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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: April 21, 2004

LOCATION: **Department of Consumer Affairs**
400 R Street, Suite 1030
Sacramento, CA 95814

BOARD MEMBERS PRESENT:
John Jones, President
James Acevedo
Richard Benson
Ruth Conroy
David Fong
Stanley Goldenberg
William Powers
Kenneth Schell
Andrea Zinder

BOARD MEMBERS ABSENT:
Clarence Hiura
John Tilley

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, April 21, 2004

CALL TO ORDER

President Jones called the meeting to order at 8:35 a.m. on Wednesday, April 21, 2004.

ANNOUNCEMENTS

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

  President Jones stated that pharmacists wanting to learn more about the issues and operation of the board by attending this board meeting can earn continuing education hours. 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 the 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. Pharmacists interested in earning this CE credit must sign in at the start of the meeting.

- **Board of Pharmacy Staff Introductions**

  President Jones asked the Sacramento board staff in attendance to introduce themselves. This is an annual tradition at board meetings in Sacramento. The staff returned to the board's suite, following the introductions and board members acknowledgment and tanks for their service to the public, licensees and applicants.

COMMITTEE REPORTS AND ACTION

Communication and Public Education Committee

Chairperson Powers stated that the Communication and Public Education Committee met March 26, 2004, in a public meeting held in Sacramento.

- **Development of New Public Education Materials with the Schools of Pharmacy**

  Chairperson Powers stated that the committee has been seeking ways to integrate pharmacy students into public outreach activities. One promising proposal 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). The board has developed a prototype template/format for a series of fact sheets, and each student could complete the information and be acknowledged with a credit at the bottom of the fact sheet. The board would check the accuracy of the information and assure it is written at an appropriate reading level. At the last board meeting, the committee was directed to explore such an activity.

Chairperson Powers stated that this cooperative project would benefit the resumes of those students who prepare the fact sheets, 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.

Chairperson Powers stated that the UCSF's Center for Consumer Self Care is very interested in working with the board on such a project. During the March committee meeting, Associate Dean of External Affairs Lorie Rice of the UCSF School of Pharmacy shared a written project proposal. She indicated that this project would fit in with the Center for Consumer Self Care's focus, and faculty of the school of pharmacy could review the fact sheets for accuracy as part of the project plan.

The committee determined that due to staff resources, the board should start with a limited program at UCSF and UCSD. Then if successful and viable, the board would offer a similar project to other California pharmacy schools.

Mr. Powers added that this project fits within the committee's strategic plan, and could be implemented and maintained with nominal expense to the board (photocopying of fact sheets in addition to placing them on the board's Web site).

John Cronin, representing the California Pharmacists Association stated that the CPhA supports this proposal.

MOTION: Communication and Public Education Committee: Initiate a pilot program with the schools of pharmacy at UCSF and UCSD for their pharmacist interns to develop consumer fact sheets on various health care topics.

SUPPORT: 7 OPPOSE: 0

- **UCSF's Proposal for a Joint Project to Develop Pharmacists Information on Atrial Fibrillation**

Chairperson Powers stated that at the March meeting, Associate Dean Lorie Rice of the UCSF School of Pharmacy advised the committee that the UCSF School of Pharmacy wishes to work with the board to produce educational materials on Atrial Fibrillation (Afib). The audience would be pharmacists and physicians. Funding for this issue would come from a drug manufacturer, which has already committed the funding. The board's role would be to place the materials on the board's Web site and help publicize the materials. The components would include:

1. A description of Afib
2. A description of risk factors
3. A description of signs and symptoms
4. Diagnosis tools
5. Potential consequences of Afib

6. Treatment (medications and other treatments), side effects duration of treatment, influence on other diseases
7. Future for "cure"

Ms. Rice thanked the board for reviewing the UCSF proposal. She reported that the UCSF in the past as collaborated with the board on several issues of *Health Notes*. She added that for this project, the UCSF plans to develop a monograph on Afib prepared by physicians and pharmacists at UCSF using a peer review process. She added that the UCSF is negotiating an unrestricted grant and is not requesting any funding from the Board of Pharmacy or the Medical Board.

Ms. Rice requested that the board review the document and consider if it would like to have its name attributed to the document. She added that the monograph would entail information for consumers with a consumer fact sheet describing what Afib is and how it is treated, the various methods of therapy and the potential for treatment in the future. The consumer component will be distributed in pharmacies and physician's offices. She added that there would be a continuing education component for both pharmacists and physicians and CE will be awarded by both UCSF School of Pharmacy and UCSF School of Medicine.

Ms. Rice stated that because the funding source is a pharmaceutical company, the dean has asked for a peer review process with a list available of both the authors and peer reviewers. No review will be made by the pharmaceutical company.

Dr. Fong asked why the subject of Afib was chosen as a topic.

Ms. Rice stated that there is need for consumer information on this topic and the UCSF was approached by the manufacturer for the schools' objectivity.

Ms. Rice stated that the information would be distributed to primary care physicians, internal medicine physicians and cardiologists. She added that the fact sheet would be sent directly to all pharmacies and physician offices so it can be duplicated for consumers.

Ms. Rice stated that the intent is to develop future consumer information via monographs and tear-out sheets such as consumer information fact sheets, and target as many consumers as possible.

Chairperson Powers stated that several members of the committee expressed concern that the funding would be coming from a pharmaceutical company and was assured that it would be completely objective.

Ms. Rice assured the board that the school also shares this concern. She added that the UCSF would receive the funding in an unrestricted grant.

MOTION: Communication and Public Education Committee: Approve the UCSF's proposal for a joint project to develop information on atrial fibrillation.

SUPPORT: 7 OPPOSE: 0

- **Proposed Strategic Objectives for 2004/2005**

Chairperson Powers stated that the committee recommends the addition of three tasks to its strategic plan to reflect several activities initiated or planned for the next year.

1. Add as new task 5: Evaluate the need for public education for patients who need to request prescription labeling in a language other than English.

   Chairperson Powers stated that at the last committee meeting, a discussion took place regarding the need for patients to understand that they can ask to have their prescription containers labeled in a language other than English, if this will aid them. A discussion was scheduled for the January board meeting, but the individuals who brought the matter before the board could not attend the meeting. The committee determined it wished to follow up on this matter in the future.
   Ms. Herold stated that many pharmacies have the software capability to translate English documents and label into another language. The intent of the discussion was to encourage consumers to learn that they could ask for information in a different language.

2. Add as new task 5: Create a consumer fact sheet series in conjunction with California schools of pharmacy on topics of interest.

3. Add as new task 6: Create public education activities to educate prescribers, dispensers, patients and law enforcement about changes in law regarding dispensing of controlled substances.

   Chairperson Powers stated that the board has produced a Powerpoint presentation on SB 151 and is developing a much larger public information program for prescribers and dispensers about the new requirements; this task would allow the board a specific area for reporting its activities.

MOTION: Communication and Public Education Committee: Add new task 5 to the Board of Pharmacy's strategic plan: Evaluate the need for public education for patients who need to request prescription labeling in a language other than English.

SUPPORT: 8 OPPOSE: 0

MOTION: Communication and Public Education Committee: Add as new task 5 to the Board of Pharmacy's strategic plan: Create a consumer fact sheet series in conjunction with California schools of pharmacy on topics of interest.

SUPPORT: 8 OPPOSE: 0

MOTION: Communication and Public Education Committee: Add as new task 6 to the Board of Pharmacy's strategic plan: Create public education activities to educate prescribers, dispensers, patients and law enforcement about changes in law regarding dispensing of controlled substances.

SUPPORT: 8 OPPOSE: 0

- ***Health Notes***

Chairperson Powers stated that *Health Notes* is a monograph, produced by the board that contains current drug therapy guidelines for a specific subject area. Because the board produces *Health Notes*, the board can convey what it believes is current drug treatment in a particular area. Pharmacists can earn continuing education credit by completing a test published at the back of the monograph. Thus the board provides information and actually is sponsoring CE in an area of importance to the board. Seven issues have been produced since 1996.

Health Notes was developed during the mid 1990s by the board. Typically it is produced via contract with recognized experts (often UCSF) who identify qualified authors, provide technical editing and coordination services, leaving the board to executively edit the articles and coordinate distribution of the published copies. A graphic artist does the layout.

Usually one issue is published annually. Total costs for development, printing and mailing to all pharmacists are about $100,000 per issue. The last issue published was in April 2003. The board paid for the graphic artist and postage (about $35,000); funding for development and printing was paid for by other sources.

Pain Management Issue:

The board is currently developing a new issue on pain management, which should be published in mid 2004, probably June or July. The new issue will contain new pain management therapies and the new prescribing and dispensing requirements for controlled substances. It is planned as an interdisciplinary issue for pharmacists as well as physicians, dentists, and nurse practitioners. Prominent pain management authors have written the articles, and board staff and Board Member Schell are editing and coordinating the issue. The CSHP is seeking funding for production and mailing costs. Depending on how many grants the CSHP obtains for this issue, the board hopes to spend $0 on this issue.

- **Proposal from UCSF to develop a *Health Notes* on smoking cessation**

Chairperson Powers stated that the UCSF School of Pharmacy, Center for Consumer Self Care has proposed a joint project with the board to develop a *Health Notes on* smoking cessation. Over the years, the board has worked with the UCSF School of Pharmacy to produce several of its *Health Notes* monographs. Typically in such arrangements, the UCSF produces the manuscript and editing services, and the board pays for printing and mailing costs.

This year, the UCSF has proposed that the board work with UCSF to produce an issue on smoking cessation. Essentially the UCSF proposes to develop the manuscript for $40,000 from the board, and then the board would publish and mail the copies. This is similar to the manner in which the board published the quality assurance program issue of *Health Notes* (for which the board received one-time funding as part of a legislative budget change proposal). The board spent $110,000 on producing and mailing the quality assurance *Health Notes*.

However, during the committee meeting, discussion focused on the board's limited finances to develop and distribute such a manuscript, and UCSF agreed with committee members' recommendations to seek funding for this issue from the manufacturers of smoking cessation products.

The committee also reviewed tobacco cessation materials recently published for primary care practitioners by the California Tobacco Control Alliance. The tool kit provides practitioners with advice on integrating smoking cessation materials into their practices.

The committee was impressed with this material, and the California Tobacco Control Alliance is interested in working with the board on joint projects.

MOTION: Communication and Public Education Committee: Work with the UCSF to develop a *Health Notes* on smoking cessation, and seek funding for this issue from manufacturers of smoking cessation products.

SUPPORT: 8 OPPOSE: 0

President Jones acknowledged the volume of work generated by the Communication and Public Education Committee and commended members and staff on all of the outreach efforts to education the public. He added that this is a difficult committee to serve on, as it requires considerable public contact. The new educational materials being developed to describe the changes in the prescribing and dispensing of controlled substances are greatly needed. No other agency is doing this. President Jones encouraged the continued progress of this committee.

- **Update on *The Script***

The March 2004 issue of *The Script* was mailed to California pharmacies at the end of March. A copy is now on the board's Web site. This issues focuses on the many substantial changes to pharmacy law that took effect in 2004 (e.g., changes in the prescribing and dispensing of controlled substances, new pharmacy technician requirements, new pharmacist licensure examinations).

The CPhA's Pharmacy Foundation of California will mail the issue to California pharmacists in the future.

Production and mailing of this issue to California pharmacies cost the board approximately $17,500.

- **New Public Education Materials**

1. Federal Medicare Drug Discount Program

Board President Jones asked the committee to develop consumer information about the new federal Medicare Prescription Drug Improvement and Modernization Act of 2003. This act will provide Medicare beneficiaries with discounts on their prescription drugs as well as provide comprehensive prescription drug coverage effective January 1, 2006. Starting June 1, 2004, Medicare beneficiaries will be able to purchase a Medicare-approved discount card program that will offer discounts on prescription drugs.

A short fact sheet has been developed by board staff and placed on the board's Web site advising the public about how they can avoid becoming a victim of a consumer scam involving the drug discount card. The federal government's Medicare Web site has extensive information to assist the public. The board's information refers the public to this Web site and to an 800 number for more information about the discount cards.

2. **FDA Consumer Information Campaign on OTC Pain Relievers**

The FDA has recently released a public education campaign on using caution with OTC pain relievers. A consumer brochure and various fact sheets and flyers emphasize the dangers of taking OTC pain relievers that sometimes are also contained in a diversity of OTC products. The goal is to educate the public to read the labels and understand the active ingredients of the OTC products they take to avoid excessive dosages that can substantially harm consumers.

3. Establishment of Internet Subscriber Lists for Board Materials and Information

Staff has been researching a way to set up a subscriber list on the board's Web site. This feature would send e-mails to interested parties announcing that the board's Web site has been updated. The interested parties would subscribe themselves to the board's Web site, and be responsible for keeping their e-mail addresses current.

This service has the potential to substantially reduce the board's mailing expenses as well as printing costs. Materials that the board currently publishes and mails could be sent without cost via e-mail. Such a notification system would allow the board to update licensees far more quickly about new information and laws.

The department's Office of Information Services has identified two software programs that could permit the board to establish such a subscriber list. Staff hopes to purchase and install a software program and start a trial for this project before the end of the fiscal year. The next *The Script* will contain information about how to sign up on this subscriber list.

After being contacted by the board, the Department of Consumer Affairs has recognized the value of such software, and is interested in pursuing this for the rest of the department.

4. Emergency Contraception Fact Sheet

The new version of the Emergency Contraception Fact Sheet, created by the Pharmacy Access Partnership, has been translated into nine languages – Cambodian, Chinese, Farsi, Hmong, Korean, Russian Spanish, Tagalog and Vietnamese. These versions have been added to the board's Web site.

5. Public Outreach Activities

Since the January board meeting, the board has not attended any consumer outreach events; however, the board provided a number of consumer materials

to the Department of Consumer Affairs for handouts during outreach events for seniors and young people during National Consumers Week in February.

Since the last board meeting, staff has revised its PowerPoint presentation on the board that highlights keyboard policies and pharmacy law. This is a continuing education course, provided by a board member and a supervising inspector. Questions and answers typically result in a presentation of more than two hours; these presentations are usually well received by the individuals present.

Since the beginning of the year, the board has begun providing presentations on SB 151 and the new requirements for prescribing and dispensing controlled substances in California. The committee reviewed the slides of this PowerPoint presentation.

- **Public outreach activities performed since the January 21, 2004 Board Meeting:**

1. Board inspectors staffed a booth at Outlook 2004, the annual meeting of the California Pharmacists Association. Additionally, Board members and staff provided information on the new examination structure, new pharmacy law and board operations as part of the published program events.
2. Board staff presented information on SB 151 to 15 investigators at a FBI Drug Diversion Meeting in Northern California on January 26, 2004.
3. Board President Jones and staff presented "Law Update 2004" (the board's CE program) to 125 students and pharmacists at USC School of Pharmacy, February 5, 2004.
4. Board Member Ruth Conroy presented information on SB 151 at a session held by the San Francisco Health Plan P & T Committee in February.
5. Board staff presented information to 125 UCSF students on legislative changes to Pharmacy Law on February 24.
6. Board Member Ruth Conroy provided information about board activities at a February 27th Circle of Advisors Meeting of the Pharmacy Access Partnership.
7. Board staff presented information to 125 UCSF students on the Board of Pharmacy on March 2, 2004.
8. Board staff presented information on SB 151 to 60 people at the California Coalition for Compassionate Care Train the Trainers meeting in Sacramento on March.
9. Staff presented information on SB 151 to 60 members at the Northern California Pain Coalition meeting on March 8 to 60, a "train the trainer" event.
10. Board staff provided a training session to complaint staff of the Medical Board of California on March 17.

11. Board Member Ken Schell presented information to the San Diego Association for Healthcare Risk Management on March 23.
12. Board staff presented information on SB 151 to physicians and pharmacists as part of a noon CE program offered by teleconference on March 23.
13. Board staff presented information on SB 151 to the California Coalition for Compassionate Care on March 29.
14. Board staff presented information on SB 151 to physicians at Sharp Hospital in San Diego on March 28.

Enforcement Committee

- **Proposed Revisions to the Public Disclosure Policy and Recommendation for Record Retention of Substantiated Complaints/Investigations**

  Mr. Goldenberg stated that the Enforcement Committee reviewed a revised public disclosure policy that included the disclosure of "Letters of Admonishment" that were added this year through new legislation. Several other technical changes to the policy were also suggested.

  The Enforcement Committee also discussed the board's "Record Retention Schedule" which governs how long the board maintains its records. As long as the board maintains public records, they must be provided to the public upon request. Currently, the board's retains substantiated complaints such as citations for five years and disciplinary actions for 20.

  When Business and Professions Code section 4315 was added to authorize letters of admonishment, it specifies that the pharmacy must keep the letter of admonishment for three years from the date of issuance. This three-year period is consistent with all other record keeping requirements required of board licensees.

  When there is a public records request for a citation or letter of admonishment, the respective documents are provided. A copy of the investigation report is not given.

  Staff requested that the board consider changing the "Record Retention Schedule" for substantiated complaints to three years. Three years provides the board with sufficient complaint history to determine if disciplinary action is warranted and is consistent with the record keeping requirements for licensees. Also, with the board's diminishing resources, it is difficult to maintain the records for five years.

  At the Enforcement Committee meeting, Collette Galvez from the Center for Public Interest Law recommended that the board not change its public disclosure of substantiated complaints to three years. She advised that such a change is not consistent with the other health boards. She also cautioned that three years of information might not be enough for a consumer to make an informed decision about a pharmacy or pharmacist.

After the meeting, staff reviewed the record retention for the other health boards. The Board of Registered Nursing keeps all its closed substantiated complaints and disciplinary actions for 101 years. The Dental Board of California keeps its closed substantiated complaints for five years and citations and disciplinary actions forever. Medical Board of California maintains its closed substantiated investigations for five years and disciplinary actions forever.

The board's Web site look-up for disciplinary actions will be available by May 1, 2004 and will include disciplinary cases as far back as January 1998. Letters of admonishment, citations, pending accusations will be added to the web look-up at a later time. However, this information is still available to the public by contacting the board.

Mr. Goldenberg referred to comments made by Ms. Galvez and asked if the board would like to reconsider a five-year record retention schedule.

Mr. Powers stated that he supports the comments from the Center of Public Interest Law.

Dr. Schell asked what the impact would be to maintain a five-year schedule.

President Jones stated that the administration asked all state agencies to review ways to maximize efficiency and reduce unnecessary laws and regulations and the fewer documents the board maintains, the less expensive it is. He added that the board must also consider public issue concerns.

John Cronin, representing the California Pharmacists Association, asked how the board defines a substantiated complaint.

President Jones stated that this is a complaint that follows with a citation and/or fine.

John Berger stated that the statute for cite and fine specifically states that paying a fine is not an admission of guilt, that no adjudication was made. He added that the board has categorized a pharmacist negatively because he or she has determined that paying a fine is better than appealing a decision because of the cost involved.

Ms. Harris stated that further clarification is needed and will be brought back to the Enforcement Committee.

President Jones stated that this also could be added as an agenda item for the July board meeting for further consideration.

MOTION: Enforcement Committee: Change the record retention for substantiated complaints/investigations to three years.

SUPPORT: 1 OPPOSE: 7

MOTION: Enforcement Committee: Revise the Board of Pharmacy's public disclosure policy to strike the word "three" from the draft Public Disclosure Policy Administrative Information and Actions

M/S/C: POWERS/SCHELL

SUPPORT: 8 OPPOSE: 0

Proposed Revision to Enforcement Committee Strategic Objectives for 2004/2005

Mr. Goldenberg stated that the Enforcement Committee reviewed its strategic objectives for implementation of its goals. Since July, the Enforcement Committee has addressed various public policy initiatives but there isn't an objective in the strategic plan to track these tasks in one place. The policy initiatives that the board has reviewed are:

Mr. Goldenberg asked if the board could pass on voting on this issue but still keep this as an agenda item.

- **Importation of Prescription Drugs from Canada**

Mr. Goldenberg stated that the Board of Pharmacy has been discussing and has sought comments on the issue of prescription drug importation from Canada. 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.

This year various legislative proposals have been introduced related to the reimportation of prescription drugs from Canada. Some of the bills impact the board in that the board would be required to establish a Web site to provide price comparisons between American and Canadian prescription drug prices and provide a link to certified Canadian pharmacies. The board would also be required to "certify" Canadian pharmacies. Other legislative bills are designed to increase the public and private sector buying power for lower prescription drug prices. The board will discuss these bills during the Legislation and Regulation Committee report.

The board's mandate is to protect the public, which includes patient access to "safe and affordable" prescription medications.

Meanwhile, the Food and Drug Administration (FDA), on behalf of the U.S. Department of Health and Human Services' (HHS) Task Force on Drug Importation, announced that it established a docket to receive information and comments on certain issues related to the

importation of prescription drugs. The FDA also announced a public meeting on April 14th so that individuals, organizations and other stakeholders could present information to the Task Force for consideration in the study on importation mandated by the Medicare Prescription Drug, Improvement and Modernization Act of 2003. The Task Force is interested in information related to whether and under what circumstances drug importation could be conducted safely, and what its likely consequences would be for the health, medical costs, and development of new medicines for American patients. The public docket will formally remain open until June 1, 2004, for written or electronic comments.

Bruce Young, representing the California Retailers Association, stated that the term "Importation of Drugs from Canada" is misleading because drugs are imported from all over the world. He added that he hopes the board will advocate pharmacists and pharmacies that dispense from unregulated countries to assess whether they dispense legitimate drugs. He added that the CRA supports this action.

Liz Harold, representing the TMJ Society of California, stated that she became a patient representative two years ago on a FDA drug appliance panel and recently had a discussion with the FDA on importation of drugs in the United States. She is concerned that the FDA could not guarantee the safety of these medications and asked who would be responsible for the liability if patients were harmed. She added that pharmacists play a huge role in the prevention of adverse effects to patients receiving prescription drugs. She encouraged the board to oppose the importation of drugs.

A pharmacist and patient advocate for seniors from the California Rural Indian Health Forum stated that he supports endorsement of pharmacies in Canada from which seniors can obtain cost savings on their prescriptions.

- **Application of Pharmacy Law Regarding the Conversion of Paper Invoices to Electronic Billing by Wholesalers for Pharmacy Drug Purchases**

The Board of Pharmacy received a letter from Ralphs seeking clarification regarding the conversion from paper invoices for drug purchases to electronic billing. Ralphs is seeking clarification of its record-keeping duties because its wholesale suppliers have decided to convert from paper to electronic invoices. Specifically, Ralphs wants to know if it is permitted to no longer keep paper copies of invoices on file but have such invoices electronically available. If so, it wants to know how long Ralphs must keep electronic invoices available for inspection.

The request for clarification from Ralphs was forwarded to the board's counsel for review and comment. Counsel advised that the pertinent statutes relating to this issue are Business and Professions Code sections 4081, 4105, and 4333. Section 4081 requires that records of "manufacture and of sale, acquisition, or disposition of dangerous drugs and of dangerous devices" be available for inspection at all times, and that such records be "preserved for at least three years from the date of making." (Bus. & Prof. Code § 4081, subd. (a)). Section

4105 similarly requires that records of acquisition or disposition be readily available on licensed premises, and that such records be preserved for three years from the date of making. (Bus. & Prof. Code § 4105, subds. (a), (c)). The same records-availability and three-year preservation period is applied to filled prescriptions by Section 4333. (Bus. & Prof. Code § 4333, subd. (a)).

The only one of these statutes that mentions electronic record keeping is section 4105. Subdivision (d) allows records to be kept electronically so long as a hard copy and an electronic copy can always be produced. (Bus. & Prof. Code § 4105, subd. (d)).

Subdivision (d) of Section 4105 does not specify a different time period of preservation from the three-year period generally required by subdivision (c). Electronic records must therefore also be preserved and retrievable for a period of three years. I t was explained that a licensed premises has the option of keeping its "records or other documentation of the acquisition or disposition of dangerous drugs and dangerous devices" (Bus. & Prof. Code § 4105, subd. (a)) in electronic rather than paper form. If it chooses to do so, however, those records must also be "retained on the licensed premises for a period of three years from the date of making." (Bus. & Prof. Code § 4105, subd. (c)). This means that the electronic records must be retained on the licensed premises for a period of three years from the date of making, "so that the pharmacist-in-charge, [or] the pharmacist on duty if the pharmacist-in-charge is not on duty," shall "at all times during which the licenses premises are open for business be able to produce a hard copy and electronic copy of all records of acquisition or disposition . . ." (Bus. & Prof. Code § 4105 (d)).

In summary, board counsel has advised that pharmacies can keep drug purchase records from wholesalers electronically rather than on paper so long as those records are retained on site and immediately available for inspection for a period of three years, and can at all times be produced in both hard copy and electronic form by an on-duty pharmacist.

- **Application of Pharmacy Law Regarding the Use of Automation/Robotic Technology in All Pharmacy Practice Settings**

The Board of Pharmacy received a request from McKesson to review and approve its proposal for a ROBOT-Rx protocol in hospital and institutional pharmacies that would not require licensed pharmacists to check every medication dispensed by the ROBOT-Rx. McKesson proposes a protocol whereby a pharmacist would check 100 percent of the medications packaged by the ROBOT-Rx on a daily basis, and would for a period of no less than 30 days after the ROBOT-Rx is first deployed check 100 percent of doses dispensed by the ROBOT-Rx, but would then taper off to sampling only 5-10 percent of these doses.

It is McKesson's opinion that the Board of Pharmacy's statutes and regulations are silent on the duty of a licensed pharmacist (or pharmacy) to verify dispensed medications from an automated dispenser and McKesson concludes that "it is within the discretion of the Board of Pharmacy staff to approve a protocol that would apply specifically to ROBOT-Rx

technology" in inpatient settings. It is McKesson's desire that the board approve this proposal for a reduced frequency of checking for errors of dispensed medications, over a requirement that all dispensed doses be checked.

Board counsel reviewed the request and advised that McKesson is correct that the Pharmacy Law is silent on the question of automated delivery systems, aside from those provisions relating to placement of such a system in nonprofit or free clinics contained in Business and Professions Code section 4186. There is no statute or regulation specifically requiring that a pharmacist check every dose dispensed by an automated drug delivery system located in an inpatient setting, nor is there any statute or regulation absolving the dispensing pharmacist of this responsibility. From this, it is McKesson's conclusion that there is a "gap" in the law that can be filled by its proposed "protocol."

It was counsel's opinion that in the absence of any statutes or regulations exempting a dispensing pharmacist or pharmacy working with an automated drug delivery system from the general requirements pertaining to prescription accuracy and propriety of drug delivery, it is the responsibility of the dispensing pharmacist and pharmacy to ensure 100 percent accuracy of dispensing. A licensee can only furnish dangerous drugs pursuant to a valid prescription (Bus. & Prof. Code § 4059), except under specified circumstances (e.g., emergency, Bus. & Prof. Code § 4062), and can only furnish those dangerous drugs as prescribed (except where substitutions and generics are permitted, Bus. & Prof. Code §§ 4052.5, 4073).

The Pharmacy Law is violated, *inter alia*, where a prescription is dispensed in an insufficiently or inaccurately labeled container (Bus. & Prof. Code §§ 4076, 4077, 4078), where the drug dispensed deviates from requirements of a prescription (Cal. Code Regs., tit. 16, § 1716), or where the prescription dispensed contains significant errors, omissions, irregularities, uncertainties, ambiguities, or alterations (Cal. Code Regs., tit. 16, § 1761). These provisions apply to all dispensing, regardless of the setting.

Thus, the licensees' duties to ensure accuracy of prescription dispensing do not depend on a particular method of delivery. Whether dangerous drugs are dispensed by hand or by use of the ROBOT-Rx or some other automated delivery system, the licensees' duties do not change.

It was explained that the same duty to seek 100 percent accuracy of dispensing that applies to hand-dispensing by way of California Code of Regulations, title 16, section 1716 (and section 1761) applies just as strongly to dispensing performed by an automated delivery system. If McKesson is correct that ROBOT-Rx is a more accurate method of filling prescriptions, taking out human error that might otherwise occur, it should increase the likelihood of compliance. The use of an automated system like ROBOT-Rx does not, however, give licensees a "free pass" for a certain number of dispensing errors that may nonetheless occur.

This interpretation is reinforced by Business and Professions Code section 4186, which states drugs may "be removed from the automated drug delivery system only upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile" and "provided to the patient [only] by a health professional licensed pursuant to this division."

(Bus. & Prof. Code § 4186, subd. (b)). Section 4186 also requires policies and procedures to "ensure safety, *accuracy*, accountability, [and] security . . ." of dispensing (Bus. & Prof. Code § 4186, subd. (a) [emphasis added]), says that the *stocking* of automated systems may only be performed by a licensed pharmacist (Bus. & Prof. Code § 4186, subd. (c)), and requires that drugs dispensed comply with all statutory labeling requirements (Bus. & Prof. Code § 4186, subd. (g)).

Section 4186 indicates that the placement of an automated drug delivery system in a nonprofit or free clinic does not eliminate or vitiate the responsibility of the licensee overseeing that system for the accuracy of the drugs dispensed. That licensee must still comply with all of the statutes and regulations requiring accurate dispensing, and Section 4186 reinforces this responsibility by requiring policies and procedures to ensure accuracy as well as the direct involvement of the licensee in the stocking of the machine and the dispensing of drugs. The licensee still remains responsible for any errors that result from this delivery system. There is no exemption stated by Section 4186 to the general duties of licensees in this regard. Moreover, there is no reason to think that such an exemption would apply to an automated delivery system placed in any other setting, including the inpatient setting.

Therefore, counsel has advised that any licensee that chooses to implement a reduced-error-checking protocol like that suggested by McKesson is assuming the risk of any errors that result. Even if such errors are less likely with the ROBOT-Rx system, the licensee is responsible for any errors that do occur. It may therefore be a risk for licensees to implement a protocol that increases the chance that such error will occur, however minor, by eliminating human 100 percent double-checking that may, in at least some cases, catch and correct those few errors made by the machine(s). Any licensee implementing such a protocol will be subject to discipline for any errors that do occur (as would any licensee responsible for errors from any other delivery system). It is possible the severity of the violation may even be greater where the error could have been caught but for this protocol.

Counsel advises that there is at present no statutory or regulatory requirement that licensees check 100 percent of all prescriptions dispensed by an automated delivery system. While licensees may elect to save costs by reducing their level of error checking, they do so at their own risk and that of the patient. If it is the desire of the board to require 100 percent error checking by a pharmacist, and not permit this election, then additional statutes or regulations are needed.

Further, counsel does not recommend that the board approve the protocol McKesson proposes. First, there is no authority for the board to approve a protocol and to do so, may constitute an impermissible underground regulation. Second, under current law, it is the decision of the individual licensees to determine the level of risk of error they are willing to assume, and the steps they take to reduce or eliminate that risk.

While the initial request was for the use of an automated delivery system in a hospital inpatient pharmacy, counsel advises that there is at present no statutory or regulatory

requirement that licensees check 100 percent of all prescriptions dispensed by an automated delivery system is any pharmacy practice settings. Further, while licensees may elect to save costs by reducing their level of error checking, they do so at their own risk and that of the patient.

If it is the desire of the board to require 100 percent error checking by a pharmacist, and not permit this election, then additional statutes or regulations are needed.

John Cronin, representing the California Pharmacists Association, asked what the current position of the board is regarding legality.

President Jones stated that the board is not taking a position on individual automation devices.

Mr. Room stated that the pharmacist is ultimately responsible for the accuracy of the prescription regardless of whether it is filled by hand or by automated delivery system.

Mr. Cronin stated that the pharmacist is not required to check the final product prior to dispensing but the pharmacist is responsible for the accuracy of the prescription.

President Jones stated that each medication delivery system is different and it would be very difficult for the board to rule on each system; the board does not intend to do this. If a robotic system has an excellent accuracy record and if a system error occurred, it would likely be the responsibility of the pharmacist-in-charge.

Mr. Room stated that there is no specific statute or regulation in place that states a pharmacist must check each drug from a delivery system but if the board finds that this should be a requirement a statutory authority is required. Mr. Room added that it is part of a pharmacist's professional duty to ensure that the drugs dispensed conform to a prescription and should an error occur, this would be considered as a factor in mitigation for disciplinary action.

Mr. Cronin stated that as the industry moves towards utilization of technology, changes will occur and he suggested that this be an outreach effort.

Ms. Harris stated that the board would consider placing information on the Web site and in its newsletter as a compliance issue or interpretation of the law.

- **Implementation of SB 151 (Chapter 406, Statutes of 2003) – New Prescription Requirements for Controlled Substances and the Elimination of the Triplicate**

  Senate Bill 151 (Burton) repeals the triplicate prescription requirement for Schedule II controlled substance prescriptions and substantially revises California law regarding the prescribing of controlled substances generally. Generally, Senate Bill 151 repeals the triplicate and replaces it with a tamper resistant prescription form that may be obtained from approved printers. This new form will be required for all controlled substance prescriptions

after the phase-in period. The bill also will require pharmacies to report Schedule III controlled substance prescriptions to the CURES system.

The triplicate requirement has been in place for over 60 years and the implementation of the new law will be complex and confusing. The board anticipates many questions and has been working hard especially with its limited resources to educate prescribers and pharmacists.

The board's newsletter with these new changes was published at the end of March. Meanwhile, the articles on SB 151 are on the board's Web site. The articles have also been provided to the prescriber boards and professional associations so that they can educate their licensees and answer questions. Staff and board members have been working with various associations and pharmaceutical companies on educational programs and outreach efforts.

Steve Gray, representing Kaiser Permanente, asked about the status of approved printing companies.

Ms. Harris responded that two companies were approved and listed on the board's Web site.

Dr. Gray referred to a situation where companies were told by board staff that prescription blanks must be mailed to the physician's address of record instead of the address printed on the prescription blank and this created problems. He asked for clarification.

Supervising Inspector Judi Nurse stated that the DEA registration must reflect the physician's practice and printers are encouraged to verify that the address on the prescription blank reflects where the practice is.

- **Charlene Zettel, Director of Department of Consumer Affairs**

President Jones welcomed Charlene Zettel as the newly appointed director of the Department of Consumer Affairs. He added that he had the pleasure of serving on one of her health care committees during her tenure as an Assemblywoman and he commented on the positive experience he had.

Ms. Zettel thanked the board for the opportunity to attend the board meeting. She stated that it is an honor to be nominated by the Governor and to be his voice for consumers.

Ms. Zettel stated that the Governor is grateful to the board for all of the hours spent participating on the board and he acknowledges the sacrifice it takes as well as the complicated issues the board is faced with. She added that in order for government to work, it takes the participation of an involved citizenry.

Ms. Zettel thanked the audience for its participation as well and added that she looks forward to working with the board. She introduced Laurie Ramirez who is the executive liaison within the Department of Consumer Affairs.

President Jones announced to Ms. Zettel that the Board of Pharmacy was accepted this year as an active member in the National Association of Boards of Pharmacy and is now using a national exam for California students instead of the board's own exam used in previous years. Because of this, the board now has voting privileges at the NABP 100th anniversary meeting April 24-27, 2004, in Chicago, IL. President Jones presented Ms. Zettel with a Board of Pharmacy pin created for this event and thanked her for attending the board meeting. President Jones thanked Ms. Zettle for her comments and stated that the board looks forward to a very productive relationship.

LICENSING COMMITTEE

Dr. Conroy gave the report on the March 3, 2004, Licensing Committee Meeting.

- **Recommendation to Restructure the Competency Committee**

Dr. Conroy reported that the board's Competency Committee develops and oversees the administration of the California pharmacist licensure examination. Until January 2004, the examination was given twice a year and was comprised of 300 multiple-choice items and a 100-point short-answer examination that had to be hand-graded.

This year, under the new examination structure created by SB 361, the board still must develop one examination, the 90-item multiple-choice CPJE. However, to prevent exam compromise, many more than 90 questions are being administered at any time. The Competency Committee develops these questions.

Appointment to the committee is an honor, but the work required of the committee is demanding. There is a minimum of seven two-day meetings annually, and additional outside time spent writing questions. Additionally, there are periodic subcommittee meetings to review performance statistics of the examination or perform other specialized tasks. Whereas the committee formerly hand-graded the short answer exam (this accounted for two of the seven two-day meetings), the committee is currently creating new items for the new examination structure.

Later this year, the committee will oversee a job analysis of the pharmacist profession; a survey of 2,000 pharmacists for each duty they perform and the importance of each task. From this job analysis, the committee develops the content outline for the examination. This job analysis must be conducted every three to seven years, to assure that the exam remains valid for entry-level pharmacist practice.

The committee is carefully structured to ensure a balance of practitioners from all practice settings. In the last six months, there have been a number of changes as some members have rotated off the committee (they typically serve for eight years) and several others have resigned early due to other commitments.

The Licensing Committee recommends that the board convert to a new structure, a structure similar to the one used by NABP. The proposed structure would be a two-tier structure, a group of item writers to develop questions for the examination, and the core committee – the group that selects items and refines them for the examination, selects a cut score and oversees issues arising from administration of the examination.

The item writers would meet once annually for an item-writing workshop. Then, throughout the year, assignments to write questions in specific areas of the content outline would be assigned to them. The questions would be sent to the board in a secure manner. There would be no other meeting for this group of individuals.

The core committee would refine and revise the questions submitted by the item writers and review items selected for examinations to assure a balanced exam for any applicant. The committee would establish cut scores and review the performance of questions in the exam pool. When necessary, the members would also write items for the examination. This group would be smaller than the current committee. The proposed structure would be:

Recommended Composition:	19 members
Schools of Pharmacy: 1 member each	6 members
Community Practice:	6 members
Institutional Practice:	5 members
Board Member:	1 member
Inspector:	1 member

Attendance at the meetings would be a requirement, and those who miss a certain number of committee meetings each year would be asked to become item writers, where attendance at meetings would not be not necessary. There would continue to be seven meetings annually, but the board's item bank of usable items would grow greatly, facilitating examination administration. At some point in the future (perhaps two years), it could be possible to reduce the number of annual meetings of this group, perhaps to five or six meetings per year.

Terms would be for four years, with reappointment to another four years. The board's president would appoint all members. Appointment would require three letters of recommendation in addition to the applicant's curriculum vitae.

The costs for the new structure ($99,724) would be about the same as the costs for the current structure if 29 members were appointed to the committee and attendance remained at current levels – about 50 percent attending any full two-day meeting ($101,810.

Restructuring the committee would reduce the burden placed on the members of the committee to attend 14 meeting days annually and write questions outside of the committee meetings. It would help prevent member "burn-out." Another benefit of using item writers for new questions would be a broader base of examination questions in the "bank." And as stated earlier, within two years, the committee could reduce its number of two-day meetings from seven to five each year if a large enough item bank exists.

MOTION: Licensing Committee: The Board of Pharmacy restructure the Competency Committee to a two-tier structure consisting of a group of item writers to develop questions for the California Pharmacist Jurisprudence Examination (CPJE) and a core committee that would select and refine the items for the examination, select a cut-score and oversee the administration of the examination.

SUPPORT: 8 OPPOSE: 0

- **Report Requirement of Business and Professions Code section 4200.1 – Four Attempts to Pass the Pharmacist Licensure Examination and Recommendation to Extend Repeal Date**

Dr. Conroy stated that since 1999, candidates for the California pharmacist licensure examination who fail the examination four or more times, are required to take 16 units of education in pharmacy in a school approved by ACPE or by the board before they can retake the examinations. This provision will be repealed January 1, 2005, unless the sunset date for this provision is extended.

Years ago, the board sponsored this provision to remove a number of applicants from the licensure examination who had repeatedly failed the examination – in fact; there were several applicants who had taken the examination more than 25 times. A major concern was that these individuals were taking the examination only to memorize questions that could be provided to preparation course providers. The provision itself was modeled after a similar provision enacted for the dental examination.

When the provision was enacted in 1997, the board was also mandated to provide a report to the Legislature after June 1, 2004 and before December 31, 2004, on the effect of this provision in four areas. These areas are:

1. The number of applicants taking the examination and the number who fail the examination for the fourth time.
2. The number of applicants who, after failing the examination for the fourth time, apply to take the additional 16 semester units of pharmacy education in California, and the number of these applicants who are accepted into the pharmacy education program.

3. The number of applicants who, after filing the examination for the fourth time, apply to participate in any pharmacy studies program, in or out of California, and the number of these applicants accepted by those programs.
4. To the extent possible, the school and country from which applicants graduated and the comparative pass/fail rates on the examination in relation to the school and country.

However, since the examination structure itself was greatly altered by last year's SB 361, staff requests that an extension in the sunset date for this provision be made. The reason for this is to allow the board time to evaluate the effect of the provision on the new examination structure.

According to a recent legal opinion prepared by Departmental Counsel Dana Winterrowd, the four-time failure provision still affects those who take the CPJE and the NAPLEX. For those who have never taken the California licensure examination, they will have four opportunities to take and pass the CPJE and four opportunities to take and pass NAPLEX.

If a candidate had taken the old examination (before January 1, 2004) and failed it one or more times, these attempts do count when determining the four failures. For example, if a candidate failed the January and June 2003 examinations, he or she would have two more opportunities to pass the CPJE and two opportunities to take the NAPLEX. Once he or she reach four failed attempts, the individual would need to take the 16 units of pharmacy education before he or she could retake the examination.

MOTION: Licensing Committee: The Board of Pharmacy sponsor legislation to extend the provision that requires an applicant who failed the board's pharmacist licensure examination four or more times to take an additional 16 units of pharmacy education. The provision would be extended to the board's next sunset review in 2008.

SUPPORT: 8 OPPOSE: 0

- **Proposed amendment to CCR, title 16, sec. 1719 (a) – Board approval of Pharmacy Schools Pending Accreditation by the Accreditation Council for Pharmacy Education (ACPE)**

Dr. Conroy stated that at the January 2004 Board Meeting, the board agreed to accept "candidate status" accreditation by the ACPE as meeting sufficient standards for the board to issue an intern license to a student at Lake Erie School of Pharmacy.

This was the second time in one year that the board had to consider accreditation of a new pharmacy school because students were seeking California intern licenses. Both schools had limited accreditation status from the ACPE, which required specific board action to assure they

could be issued intern licenses. At the board meeting, staff stated that they would suggest a more permanent resolution to the board. The proposal is to amend CCR, title 16, sec. 1719.

Internship is an integral part of the pharmacy education of students. State licensing agencies look for ACPE accreditation as a means to assure the students are receiving particular (and approved) educational coursework before an intern pharmacist license is issued. This is especially critical for new schools, where there is only provisional ACPE accreditation (full accreditation will not be given until the first students have graduated from the school).

The ACPE Accreditation Manual, 9th Edition has the following definition of "candidate status:"

> **9.3.2** **Candidate**. A new program that has students enrolled but has not had a graduating class may be granted Candidate status. The granting of Candidate status denotes a developmental program, which is expected to mature in accord with stated plans and within a defined time period. Reasonable assurances are expected to be provided that the program may become accredited as programmatic experiences are gained, generally, by the time the first class has graduated. Graduates of a class designated as having Candidate status have the same rights and privileges as graduates of an accredited program.

Mr. Goldenberg stated that in working recently with the accrediting board for a review of the University of Pacific, he confirmed that the review was very significant and universities take the accreditation review seriously. He added that upon completion of such a review and successful passing, the board can have confidence that the college will produce pharmacists who are adequately educated and trained as pharmacists.

President Jones stated that he participated at the UCSD accreditation review during a four-day process that was very thorough for both new colleges of pharmacy and for renewal of ACPE accreditations. He added that the board could take comfort in the process, as these schools must conform to rigorous national standards.

MOTION: Licensing Committee: The Board of Pharmacy amend CCR, title 16, sec. 1719 to recognize those schools of pharmacy that have been granted candidate status by the Accreditation Council for Pharmacy Education (ACPE) for purposes of application for an intern registration and being admitted to the pharmacist licensure examination.

SUPPORT: 8 OPPOSE: 0

- **Approval of the Statewide Protocol for Pharmacists to Dispense Emergency Contraception as Recommended by the Medical Board of California and Recommendation to Adopt as an Emergency Regulation to Implement**

Dr. Conroy stated that on January 30, 2004 the Medical Board of California (MBC) considered the emergency contraception protocol approved by the Board of Pharmacy at its January meeting.

Linda Whitney, representing the California Medical Board, stated that the amended protocol presented to the board at this meeting was approved by the subcommittee of the Medical Board.

Lorie Rice, representing UCSF, stated that currently the utilization of emergency contraception is not as extensive as proponents hoped it would be and the reason may be that young women may be hesitant to have a conversation face to face with the pharmacist. She asked if a phone call would be sufficient.

Dr. Conroy stated that the issue of telephone consultation has been addressed and is appropriate.

Ms. Harris stated that upon release of the protocol, board staff could also provide a question and answer sheet that will help address this type of inquiry.

Steve Gray, representing Kaiser Permanente, stated that he supports using a telephone consultation. He added that at Kaiser Permanente, it is common and accepted among physicians and nurse practitioners to gather the information over the phone and once gathered, transmit a prescription to the pharmacy. Basically, the call centers gather information and transmit the prescription to the pharmacy.

After the protocol is approved by both boards, the protocol must be adopted as a regulation. The board may want to consider adopting the protocol as an emergency regulation so that it can be implemented more without further delay. Otherwise, it will take approximately another six months for implementation after the July board meeting. To adopt the protocol as an emergency regulation, the board must be able to demonstrate the immediate public health need.

Mr. Riches stated that during the discussions on protocol, counsel advised the board that in order to enforce the protocol a regulation would need to be adopted. He added that one option could be to process an emergency rulemaking file that could be completed in 120 days and take effect immediately.

Dr. Gray stated that this should be viewed as an alternative protocol and not the only protocol that a pharmacist must use under this circumstance.

MOTION: The Board of Pharmacy adopt the recommended changes from the Medical Board of California to the statewide protocol for pharmacists to dispense emergency contraception and adopt as an emergency regulation, if necessary.

M/S/C: POWERS/ZINDER

SUPPORT: 8 OPPOSE: 0

- **Request from Cedars-Sinai Medical Center for a waiver pursuant to CCR, title 16, sec. 1706.5 to conduct a study with UCSF, School of Pharmacy to determine the impact of using technicians checking technicians to fill unit dose cassettes on patient care.**

  Dr. Conroy stated that the UCSF School of Pharmacy has requested a waiver of CCR, title 16, sec. 1793.1(f) and 1793.7(b) to allow a pharmacy technician in a unit-dose drug distribution system to check another technician. This request follows an experimental program that concluded in December 2003, evaluating technicians. Peter Ambrose, Professor of Clinical Pharmacy at the UCSF School of Pharmacy is the lead researcher.

  Dr. Conroy stated that this sequel study will evaluate the impact of pharmacists in prevention of medication errors associated with prescribing and administering of medications as a result of pharmacists being re-deployed from unit-dose medication cassette checking to more clinical and professional functions. Such functions require special expertise of pharmacists in the management of drug therapy, from which patients will benefit.

  Dr. Conroy stated that the Cedars-Sinai Medical Center (CSMC) is the sponsoring facility. The proposal requests that the board allow the "tech-check-tech" process to continue at the CSMC, while the UCSF measures the number and types of medication errors prevented during the equivalent time period that pharmacists would be checking medication cassettes. She added that Dr. Ambrose requests that the Board of Pharmacy grant the waiver for two years and that an interim report would be provided at one year. Representatives from the CSMC also state that they would continue to seek legislation to allow the "tech-check-tech" process.

  Dr. Ambrose explained that this study is not an extension of the "tech-check-tech" study, checking the accuracy of technicians checking the work of other technicians that was completed in December 2003. The results of that study demonstrated that technicians could check the cassettes more accurately than pharmacists.

  Dr. Ambrose stated that the current study is the logical sequel to that study in that it will demonstrate how a pharmacist, free from the task of checking unit dose cassettes, can focus on patient care interventions instead. The proposed study would determine the number and types of medication errors that are intercepted by pharmacists at (1) the prescribing step and (2) the administration step.

Dr. Ambrose referred to the background material showing that both the prescribing staff and administration staff are major points where drug administration errors can occur. He added that the sequel study would document how the freed up time will be spent.

Steve Gray, representing Kaiser Permanente, stated that Kaiser supports the sequel study and added that this is the next logical step. He added that parallel legislation became bogged down due to a lack of fiscal justification that this study would provide that is integral to a legislative change. This will allow pharmacists to fully apply their professional skills to improve the quality of care in hospitals. He encouraged the board to move forward.

John Cronin, representing the California Pharmacists Association, stated that the CPhA also has policy that supports tech-check-tech under certain circumstances and this study will help address some of the issues. He referred to the commitment made by the CSMC to continue to seek legislation to allow the tech-check-tech process.

A representative from California Employee Pharmacists Association (CEPA) stated that the CEPA opposes this proposal because a study they conducted concluded in the 1970s that technicians do not do as good a job as pharmacists in checking medications.

Teri Miller, representing the California Society of Hospital Pharmacists, stated that the CSHP supports granting a waiver to the Cedars-Sinai Medical Center for the purpose of this study. Results of this study will provide information on how patient outcomes can be approved by freeing up pharmacists.

Dr. Fong encouraged the board to move forward with innovative practice in pharmacy to demonstrate the real value of pharmacists taking care of patients.

Mr. Powers stated that he was uneasy with the original study and continues to have the same concerns.

MOTION: The Board of Pharmacy grant the request from Cedars-Sinai Medical Center for a waiver pursuant to CCR, title 16, sec. 1706.5 to conduct a study with the UCSF School of Pharmacy to determine the impact of using technicians checking technicians to fill unit dose cassettes on patient care for two years (from April 21, 2004 through April 20, 2006).

M/S/C: SCHELL/FONG

SUPPORT: 5 OPPOSE: 3

- **Recommended Statutory Proposal for Information Required on Application Forms**

Dr. Conroy stated that the board has applications for its 12 regulatory programs that require a range of different information from the various applicants. On the advice of counsel, requests for much of the needed information has not been included on the application forms because of a concern regarding the specific legal authority to request the information. Accordingly, staff developed a legislative proposal for inclusion in the 2004 Omnibus Bill. This proposal is intended to provide the board with clear statutory authority to request information needed to evaluate the qualifications of any applicant. This will allow the board to include necessary information on application forms without adopting regulations to do so.

The proposal is to clarify the basic information that is requested on application forms, which is consistent with the relevant law requirements to obtain a license or permit from the board.

MOTION: Licensing Committee: The Board of Pharmacy sponsor a legislative proposal for inclusion in the 2004 omnibus bill that would give clear statutory authority to request information needed to evaluate the qualifications of any applicant.

SUPPORT: 8 OPPOSE: 0

- **Report on the Implementation of North American Pharmacist Licensure Examination (NAPLEX and California Pharmacist Jurisprudence Examination (CPJE)**

Dr. Conroy stated that both contracts to implement NAPLEX and the CPJE have been approved. The CPJE was approved March 11th and NAPLEX was approved April 2nd. Both exams will be available six days a week at designated testing locations across the United States. There will be 125 individual sites for the CPJE alone.

Application forms and instructions detailing the application process are available on the board's Web site. A Candidates' Guide handbook has been developed, detailing procedures for taking the CPJE, what to expect at the test site, and how to study for the CPJE (including sample questions). The board has placed this handbook on its Web site, but Experior Assessments (the test administrator) will send a handbook to each candidate who has been qualified by the board to take the CPJE.

The NABP has a handbook containing similar information on its Web site regarding the NAPLEX that is available for downloading by applicants.

There have been changes to the security requirements for admission to the CPJE examination. Applicants are required to bring a government-issued identification (driver's license, state-issued identification card, military card) containing a recent photograph and their federal Social Security card. The name appearing on both of these identification cards must match exactly the name used to register for the CPJE, including middle names and designations such as "Jr." or "III," etc. If the applicant does not have the appropriate identification, then he/she will not be admitted to take the examination and will need to reschedule it.

The board will release examination results within 15 days after an applicant takes the NAPLEX and approximately 30 days after taking the CPJE.

The board has made proposed regulation changes to its examination procedures to fully implement the NAPLEX and CPJE. The regulations have been noticed and the board will act on them during the regulation session of the meeting.

Ms. Herold reported that the board has received 850 applications. She added that the board is approaching the June graduation date and will be very busy during this time releasing results, and licensing new pharmacists.

President Jones stated that he and Supervising Inspector Bob Ratcliff visited several universities to inform students who were graduating about the NABLEX and current changes in pharmacy law. He added that the students were very interested to learn of these developments and had many questions after each session.

- **Report from the Workgroup on Compounding – Meeting Summary**

Dr. Conroy 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 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 understanding how the board notifies individuals when pharmacy-compounding activities fall outside the scope of pharmacy practice.

The Workgroup on Compounding held its first meeting on March 3, 2004. Dr. Schell chairs the committee and Board Member John Tilley is a participant.

Mr. Cronin stated that it is the CPhA's understanding that the board received a letter from the FDA regarding compounding of veterinarian drug products. He added that this is a very controversial issue and asked that it be incorporated into the next meeting.

ELECTION OF OFFICERS

- **Board President**

MOTION: Nominate Stan Goldenberg as President of the Board of Pharmacy.

M/S/C: SCHELL/FONG

SUPPORT: 8 OPPOSE: 0

- **Vice President**

  MOTION: Nominate Bill Powers as Vice President of the Board of Pharmacy.

  M/S/C: ZINDER/ACEVEDO

  MOTION: Nominate John Tilley as Vice President of the Board of Pharmacy.

  M/S/C: FONG/GOLDENBERG

  VOTES: 5 POWERS
  3 TILLEY

- **Treasurer**

  MOTION: Nominate Dave Fong as Treasurer of the Board of Pharmacy

  M/S/C: GOLDENBERG/SCHELL

  SUPPORT: 8 OPPOSE: 0

LEGISLATION AND REGULATION COMMITTEE

- **Regulation Hearing – Pharmacist-In-Charge (PIC)**
  Proposed Amendment to CCR, title 16, sec. 1709.1

  President Jones announced that the regulation hearing is open to take oral testimony and evidentiary evidence by any person interested in the regulation for the record, which is taped by tape recorder. All oral testimony and documentary evidence will be considered by the board pursuant to the requirements of the Administrative Procedures Act, before the board adopts the proposed amendment to these regulations or recognizes changes that may evolve as a result of the hearing. He added that interested persons who want to provide oral testimony should come forward and give their name, address and the name of their organization so the board will have a record of those who appear.

  President Jones stated that the public forum is to receive comments on the proposed regulations and is not intended to be a forum for debate or defense of the regulations. Oral testimony may be summarized but should not be read. The board will give equal consideration to written and oral testimony. Questions about the proposed regulation should be rephrased into a comment. After all interested parties have been heard, the issue will stand submitted.

Dr. Fong requested that the board defer voting on this regulation until Board Members Clarence Hiura and John Tilley have the opportunity to vote and participate in the discussion.

Mr. Young, representing the California Retailers Association, stated that both the proposed pharmacist-in-charge and the clerk typist regulations are needed. He stated that the proposed pharmacist-in-charge regulation would allow licensed pharmacists to determine appropriate staffing in appropriate practice settings. The diversity of staffing and practice settings require a case-by-case determination by the pharmacist on duty.

Mr. Mazzoni, representing Albertsons/SavOn, stated that his company supports the regulation change because it would allow qualified pharmacists to manage more than one pharmacy location. By allowing pharmacists with the aptitude to manage more than one pharmacy to do so, the regulation would allow existing PICs who don't want the responsibility of a PIC to shed that responsibility.

John Cronin, representing the California Pharmacists Association, stated that the CPhA also supports this regulation. He referred to subdivision (b), which the CPhA specifically advocated for. He added that a "Compliance Guideline" for licensees is also needed in conjunction with this regulation. He noted that it is important that the board, professional organizations and pharmacists all communicate that each pharmacist has the authority to determine if he or she wants to take on the duties of a PIC at a second pharmacy.

President Jones stated that the board is conveying the importance of the PIC is presentation to graduating students at pharmacy schools. These young pharmacists may be approached to be a pharmacist-in-charge and it is important they understand their rights and responsibilities for assuring the pharmacy's compliance with pharmacy law.

Trent Smith, representing Rite Aid, stated that his company supports the proposed regulations and agrees with the comments made by Bruce Young.

Allen Gordon, representing the California Employee Pharmacist Association (CEPA), stated that the CEPA opposes the proposed regulation. This association does not understand why the board is considering the change. He questioned the need for the regulation and that it may have adverse effects. He added that currently there are 6000 pharmacies and CEPA feels this is a sufficient amount for California but this change in the responsibilities of a PIC may cause an increase in pharmacies in areas where there is already a high concentration of pharmacies. He added that this regulation might have an adverse effect on pharmacists who do not want to be the PIC at two locations and could ultimately affect the pharmacist's future due to subsequent disciplinary action by the board.

Mr. Gordon stated that it would be the employer's decision if a PIC works at two locations. Also, the language indicates that no disciplinary action could be taken against a pharmacist for refusing to become the pharmacist-in-charge at a second location but this would be difficult to ascertain in practice.

Mr. Gordon stated that the regulation might tempt young, inexperienced pharmacists to take on a second pharmacy that they may not be able to handle.

Steve Gray, representing Kaiser Permanente, stated that Kaiser Permanente supports the proposed regulation change and worked with the board during the development process. He added that the position of pharmacist-in-charge has increasingly become more demanding and requires candidates to have sophisticated skills, knowledge and abilities. Dr. Gray stated that this regulation change would allow organizations to focus greater investments in PIC with the aptitude and interest to excel as PIC.

Mr. Powers questioned whether it is rational to give PICs more responsibility knowing that these positions have become more complex and burdensome.

Dr. Gray responded that the PIC positions are more complex and require a higher level of training in order to understand the responsibilities and opportunities. Some of these include dealing with security issues, quality of care, follow-up investigations, and the requirements under the quality assurance program. The PIC must also follow through with those responsibilities and others and have leadership ability with pharmacists and non-pharmacist staff.

Dr. Fong asked how Kaiser Permanente would develop and encourage PICs to meet the challenge of working in two pharmacies.

Dr. Gray responded that Kaiser Permanente has a development process for managers, supervisors and pharmacists accepting the responsibility. This includes special training classes over several months for supervisors and managers.

Orriette Quandt, representing Longs Drugs, stated that this could be an opportunity for individuals who may be qualified managers to act as mentors to future managers. Also, this offers an opportunity for the pharmacy owner to assign a pharmacist-in-charge at a new location when the pharmacist is already the PIC at another location. This ability will make it easier for the new pharmacy to obtain permission to bill government programs. She added that this would benefit the board's application process too.

Mr. Powers asked if Longs Drugs has a training program for PICs.

Ms. Quandt stated that Longs Drugs has pharmacy area supervisors who work with new pharmacy managers advising them of their responsibilities and what is expected of them.

Steven Kyle, a pharmacist, stated that last year he served as a pharmacy manager of two pharmacies and helped to bring the pharmacies in compliance with the law. He added that this regulation is not needed because there should only be one pharmacist in charge of a pharmacy. He suggested that pharmacies could hire qualified managers to help the

pharmacist-in-charge and this would not require a regulation change. He added that this would not offer any protection for the pharmacist-in-charge who does not want to be PIC at two stores and that the PIC would simply be transferred to another store as a punishment. However, such actions would not constitute "discipline."

Mr. Powers stated that the amended language under section (f) does offer protection for the PIC.

Mr. Goldenberg asked Mr. Kyle if he felt that that a pharmacy owner would commonly punish a pharmacist who was a successful PIC at one store because he refused a second store. Mr. Kyle responded that the inference that it would occur is in the language; obviously someone felt it was necessary to place language in the regulation to protect pharmacists from any disciplinary action that may result if they declined to manage two stores. After all, the company has a business to run and must maximize profits.

Mr. Kyle stated that without a regulation change, pharmacies could hire as many pharmacy managers as they want to.

Mr. Kyle suggested that the board reconsider a regulation change.

President Jones closed the hearing.

Deputy Attorney General Joshua Room suggested a clarifying change to subsection (g) where it states, "established pursuant to this paragraph" and instead use "established pursuant to this section."

Mr. Powers expressed concern that the proposed changes to section 1709.1 would force a pharmacist to be the PIC at two pharmacies.

MOTION: Legislation and Regulation Committee: Adopt proposed amendment to CCR, Title 16, section 1709.1, and change the word "paragraph" to "section" in subparagraph (g)– Pharmacist-In-Change.

M/S/C: GOLDENBERG/CONROY

SUPPORT: 5 OPPOSE: 3

REGULATION HEARING

Proposed Amendment to CCR, Title 16, Sec. 1793.3 – Non-Licensed Person (Clerk-Typist)

President Jones announced that the regulation hearing is open to take oral testimony and evidentiary evidence by any person interested in the regulation for the record, which is taped by tape recorder. All oral testimony and documentary evidence will be considered by the

board pursuant to the requirements of the Administrative Procedures Act, before the board adopts the proposed amendment to these regulations or recognizes changes that may evolve as a result of the hearing. He added that interested persons who want to provide oral testimony should come forward and give their name, address and the name of their organization so the board will have a record of those who appear.

President Jones stated that the public forum is to receive comments on the proposed regulations and is not intended to be a forum for debate or defense of the regulations. Oral testimony may be summarized but should not be read. The board will give equal consideration to written and oral testimony. Questions about the proposed regulation should be rephrased into a comment. After all interested parties have been heard, the issue will stand submitted.

Bruce Young, representing the California Retailers Association, stated that the CRA is supportive of this regulation change. This is another example where the pharmacist-in-charge and managers can determine the staffing need based on the pharmacy's practice.

Rich Mazzoni, representing Albertsons/SavOn, agreed with the comments made by Mr. Young. The regulation change recognizes the administrative burden pharmacists face. This regulation change represents a step towards more pharmaceutical care and less paperwork for pharmacists.

Allen Gordon, representing CEPA, stated that 400 pharmacists in Southern California do not feel this way and he referred to the impact that this would have on personnel. He stated that unlicensed personnel are not as accurate as pharmacists and will perform duties such as checking in stock and cashiering but pharmacists supervising clerks will not really know what they are doing and this would have an adverse affect.

Trent Smith, representing Rite Aid, stated that his company supports this action.

Steven Kyle, pharmacist, encouraged the board not to change the regulation because of public safety issues. The factual basis for this regulation is wrong. He added that since the existing regulation was put in place, pharmacy systems have become more complicated with computers, scanning devices, biometric devices and reading fingerprints.

Mr. Kyle added that the number of unlicensed ancillary personnel employed to resolve third-party payment issues is not true. He added that in checking with others and from his experience, unlicensed personnel are not resolving third-party complaint issues; technicians are. An unlimited number of pharmacy technicians can input data into the computer system but there is a misunderstanding that under section 1793.7 CCR the number of technicians is restricted to those who perform duties outlined in subdivision (a) dealing with manipulation of and counting drugs. He added that this regulation would place an unlimited number of personnel in the pharmacy that the board has no control over compared to pharmacy

technicians who are licensed and must meet educational and training requirements. He added that the number of pharmacy technicians should not be limited in the pharmacy.

Mr. Kyle added that more unlicensed and untrained personnel cause more interruptions to the pharmacist. He suggested that companies move the function of processing through third-parties to a central location if this function becomes a burden.

Dr. Fong referred to the new Medi-Cal drug discount cards that become effective June 1 and the additional work this will add in assisting patients in determining the lowest price of drugs. He asked how the pharmacist would handle this without compromising other services the pharmacist provides.

Mr. Kyle stated that technicians handle this type of situation. He added that when patients have more than one insurance policy and a drug is not covered, the pharmacy might process it through the Medicare cash discount plan. He stated that this amendment will not add more personnel to the pharmacy and that large companies will not increase their labor force but will instead shift the work and use clerks because it is less expensive.

John Cronin, representing the California Pharmacists Association (CPhA), stated that the CPhA has a specific policy that supports this regulation change. The House of Delegates debated this issue and many of the issues raised were also issues raised by CPhA House of Delegates but the outcome was to support the change.

Orrette Quandt, representing Longs Drugs, referred to the comments already made and stated that it is usually the pharmacy technician who is assisting the pharmacist with the count, pour, lick and stick functions. The responsibilities to assist patients rest with the clerk typist who is trying to process a prescription and must also address insurance issues. Removing the clerk typist from the computer places the burden on the pharmacist to start typing the prescription. An alternative is for the pharmacist or the technician to handle the telephone issues but this prevents the pharmacist from verifying that the technician filled the prescription and also interferers with the pharmacist's consultation process. Removing the technician from the process also slows the pharmacist's activities.

Ms. Quandt stated that the reason for this regulation change is to provide greater assistance to patients. She added that 10 years ago pharmacies did not have the insurance issues and the number of third-party plans that they have now which increased the difficulty in filling prescriptions.

President Jones closed the hearing to receive public comment and opened the hearing for board discussion.

Dr. Schell that public testimony indicates that that there isn't the right mix of individuals working in the pharmacy and he expressed concern that the board address these concerns and determine what the real concern is. Pharmacy technicians are not trained to do these things,

they typically learn the particular activities on the job. He added that he is fairly certain than an employer isn't going to hire someone who isn't trained, whether it is a pharmacy technician or clerk typist. He stated that he isn't sure if he understands the argument that a clerk typist isn't able to perform the tasks that clerk typists do in a pharmacy at a level need for public protection. He stated that he supports the regulation change but wants to feel confident that he sees it from a public perspective.

Dr. Fong stated that he also shares the same concern and the board's existing regulation restricts the pharmacy from hiring for the right jobs in the right environment. He added that stakeholders were to introduce legislation to remove the current ratio, but did not do so last year. Now, the board must address this regulation to relieve pressures on the profession and focus on patient care.

Ms. Harris stated that this regulation does not require a statutory change because it mandates only one non-licensed personnel to perform these functions. Any changes to the technician law would require a legislative change where the ratio is specified as one-to-one unless there is more than one pharmacist in the pharmacy; then it becomes a two-to-one ratio. Hospitals have a two-to-one ratio.

MOTION: Adopt proposed amendments to CCR, Title 16, Section 1793.3 – Other Non-Licensed Pharmacy Personnel

M/S/C: GOLDENBERG/FONG

SUPPORT: 6 OPPOSE: 0 ABSTAIN: 1

- **Proposed Regulation Amendments to CCR, Title 16, Sections 1710, 1711, 1717.1, 1717.4, 1720, 1721, 1723.1, 1724, 1749, 1793, 1793.1, 1793.2, 1793.4, 1793.5, 1793.6, and 1793.7.**

Chairperson Zinder stated that this rulemaking consolidates many non-controversial changes to board regulations made pursuant to a 15-day notice published on April 2, 2004. It was noticed without a hearing and no party requested a hearing. The board received no comments during the comment period.

John Cronin, representing the California Pharmacists Association, noted that the sections dealing with pharmacy technicians have the word "registration" replaced with the word "licensure," and he asked why this change was made.

Mr. Riches explained that "registration" and "licensed" generally mean the same within the law. In an effort to simplify the language, "licensed" was used for consistency.

Steve Gray, representing Kaiser Permanente, urged the passage of all of the regulations because they are needed and overdue.

MOTION: Legislation and Regulation Committee: Board of Pharmacy adopt the proposed regulation with changes made pursuant to a 15-day notice published on April 2, 2004. The proposed rulemaking contains non-controversial amendments to section 1710, 1711, 1717.1, 1717.4, 1720, 1721, 1723.1, 1724, 1749, 1793, 1793.1, 1793.2, 1793.4, 1793.5, 1793.6 and 1793.7.

SUPPORT: 7 OPPOSE: 0

- **Section 1751 – Sterile Compounding**

Chairperson Zinder reported that this regulation would establish guidelines for the compounding of sterile drug products.

Mr. Riches stated that the board adopted this regulation at the October 2003 Board Meeting. The board received an exemption from the executive order that would have placed a hold on the rulemaking and therefore, the board was able to submit the file to the Office of Administrative Law for review. Mr. Riches commended Mr. Powers on his efforts to obtain the fiscal impact statement for this regulation from the Department of Finance.

Mr. Riches stated that very recently the Office of Administrative Law determined that were aspects of this regulation that may constitute a building standard. Therefore the regulation must be submitted for review with the Building Standards Commission. As the board received this notice on April 19, and the rulemaking expires April 20, the board was unable to obtain that review before the regulation passed. As such, on April 20, the board received a notice of disapproval by OAL based on a procedural defect of not having the Building Standards Commission review the file. The board has 120 days to resubmit the rulemaking pending a decision with the Building Standards Commission.

Steve Gray, representing Kaiser Permanente, asked if the USP adoption supersedes this regulation.

Ms. Harris stated that during the recent Workgroup on Compounding Committee meeting, direction from the board's counsel was that the board's regulations would be the requirements for California. Until the board receives information to the contrary, the board must consider the USP standards are guidelines.

Legislation Report and Action
Status of Bills with a Board Position

Chairperson Zinder led the board in a review of pending legislation.

- **AB 320 (Correa)**

  This bill prohibits "regulatory gag clauses" in malpractice settlements. The committee recommends has a support position on this bill that is currently before the Senate Judiciary Committee.

  MOTION: Legislation and Regulation Committee: The Board of Pharmacy support AB 320 (Correa).

  SUPPORT: 7 OPPOSE: 0

- **AB 1826 (Bogh) – Fraudulent Use of a License**

  Chairperson Zinder stated that this bill would create penalties for the theft and misuse of a professional license number.

  MOTION: Legislation and Regulation Committee: The Board of Pharmacy support AB 1826 (Bogh)

  SUPPORT: 7 OPPOSE: 0

- **AB 1957 (Frommer et al.) – Drug Importation**

  Chairperson Zinder stated that this bill requires the Department of Health Services to certify Canadian pharmacies and develop a Web site that links directly to these pharmacies.

  Mr. Goldenberg questioned whether the board should support this issue. He stated that he felt that the board is supporting a concept rather than a clear action.

  Mr. Powers stated that it is important to send a message to Washington D.C. regarding their refusal to act on this important issue regarding access and affordability of prescription drugs in the United States. Because federal law does not provide flexibility to carry this out, then the state must step in as proposed in this bill.

  Mr. Goldenberg stated that he agrees but the safety factor is an issue and the board is charged with public protection.

  President Jones stated that the issue remains a federal law issue. If the board supports a bill knowing that it is contrary to federal law, the board may not be sending the right message.

  Chairperson Zinder stated that she agrees with Mr. Goldenberg but taking no action makes a statement because consumers cannot afford prescription drugs in this country.

Mr. Goldenberg asked what options the board has to send the message of endorsing affordable prescriptions that are safe and effective.

Mr. Riches stated that the board has a range of alternatives and legislation will be considered this year. Discussing these bills independently is a challenge because of the number of bills dealing with importation and the variety of activities they address. A question for the board is does the board support importation as a means to address the affordability of prescription issues?

President Jones suggested that the board develop a policy statement and placed on the agenda for the July Board Meeting.

Mr. Powers stated that a Assembly Joint Resolution calls on Congress to pass legislation legalizing importation of prescription drugs. He added that if the board is interested in safety and also accessibility, then it must go beyond supporting joint resolutions that are meaningless.

Mr. Room stated that one of the reasons for concern is because of the transfer of responsibility for operation of the Web site from the Board of Pharmacy to the Department of Health Services. He stated that any pharmacy listed on the Web site would be required to be registered as a non-resident pharmacy with the California Board of Pharmacy.

Mr. Cronin stated that these bills do not address the real problem which is the high cost of drugs in the United States and there needs to be some general intervention to deal with that. He suggested that the board consider all of the bills at the same time and he recommended that the board take a position to deal with the underlying problem, not the issue of importation.

Greg Spiker stated that the FDA does allow for personal reimportation of medication. He suggested that the board not address this issue when the public is using these pharmacies to get their medications and this causes major risk.

Mr. Powers stated that the board has a responsibility to advise consumers on how to obtain affordable safe drugs.

Erin Cabelera, Save Mart Supermarkets, asked how the board can assure safe affordable drugs from other countries when, even with strict guidelines, there are problems with counterfeiting in our own country.

Dr. Gray stated that the California Pharmacist Association adopted a policy that states that the Federal Government should figure out a way to license entities to safely import drugs. He suggested that the Board of Pharmacy were to adopt a resolution supporting the FDA to license entities to import drugs, through appropriate regulations, licensing fees as an affective way to address the issue.

MOTION: Legislation and Regulation Committee: The Board of Pharmacy oppose AB 1957 (Frommer et al.).

SUPPORT: 0 OPPOSE: 7

Mr. Riches stated that careful consideration should be given to whether the DHS or the Board of Pharmacy is responsible for approving Canadian pharmacies for the Web site.

Dr. Fong stated that it should be a combined effort between the two state agencies.

Dr. Ratcliff stated that the board does not inspect out-of-state pharmacies to assure compliance. He added that the board should be charged with the certification process.

President Jones expressed concern that the DHS would be charged with facilitating the development of a website for safe purchases of prescription drugs from Canadian pharmacies.

Ms. Harris stated that the board must consider that a federal law prohibits the purchase of prescription drugs from another country and the Board of Pharmacy is a regulatory agency enforcing the law and this places the board in a difficult position.

Mr. Riches stated that with regard to non-resident pharmacies, the board licenses the people and processes of the pharmacy. This entity complies with all rules on storing and dispensing drugs. The board does not evaluate the drug product. He asked the board to consider whether it is seeking to ensure the product or seeking to ensure the quality of the organization supplying the product.

MOTION: The Board of Pharmacy support AB 1957 (Frommer et al.) if amended to direct that the Board of Pharmacy establish a Web sight to facilitate the safe purchase of prescription drugs from Canadian pharmacies.

M/S/C: ZINDER/POWERS

SUPPORT: 4 OPPOSE: 3

- **AB 1960 (Pavley and Frommer) – Pharmacy Benefit Manager**

Chairperson Zinder stated that this bill requires the board to license PBMs and specifies contract terms and disclosures by PBMs.

Chairperson Zinder stated that the Legislation and Regulation Committee recommends a support position on the bill, if amended.

Mr. Riches stated that the prior version of the bill declared a fiduciary relationship between PBMs and its client. As a general matter, the board is required to administer and enforce all

of the provisions of pharmacy law. If there were an instance where a PBM did not exercise its fiduciary responsibilities, it would be subject to enforcement by the board. Based on that, the board asked for an amendment to remove the provisions from the board's jurisdiction. The current version of the bill requires the board to license PBMs, establish minimum contractual requirements between PBMs and their clients and disclosure and patient protection provisions that mirror those that exist now. Board staff recommend an oppose position.

Mr. Powers stated that he participated on the PBM Ad Hoc Committee. He added that he shared concern that PBMs were unregulated. And, although it does not apply to all PBMs, it became clear that there is skimming occurring and diversion of profits to the PBMs. He added that PBMs need to be regulated and he encouraged a support if amended position on the bill.

Dr. Schell stated that the committee report indicates that the committee was unable to identify the need to regulate PBMs.

President Jones stated that the board does not have staff and funds to regulate PBMs. If the board supports this bill if is amended, it does not provide the board much muscle to move it over to the regulatory agencies that currently have a structure in place for this type of regulation. He asked that the board consider this very carefully and determine if there is staff available to handle the additional workload. There have not been consumer complaints.

Ms. Harris asked where the consumer protection issue for the board to take on this program. The board will not receive additional resources to implement new legislation and the board needs to determine if this is part of its strategic plan and whether it is a critical factor.

Ms. Zinder stated that the bill allows for fees to be collected for this program.

MOTION: Legislation and Regulation Committee: Support AB 1960 (Pavley), if amended.

SUPPORT: 3 OPPOSE: 4

MOTION: Oppose AB 1960 (Pavley), unless amended to restore the fiduciary responsibility language and move the provisions away from enforcement obligation.

M/S/C: GOLDENBERG/CONROY

SUPPORT: 4 OPPOSE: 3

- **AB 2125 (Levine) – Prescribing Practices**

Chairperson Zinder stated that this bill requires pharmacists to include a diagnosis on the prescription label if the patient requests it. She added that the Legislation and Regulation Committee recommends no position.

MOTION: Legislation and Regulation Committee: The Board of Pharmacy has no position on AB 2125 (Levine).

SUPPORT: 7 OPPOSE: 0

- **AB 2184 (Plescia) – Automated Dispensing Devices**

Chairperson Zinder stated that this bill permits the board to license an automated drug delivery system (ADDS) if the system is operated by a pharmacy in either a skilled nursing facility or an intermediate care facility.

Mr. Riches stated that this bill was amended to eliminate the requirement for separate licensure. The bill was amended to state that in a skilled nursing intermediate care facility, one of these devices could be used for general dispensing of medications if owned and operated by a pharmacy. Based on the amendments, staff recommends a support position on this bill.

MOTION: Support AB 2184 (Plescia), as amended April 16, 2004.

M/S/C: GOLDENBERG/ZINDER

SUPPORT: 7 OPPOSE: 0

- **AB 2660 (Leno) – Pharmacist DEA Registration**

Chairperson Zinder stated that this bill allows pharmacists working under protocol to obtain DEA registration numbers, among other provisions.

MOTION: Legislation and Regulation Committee: Support AB 2660 (Leno).

SUPPORT: 7 OPPOSE: 0

- **AB 2682 (Negrete McLeod) – Wholesalers**

Chairperson Zinder stated that this bill requires all out of state distributors to be licensed by the board. Current law allows wholesalers shipping to another wholesaler in the state to not have to be licensed as a distributor), and requires the board to adopt regulations essentially duplicating the Prescription Drug Marketing Act regulations.

Chairperson Zinder stated that the board is sponsoring SB 1307 (Figueroa), which is a similar bill. The committee recommends that the board support AB 2682 if amended to more closely match the provisions in SB 1307.

Dr. Fong expressed concern that the industry has not been given the opportunity to comment on these bills.

Mr. Cronin suggested that the board consider SB 1307 at the same time.

Dr. Gray stated that SB 1307 was not listed on the board's agenda and the language was only released to the public on April 14. He added that the industry did not get sufficient time to respond to the bill. There are substantial differences between the two bills and the author of AB 2682 is not interested in moving in the direction of the provisions in SB 1307. He added that AB 2682 would take the California down a much more restrictive path than any other state in the U.S. and conflict with federal law. He stated that when the board considered SB 1307, there was substantial hesitance and the board voted on language it had not seen.

Mr. Riches stated that SB 1307 requires the establishment of a drug pedigree in California by 2007, for drugs from the manufacturer to the pharmacy and increases the board's enforcement authority for wholesalers through citation and fine. Senate Bill 1307 also increases the licensing standards for wholesalers by requiring the establishment of surety bonds and defines a closed-door pharmacy. He added that SB 1307 also requires the board to designate those pharmacies and closes responsibility on wholesalers distributing to those pharmacies in terms of monitoring for excessive purchases or excessive furnishing. It also establishes transaction prohibitions.

Mark Whitney, representing long-term care, stated that one purpose of this bill is to regulate diversion. He added that the board just attempted to legalize international diversion from Canada. He questioned how the board could micro manage diversion of a FDA approved drug. He added that this bill provides support for manufacturers.

MOTION: Legislation and Regulation Committee: Support AB 2682 (Negrete McLeod), if amended to reflect provisions in SB 1307 (Figueroa).

SUPPORT 4 OPPOSE: 2 ABSTAIN: 1

- **SB 1149 (Ortiz) – Importation**

Chairperson Zinder stated that this bill requires the Board of Pharmacy to identify Internet sites selling prescription drugs that have violated recognized standards for good practice.

MOTION: Legislation and Regulation Committee: The Board of Pharmacy consider Senate Bill 1149 without a recommendation from the Committee.

SUPPORT: 0 OPPOSE: 7

Dr. Schell reiterated his opposition to this bill.

Mr. Goldenberg stated that he feels the board is acting contrary to the board's mission regarding the need to protect patients.

MOTION: The Board of Pharmacy support SB 1149 (Ortiz).

M/S/C: ZINDER/POWERS

SUPPORT: 3 OPPOSE: 4

The board then decided to reconsider its position on AB 1957.

MOTION: Reconsideration: support AB 1957.

M/S/C: CONROY/JONES

SUPPORT: 3 OPPOSE: 4

After some discussion another vote was taken.

MOTION: Reconsideration: Support of AB 1957.

M/S/C: CONROY/JONES

SUPPORT: 4 OPPOSE: 3 ABSTAIN: 1

The board re-voted on its position on SB 1957.

MOTION: Support SB 1957.

SUPPORT: 3 OPPOSE: 4 ABSTAIN: 1

The board ended this discussion with no position on AB 1957.

- **SB 1159 (Vasconcellos) – Hypodermic Needles**

Ms. Zinder stated that the committee recommends support position on this bill. This bill repeals the prescription requirement for needles and syringes.

MOTION: Legislation and Regulation Committee: Support SB 1159 (Vasconcellos).

SUPPORT: 7 OPPOSE: 0

- **SB 1333 (Perata – Importation by Pharmacies**

  Ms. Zinder stated that the committee recommended no position on SB 1333.

  Senate Bill 1333 would allow pharmacies to import drugs from Canada for ADAP and Medi-Cal.

- **SB 1427 (Ackerman) – Counterfeit Drugs**

  Chairperson Zinder stated that the committee recommends board a support position on this bill that imposes felony penalties for drug counterfeiting.

  MOTION: Legislation and Regulation Committee: The Board of Pharmacy support SB 1427 (Ackerman).

  SUPPORT: 7 OPPOSE: 0

- **SB 1735 (Figueroa) – Special Fund Agencies**

  Chairperson Zinder stated that the committee recommends a support position on this bill that exempts the Department of Consumer Affairs' boards and bureaus from the hiring freeze and restores vacant positions recently eliminated.

  MOTION: Legislation and Regulation Committee: The Board of Pharmacy support SB 1735 (Figueroa).

  SUPPORT: 7 OPPOSE: 0

- **SB 1563 (Escutia) – 340B Drug Pricing**

  Chairperson Zinder stated that the committee recommends an oppose position unless amended on this bill that would require wholesalers and manufacturers to extend 340B drug discounts to "safety net" providers.

  Mr. Riches stated that it would be the Board of Pharmacy's responsibility to enforce the provisions of the bill and it would not be appropriate for the board to enforce pricing agreements.

MOTION: The Board of Pharmacy oppose SB 1563 (Escutia) unless amended to remove the 340B pricing mandate from Pharmacy Law.

M/S/C: FONG/GOLDENBERG

SUPPORT: 5 OBSTAIN: 2

ORGANIZATIONAL DEVELOPMENT COMMITTEE

President's Report

President Jones stated that he has enjoyed the last two years as board president and commended staff and board members on the excellent support they provided. He added that the board has a good reputation because of the thoughtful approach it takes to address legislation and all of the issues that come before the board.

President Jones gave credit to his family and his employer for allowing the time and energy to serve on the board.

He offered encouragement for incoming Board President Stan Goldenberg and Vice President Bill Powers.

Mr. Goldenberg gave the report of the April 1, 2004, Organizational Development Committee meeting.

- **Recommendations for Revisions to Board Member Procedure Manual**

Mr. Goldenberg stated that 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 training materials as well.

- **Proposal Regarding Public Meetings of the Organizational Development Committee**

Mr. Goldenberg stated that one ramification of the legal interpretation involving board member' 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 little 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.

- **Proposal to Revise the Board Member Procedure Manual to Reflect the Board's Current Structure and Operations**

  Mr. Goldenberg stated that 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.

- **Proposed Revisions to the Board's Strategic Plan for 2004/2005**

  Mr. Goldenberg stated that the committee recommends adoption of the board's strategic plan.

  MOTION: Organizational Development Committee: Approve the board's strategic plan for 2004/05, incorporating all changes made to the committees' strategic objectives approved during this board meeting.

  SUPPORT: 7 OPPOSE: 0

- **Proposed Meeting Dates for 2005**

  Mr. Goldenberg stated that during the April Board Meeting, the board typically identifies future meeting dates. The committee recommended the following dates:

  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

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

  Mr. Goldenberg stated that 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.

- **Report on the Transition to the Schwarzenegger Administration**

  Mr. Goldenberg stated that 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.

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

  Mr. Goldenberg stated that 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 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. The department is currently reviewing the board's response.

- **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.

  1. **2004/05 Board Budget Approved:** In the last two weeks, the Senate and Assembly budget subcommittees have begun review of the board's budget for next year. 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. Currently, applications are processed within the week they are received.
     b. The board also has implemented many 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 access. 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).

	Rate	
	Previously	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 the board is funded. This is down from the initial estimate for the year of $865,000.

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 this. Last year, the board funded $68,000 for CURES data collection and analysis contracts. For 2003/04, the board 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 halfway 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. The first portion of the repayment occurred last year.
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 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.
11. **Board Member Expenditures and Reimbursements:** 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.

- **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.

APPROVAL OF MINUTES

Full Board Minutes
(January 21 and 22, 2004)

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

MOTION: Approve the April 21, 2004, Board Meeting Minutes

M/S/C: FONG/POWERS

SUPPORT: 7 OPPOSE: 0

NEW BUSINESS/AGENDA IEMS FOR FUTURE MEETINGS

Vicki Betker, stated that it is her understanding that emergency contraception is effective because it prevents the implantation of a fertile egg. If this is so, she asked if the board could explain its decision to withhold this information by not including it in the emergency contraception fact sheet developed by the board.

The board asked the Communication and Public Education Committee to address this issue.

ADJOURNMENT

There being no further business, President Jones adjourned the meeting at 6:00 p.m.