State of California | Department of Consumer Affairs

Memorandum

To: **Board Members** **Date: April 4, 2004**

From: **Organizational Development Committee**

Subject: **Action Items and Report on the Meeting of January 9, 2004**

The Organizational Development Committee met on April 1, 2004, in a teleconference meeting. Minutes of this meeting are provided in this tab section as Attachment A (following the numbered attachments referenced below).

Action Items

Item 1:

Proposed Revision of Board Member Procedures and Procedure Manual

Recommendation 1a: Advise board members and add to the Board Member Procedures Manual that participation of board members during committee meetings is limited by the number of board members in attendance.

Background:

During the Licensing Committee Meeting in March 2004, a question arose about whether a board member in the audience could speak during a committee meeting. During board member orientation sessions held by the Department of Consumer Affairs, board members have been advised that they cannot participate in any discussions during committee meetings if they are not part of the committee.

Following the meeting, Departmental Counsel Dana Winterrowd clarified California's requirements in Government Code section 11222.5(c)(6) that so long as a majority of board members are not present during the committee meeting, a board member can comment on items under discussion. If a majority of the board is present, the board members who are not committee members must be observers.

This information will be added to the *Board Member Procedure Manual.* The department is clarifying its materials as well.

Recommendation 1b: Public meetings of the Organizational Development Committee should be scheduled only when there is likely to be high interest in matters under discussion (e.g., proposed fee increases)

Background:

One ramification of the legal interpretation involving board members' participation in committee meetings described above, is that the Organizational Development Committee's annual public meeting, during which the strategic plan is reviewed and revised, cannot occur if a majority of the board will participate. But to adopt and revise the plan, the board needs a majority of its members to participate.

As such, the review and development of the strategic plan during this board meeting must occur during the board meeting, not a committee meeting. This eliminates the major agenda item for the annual public meeting of this committee.

There is typically low public interest during board meetings in the Organizational Development Committee's report. As such, the committee recommends that meetings of the committee be scheduled as non-public meetings, unless a controversial subject (e.g., proposed fee increases) is scheduled.

Recommendation 1c: Revise the *Board Member Procedure Manual* to reflect the board's current structure and operations (for example, participation of board members as audience members during committee meetings, eliminating the compliance committees structure)

The committee recommends that the *Board Member Procedure Manual* needs revision to reflect current board policies and operations. Proposed modifications will be brought to the board for review and approval during a future board meeting.

Item 2:

Annual Update of the Board's Strategic Plan

Recommendation 2: Approve the Board's strategic plan for 2004/05, incorporating all changes made to the committees' strategic objectives approved during this board meeting.

The committee recommends adoption of the board's strategic plan. The full plan, less any amendments made during this board meeting, is provided as Attachment 1.

Information Only

Item 3:

Proposed Meeting Dates for 2005

During the April Board Meeting, the board typically identifies future meeting dates. The committee recommends the following dates (no vote is required, but conflicts with any board member's schedule should be noted to allow rescheduling).

2004

July 21 and 22 – San Diego

October 20 and 21 – San Francisco

2005

January 19, 20 -- Orange County

April 27, 28 -- Sacramento

July 20, 21 – San Diego

October 25, 26 or 19, 20 -- San Francisco

Item 4:

National Association of Boards of Pharmacy Makes the Board a Full Member of the NABP

Since the January Board Meeting, the National Association of Boards of Pharmacy has made California a full member of the NABP. At the same time it also approved Florida as a full member.

As a full member of the NABP, the board may now vote in matters before the NABP, a right the board did not previously have as an associate member. This will provide the board with a role in the development of national policies regarding pharmacists' care and pharmacy issues, for example, regarding the importation of drugs and regulation of wholesalers.

The annual meeting of the NABP is set for April 24 –28 in Chicago.

Item 5:

Report on the Transition to the Schwarzenegger Administration

Charlene Zettel was appointed director of the Department of Consumer Affairs in mid-March. Tim Herrera has been appointed as deputy director of press relations and Kristen Triepke has been pointed as deputy director of legislation. Former Interim Director Ron Joseph has become the chief deputy director of the Department of General Services, and former Liaison Counsel Ron Diedrich has been appointed director of the Office of Administrative Hearings.

Item 6:

Sunset Review Follow Up: 360-Day Status Report to the Department on its Operational Audit of the Board

As part of last year's sunset review process, the department's Internal Audits Office reviewed the board's operations from October 2002 to 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 Organizational Development Committee has been tracking these recommendations to review board progress. The board was required to provide a status report at 180 and 360 days post audit. The 360-day status report was provided to the department in mid March. A copy of this report is provided in Attachment 2.

Item 7:

Budget Update for 2003/04

The state's fiscal crises continue. As a review, since July 1, 2003 (the beginning of this fiscal year), the board has:

- Lost six positions vacant on June 30, 2003
- Taken a 12 percent (or $411,000) cut in Personnel Services. Most of this was linked to the loss of the six positions; additionally $12,000 in board member compensation was lost as was all overtime and $9,000 from operating expenses. No staff at the board was laid off to meet the 12 percent reduction.
- Been advised that it cannot purchase three vehicles to replace existing vehicles assigned to inspectors (these vehicles were scheduled for replacement last year).

- Been advised to discontinue any travel that is not essential or to suspend non-critical training.

A complete budget report is provided in Attachment 3. Summary information is provided below.

1. **2004/05 Board Budget Approved:** In the last two weeks, the Senate and Assembly budget subcommittees have reviewed the board's budget for next year and approved it on consent. The board's budget contains no new spending proposals, and as such, will have the board continue to operate in the same manner, and with the same resources, as this year.
2. **No Funding Increases for New Programs:** The Governor's Office and the Department of Finance have stated in recent budget instructions that there will be "no discretionary funds available from any fund source for new initiatives or program expansion." As such, any new legislative mandates or program modifications must be funded within existing funding.
3. **Workload Priorities Adjusted:** The board has had to reprioritize workload to address staffing shortages. Changes enacted by SB 361 in January on pharmacy technician and pharmacist licensure examination processing functions have been implemented.
   a. The board's changes to the pharmacy technician program have dramatically reduced the backlog and processing time for this program while increasing the qualifications required for licensure. Applications are processed the same week they are received.
   b. The board also has implemented the new processing and procedural steps to license pharmacists using the new two-examination structure.
4. **E-Mail Notification Planned to Reduce Printing and Postage Costs:** A major efficiency planned for the future is the Public Education Committee's subscriber e-mail system that will allow interested parties to list their e-mail address with the board, and then they will be e-mailed when new items are posted on the board's Web site, which the subscribers can then download. This system has the potential to increase communication with licensees and others at virtually no cost to the board. It could eliminate publishing and postage costs for newsletters and *Health Notes.* It would allow the board to advise licensees of new law changes, new regulations, product recalls, and even action items from board meetings.
5. **AG Office's Hourly Rates Increase:** The AG's hourly rates for legal services increased April 1. These additional fees will have to be absorbed this year (the department is developing a BCP to augment all agencies' budgets to cover the increase for next year, which may or may not be approved).

	Previously	Rate April 1
Attorneys in the LA Office	$120/hr	$132/hr
Attorneys in other AG Offices	112	132
Legal Assistants	53	91

The impact of this will be to increase the board's overall spending for AG services (last year $865,000, and down from $1 million the year before), even if the board continues to use the same number of hours. For the last five years, the board's AG budget has been under-funded, and despite budget change proposals seeking augmentation, the board's AG budget has not been adequately funded, requiring the board to redirect money from other program areas (AG spending is a priority).

Without consideration about the rate increase, the board was recently projected to spend about $815,000 this year for AG services, which is $35,000 more than we are funded. This is down from the initial estimate for the year of $865,000 (or what we spent last year).

6. **CURES Support From Board to Increase?:** Last year, in response to the board's omnibus legislation in 2001 to extend CURES, certain regulatory boards (Pharmacy, Medical Board, Nursing Board, Dental Board, Osteopathic Board) were tapped to fund CURES data collection costs because the state's General Fund could not support it. Last year, the board funded $68,000 for CURES data collection and analysis contracts. For 2003/04, we recently learned that the DOJ is seeking $92,000 from the board. The board is awaiting documentation for the additional expenses. Since this notification occurred more than half-way through the fiscal year, and the additional $25,000 is not funded, the board would have to redirect money to fund this project.
7. **DOI Repayment:** The department owes the board about $150,000 in overpayment collected for Division of Investigation Services the board did not use. This repayment will likely be made over several years.
8. **Revenue for 2003/04:** The board's projected revenue for the year is $5,640,544. This is comprised of $5,420,423 in fee revenue and $220,121 in interest.
   - Not included in the projections is revenue collected from citations, which as of March 1 was $553,000.
   - Additionally $110,719 has been collected as cost recovery this year.
9. **Expenditures for 2003/04:** The most recent estimates prepared by the Department of Consumer Affairs (March 2004) now set maximum expenditures for the year at $7,253,000. This figure does not include the 12 percent reduction in personnel expenditures.
10. **Update: Board Fund Condition:** Last year the board "loaned" $6 million from its fund (the board's "savings account") to the state's General Fund. Repayment of this loan is required if the board will enter a deficit situation. This year, the board is expected to spend at least $1.6 million more than it projects it will collect in revenue. As such, the amount of money in reserve in the board's fund is important. The board will not have a deficit in its fund until sometime in 2005/06. (See Table 1 in Attachment 3.)
11. **Board Member Expenditures and Reimbursements:** Attachment 4 lists the expenses of board members that have been submitted this fiscal year. Board members are likely to be able to be reimbursed for time spent performing board business outside of board meetings at the end of the fiscal year. (Hours spent in board meetings have been reimbursed.)

Item 8:

Personnel Update

In January, Inspector Rosie Yongvanich resigned from the board to become a full-time parent. The board is seeking a hiring freeze exemption to fill the vacancy.

The third labor/management meeting with the union representing board inspectors took place February 11, 2004. The contract for the state requires that the board and the union convene meetings to discuss workload and management issues of concern. Two board inspectors are participating for the union (they are union stewards). There is also representation from the Department of Personnel Administration, Department of Consumer Affairs and the union.

At the most recent meeting, the inspectors discussed workload issues and the board's managers presented data describing work produced by inspectors. There will be a future meeting because the representative from the Department of Personnel Administration had to leave early, preventing a full discussion.

The full Personnel Update is provided as Attachment 5.

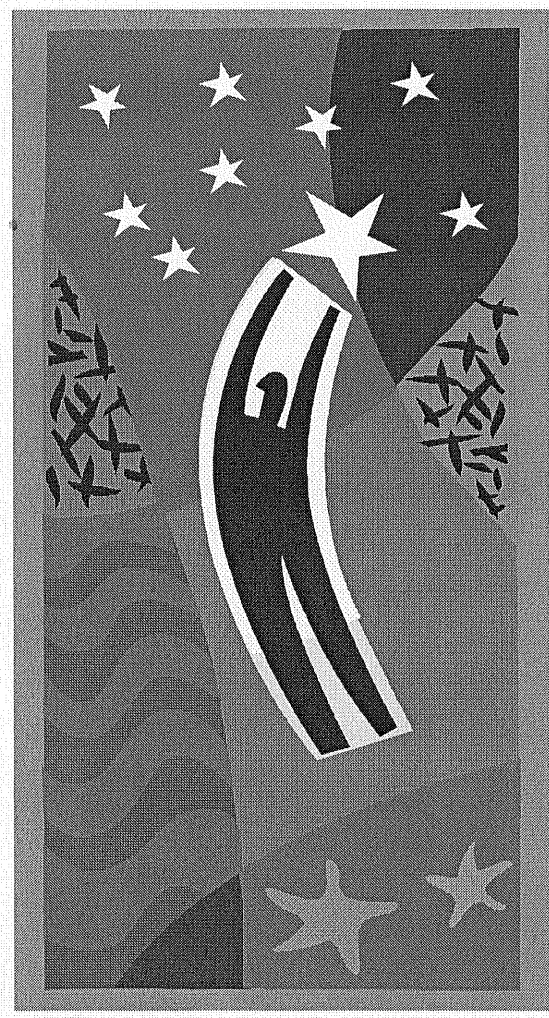
Attachment 1

Board Strategic Plan 2003/05

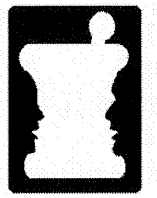
California State

Board of Pharmacy

STRATEGIC PLAN



July 2003



Be Aware, Take Care
Talk to Your Pharmacist!

For an additional copy of this plan, please contact:
California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, California 95815
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California State Board of Pharmacy

STRATEGIC PLAN

2003-2005

Members:
John Jones, President
Don Gubbins, Vice President
John Tilley, Treasurer
David Fong
Stanley Goldenberg
Clarence Hiura
William Powers
Andrea Zinder

Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer

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April 2003

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PRESIDENT'S MESSAGE

The strategic planning process of the California State Board of Pharmacy is an annual effort of the board members, staff and the public to anticipate and plan for events and issues for the coming year. Although the board considers its current strategic plan when going through the planning exercise, the board also attempts to predict upcoming changes in pharmacy practice, consumer needs and demands and health care trends. After a lengthy discussion of potential and existing issues, the participants go through a process to categorize, consolidate and finally prioritize the issues and then set the goals for the coming year. The resulting strategic plan keeps the board focused on established goals while allowing the flexibility of handling new questions and challenges as they arise.

Each board committee considers its individual strategic plan goals at every meeting and the progress on the goals are reviewed at each of the quarterly full board meetings. The careful planning and continuous monitoring of the strategic plan assures that the board achieves its stated objectives and performs with optimal efficiency.

The pharmacy board publishes advance notice for each strategic planning meeting and encourages participation and contribution by all interested citizens of California who attend. Involvement of the board, its staff and the public results in a strategic plan that truly represents the public interest and serves the consumers of this state.

CALIFORNIA STATE BOARD OF PHARMACY

Vision Statement

Healthy Californians through quality pharmacist's care.

Mission Statement

The Board of Pharmacy protects and promotes the health and safety of Californians by pursuing the highest quality of pharmacist's care through education, communication, licensing, legislation, regulation, and enforcement.

SHARED VALUES/CORE PRINCIPLES

The Board of Pharmacy will exhibit:

- Vision
- Integrity
- Flexibility
- Commitment
- Loyalty to its mission
- Relevance to important issues
- Compassion, and
- Open-mindedness

These values will be exhibited when considering all matters before the board affecting the consumers of California and the profession of pharmacy.

About the California State Board of Pharmacy

The California State Board of Pharmacy (board) was established in 1891 to protect consumers by licensing and regulating those responsible for dispensing medications to the public. Today the board oversees all aspects of the practice of pharmacy in California: the practitioner (the pharmacists), the practice site (the pharmacies), and the product (drugs and devices). Additionally the board regulates drug manufacturers and wholesalers. With an annual budget of over $7 million and a staff of 50, the board licenses over 76,000 individuals and firms, and enforces 12 complex and varied regulatory programs.

The board has five policy development committees to fulfill its charge. The five committees are: Enforcement, Communication and Public Education, Licensing, Legislation and Regulation, and Organizational Development. Each of these committees corresponds to a board mission-related goal.

The board supports an active Web site, www.pharmacy.ca.gov/, that provides application material for licensing and information for ensuring compliance for pharmacists and pharmacies. The Web site also provides times and information on board meetings as well as other critical forums vital to pharmacy services.

SCANNING ASSESSMENT

In assessing the critical data that will influence the board's ability to fulfill its vision and mission, the strategic planning team completed several scanning activities in 2002. The two primary scanning activities that were completed included STEP and SWOT analyses. Board members, all staff and key stakeholders participated in completing a survey questionnaire that was submitted to the strategic planning team for synthesis and analysis. A "STEP" analysis is an acronym for Socio-Cultural, Technologic, Economic, and Political-Legal issues that will impact the board over the next 3-5 years. All responses were aggregated for generalizations. All issues were further reviewed and prioritized at a board meeting held in April 2002. These issues are presented in "**Strategic Issues to be Addressed.**"

A "SWOT" analysis is an acronym for Strengths, Weaknesses, Opportunities, and Threats. The SWOT data were collected during the survey activity in April 2002 as part of the scanning assessment. Similar to the STEP analysis, the SWOT data were aggregated for generalizations. The final SWOT analysis was completed by the board and is contained in the "**Internal/External Assessment**" section.

The STEP and SWOT analyses were reviewed in April 2003 as part of the annual strategic plan update.

METHODOLOGY

In developing its strategic plan, the board relied upon the full participation of its entire staff, its board members and its stakeholders. After each group performed the SWOT and STEP analyses described above, the board identified the strategic issues to be addressed during the April 2002 Meeting. Additionally, the board developed a new mission and vision statements, shared values, and refocused the objectives of its committees into an outcome-oriented strategic plan, with refined objectives and tasks.

At the April 2003 Board Meeting, as part of the annual strategic plan update, the board prioritized board objectives for each committee and goal area, and modified the plan's objectives and tasks. These modifications followed comments from board staff and the public obtained during committee meetings in early 2003. The final prioritization is reflected in the objectives listed for each committee.

Thus at least two iterations by board staff, board members and stakeholders have gone into producing this strategic plan. The participation of each group has provided important information necessary for a dynamic strategic plan, capable of guiding the board in fulfilling its mission for several years.

STRATEGIC ISSUES TO BE ADDRESSED*

1. Cost of medical/pharmaceutical care

Providing necessary medication for all Californians is a concern; there is an increasing demand for affordable health care services. Also, spiraling medical care and prescription costs may influence people to take short cuts on their drug therapy. Expanded patient rights will lead to higher costs to everyone. Consequently, tier or bid pricing strategies may evolve by manufacturers. Regardless it is anticipated that the cost of prescriptions and medical services will rise.

2. Aging population

There are increasingly more senior citizens, and that population is living longer. Many senior citizens are without the benefit of prescription drug insurance coverage and the ability to purchase medications. Also, aging consumers often have decreased cognitive skills, eyesight and mobility. Consequently as the senior population increases so will the volume of prescriptions and the impact on pharmacists and pharmacy personnel to meet the demand.

3. Pharmacists' ability to provide care

The ability of pharmacy to provide optimal care for patients with chronic conditions is being challenged. Drugs are becoming more powerful and it is anticipated that more intervention by pharmacists will be required. The challenge is even greater when consumers fill multiple prescriptions at different pharmacies. The pharmacist shortage, increased consumer demand for prescription drugs, patient compliance in taking medications and polypharmacy are issues which will impact pharmacists' ability to provide care.

4. Changing demographics of California patients

The diversity of California's population is growing with respect to race, ethnicity and linguistic skills, as is the segment that seeks drugs and products from foreign countries. This requires greater knowledge, understanding and skills from health care practitioners. The increasing diversity of patients is coupled with culturally-based beliefs that

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* Revised in April 2003. Developed in April 2002 following STEP and SWOT analyses by Board of Pharmacy members, staff and stakeholders

undervalue the need for licensed pharmacists and pharmacies, and instead encourage purchase of prescription drugs from nontraditional locations and providers.

There also is widespread belief that there must be a medication solution for every condition or disease state.

5. Laws governing pharmacists

New laws enhancing the pharmacists role as a health care provider are needed. The laws must address several key issues including: expansion of the scope of pharmacy practice, the ratio of personnel overseen by pharmacists, delineation of the role of pharmacists relative to selling versus nonselling duties of personnel, and the responsibility for legal and regulatory compliance of the pharmacist-in-charge.

6. Legislative issues for pharmacies

There are several legislative trends that will impact pharmacies. The federal government has demonstrated an increasing interest in regulating health care to safeguard consumer interests. New legislation and regulation may be created in response to the September 11 disaster. It is expected that the outcome of the 2004 elections will affect whether legislation to provide medical and pharmaceutical care to the indigent, elderly and non-citizen population is introduced and passed.

7. Electronic prescribing/automation

Technology will greatly impact the processing and dispensing of medication. Electronic prescribing and 'channeling' to locations other than a traditional pharmacy may become the business model. Automated pharmacy systems and electronic prescribing will impact pharmacy. New methods of dispensing medications raise additional liability issues.

8. Internet issues

The availability of prescription drugs over the Internet is on the rise. Multiple and easy access of drugs without pharmacist participation is dangerous. Entities promoting illegal drug distribution schemes have taken advantage of the Internet. Monitoring and protecting the public from improper drug distribution from these Internet pharmacies is severely handicapped with continued resource challenges by both the federal and state agencies with jurisdiction.

9. Disaster planning and response

Pharmacists need to be ready to be positioned to provide emergency care and medication in response to natural disasters and terrorism. This requires specialized knowledge, advance planning and integration of local, state and federal resources that can be quickly mobilized.

Additionally, regulatory adjustments to the September 11 terrorism may affect persons' rights to privacy.

10. Qualified staff

The state's fiscal crisis will affect the board's ability to investigate customer complaints or hire staff. The duration of the state hiring freeze is unknown. If wages are also frozen, the retention of current employees could be impacted.

INTERNAL/EXTERNAL ASSESSMENT

The critical data stemming from the SWOT analysis is reflected below. The information represents a deliberative process of multiple iterations conducted with the board members, staff and stakeholders.

Strengths	Weaknesses
1. Staff/Inspectors: Staff's teamwork, dedication, diversity, and knowledge. Pharmacist inspectors provide necessary, specialized knowledge. 2. Leadership: Support and communication provided by management, diversity and experience of board members.	1. Resources: Budget constraints and insufficient resources to meet mandated duties at desired levels 2. Staffing Shortages: Insufficient staff to perform, manage, and review consumer protection activities of licensing, enforcement, and education programs.

Opportunities	Threats
1. Pharmacist's Role: Pharmacy profession has large potential role in healthcare delivery. Pharmacists have opportunities in roles associated with patient care and not exclusively dispensing. 2. Technology/Automation: Promoting legislation and regulations to foster the use of technological advances by pharmacies, attainment of operational efficiencies, decreased administrative burdens, and enhanced patient care services. 3. Consumer Safety/Privacy: Promoting a nonpunitive learning environment approach to improving pharmacy patient safety. Continuing emphasis on patient safety by involving	1. Board of Pharmacy staffing is insufficient to perform mandated duties at desired levels. 2. Board funding: Lack of funding for new programs; lack of fiscal control of board over much of its budget; budget constraints and deficits; hiring freeze. 3. Cost of pharmaceuticals: Impacts of the increasing costs of pharmaceuticals cannot be managed or controlled by the consumer or the board.

the pharmacist in patient care. 4. Public education: Increasingly informed consumers means the profession must be able to deliver public education on drug use safety and healthcare issues.	4. Pharmacy personnel shortage: Lack of licensees impedes the ability of patients to receive quality pharmacists care.

SUMMARY OF GOALS

Goal One
Exercise oversight on all pharmacy activities.

Goal Two
Ensure the professional qualifications of licensees.

Goal Three
Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Goal Four
Provide relevant information to consumers and licensees.

Goal Five
Achieve the board's mission and goals.

Goals, Outcomes, Objectives, and Measures

Enforcement Committee

Goal 1:	**Exercise oversight on all pharmacy activities.**
Outcome:	**Improve consumer protection.**

Objective 1.1:	**To achieve 100 percent closure or referral on all cases within 6 months by June 30, 2005:**
Measure:	**Percentage of cases closed or referred within 6 months**
Tasks:	1. Mediate all consumer complaints within 90 days. 2. Investigate all other cases within 120 days. 3. Close (e.g. issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days. 4. Seek legislation to grant authority to the executive officer to issue a 30-day Cease and Decease Order to any board-licensed facility when the operations of the facility poses an immediate threat to the public. 5. Integrate data obtained from computerized reports into drug diversion prevention programs and investigations (CURES, 1782 reports, DEA 106 loss reports). 6. Re-establish the CURES workgroup that includes other regulatory and law enforcement agencies to identify potential controlled substance violations and coordinate investigations. 7. Secure sufficient staffing for a complaint mediation team and to support an 800 number for the public. 8. Improve public service of the Consumer Inquiry and Complaint Unit. 9. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities.

Objective 1.2: **Measure:**	**To achieve 100 percent closure on all administrative cases within one year by June 30, 2005.** **Percentage closure on administrative cases within 1 year**
Tasks:	1. Pursue permanent funding to increase Attorney General expenditures for the prosecution of board administrative cases. 2. Aggressively manage cases, draft accusations and stipulations and monitor AG billings and case costs. 3. Establish a disciplinary cause of action for fraud convictions similar to current cash compromise provisions related to controlled substances. 4. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities. 5. Review and update disciplinary guidelines.

Objective 1.3: **Measure:**	**Inspect 100 percent of all licensed facilities once every 3 years by June 30, 2004.** **Percentage of licensed facilities inspected once every 3 years**
Tasks:	1. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities. 2. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public. 3. Seek legislation to mandate that periodic inspections are done of all board-licensed facilities.

Objective 1.4: **Measure:**	**Develop 4 communication venues in addition to the inspection program to educate board licensees by June 30, 2005.** **Number of communication venues (excluding inspection program)**
Tasks:	1. Develop the board's website as the primary board-to-licensee source of information. 2. Prepare two annual *The Scripts* to advise licensee of pharmacy law and interpretations. 3. Update pharmacy self-assessment annually. 4. Develop board-sponsored continuing education programs for pharmacists in the area of pharmacy law and the expectations of the pharmacist-in-charge and coordinate presentations at local and annual professional association meetings throughout California.

Objective 1.5: **Measure:**	**To monitor alternative enforcement programs for 100 percent compliance with program requirements by June 30, 2005.** **Percentage compliance with program requirements**
Tasks:	1. Administer effective alternative enforcement programs to ensure public protection (Pharmacists Recovery Program, probation monitoring program, citation and fine program). 2. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities.

Objective 1.6: **Measure:**	**Respond to 95 percent of all public information requests within 10 days by June 30, 2005.** **Percentage response to public information requests within 10 days**
Tasks:	1. Activate public inquiry screens to expand public information. Establish web look-up for disciplinary and administrative (citation) actions. 2. Establish on-line address of record information on all board licensees. 3. Respond to specialized information requests from other agencies about board programs, licensees (e.g. subpoenas) and Public Record Act requests.

Licensing Committee

Goal 2:	**Ensure the professional qualifications of licensees.**
Outcome:	**Qualified licensees**

Objective 2.1:	**Issue licenses within three working days of a completed application by June 30, 2005.**
Measures:	**Percentage of licenses issued within 3 work days**
Tasks:	1. Review 100 percent of all applications within 7 work days of receipt. 2. Process 100 percent of all deficiency documents within 3 work days of receipt. 3. Make a licensing decision within 3 work days after all deficiencies are corrected. 4. Issue professional and occupational licenses to those individuals and firms that meet minimum requirements. • Pharmacists • Intern pharmacists • Pharmacy technicians • Foreign educated pharmacists (evaluations) • Pharmacies • Non-resident pharmacies • Wholesaler drug facilities • Veterinary food animal drug retailers • Exemptees (the non-pharmacists who may operate sites other than pharmacies) • Out-of-state distributors • Clinics • Hypodermic needle and syringe distributors 5. Deny licenses to applicants not meeting board requirements.

Objective 2.2: **Measure:**	**Implement at least 50 changes to improve licensing decisions by June 30, 2005.** **Number of implemented changes**

Tasks:	1. Review Pharmacist Intern Program.
	2. Implement changes to the Pharmacy Technician Program.
	  a. Use PTCB as a qualifying method for registration.
	  b. Eliminate clerk-typist from pharmacist supervisory ratio.
	  c. Change education qualifications from A.A. degree in health science to A.A. degree in Pharmacy Technology.
	3. Administer a pharmacist licensure exam more than twice a year.
	4. Assist applicants in preparing to take the California pharmacist licensure examination by developing (or fostering the development of) educational programs and information on how to prepare for the pharmacist exam and by requesting that outside agencies (schools of pharmacy and private educational organizations) develop exam workshops that prepare applicants for the California Pharmacist Exam.
	5. Develop statutory language to give the Board of Pharmacy the authority to grant waivers for innovative, technological and other practices to enhance the practice of pharmacy and patient care that would have oversight by an independent reviewing body during the study.
	6. Continuously review and develop written exams to ensure they fairly and effectively test the knowledge, skills and abilities of importance to the practice of pharmacy in California.
	7. Implement the sterile compounding pharmacy licensing requirements by July 1, 2003.
	8. Issue temporary permits whenever change of ownership occurs.
	9. Establish means for licensee to renew permits on line.

Objective 2.3: **Measure:**	**Evaluate five emerging public policy initiatives affecting pharmacists' care or public safety by June 30, 2005.** **Number of public policy initiatives evaluated**
Tasks:	1. Explore the need to regulate pharmacy benefit managers. 2. Explore the need to regulate drugs labeled for "veterinary use only." 3. Explore the importation of drugs from foreign countries. 4. Develop language and pursue a regulation change to allow the central fill of medication orders for inpatient hospital pharmacies.

Objective 2.4: **Measure:**	**Cashier 100 percent of all application and renewal fees within two working days of receipt by June 30, 2005.** **Percentage of cashiered application and renewal fees within 2 working days**
Tasks:	1. Cashier application fees. 2. Cashier renewal fees 3. Secure online renewal of licenses

Objective 2.5: **Measure:**	**Respond to 95 percent of all requests for verification of licensing information within 5 working days by June 30, 2005.** **Percentage response for verifying licensing information within 5 working days**
Tasks:	1. Respond to requests for licensing verification

Objective 2.6: **Measure:**	**Update 100 percent of all information changes to licensing records within 5 working days by June 30, 2005.** **Percentage of licensing records changes within 5 working days**
Tasks:	1. Make address and name changes. 2. Process discontinuance of businesses forms and related components. 3. Process changes in pharmacist-in-charge and exemptee-in-charge. 4. Process off-site storage applications.

Legislation and Regulation Committee

Goal 3:	**Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.**
Outcome:	**Improve the health and safety of Californians.**

Objective 3.1:	**Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.**
Measure:	**100 percent successful enactment of promoted legislative changes**
Tasks:	1. Secure extension of board's sunset date. 2. Sponsor legislation to strengthen and update licensing requirements for pharmacy technicians. 3. Sponsor legislation to add enforcement options for non-compliance issues. 4. Sponsor legislation to update pharmacy law to standardize terminology regarding cancellation of licenses, waiving pharmacy law requirements during declared emergencies. 5. Advocate the board's role and its positions regarding pharmacists' care and dispensing of dangerous drugs and devices. 6. Sponsor clean-up language to B & P Code section 4312. 7. Sponsor public meetings 4 times a year to solicit comments on areas needing legislative changes.

Objective 3.2: **Measure:**	**Annually identify and respond with regulatory changes to keep pharmacy regulations current and consistent with the board's mission.** **Percentage successful enactment of promoted regulatory changes**
Tasks:	1. Strengthen standards for compounding sterile injectable drug products. 2. Authorize the executive officer the authority to issue citations and fines. 3. Eliminate the clerk typist ratio. 4. Allow pharmacists to be pharmacist-in-charge of two locations simultaneously. 5. Update pharmacy Self-Assessment document. 6. Allow central filling by hospital pharmacies. 7. Revise regulations concerning electronic prescribing to conform to AB 2245, and require that the pharmacist confirm the authenticity of any electronic prescription in which there is an uncertainty or ambiguity.

Objective 3.3: **Measure:**	**Review 5 areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2005.** **Number of areas of pharmacy law reviewed**
Tasks:	1. Evaluate electronic prescribing laws involving controlled substances. 2. Evaluate the prescribing and dispensing of veterinary drugs. 3. Evaluate group dispensing by prescribers.

Communication and Public Education Committee

Goal: 4:	**Provide relevant information to consumers and licensees.**
Outcome:	**Improved consumer awareness and licensee knowledge.**

Objective 4.1:	**Develop 10 communication venues to the public by June 30, 2005.**
Measure:	**Number of communication venues developed to the public**
Tasks:	1. Convert *Health Notes* articles into consumer columns or fact sheets for wide-dissemination to the public. 2. Develop and update public education materials. 3. Maintain a vigorous, informative Web site. 4. Sponsor "Hot Topics" seminars to the public.

Objective 4.2:	**Develop 10 communication venues to licensees by June 30, 2005.**
Measure:	**Number of communication venues developed to licensees**
Tasks:	1. Publish *The Script* two times annually. 2. Publish one *Health Notes* annually. 3. Develop board-sponsored continuing education programs in pharmacy law and coordinate presentation at local and annual professional association meetings throughout California. 4. Maintain important and timely licensee information on Web site.
Objective 4.3:	**Participate in 20 forums, conferences and public education events by June 30, 2005.**
Measure:	**Number of forums participated**
Tasks:	1. Participate in forums, conferences and educational fairs.

Objective 4.4: **Measure:**	**Respond to 100 percent of information requests from governmental agencies regarding board programs and activities.** **Percentage response to information requests from governmental agencies**
Tasks:	1. By June 1, 2004, submit report to Legislature on statutory requirements for remedial education after four failed attempts on the California pharmacist exam. 2. Provide information to legislators regarding board implementation of statutory requirements. 3. Provide agency statistical data information to the department.

Objective 4.5 **Measure:**	**Respond to 100 percent of public information requests regarding board programs and activities.** **Percentage response to information requests from the public**
Tasks:	1. Respond to public information requests.

Organizational Development Committee

Goal 5:	**Achieve the board's mission and goals.**
Outcome:	**An effective organization**

Objective 5.1:	**Obtain 100 percent approval for identified program needs by June 30, 2005.**
Measure:	**Percentage approved for identified program needs**
Tasks:	1. Review workload and resources to streamline operations, target backlogs and maximize services. 2. Develop budget change proposals to secure funding for needed resources. 3. Perform strategic management of the board through all committees and board activities. 4. Manage the board's financial resources to ensure fiscal viability and program integrity.

Objective 5.2:	**Maintain 100 percent staffing of all board positions.**
Measure:	**Percentage staffing of board positions**

Tasks:

1. Continue active recruitment of pharmacists for inspector positions.
2. Vigorously recruit for any vacant positions.
3. Perform annual performance and training assessments of all staf

Attachment 2

The Board's 360-Day Status Report on DCA's Performance Audit on the Board

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

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

March 18, 2004

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

Re: 360-Day Response
Operational Audit of the California Board of Pharmacy
March 2003
Audit Number 2002-103

Dear Mr. Castillo and Mr. Durette:

In response to the operational audit of the Board of Pharmacy (as named above) initiated as part of the board's Sunset Review, the following is our 360-day status report. This letter identifies the findings, the board's response to the audit and the corrective action undertaken by the board. For brevity, all actions undertaken and reported in the board's prior two responses to your office on the audit are not repeated here.

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:

March 2004 response: The board agrees with this recommendation.

For more than 10 years, the board has reviewed a fund condition report at every board meeting. This is a strategic activity of the board. The board's staff will continue to request these reports from the department's budget office, and provide a report to the board at each board meeting. When a budget deficit looms that would require initiation of repayment of the loan, the board will work with the

department's Budget Office to obtain timely repayment from the Department of Finance.

A copy of the most recent fund condition prepared by the department's Budget Office is attached. This information will be shared with the board at its April 2004 meeting.

As can be seen, the board is not expected to need repayment of the General Fund loan initiated until late 2004/05 or 2005/06, when the fund balance is projected to drop to 1.7 and –1.4 months (deficit), respectively.

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:

March 2004 response: The board has implemented this recommendation. The board's objective is to ensure that the secured evidence areas are inventoried annually.

In the last year, the board has conducted its annual inventory of the evidence stored in Los Angeles and in Sacramento. All evidence for closed cases has been destroyed.

Additionally appropriate warning signs are posted on the secured evidence rooms, even though entry into the rooms is restricted to only several employees. This posting should alert emergency personnel who may respond to calls in the building about the contents of the storage areas.

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:

March 2004 response: The board agrees that ongoing improvements will benefit its licensing program. For example, currently the board has separate tracking systems for its 12 licensing programs, and weekly status reports regarding applications are provided to board managers. The Internal Audit Office recommended at the 180-day post-audit review that the board would benefit from a single, integrated applicant tracking system to monitor processing times for all of its 12 licensing programs. The board agrees. Such an integrated application tracking system would have been a part of the Professional Licensing and Enforcement Management System (PLEMS) that was under development by the Department of Consumer Affairs, Office of Information Systems. However, in the last six months, this system was not approved for funding by the Department of Finance and has been abandoned. Because the board is not part of the applicant tracking system of the department, staff will continue to use the tracking programs developed for each licensing program. The data from these systems provide managers with information they need to monitor application processing on a weekly basis.

At the time of the initial audit, the board noted it had difficulty meeting the established timeframes for the application notification requirements for pharmacy technicians. This was due to an increasing number of pharmacy technician applications, staff vacancies and the subsequent loss of positions due to budget constraints. But the board has achieved application processing improvements since the initial audit by aggressively streamlining operations in other ways. In response to statutory changes sponsored by the board, embraced by the Joint Legislative Sunset Review Committee and enacted in 2003 as SB 361, changes to qualifying methods for pharmacy technicians changed as of January 1, 2004. These requirements both strengthened the quality of applicants' training while eliminating several labor-intensive methods to qualify for the registration. Additionally the board eliminated federal fingerprint clearances for these applicants and narrowed the scope of application investigations opened on those with convictions. As a result, the board is processing pharmacy technician applications the week they are received -- with the same staff person.

The board continues to lack the staff to provide acknowledgement letters to applicants regarding receipt of an application. Instead, the board strives to process applications and either issues a pharmacy technician license or a deficiency notice to the applicant. The board also encourages applicants to send a self-addressed postcard in with their application, which the board mails when the application is

received. Lastly, a cancelled check is also notification to the applicant that the board has received his or her application.

Additionally and concurrently, the board is implementing new changes in the examination requirements for pharmacists, changes that were sponsored by the board and authored by the Joint Legislative Sunset Review Committee as SB 361 (Chapter 539, Statutes of 2003).

Currently in 2004, the board is pursuing statutory or regulation changes have been developed to further streamline board application processes for pharmacy technicians, pharmacist applicants and pharmacist interns.

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:

March 2004 response: The board agrees with this recommendation.

The board continually strives to improve its processing times through an ongoing case review process of tracking, monitoring, assessing and prioritizing pending complaint investigations. At the time of the audit, a principal source of delay in the complaint processing time was the review of completed investigation reports by one of the board's two supervising inspectors. In March 2003, the board was able to restructure its staffing and gained two more supervising inspectors. This substantially reduced the workload of the initial two supervisors and has substantially reduced the time required to review investigation reports and permit stronger case management activities.

The board acknowledges receipt of all consumer complaints within 10 days. The board 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.

On October 11, new board regulations went into effect authorizing the executive officer to issue citations and fines instead of a committee of board members. This change will reduce case closure times by eliminating the delay of waiting for the committee to convene to issue citations and fines.

I trust that this information continues to be responsive to the findings identified in the Operational Audit Report of 2003.

If you need additional information or have questions, please call me at 445-5014 (ext. 4004).

Sincerely,

P. F. Harris

Patricia F. Harris
Executive Officer

cc: Denise Brown, Acting Director
Kristen Triepke, Deputy Director, Legislative & Regulatory Review Division
Members, California State Board of Pharmacy

attachment

BOARD OF PHARMACY

Analysis of Fund Condition

Governor's Budget 2004/05

FUND 0767

	FINAL 2002-03	2003-04	2004-05	2005-06	2006-07
BEGINNING RESERVE, JULY 1	10,810,963	4,402,422	2,789,966	1,056,227	(902,429)
Prior Year Adjustment	116,669				
TOTAL ADJUSTED RESERVES	**10,927,633**	**4,402,422**	**2,789,966**	1,056,227	(902,429)
REVENUE					
License Fees	5,915,391	5,420,423	5,346,813	5,346,813	5,346,813
Interest	131,981	220,121	133,448	52,811	0
TOTAL REVENUE	6,047,373	5,640,544	5,480,261	5,399,624	5,346,813
BUDGET ACT TRANSFERS:					
91/92 General Fund Return					
02/03 6 mil GL loan	(6,000,000)				
TOTAL TRANSFERS	(6,000,000)	0	0	0	0
TOTAL REV. AND TRANSFERS	47,373	5,640,544	5,480,261	5,399,624	5,346,813
TOTAL RESOURCES	**10,975,005**	**10,042,966**	**8,270,227**	**6,455,851**	**4,444,384**
EXPENDITURES					
Budget expenditures (net reimb. Eff. 03/04)	6,899,281	7,253,000	7,214,000	7,358,280	7,505,446
Reimbursement	(326,828)				
SCO charge	130				
TOTAL EXPENDITURES	**6,572,583**	**7,253,000**	**7,214,000**	**7,358,280**	**7,505,446**
RESERVE, JUNE 30	**4,402,422**	**2,789,966**	**1,056,227**	**(902,429)**	**(3,061,061)**
MONTHS IN RESERVE	7.3	4.6	1.7	(1.4)	(4.9)

NOTES:

1. FY 2002/03 TIES TO SCO REPORT
2. TIES TO GOVERNOR'S BUDGET 04/05

Attachment 3

Budget Report:
Board Revenue, Expenditures, Fund Condition for 2003/04

State of California Department of Consumer Affairs

Memorandum

To: Board Members Date: April 4, 2004

From: Organizational Development Committee

Subject: Budget Report

The state continues to face a huge budget deficit this year and projections continue to forecast deficits for the future. The state's fiscal year ends June 30, 2004.

Since July 1, 2003, the board has:

- Lost six positions vacant on June 30, 2003
- Taken a 12 percent (or $411,000) cut in Personnel Services. Most of this was linked to the loss of the six positions; additionally $12,000 in board member compensation was lost as was all overtime and $9,000 from operating expenses. No staff at the board were laid off to meet the 12 percent reduction.
- Been advised that it cannot purchase three vehicles to replace existing vehicles assigned to inspectors (these vehicles were scheduled for replacement last year).

New Budget Items and Issues:

- ***2004/05 and Future Year Budgets***

Spring is the beginning of budget season for state government. The Legislature is holding legislative hearings to review the state's budget for next year (starting July 1). On June 15, the Legislature is required to send the budget to the Governor. In prior years, this did not occur timely and the state entered the new fiscal year without a budget.

In the last two weeks, the Senate and Assembly have reviewed the board's budget for next year and approved it on consent. Our budget contains no new spending proposals, and as such will have us continue to operate in the same manner, and with the same resources, as this year.

In June, the board will have an opportunity to seek augmentations for its budget for 2005/06 and future years via the budget change proposal process. However, the Governor's Office and the Department of Finance have stated in recent budget instructions that there will be "no discretionary funds available from any fund source for new initiatives or program expansion." This includes new legislative mandates that will have to be funded and staffed within existing resources -- so if we start a new program, we must redirect resources to perform the duties. (Interestingly, there is a tiny exception in one place in this year's instructions that refer to new revenue-generating proposals that would make program expansion "cost-beneficial," however, the rest of the budget instructions contradict this exception.) A copy of a recent letter to all legislative offices is provided that essentially advises that any bill with any fiscal impact must clearly describe to the fiscal

committees how the legislation will be funded.

The board could greatly benefit from restoration of its 10 lost positions; however, this is not the time to pursue the augmentation as the budget instructions make clear such requests will not be approved.

Additionally budget change proposal instructions from the department's Budget Office state that any proposals seeking augmentations where the fund condition will drop below three months reserve (and especially in those situations where there is a deficit between annual revenue and expenditures, such as that of the board) will have an added hurdle for approval. Moreover, fee increases are not likely to be approved; instead program expenditures must be implemented to prevent budget deficits (see pages 4 and 5 of the attached budget instructions).

- ***Redirections and Program Efficiencies to Offset Budget and Staffing Shortages***

At the beginning of each month, the board submits a backlog report to the administration. This report reflects the status of the board's licensing and enforcement activities with respect to processing times. The board's changes to the pharmacy technician program have dramatically reduced the backlog and processing time for this program while increasing the qualifications required for licensure. Applications are processed the same week they are received.

The board also has implemented the new processing and procedural steps to license pharmacists using the new two-examination structure.

Workload priorities will continue to result in changes in how the board performs duties. For example, the board has changed its telephone system to provide callers with more automated answers to their questions, and restrict the immediate access of callers to the board's receptionists

In fact, one of the greatest hurdles the board faces is responding to telephone inquiries. The board lacks even one full-time receptionist (two part-time individuals perform this function but they are absent frequently). As a result, all staff answer the telephones at times. Status inquiries are not a priority and callers seeking assistance to be walked through the application process are directed to the Web site instead.

A major efficiency planned for the future is that the Public Education Committee is seeking a subscriber e-mail system that will allow interested parties to list their e-mail address with the board, and then they will be notified of new items posted on the board's Web site, which they can then download. This system has the potential to increase communication with licensees and others at virtually no cost to the board. It could eliminate publishing and postage costs for newsletters and *Health Notes*. It would allow the board to advise licensees of new law changes, new regulations, product recalls, and even action items from board meetings. We hope to have a system in place by July 1. The department is working to aid us in this, and plans to offer this software to other boards in the department as well.

- ***Attorney General's Office Hourly Rates Increase***

The Attorney General's Office advised us at the end of January that it will increase its hourly rates for legal services beginning April 1. The board will likely have to absorb this increase for this year because the DCA's Budget Office does not think any augmentation will occur, and may not occur next year (typically such increases in rates are matched by a budget augmentation).

	Previously	Rate April 1
Attorneys in the LA Office	$120/hr	$132/hr
Attorneys in other AG Offices	112	132
Legal Assistants	53	91

The overall impact of this will be to increase our overall spending for AG services (last year $865,000, and down from $1 million the year before), if we continue to use the same number of hours. For the last five years, the board's AG budget has been underfunded, and despite budget change proposals seeking augmentation, the board's AG budget has not been adequately funded, requiring the board to redirect money from other program areas (AG spending is a priority).

This year, perhaps due to the implementation of the citation and fine program and because the board is more closely managing and monitoring AG cases, our expenditures are lower than expected. Nevertheless, before the rate increase, we projected AG spending at $35,000 more than funding ($781,000). The rate increase will require the board to continue to closely monitor this expenditure.

- ***CURES Support by Board to Increase?***

Last year, in response to the board's omnibus legislation in 2001 to extend CURES, certain regulatory boards (Pharmacy, Medical Board, Nursing Board, Dental Board, Osteopathic Board) were tapped to fund CURES data collection costs because the state's General Fund could not support it. Last year, the board funded $68,000 for CURES data collection and analysis contracts. For 2003/04, we recently learned that the DOJ is seeking $92,000 from the board. The board is awaiting documentation for the additional expenses. Since this notification occurred more than half-way through the fiscal year, and the additional $25,000 is not funded, the board would have to redirect money to fund this project.

- ***Repayment of Division of Investigation Overcharges***

The department's Division of Investigation (DOI) provides investigation services to most agencies within the department. The DOI's investigators are peace offices (the board's inspectors are not), and so can undertake criminal investigations and prosecutions. About six years ago, the board sought a limited number of DOI's investigators' time to pursue some of our most serious cases criminally. The board received funding for approximately 00 hours per year of investigative time. However, this arrangement never worked out as the board had hoped, and the board did not use the hours allocated to the DOI.

The method by which agencies fund DOI is based on actual use two years before (actual hours used times the DOI's hourly rate). For several years and because the board never used DOI as

much as projected, the board was overcharged for DOI services. Currently the board is seeking repayment for this overcharge, which is approximately $150,000 ($56,000 was repaid to the board's fund last year).

Revenue for 2003/04

The board's projected revenue for the year is $5,640,544. This is comprised of $5,420,423 in fee revenue and $220,121 in interest.

Actual fee revenue is likely to be approximately 10 percent higher than the $5.4 million, but interest revenue will be substantially less (this figure is calculated by the Department of Finance, and is $100,000 more than last year's actual interest income, which was collected on a larger balance in our fund).

Not included in the projections is revenue collected from citations, which as of March 1 was $553,000. Additionally $110,719 has been collected as cost recovery this year.

Expenditures for 2003/04

The most recent estimates prepared by the Department of Consumer Affairs (March 2004) now set our maximum expenditures for the year at $7,253,000. This figure includes the 12 percent reduction in personnel expenditures.

Personnel is still the largest component in the budget, comprising nearly 50 percent of our expenditures.

Update: Board Fund Condition

Last year the board "loaned" $6 million from its fund (the board's "savings account") to the state's General Fund. Repayment of this loan is required if the board will enter a deficit situation.

This year, the board is expected to spend at least $1.6 million more than it projects it will collect in revenue. As such, the amount of money in reserve in the board's fund is important.

Current projections are that we will not have a deficit in our fund until sometime in 2005/06.
See Table 1.

Table 1

BOARD OF PHARMACY

Analysis of Fund Condition

Governor's Budget 2004/05

FUND 0767

	FINAL 2002-03	2003-04	2004-05	2005-06	2006-07
BEGINNING RESERVE, JULY 1	10,810,963	4,402,422	2,789,966	1,056,227	(902,429)
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NOTES:

1. FY 2002/03 TIES TO SCO REPORT
2. TIES TO GOVERNOR'S BUDGET 04/05

Attachment 4

Board Member Hours and Travel Expenses

Chart 1

Board Member	Hours		Travel	
	Bd Meeting	Other	Expense	Airfare
James E. Acevedo	32	0	$0.00	$772.08
Richard L. Benson	35	34.33	$446.53	$472.96
Ruth M. Conroy	32	0	$0.00	$473.96
David J. Fong	49	25.09	$594.70	$387.20
Stanley Goldenberg	81.25	58.75	$1,204.21	$836.50
Clarence Hiura	60.25	37.49	$1,507.12	$377.50
John D. Jones	121	22	$1,453.14	$1,406.00
William Powers	58.75	49.03	$326.35	$410.48
Kenneth H. Schell	32	0	$324.51	$770.58
John Tilley	40	7	$0.00	$345.50
Andrea Zinder	26.5	2.5	$58.68	$185.50
Don Gubbins	18.5	5	$174.55	$184.00

Board member expenses paid from July 1, 2003 to March 31, 2004

Attachment 5

Personnel Report

State of California Department of Consumer Affairs

Memorandum

To: Board Members Date: April 4, 2004

From: Organizational Development Committee

Subject: Personnel Update

This fiscal year, the board had to take a 12 percent reduction in its personnel services budget. The majority of this cut came via the mandatory elimination of all positions vacant on June 30, 2003. In the case of the board, this was six positions. The positions we lost were:

- Three inspectors
- One associate analyst (licensing of sites)
- One office technician (licensing of sites)
- One office technician (receptionist)

Vacancies:

The Schwarzenegger Administration has modified its hiring freeze policy to allow special fund agencies to hire other state employees who are designated as "surplus" employees and subject to layoff. The board has no such employees.

Inspector Rosie Yongvanich resigned in mid-January to become a full-time parent. This creates a vacant inspector position. Under the new policy of the Administration, the board could have filled this position with a pharmacist who is on lay-off notice with another state agency. However, there currently are no pharmacists on this list.

As such, the board has submitted a hiring freeze exemption request to fill this position with a pharmacist from either inside or outside state government. We hope to receive approval to fill this position.

The board itself also has two public board member positions vacant; these positions were created January 1, 2004, and are Governor appointments.

The board has two staff on parental leave (Inspector Cindy Drogichen-Rich and Manager Anne Sodergren).

The third labor/management meeting with the union representing board inspectors took place February 11, 2004. 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). There is also representation from the Department of Personnel

Administration, Department of Consumer Affairs and the union. At the this meeting the inspectors discussed workload issues, and the board's managers presented data describing the work produced by inspectors over the last 18 months. The meeting was shorter than planned because the representative from the Department of Personnel Administration had to leave early. There will be a future meeting.

Attachment A

Minutes of the Organizational Development Committee

April 1, 2004

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

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

ORGANIZATIONAL DEVELOPMENT COMMITTEE
April 1, 2004
Meeting Minutes

Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814

Via Teleconference with Committee Members

Present: **John Tilley, President**
Stan Goldenberg, Member
Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer

Call to Order

Chairperson Tilley called the meeting to order at 9:05 a.m.

Status of Pending Legal Issues

Ms. Harris updated the committee on pending legal issues involving the board.

Transition from the Davis to Schwarzeneger Administrations

Ms. Herold stated that the Charlene Zettel has been appointed director of the Department of Consumer Affairs. Tim Herrera has been appointed as deputy director of press relations and Kristen Triepke has been pointed as deputy director of legislation. Interim Director Ron Joseph has become the chief deputy director of the Department of General Services, and former Liaison Counsel Ron Diedrich has been appointed director of the Office of Administrative Hearings.

Annual Update the Board's Strategic Plan

At the April Board Meeting, the board will discuss and approve its strategic plan for 2004/05.

Ms. Herold noted that during the committee meetings of each of the other board strategic committees this quarter, the committees have reviewed their plans for

relevance 2004/05. Two of the four other committees will propose minor changes to their plans during the April Board Meeting.

The committee reviewed its plan and determined that there was no need for changes at this time.

Board Member Procedures and Procedure Manual

- *Quorum and Voting Requirements*

  Ms. Herold advised the committee that pending in the department's Legal Office is an opinion about how many votes are needed when the majority of the board abstains from a vote. Such a situation occurred at the January board meeting. Following the meeting, staff asked the department's Legal Office for an opinion on six hypothetical situations.

  Once the answers are provided, they will be added to the Board Member Procedure Manual.

- *Participation of Board Members During Committee Meetings*

  Ms. Herold noted that during the Licensing Committee Meeting in March, a question arose about whether a board member in the audience could speak during a committee meeting. During board member orientation sessions, board members have been advised that they cannot participate in any discussions during committee meetings if they are not part of the committee.

  Following the meeting, Departmental Counsel Dana Winterrowd clarified California's requirements in Government Code section 11222.5(c)(6) that so long as a majority of board members are not present during the committee meeting, a board member can comment on items under discussion. This information also will be added to the Board Member Procedure Manual.

- *Public Meetings of the Organizational Development Committee*

  One ramification of the legal interpretation involving board members' participation in committee meetings described above, is that the Organizational Development Committee's annual public meeting, during which the strategic plan is reviewed and revised, cannot occur if a majority of the board will participate. But to adopt and revise the plan, the board needs a majority of its members to participate.

  As such, the review and adoption of the strategic plan during the April meeting must occur during the board meeting, not a committee meeting. This eliminates the major agenda item for the annual public meeting of this committee.

The committee discussed several options and recommended that it keep all meetings of the committee non-public, unless a controversial subject (e.g., proposed fee increases) is scheduled.

RECOMMENDATION: All meetings of the Organizational Development Committee be scheduled non-public meetings unless agenda items of wide interest are discussed.

- *Board Member Procedure Manual*

  Ms. Herold recommended that the *Board Member Procedure Manual* needs revision. The committee agreed and staff will bring back proposed revisions to the next committee meeting.

360-Day Status Report on the Department of Consumer Affairs' Internal Audits Office Operational Audit of the Board

The Board of Pharmacy had a number of action items arise from its Sunset Review; most of the items have been initiated or completed.

Additionally as part of the sunset review, the department's Internal Audit Office reviewed the board's operations from October 2002 to 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 Organizational Development Committee has been tracking these recommendations to review board progress. Ms. Herold shared the board's 360-day post audit status report as a final response to the audit.

The committee reviewed this report. Ms. Herold noted that this ends our reporting requirement to the department on the audit.

Budget Update Report

The committee initiated its quarterly review of the board's budget and economic condition. Deficits are projected for the next few years, and budget restrictions are in place.

Since July 1, 2003 (the beginning of this fiscal year), the board has:

- Lost six positions vacant on June 30, 2003
- Identified a 12 percent (or $411,000) cut in Personnel Services. Most of this was linked to the loss of the six positions; additionally $12,000 in board member compensation was lost as was all overtime and $9,000 from operating expenses. No staff at the board were laid off to meet the 12 percent reduction.

- Been advised that it cannot purchase three vehicles to replace existing vehicles assigned to inspectors (these vehicles were scheduled for replacement last year).

New Budget Items and Issues:

- ***2004/05 and Future Year Budgets***

  Ms. Herold stated that in the last two weeks, the Senate and Assembly have reviewed the board's budget for the next fiscal year and approved it on consent. The budget contains no new spending proposals, and as such will have the board continue to operate in the same manner, and with the same resources, as this year.

  This is the time to seek augmentations for 2005/06 and future years via the budget change proposal process. However, the Governor's Office and the Department of Finance have stated that there will be "no discretionary funds available from any fund source for new initiatives or program expansion." This includes new legislative mandates that will have to be funded and staffed within existing resources -- so if the board starts a new program, the board must redirect resources to perform the duties. Additionally any proposals seeking augmentations where the fund condition will drop below three months reserve (and especially in those situations where there is a deficit between annual revenue and expenditures, such as that of the board) will have an added hurdle for approval. Moreover, the instructions state that fee increases are not likely to be approved.

  Although the board could greatly benefit from restoration of its 10 lost positions, the committee concluded that this is not the time to pursue an augmentation as the budget instructions make clear such requests will not be approved.

- ***Redirections and Program Efficiencies to Offset Budget and Staffing Shortages***

  Ms. Herold reported that at the beginning of each month, the board submits a backlog report to the administration. This report reflects the status of the board's licensing and enforcement activities with respect to processing times. The committee reviewed the March 2004 report.

  The board's changes to the pharmacy technician program have dramatically reduced the backlog and processing time for this program while increasing the qualifications required for licensure. Applications are processed the same week they are received.

  The board also has implemented the new processing and procedural steps to license pharmacists using the new two-examination structure.

Ms. Herold stated that workload priorities will continue affect how the board performs duties. For example, the board has changed its telephone system to provide callers with more automated answers to their questions, and restrict the immediate access of callers to the board's receptionists. The board lacks even one full-time receptionist (two part-time individuals perform this function but they are absent frequently). As a result, all staff answer the telephones at times. Status inquiries are not a priority and callers seeking assistance to be walked through the application process are directed to the Web site instead.

A major efficiency planned for the future is that the Public Education Committee is seeking a subscriber e-mail system that will allow interested parties to list their e-mail address with the board, and then they will be notified of new items posted on the board's Web site, which they can then download. This system has the potential to increase communication with licensees and others at virtually no cost to the board. It could eliminate publishing and postage costs for newsletters and *Health Notes.* It would allow the board to advise licensees of new law changes, new regulations, product recalls, and even action items from board meetings. The goal is to implement this system by July 1. The department is working to aid the board in this, and plans to offer this software to other boards in the department as well.

- ***Attorney General's Office Hourly Rates Increase***

The Attorney General's Office hourly rates for legal services have increased effective April 1. The board will have to absorb this increase for this year, and may not receive any increase in funding for the same level of service for next year.

	Previously	Rate April 1
Attorneys in the LA Office	$120/hr	$132/hr
Attorneys in other AG Offices	112	132
Legal Assistants	53	91

Ms. Herold explained that the overall impact of this will be to increase overall spending for AG services (last year $865,000, and down from $1 million the year before) if the board continues to use the same number of hours. For the last five years, the board's AG budget has been underfunded, and despite budget change proposals seeking augmentation, the board's AG budget has not been adequately funded, requiring the board to redirect money from other program areas (AG spending is a priority).

This year, perhaps due to the implementation of the citation and fine program and because the board is more closely managing and monitoring AG cases, the board's expenditures are lower than expected. Nevertheless, before the rate increase, we projected AG spending at $35,000 more than funding ($781,000).

The rate increase will require the board to continue to closely monitor this expenditure.

- ***CURES Support by Board to Increase?***

  Last year, in response to the board's omnibus legislation in 2001 to extend CURES, certain regulatory boards (Pharmacy, Medical Board, Nursing Board, Dental Board, Osteopathic Board) were tapped to fund CURES data collection costs because the state's General Fund could not support it. Last year, the board funded $68,000 for CURES data collection and analysis contracts. For 2003/04, we recently learned that the DOJ is seeking $92,000 from the board. The board is awaiting documentation for the additional expenses. The additional $25,000 is not funded and the board would have to redirect money to fund this project.

- ***Repayment of Division of Investigation Overcharges***

  The department's Division of Investigation (DOI) provides investigation services to most agencies within the department. The DOI's investigators are peace officers (the board's inspectors are not), and so can undertake criminal investigations and prosecutions. About six years ago, the board sought a limited number of DOI's investigators' time to pursue some of the most serious cases criminally. The board received funding for approximately 00 hours per year of investigative time. However, this arrangement never worked out as the board had hoped, and the board did not use the hours allocated to the DOI.

  The method by which agencies fund DOI is based on actual use two years before (actual hours used times the DOI's hourly rate). For several years and because the board never used DOI as much as projected, the board was overcharged for DOI services. Currently the board is seeking repayment for this overcharge, which is approximately $150,000 ($56,000 was repaid to the board's fund last year).

Revenue for 2003/04

The board's projected revenue for the year is $5,640,544. This is comprised of $5,420,423 in fee revenue and $220,121 in interest.

Actual fee revenue is likely to be approximately 10 percent higher than the $5.4 million, but interest revenue will be substantially less (this figure is calculated by the Department of Finance, and is $100,000 more than last year's actual interest income, which was collected on a larger balance in our fund).

Not included in the projections is revenue collected from citations, which as of March 1 was $553,000. Additionally $110,719 has been collected as cost recovery this year.

Update: Board Fund Condition

Last year the board "loaned" $6 million from its fund (the board's "savings account") to the state's General Fund. Repayment of this loan is required if the board will enter a deficit situation.

This year, the board is expected to spend at least $1.6 million more than it projects it will collect in revenue. As such, the amount of money in reserve in the board's fund is important. However, current projections are that we will not have a deficit in our fund until sometime in 2005/06.

NABP Makes the Board a Full Member of NABP

The committee discussed a letter from the National Association of Boards of Pharmacy that announced that the board has been elevated to become a full member of the NABP. Full membership in NABP allows the board to vote in matters before the NABP, a right the board does not currently have as an associate member. This also provides the board with a greater role in the development of national policies regarding pharmacists' care.

Mr. Goldenberg noted that the Annual Meeting of the NABP is set for April 24 –28 in Chicago. A number of board members are planning to attend at their own expense.

Personnel Update Report

Ms. Herold again stated that this fiscal year the board had to take a 12 percent reduction in its personnel services budget. The majority of this cut came via the mandatory elimination of all positions vacant on June 30, 2003. In the case of the board, this was six positions. The positions we lost were:

- Three inspectors
- One associate analyst (licensing of sites)
- One office technician (licensing of sites)
- One office technician (receptionist)

It appears that board members may receive compensation for the non-board meeting hours they contribute as board members. In July, the board suspended its payment of board members for hours spent performing non-board meeting duties; however, because the board has not spent all of its funding for the year, board members may be reimbursed for the hours they have submitted performing board business outside of the four quarterly meetings.

Vacancies:

The Schwarzenegger Administration has modified its hiring freeze policy to allow special fund agencies to hire other state employees who are designated as

"surplus" employees and subject to layoff. The board has no such employees.

Inspector Rosie Yongvanich resigned in mid-January to become a full-time parent. This created a vacant inspector position. The board has submitted a hiring freeze exemption request to fill this position with a pharmacist from either inside or outside state government

The board itself also has two public board member positions vacant; these positions were created January 1, 2004, and are Governor appointments.

The board has two staff on parental leave (Inspector Cindy Drogichen-Rich and Manager Anne Sodergren).

The third Labor/Management Meeting with the union representing board inspectors took place February 11, 2004. 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). There is also representation from the Department of Personnel Administration, Department of Consumer Affairs and the union. At the this meeting the inspectors discussed workload issues, and the board's managers presented data describing the work produced by inspectors over the last 18 months. The meeting was shorter than planned because the representative from the Department of Personnel Administration had to leave early. There will be a future meeting.

Adjournment

There being no additional business, Chairperson Tilley adjourned the meeting at 10:15 a.m.

Board of Pharmacy
Third Quarterly Status Report

Strategic Goals
Organizational Development Committee

Goal 5:	**Achieve the board's mission and goals.**
Outcome:	**An effective organization**

Objective 5.1:	**Obtain 100 percent approval for identified program needs by June 30, 2005.**
Measure:	**Percentage approved for identified program needs**
Tasks:	1. Review workload and resources to streamline operations, target backlogs and maximize services. *Oct. 2003: Board implements and identifies a number of legislative and regulatory proposals to streamline applications and application processing, complaint resolution and investigation procedures. These include:* - *citations and fines being issued by the executive officer instead of a committee of the board.* - *New requirements enacted for pharmacy technicians and use of NAPLEX exam* - *status calls on applications pending less than 8 weeks are not answered* - *processing of fingerprint clearances and conviction information altered* - *statutory or regulation changes proposed for applicants for pharmacist, pharmacy technicians, interns, wholesalers and non-resident wholesalers.* - *All Sacramento staff assigned to cover phones as routine duties* - *Board's Web site will be revamped to make information more accessible* - *Enforcement actions against licensees will be integrated into the License Verification function of the Web page to facilitate disclosure of information to the public* *Jan. 2004: Board modifies procedures for processing pharmacy technicians so that all information required to make a licensing decision is submitted at one time (previously the various required components could each be submitted at any time, creating a substantial workload to match information to files.). The goal is to reduce the volume of individual pieces of application information that are submitted at different times* - *All staff are assigned to answer phones in four-hour blocks to fill behind the board's part-time receptionists and still provide phone coverage for the public. The telephone tree is redesigned to place calls immediately on hold, without the direct intervention of a board operator.* - *Address of record information was placed on line in mid-December. This eliminates the need for staff to provide this publicly releasable information.*

	-Enforcement information will be soon added to the Web site so complete license verification information will be available on the Web site. *-Board procedures for issuing citations and fines and changed to make it easier to respond to public inquiries.* *- Data systems for monitoring enforcement cases assigned to board staff are integrated so that only one report is prepared monthly instead of two.* *March 2004: Contracts for CPJE in place; board begins notification of candidates for pharmacist licensure they may take CPJE examination. Over 750 applications processed by end of month* *- Board seeks subscriber service to board's Web site as a possible means for future communication with licensees, applicants and the public.* *April 2004: Pilot testing of Web site enforcement look up completed and process made available online.* *- NAPLEX available to California applicants for pharmacist licensure.* *- Security processes for data transfer among entities providing examination services under development* 2. Develop budget change proposals to secure funding for needed resources. *August 2003: Budget instructions from Department of Finance specify that no program augmentations will be made this year; any increase in resources must come via redirection from within an agency's budget. As such the board dissolves plans for BCPs to augment AG resources and fund a job analysis.* 3. Perform strategic management of the board through all committees and board activities. *October 2003: Strategic plan updates from all committees provided to board for review during board meeting.* *January 2004: Strategic plan updates from all committees provide to board for review during board meeting. Additionally committee readies plan for 2004 update of board strategic plan, planned for the April 2004 meeting.* *April 2004: Strategic plan for each committee and overall plan for the board reviewed and approved by board for 2005.* 4. Manage the board's financial resources to ensure fiscal viability and program integrity. *October 2003: Full budget report provided to board on fund condition, revenue, expenditures, and mandatory budget reductions.* *January 2004: Budget report provided to board on fund condition, revenue, expenditures and mandatory budget reductions.* *April 2004: Full budget report provided to board on fund condition, revenue, expenditures, and mandatory budget reductions. Board pursues departmental assistance for a funding augmentation for 2004/05 for legal services from the Attorney General's Office to retain same level of service at higher fee rates now in effect by the AG's staff.*
Objective 5.2: **Measure:**	**Maintain 100 percent staffing of all board positions.** **Percentage staffing of board positions**

Tasks:	1. Continue active recruitment of pharmacists for inspector positions. *July 2003: Three vacant inspector positions lost due to executive order mandating elimination of any position vacant on June 30, 2003* *September 2003: Department of Consumer Affairs notifies board that it is discontinuing the continuous application process for board inspector positions. The board has no vacant inspector positions and DCA can no longer dedicate staff to this function without a corresponding need by the board to have the civil service exam given.* *January 2004: Two inspectors on parental leave; however the board has no vacancies. Board has requested the department to give an annual inspector exam so that the civil service list for this classification remains active.* *February 2004: One inspector formerly on parental leave resigns from board. Board seeks recruitment of pharmacists from other state agencies on layoff lists. No such pharmacists exist, and the board submits a freeze exemption to fill the position.* *April 2004: One inspector on parental leave. Freeze waiver for one inspector position undergoing review by the Department of Finance.* 2. Vigorously recruit for any vacant positions. *July 2003: Six vacant positions lost due to executive order mandating elimination of any position vacant on June 30, 2003 – three inspector positions, one receptionist, one office technician for site licensing, one associate analyst for site licensing. As a result, the board has no vacant positions.* *January 2004: The board has no vacant positions* *April 2004: The board is seeking a freeze exemption for its vacant inspector position.* 2. Perform annual performance and training assessments of all staff. *December 2003: All inspectors have annual performance assessments done by their supervisors. State budget restrictions on training may impede the ability of the board to provide all training needed or desired by inspectors.*
Objective 5.3: **Measure:**	**Implement 10 strategic initiatives to automate board processes by June 30, 2005.** **Number of strategic initiatives implemented to automate board processes**
Tasks:	1. Perform a feasibility study to establish the board's own computer system to track licensees and enforcement activities. *July 2003: Department of Finance issues budget instructions stating all computer installation projects and proposals are postponed due to budget crisis.* 2. Continue to work with the Department on the development and implementation of the Professional Licensing and Enforcement Management System (PLEMS). *November 2003: Department of Finance denies Department of Consumer Affairs' PLEMS feasibility study report. Department discontinues project. Board suggests reassignment of existing information technology staff to resume programming modifications*

	to existing CAS system which were reassigned to develop PLEMS. This will prevent board from realizing one finding of DCA's Internal Audits Office – to have only one tracking system in place at the board. 3. CURES *November 2003: Board Inspector develops program to integrate CURES data into board's pharmacy inspection tracking program, so that summary CURES data is immediately retrievable when looking at a pharmacy's record.* 4. Miscellaneous Projects *January 2004: Board purchases new printers for board office to provide more efficient use of board's new file server.*
Objective 5.4: **Measure:**	**Provide for communication venues to communicate within the board by June 30, 2005.** **Number of communication venues to communicate within the board**
Tasks:	1. Continue the Communication Team to improve communication among staff and host quarterly staff meetings. *July 2003: quarterly staff meeting made discretionary for board inspectors due to lack of a state budget. TCT hosts annual picnic for all Sacramento staff and a number of inspectors who travel to Sacramento.* *Sept. 2003: TCT conducts mail-ballot election to replace vacancy of one analyst on the TCT* *October 2003: to reduce travel expenses, quarterly staff meetings are converted to biannual meetings (July and December), as such no TCT quarterly meeting held.* *December 2003: TCT hosts staff meeting and team building activities for all board staff. Board members provide Christmas lunch to staff.* *March 2004: LA-based inspector staff attend Enforcement Team Meeting in Burbank.* 2. Continue Enforcement Team meetings with board members and enforcement staff. *July 2003: Enforcement team meeting held in Sacramento. To reduce travel expenses, quarterly team meetings with all enforcement staff will be converted to biannual meetings. Supervising inspectors will provide inspector meetings to update Los Angeles-based staff.* *Sept. 2003: Enforcement team meeting held in Sacramento. Los Angeles inspectors not present, but supervisors hold inspector meeting in LA for these staff to reduce travel expenses.* *Dec. 2004: Enforcement Committee and Enforcement Team meetings held with all board enforcement staff.* 3. Convene inspector meetings to develop standardized investigation and inspection processes and earn continuing education. *July 2003: inspector meeting held in conjunction with Enforcement Team meeting.* *Sept. 2003: inspector meeting held in Northern and Southern CA. Topics include development of new procedures, case presentation and review, and workload discussions.* *Dec. 2003: inspector meeting held with all inspectors. Computer modifications incorporated onto all inspectors' computers.*

	March 2004: inspector meeting planned for late May to focus on improving investigation reports.

Objective 5.5: **Measure:**	**Annually conduct at least 2 outreach programs where public policy issues on health care are being discussed.** **Number of outreach programs conducted in one year**
Tasks:	1. Attend outreach programs. *September 2003: President Jones attends NABP's District VII and VIII meeting* *October 2003: Board participates in CSHP's Annual Seminar in Sacramento* *November 2003: Board participates in development of Emergency Contraception Protocol for pharmacists, as required by SB 490 (Alpert, Chapter 651, Statutes of 2003)* *December 2003: Staff attend USC Seminar in Balancing the Rx Cost/Benefit Equation* *January 2004: Board participates in CPhA's Outlook 2004* *April 2004: Board members attend NABP's annual meeting.*

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

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

DATE & TIME: January 21 and 22, 2004

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

BOARD MEMBERS PRESENT:

John Jones, President
James Acevedo (January 21, only)
Richard Benson
Ruth Conroy
David Fong
Stanley Goldenberg
Clarence Hiura
William Powers
Kenneth Schell
John Tilley (January 21, only)
Andrea Zinder (January 21, only)

STAFF PRESENT:

Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judith Nurse, Supervising Inspector
Joan Coyne, Supervising Inspector
Dennis Ming, Supervising Inspector
Joshua Room, Deputy Attorney General
Dana Winterrowd, Department of Consumer Affairs Legal Counsel

Wednesday, January 21, 2004

CALL TO ORDER

President Jones called the meeting to order at 8:00 a.m. on Wednesday, January 21, 2004.

CLOSED SESSION

The board moved into Closed Session pursuant to Government Code Section 11126, subdivisions (e), (2), (c) to confer with and receive advice from its legal counsel regarding pending litigation.

The board ended Closed Session at 8:50 a.m.

ANNOUNCEMENTS

President Jones called the public meeting to order at 9:00 a.m. on Wednesday, January 21, 2004.

- **Continuing Education Credits Available for Attending the Board Meeting**

  President Jones stated that continuing education hours could be earned by pharmacists wanting to learn more about the issues and operation of the board by attending this 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 of the board meeting to earn the continuing education credit and no partial credit will be given for attendance at part of a meeting. President Jones added that three hours of continuing education credit could also be earned by pharmacists who attend the Enforcement Workshop scheduled during the board meeting on Thursday.

- **Recognition**

  President Jones acknowledged former Board Member and Board President Steve Litsey, who was present in the audience. He also welcomed pharmacy students from USC, Western University and UCSD who were in attendance.

COMMITTEE REPORTS AND ACTION

Organizational Development Committee

President's Report

- **Election of Vice President**

President Jones announced that former board vice president Don Gubbins' term ended in July 2003 creating a vacancy.

MOTION: Nominate Stan Goldenberg as vice president.

M/S/C: TILLEY/HIURA

MOTION: Close the vice president nominations.

M/S/C: HIURA/TILLEY

SUPPORT: 10 OPPOSE: 0

- **Report on the Meeting of January 9, 2004**

Chairperson Tilley reported on the Organizational Development Committee Meeting of January 9, 2004. He thanked Stan Goldenberg for his input on budget matters and he thanked Patricia Harris and Virginia Herold for their hard work.

- **Annual Update of the Board's Strategic Plan**

Chairperson Tilley reported that each year the board reviews and updates its strategic plan. This revision typically occurs during the April Board Meeting during the annual public meeting of the Organizational Development Committee.

Chairperson Tilley stated that last year, a major revision of the strategic plan was undertaken that substantially restructured the plan. Lindle Hatton, PhD, led the board in this process. At the time of the revision (which actually was initiated in 2002 and completed in 2003), the board's intent was to make minor updating changes to the strategic plan in 2004 and undertake a major revision in 2005. This is consistent with the direction provided by Dr. Hatton that generally strategic plans should endure for more than one year in their scope and vision, and should be focused on three to five years.

MOTION: Organizational Development Committee: That the board perform its annual update of its strategic plan this year by directing each committee to review its plan during the next quarterly meeting and bringing any changes to the April 2004 Board Meeting for discussion, modification and adoption into the strategic plan for 2004.

SUPPORT: 10 SUPPORT: 0

- **Proposed Technical Amendments to Clarify Renewal of a Permit and Scholarship Donations**

Chairperson Tilley stated that several years ago, a California Pharmacist Scholarship and Loan Repayment Program was established whereby pharmacists and pharmacies could donate funding for scholarships for pharmacy students. This donation would be made at the time a pharmacist or pharmacy renews his/her/its license. The amount of this donation was established as $25 in the statute. In establishing cashiering parameters, the department concluded that contributions over $25 could not be accepted and the full amount of the donation would need to be returned.

Chairperson Tilley stated that to permit pharmacists and pharmacies to donate more than $25, the statute needs to be amended.

Dr. Fong asked how much the board has collected so far.

Ms. Herold responded that the board has not collected very much because the renewal notice does not include a statement announcing that a donation to this fund can be made. The board requested that the department revise the renewal form to include this statement and it is anticipated that the new renewal notice will be ready by February or March 2004.

Ms. Herold stated that once the board receives this donation, the money is transferred to the Office of Statewide Health Planning and Development, which is charged with handling the fund. This fund is designated for pharmacists in underserved areas, once the balance is sufficient to start the program. Ms. Herold added that the board could remind licensees about the scholarship fund in future newsletter articles.

Dr. Fong asked for more information about how the Office of Statewide Health Planning and Development will administer the fund.

MOTION: Organizational Development Committee: Add proposed amendments to Business and Professions Code section 4009 to permit pharmacists and pharmacies to donate more than $25 to a scholarship fund that would assist pharmacists and pharmacies serving underserved areas as follows:

At the time a pharmacy license is renewed pursuant to subdivision (a) of Section 4410 or a pharmacist license is renewed pursuant to Section 4401, the pharmacy or pharmacist may make a ~~twenty five dollar ($25)~~ contribution~~,~~ <u>of at least twenty-five dollars ($25)</u> to be submitted to the board, for the sole purpose of funding the California Pharmacist Scholarship and Loan Repayment Program established pursuant to Article 5

(commencing with Section 128050) of Chapter 2 of Part 3 of Division 107 of the Health and Safety Code. The contribution submitted pursuant to this section shall be plaid into the State Treasury and credited to the California Pharmacist Scholarship and Loan Repayment Program Fund established pursuant to Section 128051 of the Health and Safety Code.

SUPPORT: 10 OPPOSE: 0

Chairperson Tilley stated that technical amendment is needed to section 4403 to conform the language to current usage. The board generally "renews" rather than "reissues" licenses.

MOTION: Organizational Development Committee: Add a technical amendment to Business and Professions Code section 4403 as follows:

4403: The board shall not reissue <u>or renew</u> any license without the payment of the fees required by this chapter and the payment of all fees that are delinquent at the time that the application is made.

SUPPORT: 10 OPPOSE: 0

- **NABP Staff Recommendation that the Board Become a Full Member of NABP**

Chairperson Tilley stated that staff of the National Association of Boards of Pharmacy has recommended that the board become a full member of the NABP because California is now using the NAPLEX to assess minimum competency in pharmacists as a condition for licensure, and accepting score transfers of NAPLEX exams for candidates who have taken the NAPLEX after January 1, 2004.

Chairperson Tilley stated that full membership in the NABP would allow the board to vote in matters before the NABP, a right the board does not currently have as an associate member. This would provide the board with a greater role in the development of national policies regarding pharmacists' care. This determination will be made by the vote of the NABP executive staff in the near future.

Chairperson Tilley stated that the Annual Meeting of the NABP is set for April 24 –28 in Chicago. The committee encouraged board members who can afford to go on their own to attend this meeting. Current budget restrictions will make it nearly impossible for the board to receive funding for any board member or the executive officer to attend. However, this national meeting will allow the board to participate in evolving

national policy of state boards of pharmacy on such key areas as importation of drugs and the regulation of wholesalers.

Dr. Fong stated that he plans to attend the NABP annual meeting. His expectation is that California will take an active role within the group.

Mr. Cronin asked what the status of the board's inclusion on the NABP exam committee is.

President Jones stated that California has three members out of 30 on the NABP exam committee who are knowledgeable about the California exam and are former members of the board's Competency Committee. He added that the California members are valued for their input.

- **Budget Update for 2003/04**

Chairperson Tilley reported that the state continues to face a huge budget deficit this year and projections continue to forecast deficits for the future. The Davis Administration issued several cost containment requirements that have impacted the board's budget this year. Since July 1, 2003 (the beginning of this fiscal year), the board has:

- Lost six positions vacant on June 30, 2003.
- Identified a 12 percent (or $420,000) cut in Personnel Services. Most of this was linked to the loss of the six positions; additionally $12,000 in board member compensation was lost as was all overtime and $9,000 from operating expenses. No staff at the board was laid off to meet the 12 percent reduction.
- Been advised that it cannot purchase three vehicles to replace existing vehicles assigned to inspectors (these vehicles were scheduled for replacement last year).

The Governor has issued two executive orders regarding the budget – one extends the hiring freeze through June 2004, the other directs agencies not to contract for goods or services or to undertake unnecessary travel.

Mr. Powers referred to the $12,000 the board lost in board compensation and $9,000 lost from operating expenses and stated that the board is self funded and questioned why this money was lost, and where it went.

Ms. Herold responded that the board has lost its ability to spend the money – the board's spending authority for the years was reduced this much. The money has been returned to the board's special fund.

Ms. Herold reported that Board Inspector Rosemarie Yongvanich, who was on parental leave, recently decided not to return to work. The board will seek a freeze exemption to hire someone to fill the vacancy.

Dr. Fong asked how these reductions affect the board's ability to respond to the public about application status and general licensing questions.

Ms. Harris referred to the Licensing Committee report for the implications of these reductions. She added that because of the change in law for technicians, the board received over 1000 applications in December, and with only one technician to process the applications, the board had to creatively manage this workload by turning off the phones and by scheduling other office staff to answer the phones. This resulted in staying on top of the application process. However, because the board will begin using the NAPLEX examination and has already received many applications, the board must once again redirect the workload. The goal is for the entire process to run more smoothly, once the programs are up and running.

Ms. Harris explained that because so few staff are assigned to process applications, the board is unable to handle all of the application status calls it receives. Answering these calls reduces the amount of applications that can be processed on any day, which delays application processing overall, which further leads to increased status calls. She added that during the next few months as the board transitions through the new exam structure, the board would continue to keep the Web site updated with new exam information as well as application processes and timelines for status calls to the board.

Ms. Harris stated that in spite of these difficult working conditions staff work hard to keep on top of the process. She commended the Licensing Unit staff on their efforts.

Revenue for 2003/04

The board's projected revenue for the year is $5,640,544. This is comprised of $5,420,423 in fee revenue and $220,121 in interest.

Actual fee revenue is likely to be approximately 10 percent higher than the $5.4 million, but interest revenue will be substantially less (this figure is calculated by the Department of Finance, and is $100,000 more than last year's actual interest income, which was collected on a larger balance in our fund).

Not included in the projections is revenue from citations, which as of early December was $470,000.

Expenditures for 2003/04

The most recent estimates prepared by the Department of Consumer Affairs (December 2003) now set maximum expenditures for the year at $7,000,486. This figure includes the 12 percent reduction in personnel expenditures.

Budget detail:

- Personnel is still the largest component in the budget, comprising 49 percent of board expenditures.
- Enforcement expenses (excluding enforcement staff salaries) are 14.9 percent.
- Pro rata charges for DCA and the state are 13.7 percent of our budget (by comparison, in 1998/99 pro rata was 11.2 percent of our budget).
- Travel is budgeted for $167,011 (2.4 percent), which is nearly equal to last year's actual travel expenses of $165,294, but nearly $20,000 less than the board spent for travel in 2001/02. (In fact, travel has been steadily decreasing since 1998/99, when it was $228,235.)

Board Member Expenditures and Reimbursements

Update: Board Fund Condition

Last year the board loaned $6 million from its fund (the board's "savings account") to the state's General Fund. Repayment of this loan is required if the board will enter a deficit situation.

This year, the board is expected to spend at least $1.3 million more than it projects it will collect in revenue. As such, the amount of money in reserve in the board's fund is important.

Current projections are that the board will not have a deficit in its fund until early in 2005/06.

Budget Change Augmentations for 2003/04 and 2004/05

The board must prepare a "budget change proposal" to increase its budget for resources and staff. The board is not seeking any augmentations for 2003/04 or 2004/05 due to the state's budget crisis.

The board will have to continue to provide services to a growing licensee population with existing staff and existing resources. However, workload priorities will continue to result in changes in how the board performs duties. For example, the board has changed its telephone system to provide callers with more automated answers to their questions, and restrict the immediate access of callers to the board's receptionists. Additionally, all staff is being assigned to answer the phones for four hours at least once per month as a means to respond to the calls that we do receive in light of staffing reductions.

- **Status Update on Department of Consumer Affairs Internal Audit on the Board**

  Chairperson Tilley reported that a number of recommendations for the board were made as part of the board's sunset review process during 2002/03. The Joint Legislative Sunset Review Committee (JLSRC) and Department of Consumer Affairs issued a number of joint recommendations, and then each made several additional recommendations for the board. The Organizational Development Committee has been tracking these recommendations, and the board has initiated the work and completed most of it.

  Several of the initiated recommendations deal with public education and outreach, and work is now underway on these items. Another recommendation, making all committee meetings of the board public, will be partially implemented. All committee meetings of the Enforcement, Licensing and Communication and Public Education Committees will be public. At least two meetings of the Legislative and Regulation Committee will be public meetings. At this time, plans are that only one meeting each year of Organizational Development Committee will be noticed as a public meeting.

- **DCA's Internal Audits Office – Assessment of the Board's 180-Day Post Audit Status Report**

  Chairperson Tilley stated that as part of the sunset review, the department's Internal Audit Office reviewed the board's operations from October 2002 to 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 Organizational Development Committee also has been tracking these recommendations to review board progress. In October 2003, the committee prepared a copy of the board's status report 180 days after the audit. Progress reports to the department on the board's actions to incorporate the recommendations are required at six months and 12 months.

  Since the October Board Meeting, the Internal Audits Office has audited our 180-day status report. In early December the office issued its assessment. Of the four initial findings, the auditors indicate that the board has:

  1. Ongoing assessment and evaluation of its fund condition is in place to prevent a deficit in the fund.
  2. Partially completed inventory controls for destroying outdated evidence and posting signs regarding the board's evidence storage.

3. Tracking systems in place for monitoring processing of applications, but the board would benefit if a single, integrated tracking system existed for all of its 12 programs (the board is relying on the department to provide such a system).
4. Fully implemented changes to the automated complaint tracking system.

The auditors also stated their intent to audit all the board's activities when assessing its 360-day progress report.

- **Transition to the New Administration**

Chairperson Tilley stated that the Schwarzenegger Administration began November 17, 2003. A few new appointments have made thus far changing key administrators – Medical Board Executive Director Ron Joseph has been appointed interim director, replacing Kathi Hamilton. Former legislator Fred Aguiar began work as Secretary of the State and Consumer Services Agency on January 5. A new press officer has been appointed to replace former Deputy Director Mike Luery, who left state service.

Several executive orders have been issued dealing with budget matters and regulations.

1. **Executive Order S-2-03 – Regulations**

This executive order suspends all pending rulemaking proceedings for six months. The order requires a list of all regulations adopted during the Davis Administration, and each agency to prepare a list of any "underground" regulations.

The board's Legislation and Regulation Committee will discuss this executive order more fully during its report at this meeting.

Mr. Powers expressed concern that an exemption to submit sterile compounding regulations were denied by the agency, which will require the whole rulemaking to start over with a 45-day initial notice. He stated that this could cause considerable harm to patients. He added that the board should speak to those responsible regarding this type of irresponsibility.

Chairperson Tilley stated that the board's staff is working with the department's legal counsel to rework the exemption request.

2. **Executive Order S-3-03 -- Hiring Freeze**

The Governor continued the hiring freeze established by Governor Davis in 2001. In the case of the board, this means that the board could not fill

vacancies by hiring anyone who is not already a board employee, nor could the board promote staff into any vacant position at the board without a freeze exemption issued by the Department of Finance. Currently the board has no vacancies, should one occur, the board could not fill the position unless a freeze exemption was issued, and then the board would have to hire employees on the state layoff list. All positions vacant for six months are eliminated. The order will expire in June 2004.

3. **Executive Order S-4-03 – Contracts and Nonessential Travel**

   This executive order prohibits state agencies from contracting for goods and services without an exemption unless the contract is for legal services or expert testimony in pending litigation. The Department of Consumer Affairs recently secured an exemption for special fund agencies in the department from this order – agencies such as the board. As such the board can continue to enter into contracts, which is fortunate because without an exemption, the board would not have been able to obtain signed contracts to administer the NAPLEX or the California jurisprudence examination.

   However, the board still must make certain it does not undertake unnecessary or nonessential travel. Currently the only definition provided for this is travel to conferences, training or seminars.

- **Loss of Professional Licensing and Enforcement Management System**

  The Department of Finance suspended financing to continue work on implementing the department's proposed Professional Licensing and Enforcement Management System (PLEMS), a new computer system to replace the primary computer system CAS, which had been created in the early 1980s. The Department of Finance was not convinced that the proposed project was an essential information technology activity and had issues that require the Department of Consumer Affairs to conduct additional research. The department has suspended work on this new system, so the project is at least inactive, if not dead.

  Computer systems that provide licensing and enforcement data are essential. The board has requested that the department redirect staff from the PLEMS project to the programming unit of CAS to allow the existing system to be modified.

- **Personnel Update**

  As discussed earlier, all vacant positions on June 30th were eliminated. The board lost six positions, but currently has no vacancies.

- **Mandatory Ethics Training for Board Members and Designated Staff Must Be Completed in 2003**

  Chairperson Tilley commended all board members and designated staff that have completed the state-mandated ethics training as required before January 1, 2004.

  Everyone required to complete this training did complete it.

APPROVAL OF MINUTES

Full Board Minutes
(October 29 and 30, 2003

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

MOTION: Approve the October 29 and 30, 2003, Board Meeting Minutes

M/S/C: GOLDENBERG/HIURA

SUPPORT: 8 OPPOSE: 0

Communication and Public Education Committee

Chairperson Powers reported on the public meeting of January 8, 2004. He added that this was the first public meeting held independently from a board meeting. There were three public members present.

- **Web Site Redesign**

  Chairperson Powers reported that at the October Board Meeting, the board approved a recommendation from the committee that the board sponsor a contest for pharmacy students to redesign the board's Web site. This was in recognition that the Web site needs to be updated and pharmacy students, who often have much creativity in designing Web sites, would greatly benefit by working so closely with the information the board places on the Web site. As a result both the board and pharmacy students would benefit and the board would have an attractive and redesigned Web site.

  Chairperson Powers stated that the following the board meeting, staff researched requirements for California government Web design. There are at least 80 pages of requirements that provide little room for creativity. The goal is that the Web pages for each state agency be similar, and not contain fonts that are difficult to read, and graphics or other features that can slow the loading of a Web page by computers without fast modems or large memories.

Chairperson Powers stated that after reviewing about 25 of these pages of requirements, the committee determined that the Web design contest might not be the best way to go because the board is not likely to be able to install designs created by students.

He stated that as an alternative, the committee discussed other ways to integrate pharmacy students into public outreach activities so that students may share their knowledge and enthusiasm. One suggestion is to have students develop new public education materials on specific topics they learn about during their internships or classes, or topics that are emerging public policy matters (e.g., flu vaccines: inhalation forms vs. shots). If the board develops a prototype template/format for a series of fact sheets, each student could complete the information and be acknowledged with a credit at the bottom of the fact sheet. The board could check the accuracy of the information and assure it is written at an appropriate reading level.

Ms. Herold distributed a copy of such a prototype fat sheet. Those students who prepare the fact sheets would be acknowledged on each fact sheet, which would benefit their resumes. And via the availability of the information, the public and the board would benefit. The standardized format would make it easy for students and the board to develop and produce, and easy for the public to reference.

MOTION: Communications and Public Education Committee:
That the board discontinue its plans to sponsor a web design contest among pharmacy students, and instead identify another public outreach activity that would involve pharmacy students in the board's public education program.

SUPPORT: 10 OPPOSE: 0

- **Emergency Contraception Fact Sheet**

Chairperson Powers stated that at the last board meeting, the board approved a new Emergency Contraception Fact Sheet for use by pharmacists who provide emergency contraception under protocol. This new fact sheet has been placed on the board's Web site and will be published in the next issue of *The Script.*

Since the last meeting, the Pharmacy Access Partnership translated the fact sheet into nine languages – Cambodian, Chinese, Farsi, Hmong, Korean, Russian Spanish, Tagalog and Vietnamese. These versions will also be added to the board's Web site.

- **Update on *The Script***

Chairperson Powers stated that articles for the January 2004 issue of *The Script* have been written and are undergoing review. This issue should be published in late February. The articles will feature new laws (for example, new pharmacy technician requirements, new pharmacist licensure exam requirements, new requirements for prescribing and dispensing controlled drugs).

Chairperson Powers added that the Education Foundation of the CPhA printed and mailed the October 2003 *The Script* to pharmacists in November. The Education Foundation will also print and mail the January issue of *The Script* to pharmacists once it is available.

- **Update on *Health Notes***

Chairperson Powers stated that staff is now working to publish a wholly new Pain Management issue early in 2004, probably April. This new issue will contain new pain management therapies and the new prescribing and dispensing requirements for controlled drugs enacted by SB 151 (Burton, Chapter 406), which will take effect in 2004 through 2005 in sequential stages.

Chairperson Powers stated that staff is coordinating the development of this issue. Authors have been selected and have agreed to write specific articles, which are due at the end of January. After this, each article will be reviewed and edited by an appropriate expert, and then the edits reviewed by the authors. The board will also review the articles (Ken Schell has agreed to do this), as will the Legal Office. The same graphic designer who has designed all other *Health Notes* is available to design the issue.

Chairperson Powers stated that the board is seeking outside funding sources for this issue. Because of the interest in pain management and in the new changes to prescribing of controlled substances, there is much interest and support for this issue.

The issue also will be of interest to physicians, nurse practitioners, dentists and other prescribers.

Mr. Goldenberg stated that he encourages a proactive approach while developing the *Health Notes* by addressing anticipated questions, possibly with a section for questions and answers in each issue. Also, to provide meaningful examples describing different types of pharmacy practices.

Ms. Harris stated the board is also working with companies to develop interactive continuing education programs to get information out regarding new laws and procedures. The board has also met with other prescribing boards that have agreed to include some of the Board of Pharmacy's articles in their publications. She added that the board is working closely with the profession and the industry in getting the word out regarding the new enactments of SB 151.

President Jones stated that support from commercial interest is also involved to assure that pharmacists, prescribers and others have an understanding of the new laws on the proper use of pain medication.

- **Development of New Public Education Materials**

Chairperson Powers stated that during the Communication and Public Education Committee Meeting, the committee discussed patient medication compliance and the compliance problems caused when patients cannot read a prescription label because the patient cannot read English or perhaps see the label itself.

Chairperson Powers stated that Pharmacist Robert Siedman, who deals with patient issues for a large health maintenance organization, was one of these active participants as was Daniel Temianka, M.D., of HealthCare Partners Ltd.

Chairperson Powers stated that he invited Drs. Temianka and Seidman to the board meeting so that they could participate in a discussion with the board on ideas for improved patient compliance by improved prescription labels and more meaningful, useful labels for patient reference and use. Unfortunately, they were unable to attend the meeting.

Chairperson Powers stated that Dr. Temianka and Dr. Seidman stated that certain patients could benefit by requesting specialized prescription labels on their medication containers so that those who cannot read English or those who are visually impaired can receive their medications in containers they can read. Whereas this is not a suggestion for a mandate for labeling in a patient's native language or to accommodate a patient's visual needs, in those cases where the pharmacy can readily provide such a label, the proposal is to educate patients that they should ask for such labels on their prescription medications. There are also concerns that endanger patient health that arise from a patient's low literacy, complicated or unclear language on prescription labels in general, and the legibility of the font size used on labels.

Chairperson Powers stated that he strongly supports the introduction of legislation to require labels be printed in a patient's predominate language and in readable fonts.

Chairperson Powers added that discussion also included whether there could be better containers to provide medication to patients in other than the prescription containers used so predominately today. Different types of containers or packages for prescription drugs could facilitate improved or more helpful labeling for patients.

Dr. Fong referred to a two-year bill that would require every pharmacy to have an interpreter. He suggested that the board work with the sponsor of the bill on this.

President Jones questioned whether licensees have the ability to effectively handle the public with their prescription needs in this multi-cultural society. He asked how it is addressed in pharmacy school admissions.

Sam Shimomura, representing Western University, stated that all California pharmacy schools have a very diverse student body where 55 percent of the students are foreign born and English is their second language.

Steve Gray, representing Kaiser Permanente, stated that the only solution is to have translation services available. He added that pharmacists participating in federally funded programs are already required by federal law to have translation services available to every patient. This specifically refers to Medicare programs.

- **Public Outreach**

The board's continuing education course has been provided to eight local meetings of pharmacists since January 2003.

LICENSING COMMITTEE

Chairperson Hiura reported on the meeting of December 3, 2003.

- **Approve of Statewide Protocol for Pharmacists to Furnish Emergency Contraception (Implementation of SB 490 (Alpert) Chapter 651, Statutes of 2003)**

Chairperson Hiura stated that Senate Bill 490 (Chapter 651, Statutes of 2003) permits pharmacists to furnish emergency contraception medications based on a statewide protocol adopted by the Board of Pharmacy and the Medical Board of California. Prior legislation (Senate Bill 1196, Chapter 900, Statutes of 2001) permits pharmacists to furnish emergency contraception medications to patients based on a protocol with a single licensed prescriber.

Chairperson Hirua reported that the proposed draft protocol presented for board review synthesizes elements from protocols submitted by the Pharmacy Access Partnership and the American College of Obstetricians and Gynecologists. Staff also reviewed protocols from the states of New Mexico and Washington and a sample protocol used by pharmacists under the existing protocol requirements.

The draft protocol was prepared with the intent to keep it simple and to comply with the statutory requirements established by Senate Bill 490. Both the Board of Pharmacy and the Medical Board of California must approve the protocol. The Medical Board of California is awaiting Board of Pharmacy action before considering the protocol at its next board meeting in several weeks at its next board meeting in several weeks.

The draft protocol has the therapy as two doses administered 12 hours apart within 72 hours of engaging in unprotected sex. However, recent studies indicate that emergency contraception drug therapy remains substantially effective up to 120 hours after unprotected sex and one emergency contraceptive product (Plan B) can be administered in a single dose. While the efficacy of emergency contraception declines over time, it remains approximately

80 percent effective when taken within 120 hours. The newer timing and dosing regimens would expand access to emergency contraception that is important and the single dosing of Plan B would greatly aid in patient compliance with the therapy. The studies support no increased risk or side effects to the longer time period or the altered dosing regimen.

Language authorizing a pharmacist to dispense condoms was removed from the proposed; however, the consensus of the board was that this language should be added back in because many health plans would cover the cost of condoms with a prescription.

Shannon Smith-Crowley, representing the American College of Obstetricians and Gynecologists, referred to their concerns outlined in a letter dated January 13. She added that one objection to the standardized protocol is asking a woman for the date of her last menstrual period in order to rule out pregnancy. She stated that there are only two questions the pharmacist needs to ask patients to establish the appropriateness of the medication and that is whether the woman is allergic to any drug and whether she has had unprotected sexual intercourse within 72 hours.

Ms. Smith-Crowley stated that the EC Fact Sheet states that EC is most effective if taken within three days of unprotected sex and pharmacists should counsel clients that "EC effectiveness declines gradually over 5 days" (120 hours). She added that recent studies show that within the 5-day period EC may still be effective. She requested that the protocol reflect the 3-day period until all concerned parties agree on changing the timing to 5 days, at which time the fact sheet could also be changed.

Kathy Bessinque, representing Pharmacy Access Partnership, stated that as a pharmacist, she provides EC. She requested that the language asking the date of the last menstrual period be left in the protocol because it gives the pharmacist an opportunity to open a dialogue with the patient about if pregnancy is established, and to refer the patient as part of patient counseling.

Mr. Riches informed the board that Executive Director Jane Bogess of the California Access Partnership had unexpectedly passed away over the weekend. Mr. Riches recognized her efforts in this project and he stated that the California Access Partnership was a driving force in the emergency contraception law in California.

President Jones also recognized Ms. Bogess' extreme dedication to the coalition and added that she was very active in promoting pharmacy access throughout California. She will be missed.

MOTION: Licensing Committee: Approve the proposed statewide protocol for emergency contraception with the request that the board consider modifying the protocol to include the Plan B therapy of a single dose within 5 days.

SUPPORT: 1 OPPOSE: 9

MOTION: Approve a statewide protocol for emergency contraception to include the Plan B therapy of a single dose within 5 days and to include language authorizing the pharmacist to dispense condoms under a prescription to ensure payment by a health plan.

M/S/C: POWERS/BENSON

SUPPORT: 10 OPPOSE: 0

- **Proposed Statutory Changes To The Intern Program.**

Chairperson Hiura stated that the Licensing Committee reviewed the intern program during the last two meetings. Based on the committee's review and discussions, staff drafted modifications to the program. The modifications were drafted as a statute because current intern requirements are in regulation and should be in statute. The changes include the following: a ratio of two interns to one pharmacist (this is consistent with current board policy), the requirement that the pharmaceutical experience comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education and the elimination of the extension provision for the intern permit and the definition of a preceptor.

Chairperson Hiura stated that during the committee meeting, the public recommended proposed changes. The committee agreed with the recommended changes and directed staff to modify the language accordingly. The proposal was modified and shared with interested parties for comment. He added that staff received feedback and some additional language changes and some of the changes were added and reflected in the proposed language.

Mr. Goldenberg referred to the elimination of the extension provision for the intern permit and the definition of a preceptor and asked for clarification.

Ms. Harris stated that the intern provisions are in regulation. She stated that many years ago the board registered preceptors and when this role was eliminated, a statute provision replaced the regulation to allow for a pharmacist in good standing to supervise an intern.

Ms. Harris stated that the regulation on intern license extensions reads that the board can issue an intern permit up to five years; these longer permits are usually to first year students entering pharmacy school. Upon graduation, if the student does not take the exam right away or has trouble passing the exam, the board has the authority to extend the intern permit for another year or two. She added that the board is recommends a statute provision that the board can issue an intern permit from one to six years. Another is to add a provision that the board could issue an intern permit to a pharmacist who wants to reinstate a pharmacist license.

Steve Gray, representing Kaiser Permanente, referred to section 4209(b) of the Business and Professions Code and suggested changing the word "while" to "where" as follows: … pharmacist-in-charge at the pharmacy ~~while~~ where the pharmacist intern obtained the experience. This would allow a pharmacist-in-charge to sign an affidavit based on knowledge and a review of the training records of the facility.

MOTION: Licensing Committee: The Board of Pharmacy approve statutory changes regarding the intern program.

SUPPORT: 0 OPPOSE: 10

MOTION: The Board of Pharmacy approve the statutory changes regarding the intern program by adding proposed Section 4209 (b) of the Business and Professions Code as follows:

4209. (a) An intern pharmacist shall complete 1,500 hours of pharmaceutical experience before applying for the pharmacist licensure examination.
(1) This pharmaceutical experience must comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education or with regulations adopted by the board.
(b) An intern pharmacist is required to submit proof of his or her experience on board approved affidavits, which shall be certified under penalty of perjury by a pharmacist under whose supervision such experience was obtained or by the pharmacist-in-charge at the pharmacy where the pharmacist intern obtained the experience.
(c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, shall be exempt from subdivision (a). Certification of an applicant's licensure in another state shall be submitted in writing and signed, under oath, by a duly authorized official of the state in which the license is held.

M/S/C: GOLDENBERG/BENSON

SUPPORT: 10 OPPOSE: 0

- **Approval of New School of Pharmacy at Lake Erie College of Osteopathic Medicine**

Chairperson Hiura stated that the board received an intern pharmacist application from a student at Lake Erie College of Osteopathic Medicine, School of Pharmacy. This is a new school, which provides an accelerated Pharm.D. program, which can be completed in three years. The first students admitted into this program are currently in their second year of instruction.

President Jones stated that this request was received by the board after the December 3, 2003, Licensing Committee Meeting and consequently does not have a recommendation from the committee. He anticipated similar requests as new schools are opened in the United States.

Ms. Herold stated that according to the Accreditation Council for Pharmacy Education (which until several months ago was known as the American Council on Pharmaceutical Education) or ACPE, this program was ranked by that agency as "Pre-candidate Status."

Pre-candidate status is the lowest of the ACPE provisional accreditations, and students who graduate from such a school would not be eligible for pharmacist licensure in most states. The ACPE states that pre-candidate schools have the concepts of an acceptable ACPE program committed to paper, but the program components have not yet been fully implemented.

"Candidate Status" is the next provisional level of ACPE accreditation, which would allow graduates from such a school to become licensed pharmacists. In order to be fully ACPE accredited, the school must have graduated one class of students, among other conditions.

Internship is an integral part of the pharmacy education of students, and students need intern permits to gain experience. Students could be at risk in new programs where state licensing agencies look for ACPE accreditation as a means to assure the students are receiving approved educational coursework as a condition of issuing an intern license. The public could be at risk if substandard training and education have been provided to interns.

California Code of Regulations sections 1719, 1727 and 1729 require that intern licenses may be issued only to those students who attend ACPE or board-approved schools of pharmacy, and admission to the pharmacist licensure examination to graduates from ACPE or board-approved schools.

Ms. Herold reported that over the weekend, the ACPE did provide "Candidate Status" to the Lake Erie College of Osteopathic Medicine. She added that this is still viewed as a provisional accreditation.

MOTION: Recognize the School of Pharmacy at Lake Erie College of Osteopathic Medicine for purposes of issuing intern licenses, accepting intern hours and accepting intern hours and accepting the degree granted by the school of pharmacy.

M/S/C: POWERS/TILLEY

SUPPORT: 10 OPPOSE: 0

- **Workgroup with the Department of Health Services – State Food and Drug Branch on Pharmacy Compounding**

Chairperson Hiura stated that last April, the Board of Pharmacy agreed to form a workgroup with the Department of Health Services, State Food and Drug Branch to address pharmacy-compounding issues, including criteria used by the board to determine when compounding falls outside the scope of pharmacy practice. Because the Food and Drug Branch licenses manufacturers in California, they communicated the importance of their understanding of how the board notifies individuals when pharmacy-compounding activities falls outside the scope of pharmacy practice.

Chairperson Hiura stated that it was agreed to establish this workgroup upon the conclusion of the committee's review of Pharmaceutical Benefit Management Companies (PBMs), and was added as a committee strategic objective.

The Licensing Committee has begun the formation of the workgroup and President Jones has appointed Board Members John Tilley and Ken Schell, and Supervising Inspector Dennis Ming, to the committee. The meeting will be public with all interested parties invited to attend.

- **Final Report on the Study on the Evaluation of Pharmacy Technicians in a Unit-Dose Drug Distribution System**

Chairperson Hiura stated that in May 1998, the Board of Pharmacy approved a study on the evaluation of pharmacy technicians in a unit-dose distribution system. The UCSF School of Pharmacy coordinated the study in conjunction with Long Beach Memorial Medical Center (LBMMC) and Cedars Sinai Medical Center (CSMC). The study ended on December 31, 2003.

The Board of Pharmacy originally granted a waiver for the study pursuant to CCR section 1706.5 and the study was approved until November 1, 2000. Because of the delay in starting the study, the board extended the waiver until February 2001, and requested that UCSF, LBMMC and CSMC present the final report at its January 2001 meeting. When the final report was presented, the board agreed to extend the study another two years so that the study could be made permanent either through regulation or legislation.

Peter Ambrose, Pharm.D., Associate Clinical Professor for UCSF, School of Pharmacy, presented the final report on the study on the evaluation of pharmacy technicians in a unit-dose drug distribution system.

Dr. Ambrose thanked the board for the opportunity to speak and stated that the study was published in the American Journal of Health System Pharmacy, following peer review.

Dr. Ambrose explained the process of technicians checking technicians as outlined in the final report.

Dr. Ambrose reported that during the study, all certified technicians at both institutions passed all of the quality assurance audits. Further, no medication errors were reported as a result of technicians checking unit dose medication cassettes.

Dr. Ambrose stated that as the primary investigator of the study, he concluded that medication technicians accurately checked the unit dose medication cassettes filled by other technicians, after they have been trained and certified in a closely supervised program that incorporated quality assurance audits. Freeing the pharmacists from this activity allowed them to devote their time to other activities such as managing drug therapies for better patient care. He added that Cedars Sinai Medical Center and Long Beach Memorial provided statistics on what the pharmacists actually do and what type of clinical services that they do. He added that the study ended in December 2003. Now the pharmacists have returned to the duties of checking unit dose medication cassettes.

Dr. Ambrose thanked the board for approving the waiver. He added that they hope that the data provided will be helpful to the board when it considers issues regarding technician-checking technicians.

John Cronin, representing the California Pharmacists Association, stated that when the technician-checking-technician concept was first proposed, it was proposed as a change in regulations. CPhA had two arguments against it as a regulatory change. One argument was concern for pharmacists in hospital settings where technicians were qualified to do this, which this study addresses. The second argument was that such a change would require statutory action rather than regulation change.

Ms. Harris clarified that the board has the authority to waive regulations under experimental studies to advance the profession under CCR 1706.5, as such. the board waived a regulation to permit the technician checking technician study.

Steve Gray, representing Kaiser Permanente, stated that because more data is available and the results favor patient safety and freeing up the pharmacists to do pharmacists' care functions; the board could reexamine this issue and consider if this could be a regulation change.

Sally Chong, representing Prescription Solutions, expressed concern that technicians may not be experienced enough to accurately screen for medication errors if they are the individuals who review prescription orders.

The board asked the Licensing.Committee to review the issue of technicians checking technicians and report back to the board.

- **Acknowledgment of Students**

President Jones welcomed the many students from three schools of pharmacy, who were attending the board meeting and asked them to introduce themselves and name the school they attend.

- **Implementation of NAPLEX and California Specific Examination**

Chairperson Hiura stated that staff has worked diligently to assure that the new examination structure will be in place as soon as possible. The contracts for the NAPLEX and the California Pharmacist Jurisprudence Examination are in the final stages of completion. The goal is to be able to issue licenses to pharmacists who have taken (and passed) the new examinations by the end of March 2004. This would coincide when the board would have been able to license pharmacists had they taken the board's prior exam.

Applicants who take the NAPLEX after January 1, 2004, will have their scores available to the board if they designate California as a score transfer state before they actually take the examination. Once the contract is signed with the NABP, the score will be transferred to the board.

The board plans to administer the California Pharmacist Jurisprudence Examination via computer terminals in March 2004. The board will use the examination vendor under contract with the Department of Consumer Affairs for this portion of the examination instead of the NABP. The Competency Committee has developed a sufficient item bank of test questions for the new content outline for the examination, a significant task that required monthly meetings since August. The examination items are ready. Information about the examination is on the board's Web site and it is updated periodically. There is a question and answer section on the board's Web site to help candidates understand the process, and the new application forms are on the Web site as well.

President Jones acknowledged Kathy Bessinque and Holly Strom, members of the Competency Committee, who were present.

President Jones reported that the board has placed three members on a 30-member test committee who are actively involved in the NAPLEX development.

- **Update on the Changes to the Pharmacy Technician Program**

Chairperson Hiura stated that beginning in January 2004, changes to the licensure requirements for applicants seeking registration as pharmacy technicians took effect. These changes were the result of SB 361 (Figueroa, Chapter 361, Statutes of 2003).

Specifically, changes in Business and Professions Code section 4202 (a) alter the qualifying methods an applicant must satisfy to become registered. To be issued a technician registration, an applicant now must satisfy one of the following criteria:

- Obtain an associate's degree in pharmacy technology;

- Complete a course of training specified by the board (this is 240 hours of theoretical and practical training provided by a technician training school or by an employer);
- Be a graduate of a school of pharmacy accredited by the ACPE; or
- Be certified by the Pharmacy Technician Certification Board (PTCB).

- **Future Meeting Dates of the Licensing Committee**

Chairperson Hiura announced the Licensing Committee meeting dates for 2004:
March 3, (in Oakland). Also, June 9, September 22 and December 1; these meetings will be held either in Oakland or Burbank.

ENFORCEMENT COMMITTEE

Mr. Powers reported on the Enforcement Committee Meeting of December 10, 2003.

- **Statutory Proposals Regarding Wholesale Licensure Requirements and Wholesale Drug Transactions**

Mr. Powers stated that the Enforcement Committee is in the process of developing rules designed to strengthen the regulation of drug wholesalers. The committee considered a number of different proposals. Based on discussions at prior committee meetings and discussion at the October 2003 board meeting, staff developed a legislative proposal for the committee's consideration. The proposal includes elements that have been considered previously, particularly expanded citation and fine authority for certain violations, and elements drawn from recent legislation passed in Florida. The recent Florida legislation focused on preventing the introduction of counterfeit drugs into the system by implementing stricter licensing requirements for drug wholesalers, increasing the criminal sanctions for counterfeiting prescription drugs, and requiring pedigrees.

Additionally, the National Association of Boards of Pharmacy (NABP) has issued a "draft" model rule for the licensure of wholesale distributors.

Mr. Powers stated that the proposal is designed to address challenges presented by the existing distribution system for prescription drugs. The principal elements are:
- Require pedigrees for all drug shipments beginning January 1, 2007.
- Prohibit the wholesaling of prescription drugs by pharmacies.
- Require wholesalers to obtain a $100,000 bond to secure payment of administrative fines and penalties.
- Permit the board to issue fines on a per occurrence basis for specified violations (e.g., sale of counterfeit drugs, sale of outdated drugs, failure to preserve records, etc.)
- Prohibits the owners of closed-door pharmacies (defined as pharmacies serving skilled nursing and intermediate care facilities) from owning a wholesale facility.

Mr. Riches stated that closed pharmacies serving limited patient populations who typically obtain preferentially priced drugs for serving these populations are a source of diversion in the marketplace.

The board's proposal includes a prohibition on co-ownership of the wholesaler and a closed pharmacy because of the diversion situations encountered by the board.

Mr. Riches stated that the pedigree requirement and moving the implementation date back one year to January 1, 2007 are the two most significant changes from the Enforcement Committee's draft language.

Mr. Riches reported that another significant inclusion was the proposed citation and fine authority for wholesale violations such as distribution of misbranded or adulterated drugs or counterfeits, failure to maintain documentation and failure to maintain the pedigree.

Every out-of-state wholesaler must have an exemptee-in-charge who has demonstrated training experience and is responsible for an individual wholesaler acting in accordance with the law.

Mr. Riches referred to the bonding requirement and stated that both Florida law and the NABP model rules include a $100,000 bond to secure administrative fines and other penalties. The requirement of a surety bond or equivalent security to be in place in advance of licensure would allow the board to enforce actions and continue to provide the disincentive for illegal activity.

Supervising Inspector Judi Nurse reported that since 1994, 91 board investigations were conducted and that 150 million doses of drugs were involved in these cases. Approximately 70 percent of the cases involved a pharmacy and a wholesaler with common ownership.

Ms. Nurse stated that board investigation efforts attempt to identify how and where drugs were originally sold and repeatedly resold on paper. Meanwhile the drugs themselves are shipped back and forth throughout the country, and travel as far as Puerto Rico before winding up at the final destination back in California. This turbulent activity becomes a good environment for introduction of counterfeits due to non-existent or sketchy paperwork.

Ms. Nurse stated that typically counterfeit drugs are life style drugs, or more expensive, newer drugs that do not have generic equivalents.

Ms. Nurse encouraged the board to address diversion issues and counterfeit drugs when considering this proposal.

Ms. Nurse stated that it is also a concern to the board when large quantities of drugs are returned to the manufacturer because of the potential for counterfeiting. Often when

counterfeit drugs are returned to a major wholesaler, they are returned to stock resulting in a legitimate pharmacy ending up with the counterfeit drugs.

Ms. Nurse stated while a pharmacist-in-charge (PIC) is required within these businesses typically the PICs are filled by semi-retired pharmacists or those looking for part-time work and often they are not aware of the type of business being run and that drugs were even purchased. The PIC is usually the only connection the board has to the illegal business and the PIC is often not the responsible party.

Ms. Nurse stated that another consideration that the board might want to address is the practice of wholesalers who sell far more drugs to a given pharmacy than the business warrants.

Ron Bone, senior vice president for distribution for McKesson, stated that McKesson has an unwavering commitment for the safety of the pharmaceutical products they distribute. As such, McKesson has implemented stringent processes and procedures with their suppliers throughout its distribution network to assure customers receive safe pharmaceutical products. Currently, McKesson purchases 95 percent of all pharmaceutical products directly from the manufacturer and 100 percent of high-risk drugs (i.e., HIV drugs, biotech and oncology products) directly from the manufacturer. McKesson purchases only about 5 percent from alternate source venders.

Mr. Bone explained that McKesson conducts a rigorous due diligence process of suppliers. The process includes a Dunn and Bradstreet report on the company and its owners, background and security checks and assurances of appropriate licensing and insurance. In addition, McKesson conducts a yearly site inspection to review company purchasing practices and a detailed check of their products.

Mr. Bone stated that McKesson encourages the board to create more stringent wholesaler licensing requirements. This should include a detailed physical site inspection, criminal and financial background checks and a comprehensive review of businesses and their products.

Mr. Bone stated that the lack of due diligence on these matters in Florida, as discovered, was a major reason rough operators were able to enter the system and compromise pharmaceutical products. McKesson supports the board's efforts to increase criminal penalties for those who knowingly counterfeit and distribute prescription drugs. He expressed concern that California laws are too lenient for such offenses.

Mr. Bone stated that McKesson opposes the proposal to require a paper pedigree on all products because a pedigree cannot be effectively transmitted through a distribution network and is also subject to counterfeit. He added that a paper pedigree would impose substantial costs and efficiencies to wholesalers and customers without providing any additional guarantee to the safety of the product.

President Jones stated that the pedigree provision would not take affect until January 2007, to allow time for the industry to comply.

Mr. Bone responded that counterfeit drugs are focused on high-risk drugs and he stated that manufacturers would be willing to work towards assuring a safe secure supply chain. He added that manufacturers are now testing return products.

Mr. Tilley stated that pharmacists must be assured that the medications they receive are the medications that were ordered.

Mr. Bone suggested that the board aggressively assure that wholesalers are conducting legitimate businesses.

Melinda Johnson, director of government affairs, representing AmeriSource Bergen Corp., stated that 99 percent of their products are purchased directly from the manufacturer and they have the same process in place to buy products from alternative source venders. She explained that manufacturers hold all the power with their products and earn as much as possible. Often they are the only source for the product. She added that it is not a typical sales/purchase relationship.

Ms. Johnson referred to the proposed requirement for a pedigree and stated that if a manufacturer has met the sales allotment for the month, they will refuse to sell their products and instead refer the wholesaler to another wholesaler. She stated that distributors would not be able to have a pedigree on all drug products and it would cause a drug shortage in the country. Customers would be forced to shop wholesaler to wholesaler and the potential for diversion becomes even greater.

Ms. Johnson stated that she worked with the FDA staff and asked specifically if a corporate use identification marker could be placed on the product, and the answer was no because it is a felony to change the label. She expressed concern that the board is not considering whether manufacturers will implement the program.

Ms. Johnson stated that the first step should be to increase regulatory stipulations and penalties on the illegal activity of wholesalers. She added that in light of the current budget crisis, they would not oppose an increase in licensing fees to add additional board inspectors to assure annual inspections.

Mr. Cronin stated that the board must consider the cost involved with this legislative proposal, and how it will solve the problem. He asked what the impact is on California consumers.

President Jones stated that the board must guarantee the safety of the distribution system in California.

A representative of PharMerica, Inc. expressed concern about limiting legitimate business sales.

Mr. Cronin suggested that the board pursue electronic pedigree and asked how central-fill pharmacies within a wholesaler enters into the equation. He added that it makes sense for the wholesaler to own the pharmacy. He expressed concern with the language and asked the board to allow pharmacies to look at innovative approaches to increase efficiency, lower cost, and save money.

Steve Gray, representing Kaiser Permanente, requested clarification of definitions. He added that closed pharmacies are not open for dispensing of dangerous drugs or devices to the general population. He stated a hospital pharmacy is not open to dispensing to the general population. He asked if all hospital pharmacies are considered closed pharmacies and does this include home infusion and Costco. He added that there are inconsistencies with section 4013.

Ron Resner, representing a small wholesaler business, cautioned the board not to react to the significant problems faced in Florida because they are dealing with damage control as the result of a very lax and inefficient regulatory and enforcement system. He added that there are many legitimate wholesalers who were punished and moved out of Florida because of the prohibited and unfair language. He added that the proposed language is reactionary.

MOTION: Enforcement Committee: That the Board of Pharmacy support the proposed citation and fine statute for wholesale violations and the proposed statutes regarding wholesale drug transactions.

SUPPORT: 3 OPPOSE: 0 ABSTAIN: 7

Additional discussion ensued, noting that additional changes could still be made to the legislative proposal before it was enacted.

MOTION: That the Board of Pharmacy support the proposed citation and fine statute for wholesale violations and the proposed statutes regarding wholesale drug transactions.

M/S/C: SCHELL/ACEVEDO

SUPPORT 9 OPPOSE: 0

- **Recommendation from the Joint Task Force on Prescriber Dispensing regarding dispensing by a medical group.**

Chairperson Powers stated that the Medical Board of California (MBC) and the Board of Pharmacy held a joint task force meeting on the issue of prescriber dispensing. The meeting

was held on May 27, 2003, and the task force reached consensus on the following: (1) Under current law, an individual prescriber can own his/her own prescription stock and dispense to his or her own patients and such practice should be allowed to continue with the goal of strengthening and educating prescribers regarding record keeping requirements; (2) Allow a medical group to dispense prescription medications pursuant to a special permit issued by the Board of Pharmacy and specified conditions that require one physician from the medical group to be responsible and accountable for the security of the prescription medications, record keeping requirements, and a consultant pharmacist reviews the dispensing process; (3) Establish the authority for a pharmacy to place an automated dispensing device in a prescriber's office; and (4) Provide for joint oversight by the appropriate licensing agencies.

Chairperson Powers stated that the task force agreed that staff from the two boards would work together to draft language for each board to consider as a possible joint legislative proposal for 2004.

Draft language was developed and the Medical Board task force members provided comments on the draft. The language was reworked to address their comments. The proposal would require a special clinic license for these group practices, which would have a significant fiscal impact to the board.

The language was first provided to the Enforcement Committee at its September meeting. However, it was requested that the committee postpone its discussion until the interested parties had more time to review the proposal and submit comments. The Enforcement Committee agreed to reschedule the issue to its December meeting.

Chairperson Powers stated that there was considerable discussion that the legislative proposal would authorize the Board of Pharmacy to issue a clinic permit to a medical group and this was not in the best interest of the public. Moreover, it was argued that it was contrary to current law that prohibits prescribers from owning pharmacies. There was also concern about the proposed amendment to Business and Professions Code section 4170(a), which would allow a registered nurse to hand to a patient the medication that is dispensed by the prescriber. There is an Attorney General Opinion (57 Op. Att'y Gen. 93 (1974)) that states that a nurse may assist, at the prescriber's direction in the dispensing of such drugs, including handing them to the patient, it was noted that this opinion was prior to the most recent amendments to this section.

The board took no action on the proposal from the Joint Task Force on Prescriber Dispensing.

- **Importation of Drugs from Canada**

Chairperson Powers stated that the board has discussed the issues and has sought comments on the issue of prescription drug importation from Canada and from other countries. This has been a sensitive and controversial issue. The board has been tasked with balancing consumer access to affordable prescriptions against the safety and effectiveness of drugs obtained from

foreign sources. The board has heard from many interested parties on this issue during its committee meetings and at its quarterly board meetings.

During its October meeting, the board decided to hold a summit on prescription drug importation in April 2004. The plan was to invite leaders representing all sides of the issue in an effort to fully discuss the health care policy concerns inherent with this topic.

Since the last board meeting, the United States District Court for the Northern District of Oklahoma ruled on November 6, 2003, that Rx Depot/Rx Canada violated federal law by causing the importation of prescriptions drugs from Canadian pharmacies. Rx Depot/Rx Canada assists individuals in procuring prescription medications from pharmacies in Canada. Each location has one or two employees who accept prescriptions from U.S. customers. Customers are asked to fill out a medical history form and other forms provided by Rx Depot/Rx Canada. Customers can deliver these documents to Rx Depot/Rx Canada's stores in person, or can mail or fax them to the nearest Rx Depot/Rx Canada store.

Once a Rx Depot/Rx Canada customer has submitted the required forms and prescriptions, the papers and the customer's credit card information or a certified check are transmitted to an operating pharmacy in Canada. A Canadian doctor rewrites the prescription, and the Canadian pharmacy fills the prescription, ships the prescription drugs directly to the U.S. customer, and bills the U.S customer's credit card. Rx Depot/Rx Canada receives a 10 to 12 percent commission for each sale they facilitate for the Canadian pharmacies. They also receive commissions for refill orders, which generally are arranged directly between customers and the Canadian pharmacies. It was noted in the decision that Rx Depot/Rx Canada stores are essentially commissioned sales agents for Canadian pharmacies.

The decision called for immediate closing of the 88 nationwide Rx Depot/Rx Canada affiliates, including 17 California locations. Rx Depot/Rx Canada appealed the decision. On November 21st, the 10th Circuit Court of Appeals decision denied the motion from Rx Depot to stay the District Courts ruling.

President Jones stated that the Administration has conveyed the message that due to the considerable public interest and publicity, time is needed to consider this issue more carefully.

MOTION: That the Board of Pharmacy withholds its plan for a summit on the importation of prescription drugs from Canada to allow more time for the administration to consider all of the issues.

M/S/C: POWERS/GOLDENBERG

SUPPORT: 9 OPPOSE: 0

- **Implementation of Enforcement Provisions from SB 361**

Mr. Powers stated that SB 361 (Figueroa) was the legislative vehicle for the Board of

Pharmacy's sunset extension and contained statutory recommendations approved by the Joint Legislative Sunset Review Committee. The following compliance provisions were added to California Pharmacy Law effective January 1, 2004.

- **Section 4083 – Order of Correction**

  Mr. Powers stated that section 4083 allows an inspector to issue an order of correction to a licensee directing the licensee to comply with pharmacy law within 30 days by submitting a corrective action plan to the inspector, or the licensee can contest the order of correction to the executive officer for an office conference. If an office conference is not requested, compliance with the order does not constitute an admission of the violation noted in the order of correction and the order of correction is not considered a public record for purposes of disclosure. A copy of the order of correction and corrective action plan must be maintained on the license premises for at least three years from the date the order was issued.

- **Section 4315 – Letter of Admonishment**

  Mr. Powers stated that this authorizes the executive officer to issue a letter of admonishment to a licensee for failure to comply with pharmacy law and directs the licensee to come into compliance within 30 days by submitting a corrective action plan to the executive officer documenting compliance, or the licensee can contest the letter of admonishment to the executive office for an office conference. If an office conference is not requested, compliance with the letter of admonishment does not constitute an admission of the violation noted in the letter of admonishment. The licensee must maintain on the licensed premises a copy of the letter of admonishment and corrective action plan for at least three years from the date the letter was issued. The letter of admonishment will be considered a public record for purposes of disclosure.

- **Section 4314 – Issuance of Citations**

  Mr. Powers stated that this section allows the board to issue an order of abatement that will 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 completion of up to six hours of continuing education courses in subject matter specified in the order of abatement.

- **Implementation of SB 151**

  Mr. Powers noted the board's activities to implement and educate about SB 151.

  Senate Bill 151 (Burton) repeals triplicate prescription requirement for Schedule II controlled drugs and revises requirements for prescribing and dispensing all controlled substances by January 1, 2005. All written controlled substances prescriptions must be written on special

security paper that is printed by approved printers. The board and the Department of Justice must approve the printers. An application form and procedures for these security printers will be on the board's Web site by the end of January.

The next issue of The Script will contain many articles about the phased-in requirements for prescribing and dispensing controlled substances. Additionally the board's public outreach activities will highlight these changes as well.

LEGISLATION AND REGULATION COMMITTEE

Dr. Fong stated that he would report on the committee meeting held January 8, 2004, in Chairperson Andrea Zinder's absence.

- **Proposed Changes to Pharmacy Law – Omnibus Provisions for 2004**

1. Correct usage errors in Section 4101.

Dr. Fong stated that the proposed changes reflect the requirement that wholesalers designate an "exemptee-in-charge" and correct the name of veterinary food-animal drug retailers in this section.

MOTION: Legislation and Regulation Committee: The Board of Pharmacy sponsor a provision in the 2004 omnibus bill to correct usage errors in Section 4101

Amend Section 4101 of the Business and Professions Code, to read:

4101. (a) Any pharmacist who takes charge of, or acts as pharmacist-in-charge of a pharmacy or other entity licensed by the board, who terminates his or her employment at the pharmacy or other entity, shall notify the board within 30 days of the termination of employment.
(b) ~~Any exemptee who takes charge of, or acts as manager of,~~ An exemptee-in-charge of a wholesaler or veterinary ~~food-drug animal~~ food-animal drug retailer, who terminates his or her employment at that entity shall notify the board within 30 days of the termination of employment.
~~(c) This section shall become operative on July 1, 2001.~~

SUPPORT: 9 OPPOSE: 0

2. Make a technical correction to Section 11155 of the Health and Safety Code.

Dr. Fong stated that the proposed change would replace "physician" with "prescriber." This change reflects the reality that practitioners other than physicians are authorized to prescribe controlled substances.

MOTION: Legislation and Regulation Committee: The Board of Pharmacy sponsor a provision in the 2004 omnibus bill to correct a usage error in Section 11155 of the Health and Safety Code

Amend Section 11155 of the Health and Safety Code, to read:

11155. Any prescriber ~~physician~~, who by court order or order of any state or governmental agency, or who voluntarily surrenders his controlled substance privileges, shall not possess, administer, dispense, or prescribe a controlled substance unless and until such privileges have been restored, and he has obtained current registration from the appropriate federal agency as provided by law.

SUPPORT: 9 OPPOSE: 0

3. Correct an erroneous code section reference in Section 11159.1 of the Health and Safety Code.

Dr. Fong Stated that this proposed change is technical.

MOTION: Legislation and Regulation Committee: The Board of Pharmacy sponsor a provision in the 2004 omnibus bill to correct an erroneous code section reference in Section 11159.1 of the Health and Safety Code.

Amend Section 11159.1 of the Health and Safety Code, to read:

11159.1. An order for controlled substances furnished to a patient in a clinic which has a permit issued pursuant to Article 13 ~~3.5~~ (commencing with Section 4180 ~~4063~~) of Chapter 9 of Division 2 of the Business and Professions Code, except an order for a Schedule II controlled substance, shall be exempt from the prescription requirements of this article ~~but~~ and shall be in writing on the patient's record, signed by the prescriber, dated, and shall state the name and quantity of the controlled substance ordered and the quantity actually furnished. The record of the order shall be maintained as a clinic record for a minimum of seven years. This section shall apply only to a clinic that has obtained a permit under the provisions of Article

13 ~~3.5~~ (commencing with Section 4180 ~~4063~~) of Chapter 9 of Division 2 of the Business and Professions Code. Clinics that furnish controlled substances shall be required to keep a separate record of the furnishing of those drugs which shall be available for review and inspection by all properly authorized personnel.

SUPPORT: 9 OPPOSE: 0

4 **Correct errors in Section 11207 of the Health and Safety Code and clarify that a pharmacy technician may assist a pharmacist in filling controlled substance prescriptions.**

Dr. Fong stated that these changes are also technical.

MOTION: Legislation and Regulation Committee: Board of Pharmacy sponsor a provision in the 2004 omnibus bill to correct errors in Section 11207 of the Health and Safety Code and to clarify that a pharmacy technician may assist a pharmacist in filling controlled substance prescriptions.

Amend Section 11207 of the Health and Safety Code, to read:

11207. (a) No person other than a ~~registered~~ pharmacist as defined in Section 4036 of the Business and Professions Code ~~under the laws of this state~~ or an intern pharmacist, as defined in Section 4030 ~~4038.1~~ of the Business and Professions Code, who is under the personal supervision of a pharmacist, shall compound, prepare, fill or dispense a prescription for a controlled substance.
(b) Notwithstanding subdivision (a), a pharmacy technician may perform those tasks permitted by Section 4115 of the Business and Professions Code when assisting a pharmacist dispensing a prescription for a controlled substance.

SUPPORT: 9 OPPOSE: 0

- **Moratorium on Pending Regulations Imposed by Executive Order S-2-03**

Mr. Riches reported that Executive Order S-2-03 requires state agencies to take several actions related to rulemaking activity.

1. **Regulatory Review** –The board is required to review all rulemakings adopted since January 6, 1999, based on existing statutory criteria to assure their compliance with those

criteria. This review is required to be completed by February 17, 2004, and be submitted to the Governor's legal affairs secretary.

Mr. Riches stated that the board adopted 19 regulation packages adopted during this time period. He reported that the board also conducted a review of ongoing board practices to assure there were no underground regulations and the board conducted an additional fiscal evaluation on the sterile compounding regulations.

Mr. Riches stated that the moratorium on adopting new regulations until mid May does not preclude the board from noticing new regulations. The board had a substantial number of regulations prepared to go to notice when the executive order was issued. These regulations will be noticed in February and the regulation packages will be brought to the April Board Meeting for a vote to clear the backlog.

2. **Rulemaking Moratorium –** As stated earlier, all state agencies must suspend rulemaking activity for 180 days to provide the Administration with time to review pending proposals. The only immediate effect of this moratorium for the board is delaying the recently approved rulemaking on sterile compounding standards. This proposal must be submitted to the Office of Administrative Law for review by February 20, 2004 or it expires, unless a review waiver is also sought to permit the Department of Consumer Affairs 90 extra days to review the rulemaking.

   The board requested an exemption to the moratorium for this rulemaking because of its impact on the public health and safety, but the administration denied the initial request. The board is requesting reconsideration and is seeking a waiver. If not approved, the board will have to begin this process again.

   The USP has recently published its revised chapter on sterile compounding and that document should be considered before initiating a new rulemaking process.

3. **Review of Existing Board Standards –** All state agencies must review existing standards of practice to identify any potential "underground" regulations. An "underground" regulation exists when a state agency applies a general standard to all affected persons without adopting that general standard through a formal rulemaking procedure. With the assistance of counsel, board staff reviewed existing standards and practices. The review did not uncover any potential "underground" regulations.

   During the review process, counsel advised the board that several of the guidance documents the board has published in the past required revisions and updates. Those guidance documents have been removed from the board's Web site pending the completion of the revision process.

   Mr. Riches stated that the proposed text of those proposed regulations for action at the April 2004 Meeting have had the required information hearings. Notices for these

regulations will be published as soon as possible within the restrictions established by Executive Order S-2-03.

Regulations Awaiting Notice for Action at the April 2004 Board Meeting

1. **Section 1707.5 – Hospital Central Fill**

   This regulation will permit central refill operations for hospitals.

2. **Section 1709.1 - Pharmacist-in-Charge at Two Locations**

   This regulation will permit a pharmacist to serve as pharmacist-in-charge at two locations.

3. **Section 1711 – Patient Notification**

   This regulation will modify the patient notification provisions of the board's quality assurance regulation to require notification to the patient if the drug was actually taken or if it resulting in a clinically significant delay in therapy.

4. **Section 1717.4 and 1717.2 – Electronic Prescriptions & Electronic Records**

   This regulation will make any needed changes to board regulations to conform to changes in patient privacy laws.

5. **Section 1717.4 – Authentication of Electronic Prescriptions**

   This regulation will require pharmacists to authenticate electronic prescriptions.

6. **Section 1719 et seq. – Pharmacist Examination**

   This regulation will update existing requirements for the pharmacist examination and make those changes necessary to conform to the provisions of Senate Bill 361.

7. **Section 1793.3 – "Clerk-Typist" Ratio**

   This regulation will eliminate the clerk/typist ratio.
   An informational hearing was held and action deferred until January 2004 board meeting to accommodate staff workload and ongoing negotiations regarding a statutory revision to ancillary staff ratios.

   MOTION: That the Board of Pharmacy move the proposed amendment to section 1793.3 "Clerk Typist" Ration to a regulation hearing on April 21, 2004.

M/S/C: FONG/SCHELL

SUPPORT: 7 OPPOSE: 0 ABSTAIN: 2

Awaiting Notice and an Information Hearing

1. **Section 1715 – Pharmacy Self Assessment**

   This regulation will update the pharmacy self-assessment form to reflect recent changes in pharmacy law.

2. **Section 100 Filing**

   This filing will conform existing board regulations to the numerous changes in Pharmacy Law made by 2003 legislation. This regulation is awaiting compilation (a informational hearing is not required).

Status of Bills with a Board Position

Mr. Riches updated the board on several bills introduced last year on which the board has a position.

AB 261 (Maddox)

This bill would increase penalties for operating a "backroom pharmacy."
The board has a support position on the bill, which died in committee.

AB 746 (Matthews)

This bill would require the board to revoke a license after a second conviction for Medi-Cal fraud. The board has a support position on this bill that is currently before the Senate Rules Committee.

AB 1363 (Berg)

This bill would establish requirements for needle exchange programs. The board has a support position on this two-year bill.

AB 1460 (Nation)

This bill would permit pharmacists to perform CLIA waived tests to monitor drug therapy. The board has a support position on this two-year bill.

SB 393 (Aanestad)

This bill would permit "tech-check-tech" in hospitals. The board has a support if amended position on this two-year bill.

SB 506 (Sher)

This bill would require the board to track wholesale distribution of antibiotic drugs. The board has an oppose position on this two-year bill.

Bills of Interest

Mr. Riches noted several additional bills of interest to the board.

AB 57 (Bates)

This bill would place MDMA into Schedule II. And is currently in the Assembly inactive file.

AB 521 (Diaz)

This bill would require pharmacists to notify patients of harmful drug interactions and it is a two-year bill.

Staff does not anticipate significant activity on any of the remaining two-year bills.

Dr. Fong stated that the next Legislation and Regulation Committee meeting is scheduled for April 5, 2004, at 10:30 a.m. in Sacramento.

NEW BUSINESS/AGENDA ITEMS FOR FUTURE MEETINGS

Mr. Tilley reminded the board that the yearly dues for members is $120, and is now due.

Dr. Fong referred to record keeping requirements in pharmacies and stated that his pharmacies are inundated with lots of paperwork. Ms. Harris suggested that a written proposal be submitted for review by the Legislation and Regulation Committee.

ADJOURNMENT

There being no further business, President Jones adjourned the meeting at 5:35 p.m.

Thursday, January 22, 2004

ENFORCEMENT WORKSHOP

President Jones called the Enforcement Workshop meeting to order at 8:30 a.m. on January 22, 2004.

Staff provided an overview of the Board of Pharmacy Enforcement Unit.

The meeting was adjourned at 12:15 p.m.