. Support the board's proposal to revise registration and program requirements for pharmacy technicians – specifically:
 - a) accept PTCB certification
 - b) accept the associate degree in pharmacy technology and eliminate the other associate degrees
 - c) revise the specificity of the theoretical and practical requirements of the training curriculum
 - d) accept graduation from a school of pharmacy, and
 - e) eliminate the equivalent experience provision for the clerk typist and hospital pharmacy technician.
 12. The board should continue to ensure that pharmacists offer oral consultations on new prescriptions. Consumers should not be charged a separate fee for such consultations.

The committee also reviewed a copy of the Legislative Counsel's legal opinion of what "actively engaged in the practice of pharmacy" means with respect Business and Professions Code section 4001 regarding the appointment of professional members to the board. This was one of the initial recommendations of the JLSRC in November 2002. The opinion concludes that "actively engaged" in this instance means the performance of one or more functions for which an active pharmacist license is required." And actively engaged means "holding a pharmacist license issued by the California State Board of Pharmacy other than an inactive or retired pharmacist license and performing an activity on a full-time or part-time basis that requires an active pharmacist license."

Budget Update/Report

▪ **2002/03 and 2003/04 State Budgets and Deficit Reduction Items**

Ms. Herold stated that the state's budget deficit has increased to a staggering \$35 billion. A number of additional cost containment controls have been placed on state agencies besides hiring freezes and the elimination of vacant position (for the board this was 4 positions and an associated \$185,000 for salaries):

- In February, the board learned that any out-of-state travel would not likely be approved, allowing the board to redirect about \$20,000 to the board's AG program line item
- All agencies were required to cut their in-state travel budgets by 35 percent (in the case of the board, this is \$52,100)
- All training requests, contracts and purchases now undergo additional review by the department as a means to reduce expenses, and approval is much harder to attain

- On April 1, the Administration directed all agencies to identify cut their personnel services budgets for 2003/04 by 10 percent, and to prepare a list of employees to layoff to assure 10 percent reduction in Personnel Services. In the case of the board this will amount to a \$353,000 reduction, and the loss of all vacant positions as well as elimination of overtime salaries and board member honoraria.

- **Transfer of Board's Reserve and Proposed Fee Increases**

The board "loaned" \$6 million from its fund to the state's General Fund this budget year. This has left the board with a looming deficit of its own at the beginning of 2004/05, which will grow, to at least a \$2.7 million deficit (or 4.2 months of expenditures) by June 30, 2005.

At the October 2002 Board Meeting, the board voted to move forward with a fee increase to the statutory maximums via changes in board regulations involving fees beginning July 2003. In a second vote, the board also voted to seek an increase in the statutory maximums (this would require legislation).

Ms. Herold added that following the board's vote at the October 2002 Board Meeting, Ms. Harris spoke with the director. Department Director Hamilton stated that the \$6 million loan will be repaid to the board before it will have act to increase fees. She pledged her assistance in this. As such the board will not have to pursue fee increases effective July 1, 2003, as it had planned.

The Internal Audits Office of the department noted in its sunset review audit of the board, that the board's fiscal condition will require repayment of the loan to begin late in 2003/04. The board is working with the department and the Department of Finance to assure this repayment occurs before a deficit in the board's financial operations occurs. This is estimated to be necessary about one year from now – in April 2004.

- **2002/03 Budget Reductions**

The board's final budget for last year (2001/02) was \$7,514,523.

The board's initial budget for 2002/03 (Sept. 2002 when the state's budget was enacted) was \$7,481,000.

The board's revised 2002/03 budget (Dec. 2002) was reduced to \$7,386,597 (due to the loss of funding for four positions eliminated by the Administration because the positions were vacant).

- **Budget Change Proposals**

Ms. Herold stated that the board submitted only one budget change proposal for 2002/03 and ongoing years. This was \$354,000 for an AG augmentation and postage, the two most critical items in the board's budget. This budget change proposal was denied.

At the January Board Meeting, the board voted to move forward with a deficiency augmentation request for AG services for 2002/03. During development of the augmentation request, the staff determined that it could redirect \$230,000 from several unfilled positions for several months, out of state travel and from printing as a result of reducing our the number of newsletters and *Health Notes* published (which also reduced our postage expenses). These redirections eliminated the need for the deficiency request. However, AG spending has been capped at \$1 million because the board will not be able to redirect additional money to this line item.

- **Budget Change Augmentations for 2003/04 and 2004/05**

Ms. Herold noted that seeking any augmentation requests in this fiscal climate will not likely be successful. However, staff believe that it is important that the board document its fiscal needs. The most necessary augmentations are:

1. The board will continue to have problems with funding in its AG budget next year. The board has spent \$1 million the last three years for AG services, and to reduce the budget to the amount allocated (\$777,000) would result in a 25 percent reduction from spending in prior years. This year, the board withdrew some aging AG cases and reduced the number of AG cases referred as cost containment strategies required by the budget condition, and still the budget is estimated at \$1 million. Nevertheless, the importance of the AG services to the board's consumer protection mandate require that a BCP be prepared to augment funding to historical levels of spending.
2. Additionally, the board will need to do a job analysis in 2004 for the pharmacist exam or if NAPLEX is approved, for the CA specific portion of the exam. The costs for this will be approximately \$25,000.

Personnel Update and Report

The board has promoted two inspectors to supervising inspector positions, new positions obtained/reclassified this year by the board.

- Dennis Ming has been appointed the supervising inspector in charge of the new compounding pharmacy program.
- Joan Coyne has been appointed the supervising inspector over the Pharmacists Recovery Program and the board's probationer program. Dr. Coyne's new position was a reclassification approved during the budget process to upgrade one inspector position to that of a supervising inspector.

Over the next few months, the board's executive staff will work to redefine the duties of the supervising inspectors and the workflow within the enforcement and licensing units

to reflect the much needed additional supervisors, and the establishment of the compounding program.

In March 2003, Supervising Inspectors Ratcliff and Nurse spent a full week interviewing the 40 applicants who are interested in becoming board inspectors.

Board Receptionist Lynee Ritchie resigned from the board in early February. Ms. Ritchie had been with the board for more than five years, and started working as a seasonal employee in the enforcement unit.

The board has the following vacancies:

- Two inspectors (one new position for compounding, the other from the promotion of Dennis Ming)
- One staff analyst (enforcement)
- One associate analyst (licensing of sites, created by the retirement of Sandi Moeckly at the beginning of 2003)
- One office technician (licensing of sites, created by the promotion of Suelynn Yee for licensing compounding pharmacies)
- One office technician (receptionist)

To fill these positions, the board needs freeze exemptions. Moreover the board will be unable to fill these positions even with freeze exemptions because the board needs to reduce its personnel expenditures by 10 percent. On April 1, the Governor's Office directed all departments to prepare a layoff list of employees that would account for 10 percent of each agency's personnel services costs (the directive is attached). In the case of the board, this would be \$353,000 annually.

On February 28, Ms. Herold and Supervising Inspector Bob Ratcliff participated in the second Labor/Management Meeting with the union representing board inspectors. The contract for the state requires that the board and the union convene meetings to discuss workload and management issues of concern (to the union). Two board inspectors are participating for the union (they are union stewards) as is one pharmacist from the Department of Mental Health. The next meeting is tentatively scheduled for July.

The items discussed were:

1. The daily activity program, an automated program used by inspectors to capture data necessary for cost recovery and workload, will be modified to reduce the complexity of the recording categories and allow facilitated review by the inspector before submitting data.
2. Data describing hours by team will be compiled and discussed at the next meeting.
3. The board will ask inspectors for requests for needed equipment
4. Training will be provided to inspectors so they can learn how to access the board's Web site.
5. The "team concept" will be discussed at the next Enforcement Team

- Meeting.
6. The number of inspections assigned each month (32) versus the number inspectors want (23).

Pharmacists Address of Record Being Added to the Internet

Board Member Tilley asked about the background of why pharmacists' home addresses are considered public records, are releasable to the public and why are they being placed on the Web site.

Ms. Harris explained that currently, all addresses of record are available to any one who requests it. If a large number of addresses are requested at one time, the requestor purchases the addresses from the Department of Consumer Affairs. The licensee is not notified. If only one or a few addresses are requested, the request goes to the board, which sends a letter with the address information. The board is not allowed to notify the licensee about who has requested the pharmacist's address of record.

With staff vacancies and reductions, the board cannot promptly respond to address of record requests – within the 10 days required. The Medical and Dental Board have all licensees' addresses of record on their Web sites, and the Board of Pharmacy needs to move to such a process so that staff can respond to the other public record requests that require individual handling (e.g., subpoena requests).

Mr. Tilley stated that he believes a legislator may soon introduce legislation to bar the release of the address of record of any pharmacist.

Ethics Training Required

Chairperson Gubbins stated that it is again time for all board members and designated staff to take state-mandated ethics training. The training can be taken online or in a group setting.

The committee determined that it would be best if each individual required to take this training either take it from the Web site (<http://caag.state.ca.us/ethics/index.htm>) or via a video.

Future Board Meeting Dates

The committee agreed to recommend the following board meeting dates to the board for future meetings:

2003 Meeting Dates: Currently scheduled:

- April 29-30, Sacramento
- July 21-22, San Diego
- October 29-30, San Francisco

2004 Meeting Dates: Proposed (all dates are Wednesdays and Thursdays):

- January 21-22, Orange County (CPhA will hold its annual meeting at the end of January and beginning of February)
- April 21-22, Sacramento
- July 21-22, San Diego
- October 20-21, San Francisco (CSHP will hold its Seminar either the first week in November or earlier in October – in Long Beach or Palm Springs)

Pharmacist CE for Attending Board Meetings

Ms. Herold stated that the April 29 day of the board meeting will be available to pharmacists who wish to earn 6 units of CE. An announcement about this has been placed on the board's Web site and featured in an article in the March 2003 *The Script*. The meeting agenda also highlights this option. Copies of the completion certificates and sign in sheets were reviewed by the committee.

Adjournment

There being no additional business, Chairperson Gubbins adjourned the meeting at 11:20 a.m.

Organizational Development

Goal

Achieve the board's mission and goals.

Implementation Responsibility

Organizational Development Committee, The Communications Team and Management

Strategic Objectives		Timeline
1.	Pursue budget change proposals to meet identified program needs.	July 2002
August 2002:	<i>Due to deteriorating fiscal conditions of state budget, Dept. of Finance directs that all but most essential BCPs be withheld. Board scales back BCPs to request funding for 2002/03 and future budget years for \$302,000 for AG services and \$52,000 for postage.</i>	
October 2002:	<i>Budget change proposal for \$353,000 denied for current and future years.</i>	
November 2002:	<i>Estimated shortfall in AG funding for the year remains at \$300,000. At department's request – board requests restoration of \$185,000 targeted for elimination from the board's budget as part of elimination of vacant positions on June 30, 2002 – so that this funding could be retained by the board and redirected to the AG line item. Meanwhile board begins to reevaluate oldest cases at AG and implements steps to reduce AG services.</i>	
January 2003:	<i>Estimated shortfall in AG funding still projected. Board must submit deficiency augmentation request and scale back AG expenditures to prevent overspending.</i>	
February 2003:	<i>Board redirects \$230,000 from printing and out of state travel to redirect to AG program budget, preventing a need to submit deficiency augmentation request.</i>	
2.	Reorganize the board's management structure to oversee board programs and staff.	January 2003

September 2002:	State budget contains two supervising inspector positions. Senior management prepares questions for civil service ranking interviews for this classification. One position is new but the other is a reclassification of an existing position and must be approved by the Department of Personnel Administration. Board submits request to Department.	
December 2002:	Senior management participates in civil service interviews required to develop a list for those qualified for supervising inspector. Board receives approval to reclassify one position to that of supervising inspector.	
February 2003:	Supervising inspector positions filled by promotion of board inspectors.	
3.	Pursue regulatory changes to require inspectors to file annual conflict of interest statements with the Fair Political Practices Commission.	July 2003
December 2002:	Department of Consumer Affairs releases regulatory notice that it is ready to modify its regulations specifying departmental staff that must file annual conflict of interest statements. Board inspectors are added to this list.	
April 2003:	Department of Consumer Affairs holds regulation hearing on proposed change to amend filing requirements for DCA staff; board inspectors are added.	
4.	Manage the board's financial resources to ensure fiscal viability and program integrity.	July 2003
July 2002:	Board agrees to move forward with regulation to increase fees to statutory maximums if transfer of \$6 million from board's fund to General Fund occurs as part of the 2002/03 budget.	
September 2002:	Committee considers need for future fee increases and raising of statutory fee caps to assure ongoing future revenue matches board expenditures. Governor's Budget loans \$6 million from the board's reserve to the state's General Fund.	

October 2002:	<p>If the board's loan of \$6 million is not repaid, board's reserve will be in a deficit by the end of 2003/04. Board votes to increase fees to statutory maximums via regulation change effective July 1, 2003.</p> <p>Board votes to pursue increase in statutory fees via legislation. Fee caps would be increased to levels of the 1980s when adjusted for inflation.</p> <p>Director advises board that the board will not need to proceed with a fee increase; the loan will be repaid first.</p>	
January 2003:	<p>Governor's budget for 2003/04 released. Indicates fund condition at end of 2003/04 of only 3 three days (\$75,000). Board needs to secure repayment schedule for loan or initiate steps for fee increase.</p>	
February 2003:	<p>Staff works with department and the Department of Finance to assure repayment of the loan begins before the board has a deficit -- sometime late in 2003/04.</p>	
March 2003:	<p>Department's Internal Audit office's review of the board identifies repayment of the general fund and as a necessity to prevent a future fund deficit for the board.</p>	
April 2003:	<p>Board identifies \$360,000 in personnel services reductions, eliminating all vacant positions, in response to the Administration's directive to target 10 percent reductions in personnel services for 2003/04.</p>	
5.	<p>Perform a feasibility study to establish the board's own computer system to track licensees and enforcement activities.</p>	June 2003
November 2002:	<p>Board staff works with DCA contractor to identify systems elements needed in a new computer system for the department (integrating applications, cashiering, licensing and enforcement systems) to replace existing system.</p> <p>Board staff also initiates discussions with e-government program to establish means for online renewals and submission of applications. Program cannot be expanded to include the board at this time, future use of such technology for renewals seems feasible.</p>	
January 2002:	<p>Department prepares feasibility study for new computer system called Professional Licensing Enforcement System (PLEMS). If approved, the board's costs are estimated at \$550,000 and will be installed in 2007/08.</p>	

6. Redesign and reformat the board's strategic plan into the new strategic management plan structure.	June 2003
July 2002:	Contract solicited for facilitator for board's strategic plan.
December 2002:	Executive staff begins work with consultant to reformat existing strategic plan into new structure.
February 2003:	Executive staff reformats goals and objectives of each committee into new strategic plan structure. During committee meetings, each committee reviews and approves reformatted goals.
April 2003:	Board revises and updates strategic plan during public meeting of the Organizational Development Committee.

Ongoing Objectives

7. Ensure management systems provide adequate staff compensation, regular performance monitoring and enhancements, optimize implementation of the strategic plan and improve decision-making.	
September 2002:	New 2002/03 state budget eliminates four vacant positions at the board, and removes \$185,000 in annual expenditure authority linked to these positions. Sunset Report submitted to Legislature, as required.
December 2002:	Board participates in Joint Labor-Management Task Force with the union representing inspectors; a required contract term. These meetings will occur over a period of months to discuss workload and other issues
8. Continue the Communications Team (TCT) to facilitate and improve communications within the board.	
Sept. 11, 2002:	TCT hosts quarterly staff meeting. TCT also coordinates sales of board logo shirts.
December 2002:	TCT hosts quarterly staff meeting.
March 2003:	TCT hosts quarterly staff meeting.
9. Link policy, strategic plan, and budgeting and develop a reporting strategy.	
October 2002:	All committees provide quarterly updates during October Board Meeting.

December 2002: Strategic plan begins conversion into new structure to facilitate strategic management of the board.

January 2003: All committees provide quarterly updates during January Board Meeting.

April 2003: Board revises and updates strategic plan onto new format during public meeting of Organizational Development Committee.

10. Improve procedures to support quality improvement efforts, implement strategic objectives, create team approaches and improve decision-making.

September 2002: Restructuring of board's enforcement reports is facilitated by training staff in new procedures and a specialized writing course for inspectors. Group of staff begin integration of CURES data into proactive investigations.

December 2002 – April 2002: Citation and fine committees expand to include additional board members. Reports and processes continue to evolve to better meet enforcement priorities and efficiencies.

Board uses team approaches to respond to the workload needs for processing of applications in light of staff vacancies. Diverse staff assigned to assist with such work.

11. Ensure that staff development and resource management support organizational effectiveness.

September 2002: Sunset Report submitted to Legislature.

October 2002: DCA initiates internal operational audit of board as part of Sunset Review process.

November 2002: DCA executive office briefing on the board's Sunset Review Report. Board responds to 31 focused issues requested by the Joint Legislative Sunset Review Committee.

Board's legislative hearing on its Sunset Review Report.

January 2003: Board reviews and takes positions on five draft recommendations of the Joint Legislative Sunset Review Committee.

Annual assessments of staff begins; targeted training for enhanced performance of each employee is one area of evaluation.

February 2003: Board senior management participates in Joint Labor Management Task Force required by the Unit 19 Collective Bargaining Agreement, regarding inspector workload.

March 2003: Department's Internal Audit office releases audit findings of board. Status reports will be submitted by the board every six months.

April 2003: Department and Joint Legislative Sunset Review Committee provide recommendation following sunset review of the board. These findings include continued existence of the board to regulate the profession, the addition of two public members to the board, the use of NAPLEX to license pharmacists, the option to use non-pharmacy inspectors and implementation of changes to the pharmacy technician program.

12. Maintain and upgrade automated systems to keep the board current with evolving technology.

September 2002: All application forms on Web site are revised as board initiates program to save postage by requiring applicants to download applications instead of requesting these from the board.

October 2002: Board initiates discussions with Department of Justice to obtain board specific analyses of CURES data and to initiate modifications to the CURES system implemented by 2002-enacted legislation.

November 2002: Additional staff receive training in data management software to facilitate monitoring of board programs.

Board staff works with DCA contractor to identify systems elements needed in a new computer system for the department (integrating applications, cashiering, licensing and enforcement systems) to replace existing system.

Board staff initiates discussions with e-government program to establish means for online renewals and submission of applications. Program cannot be expanded to include the board at this time, future use of such technology for renewals seems feasible.

January 2003: Department prepares feasibility study report to implement Professional Licensing and Enforcement Management System (PLEMS) in the future. Discussions are ongoing with the Department of Finance.

April 2003: Board continues work with the Department of Justice to access CURES data.

13. Activate and integrate data collection and analysis to support strategic planning, including performance measurement and process improvement studies.

September 2002: Compilation of Sunset Report results in availability of data for management review.

December 2002: Board compiles and provides massive data to DCA in response to request for all sunset review data. This will become part of an annual submission to DCA.

Board initiates reformatting of strategic plan to improve performance measure monitoring and reporting of board activities.

March 2003: Modifications and enhancements made to the board's automated activity tracker and inspection program systems. Also, new case management and licensing data tracking systems developed.

April 2003: Board restructures strategic plan during board meeting and public meeting of the Organizational Development Committee.

14. Form task-specific process review teams to improve operations.

December 2002: Board site licensing staff redesign processing functions to enable the board to continue existing site licensing duties in light of two staff vacancies that may not be filled and implementation of the compounding pharmacy license program.

April 2003: All inspectors will undergo training to implement Sterile Injectable Compounding Pharmacy License program.



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES**

DATE & TIME: January 22 and 23, 2003

LOCATION: **The Crowne Plaza Irvine
17941 Von Karman Avenue
Irvine, CA 92614**

BOARD MEMBERS

PRESENT: John Jones, President
Donald Gubbins, Vice President
Caleb Zia, Treasurer
Dave Fong
Stanley Goldenberg
Clarence Hiura
Steve Litsey
William Powers
John Tilley
Andrea Zinder

STAFF

PRESENT: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Ron Diedrich, Deputy Attorney General
Dana Winterrowd, Department Legal Counsel

Wednesday, January 22, 2003

CALL TO ORDER

President Jones called the meeting to order at 9:00 a.m. on Wednesday, January 22, 2003.

COMMUNICATIONS AND PUBLIC EDUCATION COMMITTEE

LICENSING COMMITTEE

Chairperson David Fong reported on the Licensing Committee Meeting of December 5, 2002.

- **Approval of Two New Schools of Pharmacy – Loma Linda University and UC San Diego**

Chairperson Fong reported that the Licensing Committee acknowledged the opening of two new schools of pharmacy in California; Loma Linda University and UC San Diego. Currently, both schools are moving forward with the applications for accreditation with the ACPE; however, final accreditation is not granted until the first class graduates in 2006. According to California Code of Regulations, title 16, section 1719 (A); either the board or the ACPE must approve or accredit a school before its graduates can take the California pharmacist licensure exam.

President John Jones stated that he would be participating on the ACPE evaluation team for the initial accreditation of UC San Diego School of Pharmacy on January 28-30, 2003.

Avis Ericson, Executive Associate Dean of Loma Linda University, stated that it was her understanding that the Board of Pharmacy needs to recognize the school of pharmacy before students from the first graduating class are eligible to take the California licensure exam.

MOTION: Licensing Committee: That the Board of Pharmacy recognize the new schools of pharmacy at Loma Linda University and at the University of California San Diego pending final accreditation by the American Council of Pharmaceutical Education (ACPE) in 2006.

SUPPORT: 9 OPPOSE: 0

- **Licensure of Pharmacy Benefit Managers (PBMs)**

Chairperson Fong stated that during the December 5, 2002, meeting the committee discussed whether PBMs should be licensed, and if so, what the purpose the licensure should be. Considerations included:

1. Should PBMs be licensed under a financial regulation to prevent disruption and access to service?
2. Should PBMs be a regulation of prescription drug benefits?
3. Is formulary development professional practice?

The committee determined that if the board considered licensing PBMs, it must be consistent with the mandate to protect the public.

Chairperson Fong stated that the Board of Pharmacy has authority over pharmacists when they fail to practice safely regardless of whether they work in a PBM environment or pharmacy environment. The committee did not conclude that the Board of Pharmacy should specifically regulate and license PBMs as an entity, but should have continued discussions on this topic.

Mr. Hiura suggested that the board establish a committee to address the issue, spearheaded by the board's public members.

Mr. Goldenberg stated that the board should carefully consider this important issue because there may come a time when California consumers get their prescriptions without ever seeing a pharmacist.

Mr. Tilley stated that from his experience as a pharmacist, there is a place for PBMs. However, it is the pharmacist who must be the advocate for the patient when the patient's drug therapy has changed. Mr. Tilley added that these recurrent daily disruptions could lead to prescription errors.

Mr. Fong stated that there is considerable controversy and discussion about the role of PBMs in patient care and the board has a responsibility to monitor the impact it has.

John Cronin, representing the California Pharmacists Association, stated that although the Board of Pharmacy may not be the best entity to regulate PBMs, the board should be a driving force in any regulation passed. He suggested that the public also be involved in future discussions. Mr. Cronin recommended that the board move forward with a review of regulating PBMs with a committee of public members. He noted that the California Pharmacists Association has asked the Department of Managed Health Care to regulate PBMs.

Joseph Grasela, owner of Medical Center Pharmacies and University Compounding Pharmacy, stated that currently, there is no control over PBMs and they should be licensed. He added that under the current fee structure established by PBMs, pharmacists would not financially break even and inadequate reimbursement would force pharmacists to fill more prescriptions, causing more stress and placing the public at risk. Mr. Grasela added that PBMs expect pharmacies to dispense medication for \$4 or to compound injectable medications for only \$25, which is insufficient reimbursement.

David Robinson, representing Medco Health, recommended that the board invite representatives from PBMs to be included in these meetings. He discussed Georgia's efforts to regulate PBMs and stated that the regulation was probably not effective nor did it accomplish what was intended.

Steve Gray, representing Kaiser Permanente, suggested that the board plan a complete discussion and invite organizations that hire PBMs such as health plans, employers with self-managed groups, government and those who perform the functions of the PBMs independently. Mr. Gray also suggested that an invitation be extended to the Pharmaceutical Care Management Association (AMCP), as representatives of PBMs to share their knowledge.

Mr. Gray stated that 11 states considered legislation last year to regulate PBMs and after discussions decided against it because it is a complicated issue.

Patricia Harris suggested that the Medical Board also be included in discussions.

MOTION: The Board of Pharmacy create a subcommittee of the Licensing Committee comprised of three public board members and the chair of the Licensing Committee and invite comment and testimony from stakeholders and interested parties to review PBM issues and make a recommendation through the Licensing Committee to the board whether regulation or legislation is needed to protect California consumers.

M/S/C: POWERS/ZIA

SUPPORT: 9 **OPPOSE:** 0

- **Proposed Amendments to 16 CCR 1751 – Standards for Compounding Sterile Injectable Drug Products**

Chairperson Fong reported that at the last board meeting, the board held a regulation hearing to amend California Code of Regulations, title 16, section 1751, to establish minimum standards for pharmacies that compound medications. The proposed standards also included minimum requirements for pharmacies that compound injectable sterile drug products. Based on the comments received and testimony heard during the regulation hearing, the board deferred action on the proposed amendments pending further review and discussion by the interested parties at the Licensing Committee meeting in December. The board also voted to implement the new licensing requirements for pharmacies that compound injectable sterile drug products based on existing section 1751, pending adoption of the amended regulations. Pharmacies that compound medication after July 1, 2003, must be specially licensed by the board as compounding pharmacies.

Following this action at the October board meeting, the proposed amendments to section 1751 were redrafted during a public meeting in December.

Mr. Riches stated that the board initially took the existing regulations for sterile compounding and modified them to reflect changes relating to compounding drugs from non-sterile products, and at the same time, keep the existing rules intact. The most notable facility requirement in the proposed regulation is that this type of compounding should occur in a laminar flow hood in a clean room.

Mr. Litsey stated that during the process of developing the proposed language, a number of professional associations were represented in State and out. The goal was to develop guidelines that would protect the public while developing a workable regulation for practitioners and the board's enforcement team. Mr. Litsey stated that considerable time and effort was involved in this process and he acknowledged Mr. Riches' and Mr. Ratcliff's efforts in responding to all of the comments. He also acknowledged Chairperson Fong's efforts to move this proposed regulation forward.

Mr. Riches stated that legislation requires that compounding pharmacies have a license effective July 1, 2003, and requires the license to be issued after the board finds them in compliance with board regulations relating to sterile compounding. Pharmacies located outside California shipping sterile injectable compounded medications into California must also meet these standards.

Steve Feldman, owner of California Pharmacy and Compounding Center, referred to costs he incurred to comply with the regulations such as installation of an 8 x 12 clean room at a cost of \$19,000 and maintenance and cleaning service at \$500 per month. Mr. Feldman stated that the least expensive barrier isolator he found was \$9,500 (without outside instruction) and upwards of \$25,000 (with instruction). Mr. Feldman added that these costs are considerable for pharmacies that want to compound medications.

John Cronin, representing the California Pharmacists Association, asked how the board would enforce these regulations to out-of-state pharmacies. He suggested that the board include a "frequently asked questions" section within the regulatory package. Mr. Cronin added that many pharmacies are interested in this regulation and want to know exactly what the requirements are. He commended the board for its work to improve the process to develop the regulation.

Mr. Gray referred to a letter from Michael A. Pastrick (dated January 22, 2003) regarding the proposed revisions to section 1751.

Mr. Gray reported that Mr. Pastrick is a former president of CPhA, a hospital pharmacist and the Mayor of the City of Concord.

Mr. Gray referred to the concept of partial sampling of products and Mr. Pastrick's recommendation that testing on sampling be required for Category III drugs and not a major requirement for Categories I and II because it gives a false sense of safety when the product is released before the sample is returned from testing. He added that it is better to place the emphasis on the process validation.

Mr. Gray stated that Kaiser Permanente supports the amendments submitted by Mr. Pastrick.

Teri Miller, representing the California Society of Hospital Pharmacists (CSHP), commended Paul Riches and the board on their efforts to develop a workable practical framework for protecting consumers.

Ms. Miller referred to the technical modifications submitted by the CSHP. Ms. Miller stated that the USP is in the process of rewriting its guidelines for compounding sterile products and discussion included reclassifying that chapter within the USP so that it would have the force of federal law. Ms. Miller added that the ASHP is waiting to revise its guidelines pending the USP decision. Ms. Miller stated that the CSHP supports moving forward with the board's regulation as written with minor modifications.

Bill Blair, Pharmacy Director representing McGuff Compounding Pharmacy, commended the board's efforts on the proposed regulations but he referred to a problem with the record-keeping requirements. He provided proposed changes to the existing requirements in board regulations.

Mike Cook, representing Central Admixture Pharmacy Services, thanked the board for the opportunity to participate in the December meeting. Mr. Cook stated that he supports the draft regulation submitted by Bill Blair that addresses the record-keeping requirement. Mr. Cook added that the requirement creates a hardship in obtaining all of the records because the majority of their patients are already in a hospital institution.

Mr. Grasela, University Compounding Pharmacy, stated that the record-keeping requirement will be difficult to comply with and may have been designed for in-home care or hospitals, but does not appear to be practical for the type of medications he uses.

Steve Feldman stated that the language should be revised to allow more flexibility for those practicing to collect the data that is truly essential in providing the right medication to patients.

Hank Rohe, Containment Technologies Group, congratulated the board on the proposed regulations. Mr. Rohe asked the board to consider equipment issues, specifically, that equipment must be verified that it meets loads. Mr. Rohe referred to the incident with Doc's Pharmacy and stated that it was the operation of the autoclave that caused problems.

MOTION: Licensing Committee: The Board of Pharmacy notice a new regulation hearing with proposed amendments to California Code of Regulations (CCR), title 16, section 1751 standards for compounding sterile injectable drug products.

SUPPORT: 9 OPPOSE: 0

Notification from National Association of Boards of Pharmacy Regarding Security Breach and Halt of the Administration of the Foreign Pharmacy Graduate Equivalency Examination (FPGEE)

Chairperson Fong stated that Business and Professions Code section 4200(a)(2)(B) requires an applicant who graduates from a foreign pharmacy school to receive a grade satisfactory to the board on an examination designed to measure the equivalency of foreign pharmacy education with that of domestic graduates.

To meet this requirement, the board relies on the Foreign Pharmacists Graduate Equivalency Exam (FPGEE) developed and administered by the National Association of Boards of Pharmacy (NABP).

Chairperson Fong reported that on November 18, 2002, the NABP issued notification that it halted the examination due to a security breach. Further, NABP advised that it had taken steps to ensure the integrity of the examination: scores affected by the breach will be invalidated and those applicants must retake the examination. If certificates have been awarded to candidates who passed the exam affected by the compromise, these certificates will be invalidated and the applicants must retake the examination. Further, all FPGEE examinations have been cancelled until a new examination can be developed, likely by June 2003.

This action by NABP will affect applicants from foreign pharmacy schools that apply to be licensed in California. A review of board records indicate that there are over 100 foreign graduates who are waiting for their intern permits that could be affected and at least one candidate who cannot take the board licensure examination until the NABP completes its investigation.

- **Competency Committee Report on the January 2003 Pharmacist Licensure Examination**

Ms. Herold reported that on January 14 and 15, 2003; the board administered its January 2003 pharmacist licensure examination at the Hyatt Regency San Francisco Airport Hotel. She reported that the board had 674 candidates complete the exam.

Ms. Herold stated that the board would need board members to assist with grading on February 19, 2003, in Sacramento.

Ms. Herold stated that on June 17 and 18, 2003, the board will administer its June 2003 pharmacist licensure examination at the San Jose Convention and Cultural Facilities Center.

ENFORCEMENT COMMITTEE

- **Proposed Revisions to the Citation and fine Process – Delegation to the Executive Officer to Issue Citations**

Chairperson Goldenberg reported that during the Joint Legislative Sunset Review Committee hearing in November, Committee Chair Senator Liz Figueroa requested that the Board of Pharmacy evaluate its current citation and fine process and consider delegating the authority to issue citations and fines to the executive officer. The reason for this request is that all other DCA agencies delegate their authority to the executive officer, it would remove board members from the investigation process, it would improve the overall timeliness of issuing a citation and it would reduce costs.

In both oral and written comment, the Center for Public Interest Law (CPIL) supported the request from the Joint Legislative Sunset Review Committee. While CPIL commented that the board's process has improved tremendously over the years, it still departs substantially from (1) the way almost every other DCA board has implemented the cite and fine statute, (2) the intent of the citation and fine statute (which was to provide an alternative to long, drawn-out disciplinary proceeding which must be reviewed by board members) and (3) the existing Administrative Procedure Act (which requires board members to review a proposed ALJ decision based upon the evidence presented in that proceeding, and in that proceeding alone). They also commented that the board's process is lengthy, overly complex, and is not required under current law.

It was noted that it takes 82 days from the date a case is reviewed by the executive officer to the issuance of a citation. (It took the Compliance Committees 210 days.) The cost for the current process is \$164,000 (almost double the cost for the Compliance Committees). The Enforcement Committee also projects the issuance of 1,200 citations (a 500 percent increase from the number of citations issued the previous year).

It was also encouraged that the board continue the informal appeal process whereby the licensee can contest the citation and fine to the executive officer.

President Jones stated that this was a recommendation of the Sunset Review process.

President Jones stated that the Enforcement Committee would continue to review enforcement statistics regarding the inspector's activity and the disposition of the cases. In addition, the committee would review staff activity regarding cite and fine action.

President Jones added that this action would considerably improve overall efficiencies and ultimately benefit consumers. This is the same process used by other boards within the department.

Mr. Fong expressed concern regarding the number of cases the board handles and the additional workload placed on the executive officer. Mr. Fong requested guidelines to objectively review the board's workload.

President Jones stated that the executive staff is under financial pressure and faced with increased workload due to the current budget crises and the difficulty in filling vacant positions within the board.

Ms. Harris stated that in working closely with the supervising inspectors during the last 6-8 months, the tremendous workload they are under is evident. However, the board is in the process of hiring two additional supervising inspectors to assist with this review process.

Collette Galvez representing the CPIL thanked the board for considering these options and for working to improve the cite and fine and enforcement processes during the last year. She added that this would serve the board to manage its workload and achieve its objectives. She agreed that it is important to consider what other boards are doing and to use this information as a model for improvement.

Mr. Powers thanked Ms. Galvez for the letter dated December 9, 2002, submitted on behalf of the Center for Public Interest Law.

Chairperson Goldenberg stated that the executive officer as well as staff has demonstrated a passion for the profession of pharmacy equal to any pharmacy member that he has known. Mr. Goldenberg added that consistency and fairness that the board continues to strive for will not be compromised by this change and removing a board member from the active process does not remove the board from overseeing the process.

Mr. Gubbins expressed confidence in the executive officer's and staff's ability to handle these matters and added that the enforcement committee would continue its review in this process.

Mr. Tilley recommended that the board first take action on the committee's recommendation to sponsor legislation to add additional enforcement options.

- **Proposed Legislative Changes – Add sections 4083 (Order of Correction), 4315 (Letter of Admonishment) and 4314 (Order of Abatement)**

Chairperson Goldenberg stated that at the September Enforcement Committee meeting, the citation processes used by the Ohio and Pennsylvania Boards of Pharmacy were put

forward as models for California to consider. As described to the committee, it appears that in both states, it is the inspector (or similar type of personnel) who determines that a violation of law did occur. A notice of that violation is then issued and the licensee must respond within a specified time as to what actions he or she has taken to correct the violation or to prevent future incidents from occurring. If the licensee does not correct the violation or there are repeat violations, then he or she may be subject to a fine or other board action.

Based on this suggestion, the Enforcement Committee requested that language be drafted to model the Ohio and Pennsylvania programs. These models would provide the board with additional tools to address non-compliance issues at the administrative level. The language was provided at the October board meeting and discussed during the December Enforcement Committee meeting. The proposed language was modified to be consistent with the recommendation that the executive officer issue citations and fines, and consider an informal appeal be delegated to the executive officer or designee.

- **Add Section 4083 – Order of Correction**

This provision would allow an inspector to issue an order of correction to a licensee, directing the licensee to comply with Pharmacy Law within 30 days, would allow the licensee to contest the order of correction to the executive officer for an office conference, would provide for judicial review and would not be considered a public record for purposes of disclosure

- **Add Section 4315 – Letter of Admonishment**

This provision would authorize the executive officer to issue a letter of admonishment to a licensee for failure to comply with Pharmacy law, would allow a licensee to contest the letter of admonishment to the executive officer or designee, would provide for judicial review and would be considered a public record for purposes of disclosure.

- **Add Section 4314 – Issuance of Citations**

This provision would allow the board to issue an order of abatement that would require a person or entity to whom a citation has been issued to demonstrate how future compliance with the Pharmacy Law will be accomplished and provides that such demonstration may include, but not be limited to, submission of a corrective action plan, as well as requiring the completion of up to six hours of continuing education courses in subject matter specified in the order of abatement.

Chairperson Goldenberg stated that overall there was general support for these legislative proposals. In the original proposals, the primary concern from the Center for Public Interest Law (CPIL) was that board members would be involved in the process. This concern was considered and the language was modified accordingly. Also, the CPIL's position that the proposals may not be necessary. They contend that the current order of abatement can be drafted to require that the licensee abate the unlawful condition and demonstrate to the board how it plans to prevent such violation from recurring in the future. While this is correct, proposed section 4314 would give the board the authority to

direct the licensee on how to abate the unlawful condition and be in compliance, such as taking a continuing education course.

Mr. Fong stated that this is an efficient process that is working well in Ohio.

Herbert Weinberg, pharmacist and attorney, stated that occasionally a letter of reprimand or public reproof is accepted as a disciplinary matter and it becomes a form of discipline. He asked the board if a letter of admonishment would be considered a form of discipline when a licensee submits an application for a pharmacy permit and must answer the question asking if the person was disciplined.

Mr. Diedrich responded that it was not intended for a letter of admonishment to replace or be equal to a letter of reprimand and it is not considered a disciplinary action. Mr. Diedrich added that a letter of admonishment is intended as a lesser directive to the licensee to fix a problem without the negative impact of a disciplinary action or citation. He explained that this would not be a formal disciplinary action but it would still protect the public in minor matters and fulfill the board's obligation to enforce board regulations.

Mr. Cronin stated that the California Pharmacist Association would support this approach. He added that licensees should have a clear understanding of the process however.

Steve Gray representing Kaiser Permanente, suggested that the board issue a statement explaining that a letter of admonishment, an order of correction or a citation is not considered a formal discipline. He added that in addition to affecting responses on the board's applications, the matter of discipline also affects Medi-Cal provider applications and DEA registration. Mr. Gray added that for those who handle 100 pharmacies to know if any single pharmacy was disciplined in the past creates a huge administrative burden to report. He added that this would be relevant on an individual's application but not an organization that manages many pharmacies.

Collette Galvez representing the Center for Public Interest Law asked for clarification on the hierarchy of options available to inspectors and asked if inspectors have to issue an order of correction before they can order a letter of admonishment.

Mr. Diedrich stated that all cases should be evaluated on a case-by-case basis and the hierarchy would be determined by the priorities of the board and the Enforcement Committee.

Mr. Powers stated that it appears that the board is sending mixed messages to inspectors by trying to protect consumers on one hand and trying not to overburden pharmacists or their companies on the other hand.

Ms. Harris clarified that there is really no change from the procedure that occurs now. She added that during an inspection, inspectors are likely to find violations in a pharmacy if they look hard enough. She added that this procedure is in place now but it is not referred to as an order of correction.

MOTION: Enforcement Committee: The Board of Pharmacy sponsor legislation to add Business and Profession Code sections 4083 (Order of Correction), 4315 (Letter of Admonishment) and 4314 (Order of Abatement).

SUPPORT: 9 OPPOSE: 0

- **Proposed Revisions to the Citation and Fine Process – Delegation to the Executive Offer to Issue Citations**

This change will require regulatory notice to amend the board regulations. The board next resumed action on other Enforcement Committee recommendations.

MOTION: Enforcement Committee: The Board of Pharmacy revise its citation and fine process to delegate to the executive officer or designee the authority to issue a citation and fine.

SUPPORT: 9 OPPOSE: 0

- **Recommendation to Support the Requirement that Inspectors be Pharmacists**

Chairperson Goldenberg stated that the Joint Legislative Sunset Review Committee also requested that the Board of Pharmacy consider the current requirement that inspectors of the Board of Pharmacy be pharmacists.

During the board's last Sunset Review in 1996, the Legislative Analyst's Office recommended the elimination of the statutory requirement that board inspectors be licensed pharmacists, and instead use industry experts (pharmacist consultants) if the need arises for technical expertise. The recommendation was due in part to the board's difficulty in recruiting quality pharmacists for the board's inspector positions because of the low salary established for this classification at the state level.

The Legislative Analyst's Office stated that the board should have the option to hire pharmacist inspectors or other state investigators. Mandating that all inspectors be licensed pharmacists is unique to the board. Other boards do not require that only licensed professionals perform investigation or inspection of suspected violations of their respective licensing acts. Most will use expert professional witnesses as needed.

Subsequently, legislation (SB 827, Chapter 759, Statutes of 1997) was enacted which allowed non-pharmacist inspectors to inspect or investigate non-pharmacy licensees. The earlier version of the bill was somewhat broader and closer to what the Legislative Analyst's Office recommended, but opposition from the board and various other sources opposed those provisions and they were amended into the existing language.

The Center for Public Interest Law (CPIL) believes that the Board of Pharmacy should be open to hiring a mix of pharmacists and non-pharmacist inspectors to investigate complaints against all of its licensees. They argue that it is not necessary for an inspector to be a pharmacist to understand the elements of many violations committed by pharmacists and pharmacies. Opening all of the board's inspector positions to non-pharmacists would widen the pool of individuals eligible to apply, reduce the board's difficulties in hiring quality inspector staff, and better protect the public. Further, it is CPIL's view, that the board should increase all its license renewal fees to their statutory maximum, triple the number of investigators, hire qualified inspectors who are both pharmacists and non-pharmacists, authorize all of them to investigate complaints against any licensee, and authorize them to cite and fine on the spot for any violation that they observe.

There was general support that the board retain its staff of pharmacist-inspectors. Many law enforcement and regulatory agencies look to the board's inspectors for assistance in cases that involve prescription drugs. Moreover, one of the roles of inspectors is to educate licensees on quality of care issues that they observe during an inspection, and this important "peer review" and education cannot be done if the inspector is not a pharmacist. However, there are areas of pharmacy practice that do not require the expertise of a pharmacist, such as checking for out-dated drug stock on the prescription shelf, observing if patient consultation is being performed, and review of quality assurance documents.

Currently the board uses complaint analysts to investigate consumer complaints and other cases that do not require an inspection. All investigations that are performed by the analysts are reviewed and approved by a supervising inspector. It appears that the law does not preclude the board from using other civil service classifications to assist inspectors; however, the law may need to be clarified. Moreover, the law allows the board to use non-pharmacist inspectors to investigate and inspect other board licensees that are not pharmacists or pharmacies.

MOTION: Enforcement Committee: The Board of Pharmacy retain its pharmacist inspectors because they are vital to executing the board's public protection mandate but the board should also have the authority and flexibility to use other civil service classifications to investigate and inspect pharmacies in those situations that do not warrant the expertise of a pharmacist, such as assisting inspectors in complex investigations or performing drug audits.

SUPPORT: 9 OPPOSE: 0

- **Proposal to Grant 6 hours of Continuing Education to Pharmacists that Attend Board Meetings**

At the October meeting, the Board of Pharmacy approved the Enforcement Committee's recommendation that continuing education be awarded to pharmacists who attend board meetings. However, the parameters of this action were not decided. The board agreed that the goal is to involve more pharmacists in the board processes and to improve a pharmacist's understanding of the board's responsibilities and mandates.

The goal is to encourage more pharmacist participation at board meetings. The committee concluded that pharmacists who attend the primary business day of a board meeting should be granted 6 hours of CE credit.

Mr. Fong clarified that the maximum amount of CE credit granted for attending board meetings is recommended at 6 hours per year.

The board considered fiscal impact, the impact on record-keeping and limiting CE credit to 6 hours per year. The goal is to streamline the process so it does not become labor-intensive to administer.

Steve Feldman supported this recommendation and stated because there are a lot of CE hours offered for many non-pharmacy courses; it is valuable for a pharmacist to periodically attend board meetings.

Ms. Harris stated that pharmacists can be informed of this change through the board's website and information about it can be published in the board's newsletter.

MOTION: The Board of Pharmacy grant 6 hours per year of continuing education to pharmacists attending the business day portion of a board meeting, the board will approve this as CE (not using ACPE) and board members will not be eligible for credit.

M/S/C: GOLDENBERG/TILLEY

SUPPORT: 8 OPPOSE: 0 ABSTAIN: 1

- **Proposed Adoption of 16 CCR 1784 and 1785 – Wholesale Drug Transactions and Statement of Prior Sales – Presentation of 60 Minutes Video on Counterfeit Drugs**

Chairperson Goldenberg stated that the Enforcement Committee requested comments on proposed new regulations California Code of Regulations, title 6, sections 1784 and 1785. Concerns were expressed at prior meetings regarding the proposed language. Based on some of the concerns, the language was modified by the Enforcement Committee.

Chairperson Goldenberg stated that the proposed amendments will help the Enforcement Team and inspectors track the movement of drugs, especially those drugs that move from a pharmacy back to another avenue (wholesaler, pharmacies etc.).

The board watched a video taped segment produced by CBS for its 60 Minutes program on counterfeit drugs. The investigation found that prescription drugs make many stops from the manufacturer to nationwide distributors to pharmaceutical wholesalers, making as many as 10 stops along the way. The price charged for these drugs depends on the buyer, where the buyer is located and how much the buyer is buying. Further, this process is unregulated and almost impossible to trace the path that a particular drug takes. The report found that this could and has lead to counterfeit and tampered drugs being sold by pharmacies to patients, with serious patient harm resulting. The board expressed extreme concern over this patient harm.

In reviewing the committee's proposed language, Mr. Weinberger stated that the regulations are covered by the 1987 PDMA and reporting paper trails are mandated by that act.

Mr. Fong referred to subsection (b) where the wholesaler cannot pay more to the pharmacy, either in cash or credit, than the pharmacy originally paid to the wholesaler for the dangerous drugs. He expressed concern that when credit for returned drugs is given, the wholesaler will pay the most current amount. This proposed regulation would significantly change the way business is conducted with wholesalers and will have a financial implication.

The board determined that more time is needed to review the regulation before moving forward.

MOTION: Table the proposed adoption of 16 CCR 1784 and 1785 – Wholesale Drug Transactions and Statement of Prior Sales until the Enforcement Committee has had time to address this further at the March 5, 2003, Enforcement Committee Meeting

M/S/C: POWERS/GOLDENBERG

SUPPORT: 9 OPPOSE: 0

- **Implementation of the Federal HIPPA Requirements**

Chairperson Goldenberg stated that the Enforcement Committee discussed the new HIPPA requirements that take effect on April 14, 2003. Implementation issues were discussed. One issue is that pharmacies must account for disclosures of protected health information made to pharmacy board inspectors; however, licensees stated that they are unclear as to the threshold of when such a release must be documented. Inspectors may skim through hundreds of hard copy records and/or computerized files in one inspection. The time it would take to document each viewing will add a significant amount of time to the inspection process, increasing the burden and impeding the ability of boards to perform a thorough inspection and on the pharmacy that must track the disclosure.

The National Association of Boards of Pharmacy has written to the director of the Office of Civil Rights requesting guidance in this area. The NABP expressed concern that such a requirement would adversely affect patient care as pharmacies divert time away from patient care activities in an attempt to comply with this accounting requirement, without a resulting enhancement of the confidentiality of patient records. The NABP asked for a supporting position that a standard investigatory review of prescription files (quick viewing of or skimming) would not constitute disclosure for which an accounting is then required.

Also, the NABP requested clarification on prescription monitoring programs, which requires pharmacies to report to a designated state agency the filling of certain controlled substances. The documentation of such reporting does not enhance patient confidentiality provisions, but could hamper investigatory operations to curb or stop drug diversion. Again, the required accounting documentation would adversely affect patient care as pharmacies would have to divert time away from patient care activities to comply with record keeping requirements.

Clarification on these issues will be sought from the Health and Human Services Agency, California Office of HIPPA Implementation.

Another area of concern is that protected health information is restricted to research and education purposes. It was noted that schools of pharmacy have students review records without signed authorization from each patient and the information is not being used in the manner as allowed by the federal law.

Comments were made that pharmacies are changing many of their operating procedures because of the new HIPPA requirements. Because of this, the board may be inundated with complaints from consumers. It was suggested that the board might want to gear up for this onslaught of complaints and inquiries.

President Jones stated that he participated on the interview committee on HIPPA and the board needs to be ready to talk to consumers.

MOTION: Enforcement Committee: The Board of Pharmacy continues the discussion on the implementation of the Federal Health Insurance Portability and Accountability Act.

SUPPORT: 9 OPPOSE: 0

LEGISLATION AND REGULATION COMMITTEE

- **Adoption of Amendment 10 16 CCR 1732.2(b) – Coursework from Non-Accredited Providers**

Chairperson Litsey reported that this regulation would allow the board to accept continuing education coursework approved by the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California, upon completion of the coursework by the pharmacist. This amendment would eliminate the required written petition to the Board of Pharmacy for such coursework, and the resultant fee.

Chairperson Litsey stated that the notice of proposed action was published on November 1, 2002. The 45-day comment period closed December 16, 2002.

Chairperson Litsey stated that the board received two comments during the 45-day written comment period:

- In an email dated November 27, 2002, John Sie, Pharm.D., offered support for the board's proposal. Dr. Sie stated that working in a group of Ambulatory Care pharmacists, he assists cardiologists in managing patients' drug therapy. In order to provide such assistance, he must attend CME programs that are not given ACPE credit. In addition, he has to attend ACPE accredited programs to satisfy his continuing education requirements for the Board. Dr. Sie stated that attending disease specific symposiums or CME programs allow for better thinking processes and clinical decisions for him as a pharmacist.
- In an email dated December 5, 2002, Sharon D. Ow-Wing, Pharm.D., offered support for the board's proposal. Dr. Ow-Wing stated it would be helpful to claim hours spent at education courses provided by UCSF School of Medicine without the \$40 per unit expense. Dr. Ow-Wing fully supports pharmacists obtaining continuing education in specialty areas of interest.

Mr. Fong stated that pharmacists should be limited to the number of continuing education coursework received outside of the area of pharmacy.

President Jones stated that the board does not currently direct that a specific amount of hours of CE be obtained in a certain area and he questioned whether the board should place limits on CE when a pharmacist may benefit from specialized CE.

Steve Gray representing Kaiser Permanente requested that the board not place limits on CE at this time but consider it at a future date if needed.

President Jones stated that reviewing continuing education coursework would be a discretionary measure for staff to determine if the CE was suitable in a particular case.

Ms. Herold suggested that the board might want to consider waiting for a year or two after the regulation becomes effective to see the effect it has made on the submission of non-board –approved CE

MOTION: Legislation and Regulation Committee: The Board of Pharmacy adopt the proposed regulation to add section 1732.2 Coursework from non-recognized providers.

SUPPORT: 9 OPPOSE: 0

- **Proposal to Sponsor Amendments to Section 4312 and 4403 in the Annual Omnibus Bill**

Chairperson Litsey stated that two technical changes to existing pharmacy law have been identified for possible inclusion in the annual omnibus bill. The first, in amendments proposed for section 4312 would replace “void” with “cancel” to make the usage consistent with other aspects of pharmacy law and delete a reference to “medical device retailers” which are no longer regulated by the board. The second, in section 4403 would add “reissue” with “renew” to make the usage consistent with other aspects of pharmacy law.

MOTION: Legislation and Regulation Committee: Sponsor amendments to section 4312 and 4403 in the annual omnibus bill.

SUPPORT: 9 OPPOSE: 0

- **Proposal to Sponsor Legislation to Update the Qualifications for Licensure as a Pharmacy Technician**

Chairperson Litsey stated that this proposal came from the Licensing Committee to update the qualifications for issuing a pharmacy technician license. The proposal would eliminate the qualifying experience option for obtaining a pharmacy technician license and would restrict the associate of arts (AA) degree qualification option to those who obtain an AA degree in pharmacy technology. Pharmacy technicians who are currently licensed by the board based on existing qualifications would not be affected by this proposal; the revisions

would only affect those seeking licensure after January 1, 2004. The proposal would also add certification by the Pharmacy Technician Certification Board (PTCB) as a qualification option.

Chairperson Litsey stated that existing law for qualifying as a pharmacy technician has not been updated since the advent of pharmacy technicians in the early 1990s. Since that time, community colleges and other institutions have developed courses of study specifically for pharmacy technicians and the PTCB has been created and adopted in a number of states as a pharmacy technician qualifier (most notably Texas requires all pharmacy technicians to be PTCB certified). The proposed changes reflect developments in this area in recent years and would also have the effect of streamlining pharmacy technician application processing by the board. The qualification of an AA in a related field or the prior experience as a clerk/typist qualification both require additional evaluation of the application to ensure the adequacy of the degree program or prior experience.

Steve Gray, representing Kaiser Permanente, asked what effect this would have on private programs other than community college programs.

Mr. Riches responded that private programs will not be affected – their application will qualify under subsection (2) – Has completed a course of training specified by the board.

Gail Askew, representing Santa Ana College, expressed concern about having PTCB as the sole qualifier. She referred to a situation in Texas where training sessions were set up specifically to learn how to pass the PTCB without having a pharmacy background or education. She stated that review books can be purchased that offer candidates a good chance of passing the PTCB. She questioned whether someone could safely practice as a pharmacy technician in California under these circumstances.

Teri Miller representing CSHP stated that the PTCB as a sole qualifier may not be the best approach, but the CSHP would work with the board to help refine this issue.

Mr. Goldenberg stated that if the bar were raised on licensing technicians, it would help to eliminate some of the enforcement problems that occur.

President Jones clarified that this committee recommendation does not specify the ways the board would update the qualifications for licensure as a pharmacy technician, only that it will sponsor legislation to update the qualifications.

MOTION: Legislation and Regulation Committee: Sponsor legislation to update the qualifications for licensure as a pharmacy technician.

SUPPORT: 7 OPPOSE: 1 ABSTAIN: 1

- **Encourage Stakeholders to Introduce Legislation in Cooperation with the Board to Permit Flexibility in the Supervision of Ancillary Personnel in a Pharmacy**

Chairperson Litsey stated that at the October 2002 meeting, the board indicated its support for legislation to create flexibility in pharmacy staff ratios. The board supported a draft proposal permitting a pharmacist to supervise no more than four ancillary personnel (defined as pharmacy technicians, pharmacy technician trainees, or pharmacy interns) at any one time. The proposal permits only one pharmacy technician trainee to be on duty at any one time. The proposal also permits a pharmacist to decline to supervise additional staff if in the pharmacist's professional judgment, staff would interfere with their professional responsibilities.

MOTION: Legislation and Regulation Committee: Encourage stakeholders to introduce legislation in cooperation with the board to permit flexibility in the supervision of ancillary personnel in a pharmacy.

SUPPORT: 9 OPPOSE: 0

- **Consideration to Sponsor Legislation Permitting the Board to Waive Statutes and Regulations to Protect the Public Health in Response to a Declared Emergency**

Chairperson Litsey stated that this proposal was developed in response to recent concerns regarding emergency preparedness and terrorism responses. In such circumstances, existing legal requirements could interfere with efficient and effective responses to natural disasters or the release of biological and or chemical weapons. Specific questions have been raised regarding the use of pharmacy students and pharmacy technicians to repackage drugs released from the National Pharmaceutical Stockpile and the mechanism for dispensing those drugs to thousands of affected people.

Specifically, the proposal permits individual pharmacists to deviate from the Pharmacy Law if, in their professional judgment, it is needed to protect the public health or assure good patient care. Such deviations must be documented at the earliest possible time and retained in the pharmacy for three years. This authority could only be used during a declared emergency. In addition, the proposal would grant the Board of Pharmacy authority to waive specific statutory and/or regulatory requirements during a declared emergency to protect the public health or assure good patient care.

Steve Gray, representing Kaiser Permanente, stated the board's intent is unclear regarding deviations that must be documented at the earliest possible time and retained in the pharmacy for three years. He added that during a declared emergency, pharmacists often are involved with dispensing drugs, especially from the National Stockpile, and may be working from a school gymnasium, removed from a licensed pharmacy and he questioned whether this would allow a broad enough authority to work outside of a pharmacy during an emergency. He suggested that staff contact David Breslow, Senior Vice President of the

California Pharmacists Association, who has become an expert in this area who works with various state and local agencies on disaster and public planning involving pharmacists.

MOTION: Legislation and Regulation Committee: The board sponsor legislation permitting the board to waive statutes and regulations to protect the public health in response to a declared emergency.

SUPPORT: 9 OPPOSE: 0

- **Future Legislation and Regulation Committee Meeting**

Chairperson Litsey announced that the next Legislation and Regulation Committee meeting will be a public meeting on March 27, 2003, at 10 a.m. in the board's office in Sacramento. At that time, the board should have knowledge of all introduced 2003 legislation and will seek public input for presentation at the April Board Meeting. He encouraged the public to attend.

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Chairperson Powers updated the board on the committee's meeting on January 9, 2003.

- ***The Script***

Chairperson Powers stated that the board contracted with Hope Tamraz to produce two issues of *The Script* annually. The next issue has been written and is undergoing review by the Legal Office. This issue should be mailed in February 2003 to all pharmacies. To reduce printing and postage costs, other licensees will be encouraged to download the newsletter from the board's Web site.

Additionally, the Educational Foundation of the CPhA may be able to mail the newsletter to California pharmacists.

- ***Health Notes***

Chairperson Powers stated that also nearing completion is the "Geriatrics" issue of *Health Notes*. This issue was developed with UCSF. Since the last board meeting, all articles have been edited and approved for publication. Currently the graphic designer is working on the layout. UCSF received outside funding to develop this issue, and CSHP has obtained a grant to assist with printing. The board will pay for postage.

- **"Notice to Consumers" Poster Update**

Chairperson Powers stated that the board has obtained translations of the new “Notice to Consumers” poster into five languages -- Spanish, Vietnamese, Chinese, Korean and Russian. Each translation has been converted into an 8.5 x 11 inch sized poster that looks like a small version of the English poster. The translated posters are available for downloading from the board’s Web site and from the board.

Chairperson Powers expressed concern about the location of the “Notice to Consumers” poster in pharmacies and he suggested that the board recommend where these posters should be placed in the pharmacy so consumers have the full benefit of this information prior to filling their prescriptions.

- **“Hot Topics in Pharmacy”**

Chairperson Powers stated that the board-sponsored series “Hot Topics in Pharmacy” began with its first seminar on “Antibiotic Use and the Risk of Bacterial Infection” on October 18 in the State Capitol. The board is cosponsoring this series with the UCSF’s Center for Consumer Self Care and the Department of Consumer Affairs.

The second seminar was held January 17 on “Consumers and the Dietary Supplement Marketplace.” And the third seminar is set for February 21 on “What Everyone Needs to Know about Managing Pain Effectively.”

- **Outreach Efforts to Increase Board Attendance at Consumer Information Forums and Fairs**

Chairperson Powers stated that the committee wants to encourage and increase board attendance at consumer information forums and fairs to provide publications and information about the board. Recent activities on outreach are listed in the committee’s status report, and include:

- President Jones presented a seminar on quality assurance at the NABP Executive Officers Biennial Meeting.
- Board Member Goldenberg met with long-term care pharmacy providers.

Chairperson Powers stated that future plans include:

- A continuing education program at CPhA’s annual meeting and education forum.
- Information to pharmacists-in-charge of the California State University System.
- Consumer information to those attending a consumer education forum sponsored by the Department of Consumer Affairs at California State University Sacramento in February.

Mr. Zia announced that he was invited to participate in a discussion at Hope Hospital at 2107 N. Broadway, Santa Ana, CA. He added that he and Dr. Perry would be hosting a discussion on January 30, 2003, about purchasing drugs from other countries, buying drugs online and legality issues.

Gail Askew, representing Santa Ana College, expressed concern that pharmacists not working in pharmacies would not get the information published from *The Script* unless they routinely checked the board's website. She requested that the board notify pharmacists that the newsletter is available online. Ms. Harris stated that there is such an article in the newsletter.

Teri Miller representing the California Society of Hospital Pharmacists (CSHP) stated that when the *The Script* is available, CSHP would make an announcement in CSHP's weekly informational e-mail to their members with a link to the board's website.

Mr. Litsey asked staff to continue to keep board members informed of future public events

INFORMATIONAL HEARING ON HOW TO EDUCATE THE PUBLIC ABOUT BUYING DRUGS FROM OTHER COUNTRIES AND BUYING DRUGS ONLINE

President Jones stated that the board is interested in developing much-needed consumer information about purchasing drugs from foreign countries as a means to reduce drug costs. This is an emerging area of major consumer and media interest.

President Jones stated that there was a discussion during the second day of the October Board Meeting when public attendance was low. To provide a greater opportunity for public comment, the committee is holding an informational hearing at this meeting.

President Jones stated that a major concern for those who purchase prescription medications is the high cost. He added that often it is a difficult decision between food and housing expenses and the purchase of medication.

Patients hoping to reduce their drug costs are purchasing medications from outside the U.S., typically from Canada where the costs are less. Whereas such drug purchases are illegal, the FDA is not enforcing restrictions against patients who obtain a 90-day supply for personal use.

There is some indication that some drugs purchased from such sources are occasionally not what they are labeled to be. But these reports are rare and some states are encouraging their citizens to purchase drugs from Canada. In October a large prescription benefit company agreed to reimburse patients for drugs obtained from

Canada or other foreign countries. Recently other companies have agreed to reimburse patients for drugs purchased in Mexico.

Chairperson Powers stated that the committee envisions a fact sheet that provides the pros and cons of such purchasing.

Another comment was made that Congress should pass a meaningful drug benefit for Medicare because over 50 percent of those 65 and older do not have a benefit for prescription drugs and if they do have a benefit, it is insufficient. Also, seniors should be encouraged to use generic brand medications.

President Jones stated that the board plans to have discussions with wholesalers to determine how they are responding to concerns about counterfeit drugs and what they are doing to ensure product safety.

Mr. Fong suggested that the board make public service announcements to educate consumers.

Mr. Hiura stated that patients want drugs at the lowest price. Many solutions to getting patients lower priced drugs are beyond the control of the board.

Former Board Member Bob Elsner recommended that the board focus on education. He added that the board has to consider the efficacy of the drugs and warn consumers that if they purchase drugs on-line or out of the country, they may be purchasing outdated, ineffective medicine.

President Jones also stated that consumers should be warned that if they take drugs purchased on line or out of the country they risk complications from other drugs they may be taking or from existing physical conditions they may have. Consumers would not be under the care of a health care professional under these circumstances.

Mr. Gray stated that seniors and the public should approach the FDA to adopt regulations and issue special licenses to allow the public to take advantage of the global market and avoid driving health care out of the country.

COMMITTEE REPORTS AND ACTION

Organizational Development Committee

President's Report - Sunset Review Process

President Jones reported that the Department of Consumer Affairs held two public hearings on the regulatory programs scheduled for Sunset Review before the Joint Legislative Review Committee (JLSRC) this year. The purpose of the hearings was to provide comments to the department to assist it in preparation of recommendations to the JLSRC. Members of the public

were encouraged to attend. The first hearing was October 29, 2002, in Sacramento and the second one was November 6th, in Los Angeles.

President Jones reported that on November 4, 2002, he and Vice-President Don Gubbins, and Executive Officer Patricia Harris met with the Department of Consumer Affairs.

Representatives from the department were: Kathleen Hamilton – Director, Lynn Morris – Deputy Director, Board Relations, Kristy Wiese – Deputy Director, Legislative & Regulatory Review Division, and Terri Ciau – Manager, E-Government and Special Programs Division. This meeting provided the board with the opportunity to advise the department of the board's significant accomplishments, to address issues that were presented during the public hearings and to respond to any departmental concerns.

On November 5, the JLSRC released 31 questions and issues for the Board of Pharmacy. The committee identified these issues for the board's response during its hearing on November 19, 2002. At the hearing, President Jones presented an overview of the board and its significant accomplishments. Committee Chair Senator Figueroa asked President Jones to respond to about 15 of the 31 issues. During the hearing, Senator Figueroa requested that the board discuss the following issues: changes to the citation and fine process, the requirement that board inspectors be pharmacists, the addition of two public board members, the definition of "actively engaged in the practice of pharmacy" as a requisite for pharmacists appointed to the board, and making all committee meetings public. Upon conclusion of the board's testimony, other interested parties were invited to testify and submit written comments.

President Jones stated that during the next two months the JLSRC and the Department of Consumer Affairs would be preparing their recommendations. The department's recommendations will be presented at a public hearing sometime at the end of March. Then in early April, the JLSRC will issue recommendations at a subsequent hearing.

- **Report on the Meeting of January 9, 2003**

Chairperson Gubbins stated that the Organizational Development Committee met on January 9, 2003, in a teleconferenced meeting.

During the board's legislative hearing before the Joint Legislative Sunset Review Committee (JLSRC) on November 11, there were five items the committee requested the board to consider. Three of these items were referred to the Organizational Development Committee for initial discussion.

- **Consideration to Make all Committee Meetings Public**

Chairperson Gubbins stated that under California law, the board must make its decisions in public meetings. The involvement of the public is important in this process and the board accepts comments on matters before it or in bringing matters to it during public meetings as well as in correspondence.

Chairperson Gubbins stated that over the last five years, the committee believes that the board has widely expanded the opportunities for the public to provide comment to the board on matters before it. For example, as the board has fully transitioned to the committee structure of its strategic plan, the board has gone from five public board meetings each year to a minimum of 16 meetings planned for 2003 (four board meetings, four Licensing Committee meetings, four Enforcement Committee meetings, two Legislative Committee meetings and one public meeting for the Organizational Development and Public Education Committees).

Chairperson Gubbins reported that the high interest in enforcement and licensing issues would continue to assure that these committees hold each of their meetings as public meetings each quarter. Also in response to public comment, the Legislative Committee will increase to two public meetings this year to permit greater input from the public as the committee considers positions to recommend to the board on introduced legislation (as well as the public meeting where the committee seeks recommendations for future legislative proposals from the public).

Chairperson Gubbins stated that meetings of the Competency Committee (which develops and grades the California pharmacist licensure examination) and the Citation and Fine Committee could not be public meetings. However, matters involving the exam or the Cite and Fine Committees are ongoing agenda items for the Licensing or Enforcement Committees, and activity reports of these committees are provided at board meetings.

The Administrative Procedures Act now also requires informational hearings before the board can initiate the rulemaking process required for adopting regulations.

This leaves up to three meetings of the Organizational Development Committee, Communication and Public Education Committee and two meetings of the Legislative and Regulation Committee each year as non-public meetings. Typically these meetings are short (one hour or less) and are done via telephone with board members. Meeting summaries, recommended actions to the board and minutes of each of these meetings are provided to the public at the same time the board members receive this information.

Moreover, establishing these additional eight meetings each year as public meetings will increase board expenses when its budget can least absorb additional expenses.

Nevertheless, the committee recommends that the committees that hold only one or two public meetings annually carefully evaluate the need for informational hearings during board meetings or on days where other public meetings will be held to facilitate public comment on controversial or highly visible topics. As an example, the Communication and Public Education Committee convened a specifically scheduled informational hearing during this board Meeting on purchasing drugs from foreign countries.

John Cronin representing the California Pharmacists Association stated that the CPhA is a strong proponent of public meetings and that they hope to participate in these meetings to the greatest extent possible.

MOTION: Organizational Development Committee: The board will determine if a committee meeting should be public based upon the interest of the public in matters before the committee.

SUPPORT: 8 OPPOSE: 0 ABSTAIN: 1

- **Consideration to Increase the Number of Public Board Members**

Chairperson Gubbins stated that the committee believes that the board's current structure and size encourages and requires the active participation of every board member in board activities. The expansive description in the board's Sunset Review Report of its activities over the last five years, including its three national awards for innovations in developing significant public policy initiatives, attests to the board's successes from the integrated efforts of both its public and professional members. The committee knows of no other board with such an extensive list of achievements, activities or awards. Professional and public members have active roles in all board matters and in developing board policies, and are essential to this success.

However, if the Legislature and/or administration determine that additional public members would strengthen the board's public protection efforts and productivity, then this decision needs to be made by these entities.

The addition of board members would increase board costs and as such would require the allocation of additional resources as a fiscal impact of any change.

Mr. Powers stated that it is the nature of boards and commissions for the industry to dominate and this does not always prove to be the most productive for consumers. The addition of public members will provide more tools for the board to address consumer concerns.

Collette Galvest representing the Center for Public Interest Law agreed with Mr. Powers and stated that the position of the Center for Public Interest Law is that all boards and commissions have public member majorities.

John Cronin questioned how an increase of the board's public members would better serve the board. He added that there are many issues that public members do not understand because they do not have experience in the profession.

Mr. Powers stated as a public member, he listens to the issues as they are presented and seeks further understanding if needed to represent public interest to the best of his ability.

Mr. Zia stated that having been a public board member for 10 years, he has found that the interest level differs from public members versus pharmacist members and it helps to have a more balanced representation on the board. He recommended the addition of two public members.

Shane Gusman representing United Food and Commercial Workers stated that the proposals made during the Sunset Review process was to increase the board by two (13-member board with 6 public members), one member appointed by the pro tem and one member appointed by the speaker. He added that the UFCW is supportive of this effort and that the increase in consumer perspective helps the board. He acknowledged the perspective of professional members on the board and their importance, and stated this is why public membership should not be a majority of the board.

Mr. Fong stated that pharmacy is a profession rather than an industry and input from public members assists the board in making the best recommendations and decisions but professional membership of the board should not be reduced to accomplish this.

Mr. Tilley expressed concern that too many board members serving on the board may hinder the board's ability meet its goals.

MOTION: Organizational Development Committee: No position on the recommendation of the Sunset Review Committee to expand the number of public members on the board by two, increasing the board's composition to 13 members.

SUPPORT: 2 OPPOSE: 7

MOTION: Support the recommendation of the Sunset Review Committee to expand the public membership of the board by two.

M/S/C: POWERS/ZINDER

SUPPORT: 6 OPPOSE: 2 ABSTAIN: 1

- **Appointment of Pharmacist Board Members “Actively Engaged” in the Practice of Pharmacy to the Board**

Chairperson Gubbins stated that the committee recognizes that the knowledge of a pharmacist is required in a number of diverse environments. Moreover, the scope of practice of a pharmacist has been broadened in recent years by the Legislature to now be wherever the pharmacist is, recognizing the important cognitive skills required of pharmacists in areas that are not limited to dispensing prescriptions in a pharmacy.

Ms. Harris stated that the Governor’s Office appoints all professional board members. She added that several years ago a Legislative Counsel’s opinion addressed this issue. Staff of the Joint Legislative Sunset Review Committee is seeking a copy of this opinion. A copy will be shared with the board once it is received. She added that generally the opinion was very broad and that an individual is “actively engaged” if he or she is working in any capacity that requires a pharmacist license.

- **Proposed DCA Regulations Regarding Conflict of Interest – Addition of Board Inspectors**
Chairperson Gubbins stated that two years ago, as a board strategic objective, the board requested that inspectors be added to those board staff who must file annual conflict of interest statements with the Fair Political Practices Commission. The department has now acted upon this request by preparing a revised list of those departmental staff and individuals who need to submit annual conflict of interest statements.

Currently board members, the executive and assistant executive officers and the supervising inspectors must file these statements. However, the board believes that board inspectors, whose autonomous activities in the field will directly influence any subsequent board action, also need to file such statements. The department agreed and is proceeding with this pending rulemaking. There is no timeline for implementation.

MOTION: The Board of Pharmacy not take a position on the proposed DCA regulations regarding Conflict of Interest – Addition of Board Inspectors

SUPPORT: 7 OPPOSE: 0 ABSTAIN: 2

BUDGET REPORT

- **Request for AG Deficiency Augmentation for 2002/03**

Chairperson Gubbins stated that the board’s AG funding level would be inadequate to meet board needs this year. Over the last few years, the board has submitted budget change proposals, deficiency augmentations and finance letters to secure adequate funding on an ongoing basis to this important area of board operations. The board has had only limited success in augmenting this item. To assure that the board would have adequate AG resources this year, the board submitted three separate requests to augment its AG funding. All have been denied.

As of November 1, 2002, the board has spent \$318,306 of its \$777,000 annual AG budget. If AG spending continues at this rate, the board will spend a total of \$954,918 this fiscal year for AG services – and will deplete its AG budget in March or April, leaving it without access to legal services.

The board is unlikely to be able to redirect sufficient money to its AG line item to allow it to continue spending as it has for the last three years.

Any money approved for the augmentation that is not needed for AG services will revert to the board's fund at the end of the fiscal year.

MOTION: Organizational Development Committee: That Board of Pharmacy staff submit a deficiency augmentation to maintain ongoing access to AG services.

SUPPORT: 9 OPPOSE: 0

This report provides data from the Governor's newly adjusted 2002/03 and 2003/04 state budgets.

1. 2002/03 Budget Year

Projected Revenue: \$5,170,890

Actual revenue for the year is likely to be higher than this because:

- Fees for the sterile compounding licensure program, which must be in place by July 1, 2003, are not included (likely start up is planned for April 2003). As the legislation was being considered, the board projected 300 pharmacies would become licensed; if accurate, this will add \$150,000 more in revenue.
- No estimated cost recovery or fines paid are included in this figure. Instead cost recovery payments and fines paid via issuance of citations and fines are added to revenue over the year only after these amounts are collected.

Projected Expenditures: \$7,386,597

The board's authorized expenditures for this year have recently been reduced by \$185,000 due to the elimination of four vacant positions, as part of the Governor's cost cutting measures.

Fund Condition Estimate: \$2,595,256 (or 4.2 months)

The board is expected to end the fiscal year on June 30, 2003, with only 4 months of reserve.

2. 2003/04 Budget Year

Projected Revenue: \$4,855,000

Actual revenue for next year is projected to be lower than projected revenue for

this year due to the much lower amount of interest the board will be paid on its fund (\$541,000 in 2002/03 versus \$125,000 in 2003/04).

Projected Expenditures: \$7,374,000

Fund Condition Estimate: \$76,281 (or 0.1 months)

The board expects to end the fiscal year on June 30, 2004, with only 2.7 DAYS of reserve. This is obviously insufficient.

The board will need to seek the Administration's assistance in establishing repayment of its \$6 million loan to the state's General Fund sometime about mid-2003/04. The Administration (specifically Director Kathleen Hamilton) and the Governor's Budget have expressed the intent that the loan will be repaid before there is an adverse effect on the board's programs.

However, if this repayment is not feasible, the board will have to increase fees no later than January 1, 2004 via a regulation change. The board would likely need to take action on an increase in fees at the July 2003 meeting (via adoption of noticed regulations to increase fees) in order to have the fees in place by January 1, 2004. Increasing fees to their statutory maximum will generate \$1.3 million more annually in revenue.

- **Personnel Update**

The board lost four positions this fiscal year with enactment of the state budget. These positions were vacant on June 30, 2002, and 6,000 such positions were eliminated statewide. The board will pursue reestablishment of these positions once the fiscal climate permits; there is a need for restoration of these positions:

- Associate analyst – public outreach
- Associate analyst – newsletter editor
- Office assistant – receptionist
- Office technician – complaint assistance

Sandi Moeckly, an associate analyst with the board's licensing program, retired December 27, 2002. Among other duties Ms. Moeckly dealt with difficult licensing issues involving pharmacies.

The board received three new positions to start in November 2002 to implement the sterile compounding licensure program. The board has been authorized another supervising inspector, one inspector and one application technician.

The board filled the application technician position by promoting Suelynn Yee. Ms.

Yee is currently a lower level technician in the Licensing Unit. By doing so, the board did not use a hiring freeze exemption granted for the position.

In December, the executive and assistant executive officers served on the interview panel to create a new hiring list for the supervising inspector classification. Six individuals (four of them current board inspectors) participated in these interviews. Actual employment interviews of those who scored in the top 3 ranks are planned for later this month or in early February. The new supervising inspector should start in late February.

Board staff now is working with the department to assure the scheduling of the inspector classification qualification interviews so that the board may fill the new inspector position.

Current Vacancies:

Associate Analyst (Licensing)
Office Technician (Licensing)
Two Supervising Inspectors
Inspector (Compounding)

For the first two positions, the board will seek to hire existing state employees on layoff lists. If this is not productive, the board will seek hiring freeze exemptions.

Other Personnel Issues

- **Communications Team Report (TCT)**

The board reviewed the report of the TCT. The TCT conducted the December staff meeting in Sacramento, and provided an opportunity to update staff on budget issues that will affect the board in the coming year and brief staff on the Sunset Review process. Team building exercises also occurred.

APPROVAL OF MINUTES

**Full Board Minutes
October 24 and 25, 2002**

President Jones asked if there were any corrections to the minutes. There were none.

MOTION: Approve the October 24 and 25, 2002, Board Meeting Minutes.

M/S/C: POWERS/ZIA

SUPPORT: 9 OPPOSE: 0

ITEMS FOR FUTURE AGENDA AND PUBLIC COMMENT

A request was made that the board define which actions are “disciplinary” and which are not (e.g., is a citation and fine “disciplinary”. Such questions are asked on applications for board-issued permits.

Caleb Zia suggested the board establish a rating system for pharmacies (e.g., “A”, “B”, “C”).

ADJOURNMENT

There being no further business, President Jones adjourned the meeting at 5:05 p.m.

Thursday, January 23, 2003

CLOSED SESSION

The board also moved into Closed Session to confer with legal counsel pursuant to Government Code Section 11126(e) regarding the following pending litigation: Doumit v Board of Pharmacy, Sacramento Superior Court Case #98A504499.

The board moved into Closed Session pursuant to Government Code Section 11126(c)(3) to deliberate upon disciplinary cases.

REINSTATMENTS

The board moved into Closed Session pursuant to Government Code Section 11126(c)(3) to deliberate upon disciplinary cases and the petitions for reinstatement and early termination of probation.