



California State Board of Pharmacy

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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: July 20 and 21, 2005

LOCATION: Hilton Hotel
San Diego Mission Valley
901 Camino del Rio South
San Diego, CA 92108

BOARD MEMBERS

PRESENT: Stanley Goldenberg, President
William Powers, Vice President
Richard Benson (July 20 only)
Ruth Conroy
David Fong
Clarence Hiura
John Jones
Kenneth Schell
Andrea Zinder (July 20 only)

BOARD MEMBERS

ABSENT: Marian Balay

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
Jan Perez, Legislative Coordinator

CALL TO ORDER

President Goldenberg called the meeting to order at 9:11 a.m. on July 20, 2005.

ORGANIZATIONAL DEVELOPMENT COMMITTEE

- **Board President's Report**
- **Introductions**

President Goldenberg welcomed former board members Darlene Fujimoto and Raffi Simonian, former Liaison Attorney General Bill Marcus and George Pennebaker, President of the California Pharmacists Association.

- **Announcements**

President Goldenberg announced that Patricia Harris was elected to the National Association of Boards of Pharmacy Executive Committee at the NABP National Meeting in New Orleans in May. He added that he also attended this meeting with Ruth Conroy, John Jones and Ken Schell. He reported that they attended this meeting at their own expense on personal time. President Goldenberg stated that this is one example of the board's commitment to protect and serve the public and identify trends in the pharmacy practice setting.

Ms. Harris stated that the NABP Executive Committee represents eight districts of the National Association of Boards of Pharmacy and is comprised of members of all state boards of pharmacy. She added that this was California's first opportunity to participate at the national level since California became an active member. She stated that the NABP 2005 Fall Conference is scheduled for December 2-4, 2005, in Sunny Isles Beach, Florida.

Ms. Harris stated that her responsibility as an executive committee member of the NAB is to govern the operations of the national board and the initiatives that they are moving forward. She added that even though the California Board of Pharmacy has not been an active member in the NABP over the past years, it has been very supportive and has taken a leadership role to implement many of the policy initiatives.

President Goldenberg thanked Ms. Harris for her commitment to serve on this committee.

President Goldenberg announced to those interested in presenting information to the board, to identify the appropriate committee to handle the issue and submit a written request outlining the issues, at least 30 days prior to the committee meeting. After the committee has addressed the issue, it can be presented to the board at the next board meeting. He added that the board

is composed of five committees and one subcommittee that meet quarterly to consider their issues.

- **2006 Board Meeting Dates**

February 1 and 2, 2006 – Los Angeles Area

April 26 and 27, 2006 – Sacramento

July 19 and 20, 2006 – San Diego

October 25 and 26, 2006 – San Francisco/Oakland

- **Report on the July 13, 2005 Meeting**

President Goldenberg provided the report on the Organizational Development Committee Meeting on July 13, 2005, which was a subcommittee meeting as only President Goldenberg was present. This was not a public meeting.

- **Recognition Program for Pharmacists Who Have Been Licensed for 50 Years**

President Goldenberg announced that at this meeting the board was initiating a new program to acknowledge pharmacists who have been licensed for at least 50 years as a pharmacist. This is part of his efforts to improve communication between the board and its licensees and the public. He added that each quarter, board staff will identify those with 50 years of licensure as a pharmacist. These individuals will be mailed an award certificate and a congratulatory letter signed by the board president. These pharmacists will also be invited to attend a board meeting when the meeting is held in the pharmacist's regional area so they can be publicly commended.

President Goldenberg stated that approximately 486 pharmacists were in the first group for recognition.

The board congratulated Jessie Drake Jr, Alfred Barrack and Samuel Perlman, who were in attendance, for their 50 years of service as pharmacists.

The names of these pharmacists with 50 years of licensure will be published in the newsletter.

- **Committee Appointments**

President Goldenberg announced the appointment of committee members as follows:

Communication and Public Education

Andrea Zinder (Chair), Richard Benson,

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William Powers and Kenneth Schell.

Subcommittee on Medicare Drug Benefit Plans

Stanley Goldenberg (Chair), William Powers, John Jones and Andrea Zinder

Organizational Development

Stanley Goldenberg (Chair) and Ruth Conroy

Enforcement Committee

William Powers (Chair), Marian Balay, David Fong and Stanley Goldenberg

Legislation and Regulation Committee

John Jones (Chair), David Fong, Kenneth Schell and Andrea Zinder

Licensing Committee

Ruth Conroy (Chair), Richard Benson, John Jones and Clarence Hiura

Competency Committee

Kenneth Schell

- **Request from California Pharmacy Students Regarding the Availability of Intern Addresses of Record Online**

President Goldenberg stated that since the board's October 2004 meeting, the board has had discussions with a group of California pharmacy students who are concerned about their addresses of record being available online. In the case of the students, this address of record is most often their residence address and the students expressed great concern about their safety from this information being available online.

The students requested the board to examine its policies in this area, and requested that their address of record be removed from the board's Web site. At the April Board Meeting, in accordance with a legal opinion from Departmental Counsel Dana Winterrowd, the board agreed to promulgate a regulation excluding pharmacist interns from having their addresses of record posted on the board's Web site.

The board will hold an informational meeting on proposed language to exclude the address of record of intern pharmacists on the board's Web site during the Legislation and Regulation Committee session of this board meeting.

President Goldenberg commended the students for presenting the problem to the board and cooperatively working with the board to resolve the issue.

- **April 8-11, 2006**
NABP's 102nd Annual Meeting
Westin St. Francis, San Francisco, CA

President Goldenberg announced that the National Association of Boards of Pharmacy is holding the next national meeting in April in San Francisco and California will be the host state. This represents the first national meeting for California since becoming a member of the NABP and he encouraged everyone to participate and attend.

- **Subcommittee on Part D of the Prescription Drug Benefit Plans**

President Goldenberg stated that at the April Board Meeting, the board moved forward with his suggestion to form a board task force to address issues relating to Part D of the new Medicare and Medicaid provisions. This subcommittee of the Communication and Public Education Committee held its first meeting on July 7th and a number of knowledgeable parties shared information. He added that the goal of the subcommittee was to gather information in preparation for professionals of California to meet the challenge of the prescription drug plan. He thanked Teri Miller of the California Department of Health Services for her time and efforts in this process and for her presentation at the meeting. A meeting summary is in the board materials for this board meeting.

- **Consideration to Award Continuing Education Credits for Attending Board and Committee Meetings**

President Goldenberg stated that the committee discussed the awarding of 2 hours of continuing education for attending public committee meetings.

Currently the board awards 6 hours of CE to individuals who attend the full business day of a board meeting. Only 6 units can be earned per year.

The committee is currently considering whether to recommend 2 hours of CE be awarded to individuals who attend full committee meetings. A maximum of 4 hours annually could be earned from attending committee meetings.

The committee will further discuss this item at the next committee meeting and may bring the final proposal to the full board in October.

- **Partner with the California Pharmacists Association in Developing a Joint Web Site for Data Collection**

President Goldenberg stated that the CPhA is interested in exploring with the board development of a joint Web site where information could be more readily made available for example, online renewal, e-mail addresses, release of exam scores.

Staff is currently exploring this proposal with the department's Information Technology Office. More information should be available at the next committee meeting. President Goldenberg commended CPhA on their efforts to distribute information regarding Part D of the Prescription Drug Benefit Plan.

- **Recognition Program for Preceptors and People who help Train Future Pharmacists**

President Goldenberg suggested that the committee work to develop a board recognition program for preceptors for the extraordinary efforts in developing the skills of future pharmacists. This proposal will be discussed more fully at the next committee meeting.

- **2005-06 Strategic Plan**

The board's 2005-06 Strategic Plan has been updated, as approved at the last board meeting. It is available on the board's Web site.

- **Board Member Procedure Manual**

The Board Member Procedure Manual has been updated as approved at the last board meeting.

- **Budget Update and Report**

Ms. Herold stated that the new fiscal year started July 1, 2005. The state budget for the year was signed by the Governor on July 11.

The board's 2005-06 budget is nearly the same budget as the board had for 2004-05, with one major exception – the board received repayment of \$3 million for the new fiscal year. This repayment is for the \$6 million loaned to offset the state budget crises four years ago.

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

Ms. Herold stated that the final budget figures for this year will be available in mid-August, thus the figures reported below are estimates

Revenue Projected: \$6,042,113

The board's revenue for the year is expected to be comprised of \$5,346,813 in licensing fees and \$97,474 in interest. The revenue estimate projected from fees is conservative and traditionally is about 10 percent less than actual revenue will be.

The board has also collected \$428,404 in fines, and \$169,422 in cost recovery as of June 30, 2005.

Expenditures Projected: \$7,990,998

Ms. Herold stated that the board's maximum expenditure authority for the year is \$7.99 million. Personnel is the largest expenditure: \$3,994,568 or 50 percent of the board's budget.

Actual expenditures will be less than this amount. The board estimates that it will end the year with expenditures approximately 5 percent less than maximum spending authority (7,590,000).

- **Board Fund Condition**

During 2004/05, the board is projected to spend nearly \$2 million more than it will collect as revenue. The difference between revenue collected and the amount spent (or expenditure) will come from the board's fund (the board's "savings account").

The board's fund condition displays the amount of savings remaining at the end of each year after collection of revenue and all expenditures are calculated.

The board's fund condition is currently adequate.

The board's fund condition projected over the next three years is:

1. 2004-05: The board is projected to end this fiscal year with a reserve of 4.1 months of annual expenses.
2. 2005-06: The reserve is estimated at 5.3 months (after repayment of the \$3.2 million borrowed).
3. 2006-07: A reserve of 1.4 months is projected as of June 30, 2007. Repayment of the remaining \$3 million appears to be needed before the end of this fiscal year.

- **Relocation of the Department of Consumer Affairs**

President Goldenberg stated that the board will relocate to a new office location about 8 miles north of its current location (about half-way between our office and the airport), in an area known as North Natomas.

The expected move date is December 2005 or January 2006. The new building's owner has promised to pay for the purchase and installation of new systems furniture as well as utilities and janitorial service for the half of the new lease (the lease is 15 years).

The board's office space will be reduced to about 80 percent of its current space, and will no longer include a conference room within the board's suite. The board will also have wholly new phone numbers as well.

- **Personnel Update and Report**

Office Technician Yolanda Powell has accepted a promotion with another agency and will be leaving the board around July 15. Ms. Powell has worked on the pharmacist examination desk and more recently on processing pharmacy technician applications. The board has begun recruitment for Ms. Powell's position.

Inspector Cindy Drogichen-Rich resigned in mid June. The board now has three inspector vacancies.

In June, the board in conjunction with the department's personnel office developed a new civil service hiring list for the inspector classification. Job interviews with these qualified applicants will be conducted in August, and hopes to fill all three vacant positions.

John Tilley's term as a board member ended June 1, 2005, after Mr. Tilley served one year of grace. A celebration for Mr. Tilley is planned for a future board meeting since he is unable to attend the July Board Meeting.

The board itself has three board member positions vacant: two public members and one professional member. All three positions are Governor appointments. The two public member positions were created January 1, 2004, and have not yet been filled.

Mr. Powers referred to the amount the board has received in fine collection and asked if this money is distributed into the General Fund. Ms. Herold responded that the money is deposited into the board's fund for appropriation in future years if authorized by the state's budget.

John Cronin, representing the California Pharmacists Association, referred to the board packet material and stated that there is insufficient time for review of the materials between the time the packet is available on the board's Web site and the board meeting. He asked that the board provide this information earlier and also to separate the new material from the material already posted on the Web site.

APPROVAL OF FULL BOARD MINUTES

President Goldenberg asked if there were any corrections to the board minutes of April 27 and 28, 2005. The corrections were noted.

MOTION: Approve the board minutes of April 27 and 28, 2005, after corrections are made to Jan Hirsch's name and the word "insight" is corrected.

M/S/C: POWERS/FONG

SUPPORT: 8 OPPOSE: 0

COMMUNICATIONS AND PUBLIC EDUCATION COMMITTEE

- **Report on the Meeting of July 7, 2005**

On behalf of Chairperson Zinder, Dr. Schell provided the report on the public meeting of the Communication and Public Education Committee held on July 7, 2005, in Sacramento.

- **Consumer Self Care and Recommendation to Develop Joint Web site with the UCSF's Center for Consumer Self Care to House Consumer Fact Sheets**

Dr. Schell stated that at the April 2004 Board Meeting, the board approved a proposal by the committee to integrate pharmacy students into public outreach activities. The project chosen was the development of a consumer fact sheet series by student interns. This project is being coordinated by the UCSF Center for Consumer Self Care under the direction of R. William Soller, Ph.D.

Dr. Schell reported that by January 2005, the program had been initiated. Since then, four fact sheets have been developed, and a fifth is undergoing work by the board. The first fact sheets have been prepared – “Generic Drugs – High Quality, Low Cost,” “Cut Your Drug Costs,” “Antibiotics – A National Treasure,” and “Is Your Medicine in the News?” The fact sheets contain general information on the topic, but then contain questions consumers can discuss with their pharmacists on making wise decisions in the subject area.

Beginning this fall, Dr. Soller advises that he now has 11 students who have recently agreed to develop at least three fact sheets each.

For this influx of fact sheets, a structured list of topics has been designed to focus the students initially. Dr. Soller suggests that the board work with the Center for Consumer Self Care to establish a joint Web site to house the facilities and provide a link to the site from the board's Web site.

Dr. Schell stated that because a number of fact sheets will soon exist (perhaps within six months), the committee believes there is merit to Dr. Soller's suggestion to establish a joint Web site where these consumer fact sheets will be listed. The Center for Consumer Self Care will develop and maintain the Web site. The board will appear as co-host.

MOTION: Communication and Public Education Committee: Develop a joint Web site with the Center for Self Care to house the consumer fact sheets the board and the center are developing together.

M/S/C: SCHELL/FONG

SUPPORT: 8 OPPOSE: 0

- **Update Report on the Activities of the California Health Communication Partnership**

Dr. Schell stated that during the July meeting, the committee received an update on the activities of the California Health Communication Partnership. This group is spearheaded by the UCSF's Center for Consumer Self Care to improve the health of Californians by developing and promoting consumer health education programs and activities developed by the members in an integrated fashion.

The first integrated campaign was antibiotic misuse and overuse, a campaign whose materials were developed by the FDA and promoted to physicians, pharmacies and pharmacists in the winter newsletters of the board and the Medical Board. The board also produced and distributed its consumer fact sheet on antibiotic misuse at public outreach events.

The next campaign was May 2005, which was seniors' month. Generic drugs were the focus of this effort. Various materials from the FDA and the board's new consumer fact sheet on generic medications were distributed at consumer fairs attended by the board. Also, at the National Association of Boards of Pharmacy Meeting, Executive Officer Harris hosted a poster session on the partnership, which was well received.

The next campaign is planned for the fall on cancer screening. The Center for Consumer Self Care has obtained funding for a consumer column to be distributed nationwide through the NAPS distribution system. Public service announcements encouraging mammograms and prostate cancer screening have been developed.

Dr. Schell stated that since October is Talk About Prescriptions Month, the board would continue to highlight the value of generics. Work is also aimed at a higher visibility program for generics in May 2006. The Center for Consumer Self Care is seeking outside funding for this effort.

- **Update on The Script**

Dr. Schell stated that articles have been written for the next issue of the board's newsletter, *The Script*. These articles are under review and this issue should be published late in the summer, once a pending rulemaking is completed.

Dr. Schell added that articles would promote the new award for pharmacists who have been licensed for 50 years, as well as the Subcommittee on Medicare Drug Benefit Plans formed by the board. The bulk of the newsletter's articles will provide amplifications of Pharmacy Law.

- **Update on Health Notes**

Dr. Schell stated that *Health Notes* is a monograph produced by the board that contains up-to-date drug therapy guidelines for a specific subject area. Because the board produces *Health Notes*, it conveys what the board 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.

Dr. Schell reported that there are two issues under development:

1. Pain Management Issue:

The board's staff is working to complete this new issue on pain management. The new issue will contain new pain management therapies and the new prescribing and dispensing requirements for controlled substances. This will be an interdisciplinary issue for pharmacists as well as physicians, dentists and nurse practitioners.

Dr. Schell stated that prominent pain management authors wrote the articles and he was involved with editing. He added that work on the manuscript for this issue will be completed this summer.

2. Pharmacy Emergency Response to Patients in a Declared Disaster Area:

Dr. Schell stated that at the January 2005 Board Meeting, the board approved the development of a pharmacist emergency response *Health Notes* for the board.

RoseAnn Jankowski, former chair of the board's Competency Committee is coordinating this issue. Completion of this manuscript is scheduled for later this summer.

- **Redesign of the Board's Web site**

Dr. Schell stated that the board's redesigned Web site was activated at the beginning of the year and the new format fits the mandated style of design of the Governor's Office.

He added that several modifications would be made to the Web site in the coming months, as the new Web page is too wordy and it's difficult to find desired items.

- **Update on Public Outreach Activities**

Dr. Schell stated that the board continues to operate a vigorous outreach program to provide information to licensees and the public. The board has a number of consumer materials to distribute at consumer fairs and strives to attend as many of these events as possible, where attendance will be large and staff is available.

The board's Power Point presentation on the board (containing key board policies and pharmacy law) is a continuing education course, typically provided by a board member and a

supervising inspector. Questions and answers typically result in a presentation of more than two hours, and these presentations usually are well received by the individuals present.

Since the beginning of 2004, the board has provided presentations on SB 151 and the new requirements for prescribing and dispensing controlled substances in California. This information is also presented via telephone conference call to large numbers of individuals. However, in recent months interest in this topic has been waning, ideally because pharmacists and prescribers are learning the new requirements.

During 2004-05, the board and its staff have performed an impressive list of public and licensee educational activities that Dr. Schell commended:

- At least 17 public education fairs or outreach events
- More than 56 forms to educate the profession or other health care providers and law enforcement staff

For the quarterly report of public and licensee outreach activities since the April Board Meeting, board members and staff have:

- Presented 2 public presentations about the board and new pharmacy laws
- Provided 6 public presentations about the new controlled substances dispensing and prescribing requirements, including one by Executive Officer Harris at the National Association of Boards of Pharmacy annual meeting
- Staffed 5 public booths at consumer fairs and 1 poster session at the National Association of Boards of Pharmacy annual meeting.

MOTION: To separate the Subcommittee on Medicare Drug Benefit Plan from the Organizational Development Committee, having two separate meetings.

M/S/C: POWERS/FONG

SUPPORT: 8 OPPOSE: 0

Steve Gray, representing Kaiser Permanente, suggested that the board add a paragraph to the Pain Management article of *Health Notes* stating that pharmacists, under a new law, can now get their DEA registrations. This allows pharmacists to fully participate in programs to help patients with their pain management. He added that many pharmacists are not aware of this and because the *Health Notes* is distributed to many different professions, this would be a good way to send the message.

Ms. Harris stated that the board recently intervened with the DEA in a situation where a community practitioner pharmacist was denied an application to obtain a mid-level DEA number. She added that AG Liaison Counsel Joshua Room contacted the Washington Office of the DEA regarding the issue.

Mr. Room stated that after a conversation with counsel in Washington, it is anticipated that mid-level practitioner registration numbers would be issued to community pharmacists who are acting on the protocol of the pharmacists, in the same way that they currently do to those pharmacists working in licensed facilities.

Dr. Gray stated that eight Kaiser pharmacists have successfully received DEA registration numbers and several more are in process.

John Cronin, representing the California Pharmacists Association, referred to the Subcommittee on Medicare Drug Benefit Plan and stated that it was his understanding that the purpose of the subcommittee was to gain information about other programs and outreach efforts. The meeting summary of the board's subcommittee meeting states that the purpose of the committee is to deal with the implementation of Part D. Also, public interest groups at that meeting suggested new regulation may be needed or new activities may need to be taken by the board to gain oversight of how pharmacies would implement Part D. He asked for clarification.

President Goldenberg stated that the original intent for the subcommittee has not changed. The subcommittee is charged with gathering information for board members, the inspectors and the public to share this information with others involved in the prescriptive process.

Mr. Powers stated that he also attended this meeting and the people making these recommendations were representing consumers. He added that the board has a responsibility to address problems that consumers may face by this new federal program because this represents a significant change in current law that affects approximately a million Californians who are on Medicare but are low income and qualify for Medi-Cal. These individuals will have to sign up for the program or be placed in the program by January 1, 2006, and consequently will have to pay more for prescription drugs than they have in the past under the Medi-Cal program.

Mr. Powers stated that through this subcommittee the board hopes to get a full range of information on not only how pharmacists address the issues but also how beneficiaries of Medicare are affected. The committee could monitor how the program is working and report back to pharmacists with important issues, such as the appeals process and how it works for people who have been denied important medications.

President Goldenberg stated that one group attending the subcommittee meetings is actually developing procedures for the appeal process with direction for completing the forms. Other groups are making themselves available not only seniors but to the board as well. President Goldenberg added that this will not be an easy program to grasp and even though pharmacists are not required to act under the program requirements, the hope is that pharmacies will have the resources to direct individuals and to develop procedures to help them, even if only advising them of other groups to contact.

Mr. Pennebaker stated that he is involved with implementing Medicaid Part D and it is very difficult. He added that the Center for Medicare and Medicaid (CMS) has expressed concern about pharmacists directing patients to a particular program.

As an example, Mike Reed, representing Crescent Health Care, stated that the National Home Infusion Association's position is for Medi-Cal Part D not to cover infused drugs but Part B to cover them instead. He added that this issue is before Congress now with many Senators and Representatives being lobbied because Part D does not cover infused drugs properly at home; covering only the drug and not the pump, the nurse, supplies or anything else.

Ms. Herold reported that the board is working with the CMS to assure one of its staff will attend the next subcommittee meeting. It is anticipated that the meeting will be held in mid October.

LICENSING COMMITTEE

- **Report on the Meeting of June 15, 2005**

Chairperson Conroy provided the report on the Licensing Committee Meeting held June 15, in Burbank.

- **Recommendation to Amend Business and Professions Code Sections 4180-4186 and Business and Professions Code Sections 4190-4195 Related to the Regulation and Licensure of Clinics**

Chairperson Conroy stated that a board-licensed clinic is authorized to purchase dangerous drugs at wholesale and own the dangerous drugs. This means that the authorized prescribers of the clinic can dispense from one central stock. Otherwise, each prescriber must dispense from his/her own stock of dangerous drugs and these drug stocks cannot be commingled with those of other practitioners.

Consistent with the board's Strategic Plan objective to review all licensing programs, board staff reviewed the board's licensing requirements for clinics. During the review several inconsistencies between the requirements for nonprofit or free clinics and surgical clinics were noted.

The committee was provided with proposed changes to statutes that would streamline the application process, better define who is accountable for the license and make license and regulatory requirements consistent between the two types of clinic licenses. The proposed changes were shared with the associations and based on comments received the language was modified to the version provided to the board at this meeting.

MOTION: Licensing Committee: That the Board of Pharmacy approve the proposed statutory changes to the clinic requirements.

SUPPORT: 8 OPPOSE: 0

Chairperson Conroy stated that the statutory changes to the clinic requirements would be introduced in 2006 legislation as omnibus provisions.

- **Interim Report of the Study Conducted by UCSF School of Pharmacy and Cedars-Sinai Medical Center – Evaluation of the Impact of Pharmacists in the Prevention of Medications in the Hospital Setting**

Chairperson Conroy stated that at the April 2004 meeting, the Board of Pharmacy approved a waiver of CCR, title 16, sections 1793.1(f) and 1793.7(b). The purpose of the waiver was to allow a pharmacy technician in a unit-dose drug distribution system in inpatient facilities to check another technician. The study is a sequel to the successful experimental program that evaluated technicians checking technicians that concluded in December 2003.

This study is evaluating the impact of pharmacists in preventing medication errors associated with prescribing and administering medications because the pharmacists have been 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.

Cedars-Sinai Medical Center (CSMC) is the sponsoring facility. The study authorizes the “tech-check-tech” process to continue at CSMC, while UCSF measures the number and types of medication errors prevented during the time that pharmacists would otherwise have checked the medication cassettes. The board granted the waiver for two years, until April 2006.

Rita Shane, Director of Pharmacy Services, CSMC, and Assistant Dean, Department of Clinical Pharmacy, School of Pharmacy, UCSF, presented an interim report of the study conducted at CSMC. She stated that the first study showed that technicians were more accurate than pharmacists in checking technician-filled cassettes. In this study, she indicated that 1.5 pharmacist hours per day that once were spent checking cassettes have now been redirected to patient care activities outside the pharmacy.

Dr. Shane provided the following results of the study:

Summary of Study Results to Date

Results of the 48 week study demonstrates the impact of pharmacists on prescribing and administration errors:

- 1296 errors intercepted by the pharmacist
- 27450 medication related encounters including dosing of medications per MD request, participation in codes, rounds and drug information questions
- Preliminary evaluation of outcomes: 422 pharmacist encounters prevented potential harm of which:
 - 387 prevented temporary harm
 - 11 prevented permanent harm
 - 23 prevented an increase in length of stay
 - 1 prevented death

Dr. Fong commended Dr. Shane for the progress made and asked what the biggest challenges that staff face while ensuring that the protocol is in place. Dr. Shane responded that it is difficult to deal with the pharmacist shortage. She added that the waiver enables CSMC to study the process of “technicians checking technicians,” continue quality assurance efforts to assure that no adverse events occur and allow pharmacist staff to be directly involved in patient care activities.

Ms. Zinder asked if errors would have been caught if the pharmacist had checked the prescriptions rather than the technicians.

Dr. Shane stated that most of the bedside and administrative errors would not have been caught because the pharmacist would not have been at the bedside but instead in the pharmacy. She added that prescribing errors might have been caught.

Dr. Schell asked if data was collected on prescribing errors during the interval between waivers so that it could be used as a baseline for comparison.

Dr. Shane responded that CSMC did not collect data on the administration errors but they did see a drop in prescribing errors that were intercepted, based on routine data collection.

Dr. Fong asked if the study revealed what the optimal pharmacist/patient ratio might be.

Dr. Shane responded that staffing levels in acute care were discussed during a meeting she had with the University Health System Consortium and they plan to analyze literature and study the correlation between errors prevented and staffing levels. Certain patient populations

must have safe staffing levels to intercept critical errors, such as in the pediatric units where every prescribed order is checked.

Dr. Shane stated that because of the number of new complex drugs, chemotherapy drugs and biologic agents released every year requiring careful handling and monitoring, the demand for more pharmacists will continue to increase.

Dr. Shane thanked the board for the opportunity to conduct the study and to present the interim report to the board.

- **Development of Proposal to Update the Definition of a Pharmacy, a Nonresident Pharmacy, Pharmacist Practice and Licensure of Out-of-State Pharmacists**

Chairperson Conroy stated that for the December 2004 Licensing Committee meeting, staff prepared an overview of the many issues and questions that the board has received regarding pharmacists' care and the practice of pharmacy for California patients. The purpose of the document was to provide a foundation to begin a discussion on how the board should address these many issues that do not fit the traditional statutory definition of pharmacy and which are part of the growing and developing independent practice of pharmacist as health care professionals, often outside a licensed pharmacy.

The committee agreed to address the various issues through its quarterly meetings. However, the committee was encouraged to develop a proposal sooner rather than later in anticipation of the provisions of the Medicare Modernization Act (MMA) addressing pharmacists' services within the Medication Therapy Management Programs (MTMP) of the Medicare Act that are expected to take effect in 2006. The drug benefit in Medicare Part D provides reimbursement for pharmacists (or other health care providers) to provide MTM for Medicare beneficiaries. Examples of MTM services are: patient health status assessments; medication "brown bag" reviews, formulating/adjusting prescription treatment plans, patient education and training, collaborative drug therapy management, special packaging, refill reminders; and other pharmacy-related services.

For the March 2005 Licensing Committee meeting, board counsel and staff drafted a proposal, including draft statutory changes, as a vehicle through which the committee could begin addressing the many issues. It was explained that the proposal was merely a means by which to begin the discussion. To spur discussion, the concepts were written as proposed statutory changes. As drafted, the proposed statutory changes update the definition of a pharmacist, and the definition of a pharmacy (to include an intake/dispensing pharmacy," a "prescription processing pharmacy," and "advice/clinical care pharmacy" and a "nonresident pharmacy") and also refine and expand the acknowledgment that pharmacy is an evolving profession that now includes more sophisticated and comprehensive patient care activities. The proposal also updates pharmacy law to more accurately reflect current pharmacy practice and the current functions of a pharmacist.

Other proposed statutory changes update the definition of a nonresident pharmacy to include entities performing prescription review, patient consultation drug utilization review, medication therapy management and other cognitive pharmacy services. One of the proposals would require that the pharmacist-in-charge of a nonresident pharmacy be a California licensed pharmacist. Another proposal would require that only a California-licensed pharmacist be able to perform prescription review, consultation, drug utilization review, medication therapy management or other cognitive pharmacy services for California patients.

The Licensing Committee and members of the industry and the public in attendance at the meeting discussed the proposals at length. There appear to be three primary areas of philosophical debate regarding the proposals, and/or regarding the question of whether and how to regulate entities and/or pharmacists performing pharmacy services other than drug dispensing, whether inside or outside of California. During this discussion, counsel repeatedly advised that pursuant to Business and Professions Code section 4001.1, the Board of Pharmacy's primary duty is public protection, and opined that it seemed there was little if any disagreement that the surest way to assure public protection was through licensure and control, over both in-state and out-of-state entities or individuals providing services to patients in California. The Board would need to be persuaded that the public could still be adequately protected.

Dr. Conroy stated that some individuals at the meeting expressed that the definition of "pharmacy" should refer only to those entities that store and dispense dangerous drugs. These participants asserted that an entity providing related "pharmacy" services such as prescription processing and advice/clinical care should not be licensed as a "pharmacy." Others argued that the entities providing these services should not be licensed at all, but if they were they should be called something other than a "pharmacy." It was also discussed that the advice/clinical care "service center" should not be required to be part of a licensed entity. Pharmacists should be allowed to perform such services as part of their California (or other state) pharmacist license.

In reviewing the laws from other states, it was observed that most states do include the related "pharmacy" services in the definition and licensure of a "pharmacy."

2. Nonresident Pharmacy

The proposal updates the definition of nonresident pharmacy to include not only those out-of-state pharmacies that dispense prescription medications to California patients, but also those that perform drug utilization review, patient consultation, medication therapy management and/or other cognitive services for California patients (or providers).

3. California Licensure of Out-of-State Pharmacist

As part of the discussion regarding the "out-of-state call centers," it was noted during the committee meeting that the pharmacists providing the drug utilization review, consultation

and medication management therapy (and even those pharmacists that dispense medications) to California patients are not presently required to be licensed as California pharmacists. The proposal would require that the pharmacist providing these services be a licensed California pharmacist.

Consistent with the requirement that pharmacists providing pharmacist care to California patients be licensed California pharmacists, the proposal would also require that the pharmacist-in-charge of a nonresident pharmacy be licensed in California. As specified above, requiring California licensure for out-of-state pharmacists-in-charge and requiring that all pharmacists providing services to California patients be affiliated with an entity with such a PIC was discussed as a possible compromise to licensing all such out-of-state pharmacists.

Chairperson Conroy stated that discussion of these proposals was a very lengthy discussion during the Licensing Committee Meeting and the committee does not have a recommendation for the board at this time, but plans to discuss the issue at the next committee meeting and present it to the full board again in October.

Ms. Harris referred to the background information in the board packet that provided examples from other states. Seven or eight states have a similar model to California and no other state requires licensure of the pharmacist from another state as this usually falls under the umbrella of the licensed entity.

Ms. Harris stated that the board's non-resident pharmacy requirements were passed during the mid-1980s. At that time, California was one of the first states to recognize mail order.

Mr. Jones referred to a comment made during the discussion during the committee meeting about the National Association of Boards of Pharmacy's possible role to determine the qualification of an individual practitioner who might be doing business over interstate lines. It was asked whether the NABP would be willing to credential a pharmacist who performs medication therapy management services in 50 states or where the business is located rather than requiring that person to get a license in all 50 states.

President Goldenberg referred to a resolution passed at the 2005 NABP meeting to endorse the ability to respond to enforcement matters involving another state's licensee as if the problem occurred in the state where the patient is. He added that the challenge is how to regulate an adverse event. He added that to require these licensed individuals to also become licensed in California is restrictive and may be a disadvantage to California consumers.

President Goldenberg commended the committee on the progress made on this issue as everyone moves towards implementation of Medicare Part D.

Mr. Pennebaker expressed concern that pharmacists be paid for their services. If the board begins licensing facilities that do not store drugs, then any type of entity could be considered a pharmacy. He added that the Board of Pharmacy has a unique position because it has licenses

authority for both people and places and it is important that the two functions be handled separately.

Bill Marcus expressed concern with the definition of pharmacy. He added that the board needs to address these issues but not to restrict advice centers or consultation centers from working in a physically licensed pharmacy. And, at the same time not allow individuals to escape from board jurisdiction or licensure as a pharmacy if they are involved in processing prescriptions, even if prescriptions are sent to a central fill facility by contract or because they are part of the same entity.

John Cronin, representing the California Pharmacists Association, stated that CPhA is working on alternative language as requested at the last Licensing Committee. He added that Medicare Part D would have a significant impact on the practice of pharmacy and the final outcome cannot be predicted at this time. He added that pharmacists are not the only ones that can perform medication therapy management and there is a risk involved that the board could end up regulating pharmacists out of this activity. He added that the public would not be as protected if another professional performs this activity.

Dr. Cronin stated that the Medicare Modernization Act requires each plan to have a medication therapy management programs as part of the plan structure. Pharmacists may provide this level of service but there is no requirement for it.

Dr. Cronin stated that he would submit alternative language by mid August.

Steve Gray, representing Kaiser Permanente, encouraged the committee and the board to carefully consider the value of licensing nurse call centers. He expressed concern that if the board licenses a room or facility as a call center, and if physicians, nurse practitioners, and physician assistants must be under the jurisdiction of the Board of Pharmacy as a licensed facility then they would end up excluding pharmacists in the process.

Dr. Gray stated that some entities feel that that they must be licensed as a pharmacy in order to get a NCPDP number for billing. He added that the NCPDP has an alternative provider indicator number that can be used by physicians and other non-pharmacists for billing purposes if they want to participate in that program, which is different from the national provider identification number that was mentioned earlier. Mr. Gray cautioned against implementing a solution that may not be necessary and may be restrictive.

- **Pharmacist Practice in Infusion Services/Suites**

The Licensing Committee was provided a copy of a letter that was jointly issued by the Department of Health Services (DHS) and the Board of Pharmacy in 1997. The DHS has asked about updating and reissuing this joint letter. The letter addresses whether or not a pharmacist who operates an infusion service or suite where patients receive intravenous drug therapy is exempt from licensure as a primary care clinic.

Mike Regis, representing Crescent Health Care, stated that currently Crescent Health Care provides monthly infusion services to 2,500 patients either in the home, a doctor's office or in a hospital outpatient setting. He stated that Crescent Health Care has received requests from numerous insurance companies as well as patients asking if these services could be provided in the office where their nurses and pharmacists are located. Each of Crescent Health Care Offices is a licensed pharmacy, and each are located in a different areas of the building. He added that it is their intention to provide this infusion service the same way it is provided in the home.

Dr. Regis stated that the 1997 letter clarifies the issue but the question is whether they need to be licensed as a clinic as well. It is Crescent Health Care's intent to structure this with the Board of Pharmacy before moving forward with plans for an infusion suite. He added that by offering this service, Crescent Health Care would have more control and oversight and more effectively assist patients.

- **Licensing Statistics**

Ms. Harris referred to the licensing statistics in the board packet and stated that this is an update for the end of the fiscal year and an overall summary of the number of licensees of the board. She added that this is a comparison between the last two fiscal years and shows the increase in the number of applications the board has processed.

- **Competency Committee Report**

Ms. Herold stated that the board transitioned to the new examination structure in January 2004 and began administering the California Pharmacist Jurisprudence Exam (CPJE) in March 2004. She added that the Competency Committee develops and oversees administration of the CPJE.

Ms. Herold announced that President Goldenberg recently appointed 12 new members to participate on the committee as committee members or item writers. Orientation of these new individuals will occur this summer. The new two-tier structure for the CPJE should be in place by October 2005. Additional members for the committee have been sought from the two new schools of pharmacy and the board is actively looking for newer-licensed pharmacist to serve on the Committee, particularly from the community setting.

Ms. Herold stated that interested candidates should submit a C.V. with three letters of recommendation from pharmacists, and write a letter of interest addressed to the board president. Committee members serve a term of four years and members can be reappointed to an additional term. Item writers can serve at will.

David Trump, a pharmacist student from the USC School of Pharmacy, thanked the board for working with students to resolve the address of record issue for interns.

Mr. Trump stated that as the scope of pharmacy practice continues to expand he suggested that the board consider a proposal to allow intern hours accrued within different practice settings to count towards the 1500 hours needed for licensure.

Ms. Harris stated that the board addressed the intern requirements a few years ago through legislation. One proposal considered by the board was that any training or experience students received when graduating with a Pharm.D., would be accepted. However, one of the schools expressed concern and expressed the need for the board to require intern experience in a pharmacy. She added that currently there are 600 nonspecified intern hours (but the schools use these hours for the clinical clerkship) and 900 intern hours are the required practice in a pharmacy setting.

She suggested that students work with the schools and review the regulations and determine the best structure and then bring a uniform suggestion back to the board. Nancy Pennebaker stated that this is a training issue and she offered support.

Susana Sau, a pharmacy graduate from U.S.C., spoke of the distraction she experienced during the pharmacist's exam because the computer clock available was not in real time and could not be used to calculate how much time was spent on each question.

Ms. Herold stated that candidates are not allowed to bring watches into the exam area or calculators. This matter will be addressed through contract specifications currently underway by the Department of Consumer Affairs with test administration.

Release of Exam Scores

Ms. Herold stated that the Board of Pharmacy recently completed a quality assurance assessment to ensure the appropriateness of the CPJE. The board initiated the study on May 16, 2005. To assure the thoroughness of this assessment, 400 individuals were needed for participation. She added that the process ended July 15 and scores were released. The board will resume releasing exam scores on a weekly basis usually within 14 days of the time a candidate takes the examination.

Annual Meeting

Ms. Herold stated that the Competency Committee would meet on August 18 and 19, 2005, for its annual meeting. The purpose of the annual meeting is to focus on long-term goals of the committee and to recommend improvements. The committee will also review the results of the job analysis survey and develop a new content outline. It is anticipated that the new content outline will be used sometime in 2006. The committee will also develop questions for the item bank.

Ms. Herold stated that the board relies on the Department of Consumer Affairs to provide the test administration services for the CPJE exam in California and nationwide. She added that the contract expires December 1. The Department of Consumer Affairs is developing and releasing a new request for proposals for a new exam vendor. The new vendor should begin providing test administration services about December 1, 2005.

ENFORCEMENT COMMITTEE

Dave Fong reported on the Enforcement Committee Meeting held on June 22, 2005.

- **Clarification of Business and Professions Code Section 4186 Regarding the Use of Automated Delivery Systems in Board Licensed Clinics**

Dr. Fong stated that during the June Enforcement Committee Meeting, Dr. Louie, Associate Dean at UCSF School of Pharmacy, presented an overview of a telepharmacy network that the school would like to set up in urban center indigent clinics.

Dr. Fong stated that these clinics are licensed with the Board of Pharmacy pursuant to Business and Professions Code section 4180. The proposal is to place an automated drug delivery system with a video-conferencing system in these clinics. The system will be placed in the clinic with a video-consulting link to the UCSF, School of Pharmacy where patients will receive consultative services from a pharmacist intern through the teleconference system. The system is called PickPoint.

Kevin Delaney, president of PickPoint, presented a slide presentation to the board. He explained how the system is used in military emergency rooms and clinics and stated that approximately 100 systems are in use throughout the U.S., including U.S. military facilities in Germany. He added that the systems are used as inventory management system for physicians.

Mr. Delaney stated that Business and Professions Code (B&PC) section 4181 authorizes the use of PickPoint in these clinics but B & P C section 4186 does not govern this type of automation unit because the PickPoint system is only automating the manual prescription drug dispensing system currently allowed in clinics.

Mr. Delaney stated that section 4186 authorizes and defines ADDS in licensed clinics. B & P Code section 4186(b) requires that the drugs be removed from the ADDS only upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions, which can be done remotely by a pharmacist in California. Additionally, the law requires that a pharmacist must stock the ADDS and the ADDS must provide for patient consultation with a pharmacist via a telecommunication link that has two-way audio and video.

B & P Code section 4186(h) defines an ADDS as a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. This section also specifies the recordkeeping and accountability requirements for the ADDS.

While the UCSF School of Pharmacy's proposal will provide clinic patients access to the pharmacist and pharmacist intern through a ADDS video-conferencing link, the issue is whether the PickPoint system must meet all the requirements of B & P Code section 4186 in order for it to be used in board licensed clinics. Dr. Louie stated that if this telepharmacy system is not authorized, they request a waiver to perform a demonstration project using the system.

Dr. Fong stated that the Enforcement Committee advised UCSF that the board does not have the authority to approve such a waiver but asked counsel to review the clinic provisions to determine if they only apply to those systems controlled remotely by a pharmacist.

Deputy Attorney General Room clarified that the patients in this case would receive the drugs from a prescriber who gets the drugs from the machine. There is no direct patient interaction with the machine. The term "after hours" is used in military context meaning that the prescribers authorized to dispense in the emergency rooms are doing so at times when the pharmacy is closed. He added that the unit is not actually an ADDS machine within the meaning of Business and Professions Code section 4186 but used as an on-site storage cabinet instead. The doctor will replenish the drugs in the cabinet.

Mr. Room stated that section 4186 initially provided a way of expanding pharmacy services in light of the pharmacist shortage, especially in rural areas. Section 4186 was specifically directed to pharmacists that would be remotely controlling dispensing of the drugs and the 4170 section series already allows prescribers to dispense directly to patients. Under section 4170, the prescriber must do this within his or her own office and must own the drugs and if a dispensing device is used, the prescriber must own the device. Section 4180 exempts clinics from the 4170 requirements. He added that there is no language within the 4180 series that states that the prescribers cannot dispense in clinics using a storage cabinet to facilitate the process.

Dr. Fong asked how the system is working in other states and how long it has been in operation.

Mr. Delaney stated that the first unit was installed in Colorado in October 2001, and used in about 25-30 different states, including Alaska.

Mr. Jones asked about security issues.

Mr. Delaney responded that a clinic in Alaska was broken into about three weeks after installation of the unit and the same occurred in a military facility but there was no entry into the machine. He added that the clinics are locked facilities and the units provide additional security compared to storage cabinets.

Ms. Harris stated that clinics are governed with a clinic permit from the Board of Pharmacy that allows them to purchase drugs under that clinic ownership. Policies and procedures are also in place. The difference is that instead of storing the drugs in a closet, the drugs are stored in a machine.

Supervising Inspector Robert Ratcliff stated that he visited PickPoint and received a demonstration of the unit.

Mr. Delaney explained that the drugs are prepackaged, bar coded, and labeled and scanned. Once the prescriber verifies that he or she is the one to dispense the drug, the drug drops out as it is scanned to assure it is the correct drug dispensed. He stated that the unit is an electronic storage unit that will provide better inventory control that can track by name and product. It holds 121 different line items averaging 10-12 units deep.

Mr. Room stated that 4181 exempts clinics from all the requirements of 4170 but would include the requirement that a dispensing device used by a prescriber must be owned by the prescriber.

Mr. Room stated that the problem is that section 4186(h) was written to include storage as one of the dispensing activities performed by an ADDS. He added that storage is typically part of dispensing but the board may need to clarify that when the drugs are solely stored and not dispensed directly to patients then it may not have to meet these standards.

Steve Gray representing Kaiser Permanente, stated that he agrees that this unit should not be considered an ADDS but a storage device instead. The unit does capture information making it easier and safer for the physician and could also be used for medical information for transmission to the CURES program.

Mr. Room stated that PickPoint is not requesting that the board approve of this process but only seeking clarification of the law.

- **Request to Repeal 16 CCR Section 1717.2 – Notice of Electronic Prescription Files**

Dr. Fong stated that on December 10, 2004 the board received an e-mail from Steve Gray, representing Kaiser Permanente, inquiring on the status of repealing California Code of Regulations (CCR) section 1717.2, Notice of Electronic Prescription Files. In his e-mail Mr. Gray outlined the chronology of the board's efforts to repeal section 1717.2. Board discussion ran from January 2002 through September 2003 with the board taking no action to

repeal the section. A review of the board's file on 1717.2 found that there is no written record as to why the board stopped its efforts to repeal 1717.2.

Paul Riches, former board Chief of Legislation and Regulation, recalled that the board did not pursue repealing section 1717.2, because of concerns that repealing the section might conflict with provisions in the Confidentiality of Medical Information Act. Many laws governing the use of patient information require a patient to give their consent to having their medical records shared with additional parties. CCR 1717.2 is unique in that a patient's information is shared unless a patient specifically request otherwise. If, at some point, the board chooses to repeal 1717.2 it might be perceived as a move to limit patients' ability to control their medical record information. As such, its repeal might be met with significant opposition from privacy protection advocates.

Dr. Gray spoke before the Enforcement Committee to advocate for the repeal of 1717.2. He argued that the sharing of a patient's prescription information is paramount to good patient care in some instances; patients who are abusing controlled substances are shielded from detection when they choose not to have their prescription information shared. It was also his position that federal privacy laws (Health Insurance Portability and Accountability Act (HIPAA)) allows for the sharing of patient information and this notice is just duplication of the federal law. It was felt that the regulation was out-of-date and state and federal law protects a patient's privacy and this notice is no longer necessary.

As requested by the Enforcement Committee, counsel reviewed the federal and state laws and advised that a patient's medical information cannot be disclosed without the patient's consent; however, consent is not required when the sharing of the medical information is with other health professionals for the purposes of medical treatment. Therefore, the board's regulation could be considered an additional requirement to current federal and state law and is not mandated.

Mr. Room asked Dr. Gray at the last Enforcement Committee Meeting whether he knew whether this kind of notice would in any case be required by HIPPA or by the California Confidential Medical Information Act, and if required, what would be the point of deleting this section.

Mr. Room stated that it appears that this requirement is additional to those requirements that are set forth by HIPPA or by the California Confidential Medical Information Act in the sense that both HIPPA and CMIA allow for sharing of confidential medical information for the purpose of treatment or diagnosis and assuming that this information is being used for that purpose, there appears to be no prohibition or no restriction in HIPPA or CMIA in sharing that information with other providers of prescription drugs.

Dr. Gray stated that sharing information by medical professionals is very important in monitoring patients' drug history and explicit patient permission is not needed. Only in California can a patient "opt out." He added that Kaiser has discovered that the provisions are

used most of the time by people who are trying to shield Schedule II or other controlled substance activity from other pharmacies.

Dr. Gray encouraged the board to repeal section 1717.2 to allow this information to be shared among the pharmacy health professionals and to solve a potential drug diversion problem.

Dr. Fong expressed concern for employees that do not want their drug information known by others working within the company so they go elsewhere for their prescriptions and this is an example of where you would want to respect that person's records.

Mr. Jones stated that safeguards to unauthorized access to computer information exists but terminals can track access information and penalties are severe for inappropriate use of the information.

MOTION: Enforcement Committee: That the Board of Pharmacy consider a request to repeal 16 CCR Section 1717.2 – Notice of Electronic Prescription Files.

SUPPORT: 5 OPPOSE: 4

- **Update on Research Study by UCSD, School of Pharmacy Related to the Use of a Self-Service Automated Drug Delivery System**

Dr. Fong stated that at the April Board Meeting, the Board of Pharmacy approved the request from the UCSD School of Pharmacy for waiver of California Code of Regulations section 1717(e) to install and utilize a self-service drug delivery system in its hospital outpatient pharmacy. The board approved the waiver with the following specified conditions that are required of all approved waivers:

- The automated dispensing device is used for refill prescriptions only.
- It is the patient's choice to use the automated drug delivery system.
- The system is located in reasonably proximity to the licensed pharmacy premises.
- The system is secure from access and removal by unauthorized individuals.
- The pharmacy is responsible for the prescriptions stored in the device.
- A pharmacist is not to use the device to dispense refilled prescriptions if the pharmacist determines that the patient requires counseling pursuant to CCR, title 16, sec. 1707.2(a) (2).

Another condition for approving the waiver, the board agreed to the request of the UCSD Skaggs School of Pharmacy and Pharmaceutical Sciences (SSPPS) to perform a research study on the impact of this technology to pharmacy and patients.

Charles Daniels, representing UCSD Skaggs School of Pharmacy and Pharmaceutical Sciences, thanked the board for the opportunity to update the board on their progress. He

reported that during the last few months they worked in research activities at the UCSD and held reviews and discussions of the plan. He asked Dr. Jan Hirsch, who leads the research project, to provide a summary to the board.

Dr. Hirsch presented the update through a PowerPoint presentation. She added that both Longs and Safeway have agreed to participate with the research project.

President Goldenberg asked about the benefit of the phone attached to the unit for after hours consultation. Dr. Hirsch responded that consultation can be monitored in terms of determining whether it was provided by telephone from a unit or user or conducted in person. The telephone would be installed as close to the machine as possible.

Mr. Jones asked if the telephone would be active to a pharmacist whenever the ScriptCenter is available.

Dr. Hirsch explained that the ScriptCenter would not to be available for drug delivery after hours.

Dr. Hirsch stated that progress reports would be provided to the board in April and July 2660 and the final report will be provided to the board February 28, 2007.

Dr. Fong thanked Dr. Hirsch and Dr. Daniels for the update and stated that this provides an opportunity to see how technology can improve quality care. He added that the board is interested in receiving periodic updates.

- **Request to Require a Pharmacy to Submit a “Pharmacy Services Plan” When a Waiver is Granted pursuant to 16 CCR Section 1717(e) to use a Self-Service Drug Delivery System**

Dr. Fong stated that the California Pharmacists Association (CPhA) is requesting that the Board of Pharmacy require a pharmacy that is granted a waiver to use a self-service drug delivery system for refill medications to have a “pharmacy services plan” as a condition of granting the waiver.

The CPhA is proposing that the pharmacy be required to have a pharmacy services plan that includes a clear description of how the requested waiver would facilitate pharmacists’ care and improve patient care in the pharmacy. It would include a description of how the pharmacy would monitor and measure attainment of the plan’s goal. The plan could also include a description of the anticipated impact on business operations, hours of operation and staff. Compliance with the plan would be monitored by periodic visits by board inspectors. Failure to comply with the pharmacy services plan would be basis for withdrawal of the waiver, or other action by the board.

Mr. Cronin, representing the California Pharmacists Association, requested that the board consider requiring a pharmacy services plan as a condition for these waivers.

Mr. Jones agreed that it would be beneficial for those requesting a waiver to have a pharmacy service plan but did not know if the board has the authority to impose this on anyone.

Mr. Cronin stated that because the board grants the waivers, it can impose any requirement it wants.

Mr. Winterrowd stated that may be true on an individual basis, but once the process becomes a requirement, it becomes an underground regulation. He added that the requirement for a service plan should be in regulation if the board intends to require one.

Mr. Room stated that the board could make conditions on the waivers but non-compliance would be difficult to enforce. However, the board would be more likely to grant a waiver to those who have a pharmacy services plan.

Ms. Harris stated that the board voted to move forward with regulation change but the board has not noticed it yet. If the intent is to move forward, the notice could move forward with a regulation hearing at the October Board Meeting and it would be approximately 6 –9 months before the regulation becomes effective.

- **Request from White Cross Drug Store for Waiver of 16 CCR, Sec. 1717(e) to Use a Self-Service Drug Delivery System**

Dr. Fong stated that White Cross Drug Store is requesting a waiver of California Code of Regulations section 1717(e) to install and utilize a self-service drug delivery system in its pharmacy. White Cross Drug Store plans to install and utilize a self-service drug delivery system, such as the ddn, APM (Automated Product Machine). The board considered this request at its April meeting but tabled the discussion until such time the pharmacist-in-charge could be present.

The board granted the prior waivers to Longs and Safeway/Vons to permit the use of a self-service drug delivery system that allows a patient to access his/her filled prescriptions under the following conditions:

- The automated dispensing device is used for refill prescriptions only.
- It is the patient's choice to use the automated dispensing device.
- The device is located in reasonable proximity to the licensed pharmacy premises.
- The device is secure from access and removal by unauthorized individuals.
- The pharmacy provides a means for the patient to obtain a consultation with a pharmacist if requested by the patient.
- The pharmacy is responsible for the prescriptions stored in the device.

- A pharmacist is not to use the device to dispense refilled prescriptions if the pharmacist determines that the patient requires counseling pursuant to CCR, title 16, sec. 1707.2(a) (2).

Mr. Fazziola, representing White Cross Drug Store, stated that in their first letter to the board stated that a few items would be placed away from the pharmacy toward the front of the store. He corrected that statement saying that the unit will be adjacent to the counter, five feet from the pharmacist. He presented a pharmacy services plan to the board.

Mr. Fazziola read the following:

The APM 448 Automated Dispensing Device is to be used for refill prescriptions only once the waiver has been granted by the board.

The patient, at their own choice has to complete and sign an enrollment form to be able to utilize the automated dispensing device; otherwise the patient would be required to pick up their refill prescriptions from the pick-up window.

The APM Dispensing Device is currently located in the pharmacy within five feet of the pharmacist's workstation and will remain there at all times.

The APM Dispensing Device will be secured (that is bolted to the pharmacy floor) once the waiver has been granted. This will further ensure that access and removal by unauthorized individuals is impossible. The proximity of the APM to the pharmacist makes it more convenient to interact with the pharmacist. Due to the location of the APM Dispensing Device, we are providing easy and immediate access to a pharmacist for a patient to obtain consultation as requested.

White Cross Drug Store will be responsible for the prescriptions stored in the device at all times.

White Cross Drug Store will not use the device to dispense refill prescriptions; the pharmacist determines that the patient requires counseling pursuant to regulations.

The APM will not replace any employee on the staff. The APM is an alternative will-call storage methodology and convenience for the customer.

The APM will help alleviate large lines at the prescription pick-up window which at times can be overwhelming, even with a full staff generating up to 1200 prescriptions a day, customer wait times need to be reduced.

The integration of the unit is foreseen as a huge customer convenience, relieving them of the waiting period. If they so choose, the APM will only be open during store hours, which are 9:00 a.m. to 6:30 p.m., Monday through Friday and Saturday, 9:00

a.m. to 12:30 p.m. At no time after the store is closed or that the pharmacist is off the premises will the APM will be accessible.

This APM has been proven to be an asset to the White Cross Drug Store through numerous product demonstrations and training over the past months however, White Cross Drug Store will monitor the goals and the APM's performance through software designs and transaction logs.

Mr. Fazziola stated that White Cross Drug Store would also like to participate in the UCSD study.

Mr. Fazziola stated that a telephone wouldn't be necessary for patient consultation because the patient would pick "yes" if they want consultation and would be referred to the clerk or pharmacist at the next counter.

Supervising Inspector Ming stated that the dispensing unit is similar to the Asteres Unit used at Longs Drugs.

Dr. Ming stated that the location of the machine at White Cross Drug Store is similar to the location of the unit at the Longs facility. There is no access after hours. It was stated that the staff at White Cross Drug store would have ongoing training.

Mr. Jones stated that the training aspect should be added to the self-assessment so all training is documented for accurate machine operation. He stated that White Cross Pharmacy handles 1200 prescriptions per day and asked how the pharmacists are equipped to handle consultation currently.

Mr. Holmes stated that if the patient elects to have consultation, the product is not released until the consultation takes place.

Dr. Schell asked about the process for patients to sign up to use the product.

Mr. Grazzaio stated that pending the board's approval, the store will inform patients that the service is offered to them and if they want to sign up they can complete a card and pick their pin number. The patient will talk to the pharmacist to determine if this is safe.

Dr. Schell expressed concern that once the waiver is granted, there is no guarantee that the patients will be screened carefully. He requested White Cross' criteria for screening patients.

Mr. Powers stated that he has voted against all of the previous waiver requests because he does not feel that patients have the same access to pharmacists as they currently have.

Mr. Holmes stated that when he first approached the board with this request, he provided information on a three-year historical basis on the use of this technology in another state that no errors were made in the matching the prescriptions to the patient.

MOTION: That the Board of Pharmacy grant White Cross Drug Store a waiver of 16 CCR Section 1717(e) to install and use a self-service drug delivery system.

M/S/C: HIURA/JONES

SUPPORT: 5 OPPOSE: 4

- **Request from Walgreens for Waiver of 16 CCR Section 1717(e) to Use a Self-Service Drug Deliver System**

Dr. Fong stated that the Board of Pharmacy has received a request from Walgreens for a waiver of 16 CCR, Section 1717(e) to install and use a self-service drug delivery system.

Mr. Room announced that Board Member Ruth Conran has recused herself from this discussion.

Dan Luce, representing Walgreens, stated that Walgreens is looking to pilot the Asteres SriptCenter delivery system in a limited number of Walgreen stores. Mr. Luce added that he did not have a pharmacy services plan at this time.

Mr. Luce stated that Walgreens is looking to find a way to deliver prescriptions safely and effectively to their patients. He added that as part of this waiver request, Walgreens would like to participate in the UCSD study.

He requested a conditional waiver in the absence of a pharmacy services plan.

Dr. Fong asked about the units that would be placed away from the pharmacy toward the front of the store and access for patients who are ambulatory impaired. He added that he did not feel this is consistent with the same conditions of previous waivers.

Mr. Luce stated that they would remove this aspect. He explained the logistics of the prescription pick-up windows in the store.

Ms. Zinder asked if the unit is accessible when the pharmacy is closed.

Dr. Luce stated that Walgreens would like this option.

Mr. Jones asked the UCSD is considering having these other entities be a part of the study.

Dr. Hirsch stated that although there is still an issue of funding, having more input of information would allow them to gather data for answers faster.

MOTION: That the Board of Pharmacy grant the request from Walgreens for a waiver of 16 CCR Section 1717(e) to install and use a self-service drug delivery system subject to integration with the UCSD study.

M/S/C: JONES/HIURA

SUPPORT: 5 OPPOSE: 3

- **Consideration of Policy Regarding the Legal Requirements and Process for a Petition for Reconsideration**

Dr. Fong stated that the Enforcement Committee was provided with an overview of the process for a petition for reconsideration. This is the legal authority by which a respondent (licensee) can appeal or protest all or part of the decision adopted by the board by filing a request (petition) for reconsideration. Often the licensee is contesting part or the entire penalty and is requesting a reduction or modification of the disciplinary action. Petitions are usually in a letter format and state the reasons or grounds for reconsideration. The board itself may also order reconsideration of a decision on its own motion. This might be done at the request of staff or the Attorney General's Office to correct or clarify a decision.

The board's current policy for handling petitions for reconsideration of a board-adopted decision issued by an Administrative Law Judge (ALJ) is:

- Petitions received after the time allowed for reconsideration (on or after the decision's effective date): The petitioner is notified in writing that the board's authority to order reconsideration has elapsed and his/her option to file for judicial review.
- Petitions received not timely (within a few days of the effective date): The Board of Pharmacy has delegated to the board president the authority to either staff the effective date of the disciplinary order to allow the board to decide whether they will agree to reconsider; or to not take action and consider the petition denied. The board president considers whether there are sufficient reasons provided by the petitioner to grant a request to issue a stay, or to deny the request. If the president decides to issue a stay of the effective date, a stay order of not more than 10 days is issued to allow the board time to decide whether to reconsider the decision. The petition will then be sent to the board for mail vote.
- Petitions received timely (within a sufficient time frame to have the board consider without issuing a stay order): Staff prepares the petition for board review by mail vote. Again, at this stage, the board is only making a decision on whether to reconsider its decision. If the board agrees to reconsideration, a stay order is issued allowing the board sufficient time to reconsider the decision.

Although a licensee who agrees to a stipulated settlement also agrees to waive reconsideration rights, the board has applied its reconsideration policy to those disciplinary decisions adopted by stipulation.

The board's decision whether to consider a petition is done by mail vote. Because of the short time frame in which to make a decision, this is an expedited process and requires immediate mailing to the board and close monitoring of the mail votes, oftentimes requiring daily contact with board members.

During a mail vote, based on the information provided in the petition, the board is making a decision on whether to consider a petition. The board is not in the initial vote, deciding on the actual merits of the case or concluding the previously adopted decision should be set aside; it is merely, by its vote to grant reconsideration, concluding that there is adequate legal, factual, and/or policy basis for reviewing the factual findings, legal conclusions and/or disciplinary order.

In the last three years, the board has received nine petitions for reconsideration. Five of those petitions were sent to the board for mail vote, three were denied by the board president, and one was received on the effective date of the decision, thus not timely and denied. All of the petitions were subsequently denied. Three of those have filed for judicial review and are still pending in the courts. One licensee did not request reconsideration, but requested a stay of the decision pending judicial review of the case. That stay request was denied and the writ review is still with the courts.

Due to the significant resources that are involved in the initial hearing process and required to process petitions for reconsideration of those decisions and penalties already adopted by the board and the immediate turn-around time required, the Enforcement Committee reviewed the board's policy on consideration such as reducing the effective date from 30 to 15 days and not to reconsider any petitions or to delegate to the board president the authority not to take action on these petitions and that notice be sent to the licensee that action will not be taken by the board on his/her right to judicial review.

The committee discussed the options. It was noted that when petitions for reconsideration are submitted, the evaluation of the petitions should be based on whether the petitioner has provided new facts that would support a reconsideration, or whether new laws have been enacted that might impact the decision. When petitions are provided that purportedly argue new facts, the deputy attorney general who represented the board reviews the petition to determine if indeed new facts have been presented. However, the petitions are usually requesting reconsideration of the discipline that has already been adopted by the board.

If a petition for reconsideration is granted, then the effective date of the penalty will be stayed to allow the board time to consider the issues raised in the petition. The board may reconsider by: (1) receiving written argument from the petitioner and the Attorney General's Office; (2)

reviewing pertinent parts of the record or by taking additional evidence, or both, and at its option considering additional argument; or (3) assigning the matter back to the administrative law judge. The board considers the petition and additional written argument during closed session at the next regularly scheduled board meeting or, depending on the complexity of the request, by mail vote.

- **Importation of Prescription Drugs**

Dr. Fong stated that the importation of prescription drugs has been an ongoing agenda item for the Enforcement Committee and Board of Pharmacy meetings for over the last three years. 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. The board's mandate is to protect the public, which includes patient access to "safe and affordable" prescription medications.

- **Clarification of Pharmacy Law Related to Intern Pharmacists, Orally and Electronically Transmitted Prescriptions and Filling of Non-Security Prescription Forms**

The Board of Pharmacy requested from its counsel clarification of certain statutes and regulations pertaining to two general areas of inquiry: (1) whether licensed intern pharmacists may perform certain tasks, including "advanced" techniques such as emergency contraception protocols under Business and Professions Code section 4052, skin puncture under Business and Professions Code section 4052.1, or final checks on prescriptions; and (2) whether and how California pharmacists may accept prescriptions not written on security prescription forms, and how these prescriptions fit with the treatment required of orally or electronically transmitted prescriptions.

In responding to this request, counsel advised the board that as always it should not issue any "regulation," guideline, criterion, or rule of general application, giving the agency's interpretation or application of its laws and/or procedures, or the like, except where the formal processes of the Administrative Procedure Act are followed. To avoid an underground regulation, counsel reminded the board that it should refrain from offering or suggesting a binding interpretation of law, or supplementing the existing law.

Performance of "Pharmacist" Tasks by Intern Pharmacists

Counsel concluded that Business and Professions Code section 4114 places no limitation on the scope of intern pharmacist practice, other than that: (i) any task must be done under the supervision (soon to be "direct supervision and control") of a licensed pharmacist; (ii) the supervising pharmacist must consent/agree to the performance of any task by the intern pharmacist; and (iii) the supervising pharmacist must be licensed and in good standing with the Board. Section 4114 no longer allows the board to limit intern pharmacists' scope of

practice by board regulation. Nor, in any event, are there any regulations attempting to do so. (See, e.g., Cal. Code Regs., tit. 16 Sections 1727, 1728).

Accordingly, properly supervised intern pharmacists may, with the consent/supervision of a supervising pharmacist, perform any function authorized for licensed pharmacists. Included in the authorized functions for both pharmacists and intern pharmacists, therefore, are EC therapies (Bus. & Prof. Code Section 4052(a)(8)), skin punctures (Bus & Prof. Code Section 4052.1), and final check on prescriptions (Bus. & Prof. Code, Sections 4051, 4115; Cal. Code Regs., tit. 16. 16. 16, Section 1793 et seq.).

Both the intern pharmacist and his/her supervising pharmacist must, however, meet any necessary prerequisites to performance of any particular function before that function is properly performed by the intern pharmacist. For instance, with regard to provision of EC drug therapy, pursuant to Business and professions Code section 4052, subdivision (a)(8), prior to performing any procedure authorized under this paragraph, both the intern pharmacist (to ensure appropriate provision of services) and the supervising pharmacist (to ensure appropriate supervision thereof) must first (i) have participated in instituting and implementing standardized procedures/protocols meeting subdivision (a)(8)(A)(i) and/or (a)(8)(A)(ii), and (ii) have received the training required by subdivision (a)(8)(B). Obviously, intern pharmacists cannot receive CE credit for the training, but they must nonetheless have participated in an approved course of training on EC therapy.

What effect(s) ought to be given by pharmacists or pharmacies to written prescriptions not written on the security prescription forms required (as to controlled substances) by Health and Safety Code section 11150 et seq. (particularly 11162.1 and 11164 For a pharmacist faced with a written prescription not made on a security prescription form, the board has advised that the best course for the pharmacist is to treat that prescription as if it had been orally transmitted. In doing so, however, a pharmacist must actually transform the writing into an oral prescription. In other words, the pharmacist cannot rely on the written document as assurance of the validity or accuracy of the prescription, and has to contact the authorized prescriber and orally verify and record all of the information that is required by Business and Professions Code section 4070 (dangerous drugs), Health and Safety Code section 11164(b)(1) Schedule III-V drugs), or Health and Safety Code section 11167/11167.5 (Schedule II drugs in applicable circumstances).

A written prescription on an “old” triplicate form or any other non-secured prescription form is essentially irrelevant to the validity or accuracy of the prescription. The only purpose it serves is that there is no need for the pharmacist to entirely “recreate” a new hard copy of the prescription. Instead, the pharmacist may use the non-security form prescription to record the necessary information, and/or attach documents to that form containing that information. In the strictest sense, the pharmacist is not required to “rewrite” the prescription, but he or she must be sure that all of the pertinent information was received/verified orally, sign and date it, etc.

- (2) As to the second question, pertaining to direct entry of orally-received prescription into a pharmacy computer, it does not appear that this procedure would exempt the pharmacist from the requirement(s) of hard copy production, personal signature and dating, and recording of all of the required information. Direct entry of orally transmitted information is not “electronic transmission” exempting the pharmacy from keeping hard copies per Business and Professions Code section 4070 (dangerous drugs) or Health and Safety Code section 11164.5 (controlled substances). (In other words, direct entry does not eliminate any of the hard copy requirements).
- (3) The third question, pertaining to prescriptions sent electronically from a prescriber or hospital computer to a pharmacy computer, has been answered already by the foregoing general discussion. As a general rule, a hard copy of these prescriptions must be printed out, the required signatures affixed, the required information collected, and the hard copies retained. A hard copy of electronically-transmitted dangerous drug/device prescriptions need not be produced/retained when the conditions in Business and Professions section 4070 are all met, and a hard copy of an electronically-transmitted controlled substance prescription need not be produced/retained when permission is given and all of the conditions in Health and Safety Code section 11164.5 are met.
- (4) Finally, counsel responded to the board’s question as to whether it should consider revisions to California Code of Regulations, title 16, section 1717, subdivision (c), to account for technological updates. Because section 1717(c) only covers oral transmissions, it has not yet really been affected by the increasing availability of electronic prescription transmission. However, if the board wanted to also specify treatment of electronically-transmitted prescriptions, either in affirmance of section 4070, or in addition thereto, it might want to include this treatment in section 1717. This might give the board some flexibility to respond to upcoming changes in these technologies.
As requested by the Enforcement Committee these pharmacy law clarifications will formatted into questions and answers for the next newsletter.

- **Implementation of SB 151 (Chapter 406, States of 2003) Requirements for Prescribing and Dispensing Controlled Substances Prescriptions as of January 1, 2005 and CURES Update**

Dr. Fong stated that over the past year and a half, the Board of Pharmacy has been implementing the changes to prescribing and dispensing laws for controlled substances that resulted from SB 151 (Chapter 406, States of 2003). The board has been working hard at educating pharmacists and prescribers on the new requirements and coordinating its efforts with the Bureau of Narcotic Enforcement, the Medical Board of California, other prescribing boards, and professional associations. Since January 2004, the board has provided more than 50 presentations on SB 151. Some of the presentations were provided by teleconference to reach large numbers of individual prescribers and pharmacists. In addition, the board has

included numerous articles in *The Script* newsletters, and a large number of articles and frequently asked questions and answers are provided on the board's Web site.

In the April 2005 Action Report publication, Medical Board of California (MBC) cautioned physicians regarding DEA's interim policy statement on prescribing Schedule II controlled substances. The interim policy statement prohibits physicians from issuing multiple prescriptions from Schedule II controlled substances on the same day to the same patient with instructions for the pharmacy to fill some of the prescription on a specific date in the future.

The MBC stated in its newsletter that unless DEA changes its position, physicians must see their patients each a prescription for a Schedule II drug is written. In its next newsletter, MPC will be providing the following statement to provide guidance and clarity to physicians who prescribe Schedule II controlled substances their patients:

When prescribing Schedule II controlled substances to patients, the length of time and quantity of each Schedule II prescription should be based on the needs of each patient and must be within the standards of responsible prescribing.

It was noted that the Medical Board's position regarding the DEA interim policy statement prohibiting physicians from issuing multiple prescriptions for Schedule II controlled substances on the same day to the same patient with instructions for the pharmacy to fill some of the prescriptions on a specific date in the future will be added to the board's web site and in the next newsletter. It also requested that the board include an article on electronic signatures as well.

- **Implementation of SB 1307 (Chapter 857, States of 2004) Relating to Regulation of Wholesalers**

Dr. Fong stated that last year, the Board of Pharmacy sponsored SB 1307 (Figueroa). Governor Schwarzenegger signed the bill, which became effective January 1, 2005. The bill made various changes to the wholesaler requirements and distribution of dangerous drugs. Most of the changes strengthened and clarified the requirements for the distribution of dangerous drugs and dangerous devices in California.

The Enforcement Committee is monitoring the implementation of this legislation. One area of close oversight is the pedigree requirement. The bill requires an electronic pedigree by January 1, 2006 and gives the board the authority to extend the compliance date for wholesalers to January 1, 2008. The Legislature may extend the compliance date for pharmacies to January 1, 2009. The purpose of the pedigree is to maintain the integrity of the pharmaceutical supply chain in the United States.

It is anticipated that Radio Frequency Identification technology (RFID) will be the method used to track a drug's pedigree. The manufacturer would tag the drug with a small chip and antenna. When the tag is in close proximity of a reader, it would receive a low-powered radio

signal and interact with a reader exchanging identification data and other information. Once the reader receives data, it would be sent to a computer for processing. At an Enforcement Committee Meeting, SupplyScape presented its electronic pedigree software program that enables a safe and secure pharmaceutical supply chain that complies with federal and state regulations to prevent counterfeit drugs.

Acerity Corporation presented to the Enforcement Committee its security software program, which is an electronic authentication process. The presented their system at the April board meeting as well. The system employs a cryptography technique in conjunction with RFID forming a multiplayer secure process, which provides numerous advantages and allows versatile applications.

Dr. Fong stated that it is not the intent of the Board of Pharmacy to support or endorse any specific technological solution for the electronic pedigree requirement.

- **Implementation of SB 1159 (Chapter 608, Statutes of 2004) – Disease Prevention Demonstration Project**

Dr. Fong stated that on September 20, 2004, Governor Schwarzenegger signed into law SB 1159, which provides for the pharmacy sale of sterile syringes without a prescription. Cities and counties may elect to authorize a Disease Prevention Demonstration Project, which will permit certified pharmacies to sell ten or fewer syringes to individuals 18 years of age or older. The purpose of the legislation is to further efforts across the state to prevent the spread of HIV, hepatitis and other blood-borne diseases.

SB 1159 mandates, among other provisions, that the State Department of Health Services (DHS) conduct an evaluation of the Disease Prevention Demonstration Project, and that DHS convene an uncompensated advisory panel to design the evaluation. The panel has already met twice. It includes representatives from law enforcement, the waste management industry, pharmacies, chain and independent, community advocates and government, including waste management, the state Board of Pharmacy and the state Office of AIDS (OA). DHS/OA is also encouraged by the bill to seek outside funding for the evaluation of SB 1159; possible funding sources have already been identified and a draft grant proposal is currently under revision.

More than 20 other county health departments are currently preparing for implementation. Activities include meeting with local stakeholders, weighing different disposal plans for syringes and other potentially hazardous household waste, collaborating with pharmacies and developing health education materials.

- **Report on Enforcement Actions**

On July 1, 2001, the board implemented its inspection program toward reaching its strategic goal of inspecting all licensed premises at least once every three years. At program

implementation, there were approximately 5, 530 licensed premises to inspect. That as of July 1, 2005, a total of 5,524 of those sites or 99.89 percent have been inspected at least once during this 4-year inspection cycle. Staff anticipates completing all remaining inspections by July 20, 2005 to reach the board's strategic goal albeit in four years instead of three years.

Dr. Fong also commended the inspectors on a job well done and noted that this type of quality inspections create a higher standard for compounding pharmacies.

LEGISLATION AND REGULATION COMMITTEE

Regulation Report and Action

Pending Regulations

Mr. Jones stated that staff published a 15-day notice on February 2, 2005, to make minor change to the omnibus group of regulations approved by the board at the January 2005 board meeting. That notice period ended February 22, 2005. There were no changes or comments made to this language.

The rulemaking package was submitted for administrative review in April and is still undergoing review by the Administration; the regulations should be in place by late summer.

Board Approved – Awaiting Notice

- **Proposed Amendment to Repeal CCR, Title 16, Section 1717(e) and to add CCR, Title 16, sec. 1713 – Authority to Use Drop Boxes for Prescriptions and Automated Dispensing Devices to Pick-up Refill Prescriptions**

Mr. Jones stated that at the October 2004 Board Meeting, the board moved to regulation hearing proposed regulation changes that will permit the use of drop boxes to drop off prescriptions, and the use of automated dispensing devices to dispense refill medication when the patient has “opt-in” to use this system. This regulation is awaiting notice.

Information Hearing

- **Proposed Amendment to CCR, Title 16, Section 1727 and Addition of CCR, Title 16, Section 1727.1 – Exemption for Intern Addresses from Posting On-Line**

Mr. Jones referred to the proposed amendment and asked if there were any comments.

George Pennebaker, representing the California Pharmacists Association (CPhA), stated that the CPhA supports the adoption of section 1727.1.

Mr. Marcus stated that this is a good idea for the protection of student interns until the time that they become full licensees. He asked why the language did not include: “including, but not limited to” the World Wide Web and the Internet.

Legislation Report and Action

Board-Sponsored Legislation

Mr. Jones stated that at the Legislation and Regulation Committee Meeting on July 13, the committee reduced the number of bills to present to the board to four because the majority of bills did not have substantive changes and the board already had a position on many of these. Copies of all bills relating to the practice of pharmacy that the board had positions on were provided in the board packet, along with legislative committee analysis.

- **AB 21 (Levine) Pharmacists: Practice Requirements**

Mr. Jones stated that this bill would require a pharmacist to dispense a prescription except in specified circumstances. The bill would allow a pharmacist to decline on ethical, moral, or religious grounds to dispense a drug pursuant to a lawful request only if he or she satisfies certain conditions. The bill would make a violation of the provisions unprofessional conduct and would also make harassment, as specified, of a patient by a pharmacist unprofessional conduct, subject to disciplinary action by the board. (B&P 4069).

Jan Perez, Legislation Coordinator for the board, stated that this is a two-year bill. She noted a provision in the bill that states: “It shall constitute unprofessional conduct and a violation of this chapter for a pharmacist to harass a patient by engaging in extreme or outrageous conduct and intentionally causing the patient emotional distress or by engaging in conduct with reckless indifference to the likelihood of causing the patient emotional distress. For these purposes, the emotional distress shall be actual and severe as determined by a reasonable person.”

Mr. Jones stated that this bill is worded very broadly for all pharmacy practice. He added that if a patient felt harassed by the pharmacist, this action could constitute unprofessional conduct regardless of the situation. He added that the committee discussed this and determined that a more appropriate position to take on this bill is oppose, rather than one of no position.

Mr. Room stated that the intent of this bill appears to incorporate intentional infliction of emotional distress into the licensing statutes and he cautioned that this is likely to increase the number of personal relation complaints received by the board. He added that it would be difficult having this type of subjective standard in the licensing statutes.

Mr. Jones stated that this action could be used against a pharmacist simply for not filling a prescription when the pharmacist may feel that a drug abuse situation is occurring.

Mr. Marcus stated that he did not see the need for this language.

Dr. Gray expressed concerned about this language because 90 percent of the unease between pharmacists and patients stems from insurance issues and these kinds of issues may also come before the board if this legislation is passed. He urged the board to oppose AB 21 unless it is amended.

MOTION: Legislation and Regulation Committee: That the Board of Pharmacy oppose AB 21 (Levine) – Pharmacists: Practice Requirements.

SUPPORT: 6 OPPOSE: 1 ABSTAIN: 1

- **SB 644 (Ortiz) Dispensing Prescription Drugs and Devices**

Ms. Perez stated that this bill would require a health care licentiate to dispense drugs and devices pursuant to a lawful prescription or order except in specified circumstances, including on ethical, moral, or religious grounds asserted by the licentiate. (B&P Section 733).

Ms. Perez stated that the board has a support position on the bill.

Ms. Herold added that the bill amends section 733 of the Business and Professions Code. Following discussion at the Legislation and Regulation Committee Meeting, the board requested amendments so that the board may issue a cite and fine, letter of admonishment or take other disciplinary or enforcement sanction for violations of procedures for a pharmacist to follow if he or she has an objection to dispense. Such an amendment is needed because SB 644's provisions are located outside Pharmacy Law. She added that amendments were submitted to Senator Ortiz's Office. The sponsors of the bill consist of a group of approximately 20 interested parties who are negotiating and all parties must agree to the amendment.

Dr. Gray stated that subsection (d) only applies to emergency contraception and he encouraged the board to seek further clarification.

MOTION: That the Board of Pharmacy support SB 644 (Ortiz) – Dispensing Prescription Drugs and Devices.

M/S/C: ZINDER/POWERS

SUPPORT: 8 OPPOSE: 0

- **SB 401 (Ortiz) Medical information: Pharmacies: Marketing**

Ms. Perez stated that this bill would define marketing to include written communication distributed by a pharmacy to a patient and paid for or sponsored by a manufacturer, labeler or

distributor, about different drugs or treatment options, other than the drug dispensed by the pharmacy.

Ms. Perez stated that the board currently has no position on this bill. The committee recommends amendments that would allow a patient the ability to opt out of receiving paid advertisements with their medications and require paid advertisements to be labeled as such and identify the sponsor of the advertisement.

Mr. Powers stated that consumers are confused already. He added that when this information is received and it appears official to the patient, the small print indicating this is an advertisement is meaningless. He added that he opposes a no position on this bill.

The committee suggested that a patient should be able to “opt out” of receiving paid advertisements with their medications, and any information provided as a paid advertisement be specifically labeled as such.

MOTION: Legislation and Regulation Committee: That the Board of Pharmacy oppose unless amended SB 401 (Ortiz) – Medical Information:
Pharmacies: Marketing

SUPPORT: 5 OPPOSE: 3

- **SB 798 (Simitian) Prescription Drugs: Collection and Distribution Program**

Ms. Perez stated that this bill would authorize a county to establish, by local ordinance, a repository and distribution program for purposes of distributing surplus unused medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies.

Ms. Perez stated that the board previously had no position on this bill. She added that staff notified the author’s office about significant problems with the bill based on May amendments. The author was receptive on working out the amendments to bring the measure in conformity with state law. The current version of the bill is very broad and would undo much of the benefits that the pedigree requirements enacted last year would establish.

MOTION: Legislation and Regulation Committee: That the Board of Pharmacy oppose SB 798 (Ortiz) unless amended – Prescription Drugs:
Collection and Distribution Program Committee Recommendation

SUPPORT: 8 OPPOSE: 0

Reviewed Pending Legislation

Mr. Jones stated that the board reviewed the following pending legislation.

- **AB 595 (Negrete McLeod) Pharmacy: Compounding of Prescription Drugs**

Ms. Perez stated that this board-sponsored bill would define compounding of a prescription drug for the purposes of the Pharmacy Law and would make other related changes in that regard. The board has a support position on this bill.

- **SB 1111 (B&P Committee) Omnibus Bill**

Ms. Perez stated that the board's omnibus bill includes eight changes the board is proposing for the Business and Professions Code. These change are:

1. **Rules of Professional Conduct: B&P 4005 & 4206**

Repeals outdated rules of professional conduct code.

2. **Recast and Revision: Requirements For Designated Representatives: B&P 4053**

Makes technical amendments to clarify the requirements for designated representatives, the non-pharmacists who oversee the operations of drug wholesalers.

3. **Technical Updates to Licensing Provisions: B&P 4127.5, 4205 & 4400**

Amends 4127.5 to specifically exempt government and tribal governments from the license fee for sterile injectable compounding pharmacies. Deletes the reference to B&P Section 4130 in B&P Section 4205 because this section was repealed in 2000. Section 4400 has numerous changes.

4. **Continuing Education Requirements: B&P 4231 & 4232**

Establishes in the B&P code 30 hours of CE for license renewal; specifies that a pharmacist who fails to provide proof within 60 days of license renewal of CE completion will be issued an inactive license and barred from practicing pharmacy; changes the requirement for the CE exemption from two years after graduation to the first renewal of a pharmacist license; and changes the term "pharmaceutical education" to "pharmacy education."

5. **Pharmacist Recovery Program: B&P 4360-4373**

Makes changes to the Pharmacist Recovery Program most of which are technical changes.

6. **Pharmacy Technician Program: B&P 4023.5, 4038, 4114, 4115, 4115.5 & 4202**

Updates the statutes for the Pharmacy Technician Program and establishes “direct supervision and control” as the standard for pharmacist supervision of pharmacist interns, pharmacy technicians, and pharmacy technician trainees.

7. Letter of Admonishment: B&P 4315

Deletes the requirement that a copy of a pharmacist’s letter of admonishment be kept on the pharmacy’s premises.

8. Impairment or Theft by Licensed Individuals: B&P 4104

Requires pharmacies to notify the board within 30 days of a pharmacist who engages in theft, diversion, or self-use of dangerous drugs. Additionally, require pharmacies to handover evidence against pharmacists’ engaged in these activities. This proposal would include a provision that would give immunity from liability to a person, who in good faith makes a report to the board.

These changes clean up previous legislation, update the law or respond to state and national trends in regulating pharmacies and pharmacists. All the proposals are non-controversial. They have been reviewed and discussed at least twice during a public meeting of the board, and have been approved by the board for sponsorship. The board has a support position on this bill.

- **AB 225 (Negrete McLeod) Electronic Prescription Information**

Ms. Perez stated that this bill allows health care professionals to receive nonmonetary remuneration, in the form of hardware, software, or information technology and training services, necessary and used solely to receive and transmit electronic prescription information in accordance with the standards set forth in Section 1860D-4(e) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (42 U.S.C. Sec. 1395w-104), in specified circumstances.

Amendment: Require the prescriber, prior to the electronic transmitting of a prescription, to offer to transmit the prescription to a pharmacy of the patient’s choice.

Ms. Perez added that the board has a support if amended position on this bill and this is a two-year bill.

- **AB 283 (Koretz) Pseudoephedrine: Retail Sale**

Ms. Perez stated that this bill would limit access to ephedrine and pseudoephedrine products by requiring a retailer to place the products in a locked cabinet, and that The retailer or employee of the retailer shall at all times act to prevent the theft or diversion of the products. AB 283 would place these provisions in H&SC 11100.01.

Ms. Perez stated that this is a two-year bill and the board has no position on the bill.

- **AB 446 (Negrete Mcleod) Settlement Agreements (Gag Clauses)**

Ms. Perez stated that this bill is intended to close a loophole in current law that allows a licensee under the supervision of DCA to prohibit a consumer who settles a civil suit from also filing a complaint or otherwise cooperating with a regulator. The board supported similar legislation, AB 320, in 2003, that was vetoed. The board has a support position on the bill.

- **AB 497 (Negrete McLeod) Drug Wholesalers and Manufacturers:**

Ms. Perez stated that existing law, operative January 1, 2006, to January 1, 2011, requires an applicant for the issuance or renewal of a nonresident wholesaler license to submit a surety bond of \$100,000, or an equivalent means of security, for each site to be licensed by the nonresident wholesaler through which dangerous drugs or dangerous devices are to be shipped, mailed, or delivered to a site located in California. This bill would instead require a single \$100,000 surety bond, or an equivalent means of security, to be submitted by an applicant for the issuance or renewal of a nonresident wholesaler license. The board has a support position on this bill.

- **AB 522 (Plescia) Automated drug delivery system**

Ms. Perez stated that this bill provides clean-up language for AB 2184 (Chapter 342, Statutes of 2004), Automated Dispensing Devices. Additionally, the measure would prohibit the Department of Health Services (DHS) from paying for any prescription drug or other therapy to treat erectile dysfunction for registered sex offenders and authorize the Department of Justice to share information with DHS concerning registered sex offenders.

Amendment: Add the words “and dosage” to page 4, line 33 to read:

“After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated drug delivery system shall be limited only to the drug and dosage as ordered by the prescriber and reviewed by the pharmacist and that is specific to the patient.”

Ms. Perez stated that board has a support if amended position on this bill.

- **AB 657 (Karnette) Pharmacies: Prescription Containers: Labels**

Ms. Perez stated that this bill revises the prescription labeling requirement to require a container to be labeled with, among other things, the “intended purpose” for which the drug was prescribed, if the intended purpose is listed on the prescription. The board has a support position on this two-year bill.

- **SB 152 (Speier) Pseudoephedrine**

Ms. Perez stated that this bill would require 1) pseudoephedrine products to be sold in a pharmacy and by a pharmacist or pharmacy technician; 2) pseudoephedrine to be stored in a locked area in view of the pharmacist; 3) limit the quantity of product sold to no more than nine grams of pseudoephedrine in a within any 30 day period; 3) the purchaser produce photo identification; and 4) the purchaser to sign a document with specific information about the transaction. SB 152 would place these provisions in B&P 4051.1. The board has no position on this two-year bill.

- **SB 592 (Aanestad) Acute Care Hospitals: Inpatient Pharmacy Technician Services**

Ms. Perez stated that this bill permits general acute care hospitals to employ specially trained pharmacy technicians to check the work of other pharmacy technicians (TCT) filling floor stock, ward stock, and unit dose cassettes. The board has support position on this two-year bill.

- **SB 734 (Torlakson) Controlled Substances**

Ms. Perez stated that this bill is sponsored the Department of Justice. The author's intent is to make clean-up changes to facilitate the effective operation of the CURES, the prescribing and dispensing of controlled substances, and the program duties of the Bureau of Narcotics Enforcement. The board has an oppose unless amended position on this bill. The board's amendment would cap board's funding of CURES each year unless the board receives an appropriation augmentation sufficient to cover the additional cost billed by the DOJ.

NEW BUSINESS

- **Pain Management**

Mr. Marcus stated that the Pain and Policy Studies Group conducted an exhaustive examination of the laws affecting pain management in all the states in the country, which was published in 2004. Lorie Rice representing the Medical Board created a task force to examine California's laws affecting pain management. It is anticipated that the task force will hold its first meeting in August.

- **Consumer Safety**

Jim Colucci, pharmacist, stated that with all of the laws that are designed for consumer safety, errors are occurring due to poorly written prescriptions that account for 80 percent of errors made. He added that for example, of 1000 people becoming ill, 800 of them become ill due to errors in reading the prescriptions incorrectly.

Mr. Colucci requested that the board consider a law proposing that doctors print, stamp, type, use computers, or another means other than handwriting their prescriptions to eliminate this 80 percent rate of errors. He added that 30-35 years ago in Israel a law was passed when they experienced the same problem because doctors were coming to Israel from all over the world. This law has been in effect for 35 years and resulted in eliminating the 80 percent error rate.

Mr. Colucci submitted examples of poorly written prescriptions to the board. However, legal counsel advised him that he should remove any personal information from the examples before he submits them to the board.

President Goldenberg stated that along with the Medicare Modernization Act, there was a requirement by the federal government to create a task force with timelines on electronic prescribing allowing electronic transfer of prescriptions which would solve this type of problem. He suggested that the Enforcement Committee review this issue.

Ms. Harris stated that the California Retailers Association brought this issue before the board a few years ago and a newsletter article was printed in the Medical Board's newsletter about the issue. She added that requiring all prescriptions to be typewritten or something similar would require legislation

President Goldenberg suggested that Mr. Colucci attend the Enforcement Committee Meeting and gather supporting information. He also requested that this item be placed on the agenda.

Dr. Gray suggested that the committee also include the report on the legislation that was passed two years ago requiring the establishment of a joint committee between the pharmacy board and the Medical Board to study the issue of electronic transmission to facilitate the discussion. He added that the law was passed but there doesn't seem to be anything happening with it.

CLOSED SESSION

The board moved into Closed Session pursuant to Government Code section 11126(a) regarding personnel matters to perform the evaluation of the Executive Officer.
The board moved into Closed Session pursuant to Government Code section 11126(c)(3) to deliberate upon disciplinary cases.

The board moved into Closed Session to confer with Legal Counsel Pursuant to Government Code Section 11126(e)(2)(A) regarding the following pending litigation: Doumit v. Board of Pharmacy, California Court of Appeal, Third District Case No. C039012, Pharmacy Defense Fund v. Board of Pharmacy, California Superior Court, San Francisco County Case No. CPF 05-201 05-505201 and Blackburn v. Board of Pharmacy, California Superior Court, Orange County Case No. 03CC11189.

ADJOURNMENT

There being no further business, President Goldenberg adjourned the public Board Meeting at 5:09 p.m.

Thursday, July 21, 2005

- **Petition for Early Termination of Probation**

Meredethe Cone
Debra Ryan

- **Petition for Reinstatement**

Erik Paden Bailey
Sid Chakravarti
Robert Fortner

CLOSED SESSION

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