



**California State Board of Pharmacy**

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

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

**MINUTES**

**DATE:** May 19-20, 1999

**TIME:** 8:00 a.m. – 3:00 p.m.

**PLACE:** Hanalei Hotel (Paradise Room)  
2270 Hotel Circle North  
San Diego, CA 92108  
(619) 297-1101

**BOARD MEMBERS**

**PRESENT:** Tom Nelson, President  
Sandra Bauer, Vice President (Absent 5/20/99)  
Robert Elsner  
Darlene Fujimoto, Pharm.D  
John Jones , Pharm.D  
Steven Litsey, Pharm.D  
Richard Mazzoni, Pharmacist  
Marilyn Shreve, Pharmacist  
Holly Strom, Pharmacist  
Caleb Zia  
Andrea Zinder

**STAFF PRESENT:** Patricia Harris, Executive Officer  
Gilbert Castillo, Supervising Inspector  
Bob Ratcliff, Supervising Inspector  
Ruta Arellano, Associate Analyst  
Sandi Moeckly, Licensing Analyst  
Sherri Stock, Secretary  
Chris Grossgart, Department Legal Counsel  
William Marcus, Deputy Attorney General

## **CALL TO ORDER**

President Nelson called the meeting to order at 8:00 a.m. on May 19, 1999.

## **INTRODUCTIONS/ANNOUNCEMENTS/ACKNOWLEDGEMENTS**

President Nelson welcomed new board member, Andrea Zinder. Ms. Zinder was appointed by the Speaker of the Assembly replacing public member Ken Tait.

## **COMMITTEE REPORTS AND ACTION**

### Organizational Development

#### Approval of Revisions to 1999 Strategic Plan

Ms. Harris reported that a draft of the strategic plan was sent to Kathleen Hamilton, Director of Consumer Affairs, on May 3, 1999. Ms. Hamilton was advised of the revisions that the board made to its Strategic Plan from last year. The revisions were to:

- The performance measures and indicators to more accurately reflect the measures that the board uses to track its progress in achieving its goals, provide ongoing feedback and identify areas for improvement.
- The strategic objectives for the five goal areas: Communication and Public Education, Licensing, Enforcement, Legislation and Regulation, and Organizational Development.
- The Environmental Scan.

The board acknowledged that the Strategic Plan is a working document that may require modifications throughout the year.

MOTION: Approve the Strategic Plan.

M/S/C: Strom/Elsner

SUPPORT: 9                      OPPOSE: 0

### President's Report

Mr. Nelson thanked all staff, board members, the Executive Officer Patty Harris, and Assistant Executive Officer Virginia Herold for all of their hard work and support this past year. He then presented board member Shreve and former board

member Dreyfus with a clock recognizing and acknowledging their time on the board and many contributions.

## Executive Officer's Report

### Personnel Update

Ms. Harris reported that Stephanie Jones has been promoted to Management Services Technician, and is processing applications for wholesalers, medical device retailers, and the exemptees for these sites. Cheryl Hayer has changed positions and is now working in Stephanie Jones' prior position as a consumer assistance technician. Ms. Hayer was formerly a board cashier. Elizabeth Nowacki began working with the board on May 3, 1999, as a new board cashier, filling a position created by the promotion earlier this year of Linda Alderman. Ms. Nowacki transferred to the board from elsewhere in the Department of Consumer Affairs.

Board Inspector Cooky Quandt retired from state service in April, after five years with the board. She will begin work with Longs, as compliance officer for Longs' western region stores. Board Inspector Labib Doumit also retired from state service in April. Mr. Doumit has been with the board since 1985.

Kim Madsen, a consumer technician with the board, gave birth to Zachary Paul Madsen on April 12. Ms. Madsen will return to the board at the end of May on a part-time basis. Helen Turner, a retired annuitant who has worked for the board for over 10 years, is still convalescing following her injury in January. We wish her a speedy recovery and hope for her return to the board soon.

The board is recruiting for two positions created by board promotions, a cashier (office technician) and an analyst to issue citations and fines. The board will also begin recruiting an associate analyst to perform legislative analyses and regulations (a position that will begin 7/1/99). The board also plans to hire a limited-term associate analyst to perform support to the CURES program, and sometime in July, an associate analyst to assist with the assessment of the public education program.

Ms. Harris also reported that the board has eight of its 19 inspector positions vacant. Ms. Harris and Supervising Inspector Bob Ratcliff will hold interviews for these positions and hope to have at least four new inspectors on staff by August.

All of the inspectors attended the Professional Diversion Information Network Training (PDIN) that was held in April. Mr. Marcus received an award by the PDIN for his many contributions.

The Bureau of Medi-Cal Fraud in the Attorney General's Office recently commended board participation in a multi-agency investigation. Supervising Inspector Gilbert Castillo, Inspector Brenda Barnard, Inspector Robert Venegas and Technician Linda Kapovich were recognized for their contribution to this case.

### Budget Update

#### 1998/99 Budget Year

Revenue Projected: \$9,845,675

Ms. Harris reported that revenue for the year includes \$5,603,823 in revenue from licensing fees, \$443,655 in interest income, and a one-time repayment of \$3,798,197 returned to the board from the 1991-92 transfer of board revenue to the state's General Fund (this is a 4/5 repayment, only 1/5 of the \$5.4 million transferred – or \$1.14 million with interest – remains unpaid). There was a \$70,200 reduction in this year's revenue due to the \$75 rebate that was paid to the 2,300 pharmacies that submitted data to CURES by July 18, 1998. There has been \$138,781 in cost recovery paid to the board through April 30, 1999.

Expenditures Projected: \$6,092,208

The board's expenditures of \$6,092,208 includes a baseline budget of \$5,605,000, plus \$474,750 for CURES, and \$11,961 to pay for a 5.5 percent salary increase for board clerical and analyst employees that became effective April 1, 1999.

As we near the end of the fiscal year (July 1, 1999), projections are that the board will complete the year with about a \$100,000 surplus (due to the inspector vacancies during the year that have generated "salary savings"). Since the March Board meeting, expenditures at the AG's Office have continued at higher levels than seen in previous years. It is likely that the board will expend its full AG budget (\$521,091 for the year; already \$442,011 has been spent as of 4/1/99). The \$100,000 surplus in the board's annual budget already includes a redirected \$70,000 to the AG's estimated annual expenditures for a total of \$591,000.

Fund Condition Projected: \$9,972,500

At the end of the fiscal year, 19 months of operating expenses is projected in the board's fund at current expenditure levels.

1999/00 Budget Year – with a decrease in fees

Revenue Projected: \$4,820,669

The board will decrease fees effective July 1, reducing annual revenue by an estimated \$1,123,125. The projected revenue for the year is comprised of \$4,425,223 in revenue from licensing fees and \$403,041 in interest.

Expenditures Projected: \$5,992,000

The California Legislature is currently finalizing its work on a budget for 1999/00.

The board's budget for next year has been approved by both houses of the Legislature, and by the administration (via the Department of Finance). However, the board will not have an appropriation until the Legislature passes and the Governor signs the budget bill for California State government.

Beginning July 1, the board is expecting \$5,654,000 in baseline expenditures. This includes a \$49,000 increase in statewide pro rata and a \$12,000 increase in pro rata that will be paid to the department.

Another \$338,000 has also been added to the board's baseline budget by budget change proposals that allocate \$238,000 for the public education program, create an analyst position to perform legislative analyses and pursue regulation changes, and \$25,000 to perform a job analysis of the board's pharmacist licensure exam.

Fund Condition Projected: \$8,304,365

The board will have approximately 16 months in its reserve on June 30, 2000.

2000/01 Budget Year

Revenue Projected: \$5,949,864

Revenue for the year is expected to be comprised of \$4,425,223 in licensing fees, \$385,651 in interest and \$1,138,990 as the final repayment of the 1991/92 money transferred to the state's General Fund.

Expenditures Projected: \$6,155,564

The board is currently developing two budget change proposals to augment the board's budget beginning July 1, 2000. The board is seeking only two augments: \$300,000 for an ongoing public education program, staffed with one associate analyst and \$125,000 for staff development and an associate analyst to coordinate the training programs of staff. The amount listed as the projected expenditures include these BCP's in the estimate.

Fund Condition Projected: \$8,098,655

At the above projected revenue and expenditure levels, the board will have approximately 15 months remaining in its reserve on June 30, 2001, which is projected to decrease to 12 months at the end of 2001/02 if revenue and expenditures remain constant.

Additional Budget Issues

- **Y2K Issues**

Ms. Harris reported that much concern and focus, especially of information services staff, have been dedicated to assure the state's systems are Y2K compliant.

In the case of the Board of Pharmacy, the board was advised that they would receive \$375,000 to hire a consultant to upgrade internal programs and purchase a new telephone system. However, on May 10, 1999, the board learned that this funding would not be provided to the department.

Associate Analyst Anne Farrenkopf has been programming some of the board's most essential "in-house developed" programs that are not Y2K compliant. She has completed a new program to manage the board's diverse mailing lists, and is finalizing work this month on a program to track and process applicants for the California pharmacist exam, and is working with Inspector Roger Toevs on a new activity reporting program for board inspectors. This portion of the Y2K plan is going well.

The board has undergone several Y2K checks by the department's Y2K team, and passed this check when it was done in early March. However, in the last few weeks, the board received additional information that while our hardware is Y2K compliant, the operating system for the board's computers (Windows 95) is possibly not Y2K compliant. Upgrade "patches" have been made on the software, but under review is whether this operating system should be switched to Windows NT. If replacement is done, this will cost about \$25,000 for all our machines.

Ms. Harris added that the board's phone system is not Y2K compliant, and will be replaced in the next few months.

Fortunately, the upgrade of the board's computers and purchase of the new telephone system can be funded by redirection of money from this year (the \$100,000 surplus).

- **Additional Office Space**

Ms. Harris reported that the board may soon be able to expand into the office suite next door, increasing space by 5,000 square feet. This will permit the board to have among other things, a conference room to hold full staff meetings, NCC meetings and committee meetings and to administer exemptee exams. The additional space will also include filing space and small meeting rooms.

Cost estimates will be prepared in the future on the expense of expanding into this space, and to purchase and install systems furniture and re-cable the space for telephones and computers.

#### Communications Team Report (TCT)

Sandi Moeckly reported on behalf of The Communication Team (TCT). The TCT has had three team meetings. During these meetings, the TCT has assigned roles and responsibilities within the team and established team ground rules. They have developed methods to help track issues brought to the team as well as the amount of time devoted to the TCT. Ms. Moeckly added that to date, two issues have been brought to the TCT. TCT resolved the first issue and the second issue is currently being worked on by the TCT. The team sponsored an all staff meeting on May 11, 1999. TCT asked for staff input on a proposed exit interview survey form that it's preparing. This survey will be used for staff leaving the board and in conjunction with the exit interview done by management. Past members of the Transitioning Monitoring Team (TMT), were provided with plaques recognizing their commitment and accomplishments over the last year.

Mr. Nelson complimented the TCT on their hard work and the success of the team.

#### **PUBLIC COMMENTS ON MATTERS NOT ON THE AGENDA**

Bruce Young, California Retailers Association, expressed appreciation to the board staff for all of their assistance. He commented that he is very pleased about the appointment of new board member, Andrea Zinder.

He expressed concern about the \$100 fee required for each PIC change and the cost impact it will have on chain stores.

#### Public Education and Communication Committee

Ms. Shreve reported on the April 22, 1999, Public Education and Communication Committee meeting. The *Health Notes/Anticoagulant Therapy* is in the final stages of design. Ms. Shreve will compose a cover letter to be included with this publication. In addition she stated that the Spanish version of the consumer column on asthma was distributed last week. She reminded board members to submit ideas for next year editions of *The Script*.

Ms. Harris reported that on April 1, 1999, she did a live interview on cable television (Bay TV) in San Francisco about questions consumers should ask when they have prescriptions filled. Mr. Zia also reported that he did a television interview with Pharmacist Gerry Graf in San Diego. He gave an update on board activities.

Ms. Bauer updated the board on the next Health Notes on the developmentally disabled. She stated that the table of contents has been completed.

Mr. Jones stated that he participated in the White House roundtable discussion on Y2K issues affecting pharmacy. They are developing a statement to assure consumers of the availability of prescription drugs on January 1, 2000. The board agreed that this statement should be included in the next newsletter and develop a consumer column on this issue as well.

#### National Council on Patient Information and Education Conference (NCPIE)

Mr. Elsner reported on the National Council on Patient Information and Education Conference (NCPIE) that was held May 12-14, 1999. Other board members that attended were Ms. Bauer and Ms. Shreve. Ellie Enriquez Peck, Program Director of the Senior Medication Awareness & Training (SMART) Program also attended.

Mr. Elsner reported that the NCPIE selected the California State Board of Pharmacy to receive an inaugural Paul G. Rogers/NCPIE Medication Communicators Award (for the category of business/health corporations/government agencies). The engraved, crystal award was presented at the luncheon on May 13, 1999. Ms. Bauer accepted the award, on behalf of the board, with some very appropriate remarks regarding the board's projects and background.



Mr. Elsner stated that most of the speakers were quite good. The exhibits showcased a number of informative booths and some excellent brochures, pamphlets and handouts.

#### Medication Technology Subcommittee Meeting

Ms. Shreve reported on the Medication Technology Subcommittee meeting held May 3, 1999. She explained that the purpose of the committee is to collect information on new pharmacy compatible technological capabilities; identify privacy and confidentiality issues related to technology and prescription medications; research and analyze California pharmacy law and regulations to determine what changes are necessary to accommodate new technology capabilities; identify the obstacles to patient-focused technology; and make recommendations to the board on these areas.

Each member of the committee described his or her goals for the committee. These goals include patients need medication information from pharmacists for their health, patients and others need education so that they do not fear the use/misuse of technology; pharmacists need to be providing services not pills, and laws may need revision to prevent pharmacists from being required to perform duties not requiring the expertise of a pharmacist.

Ms. Shreve added that the next meeting will be held on July 7, 1999. The committee will discuss the following at the next meeting: patient confidentiality laws in California, and pending legislation in the California Legislature; what laws exist in other states regarding automation technology; and how confidentiality and privacy issues have been addressed in the financial industry.

The board discussed the subcommittee goals and overlap with the strategic goals of the Licensing Committee. The subcommittee was originally formed to review the legality of patient compliance programs and patient confidentiality issues. The board agreed that the task force would present at the public meeting of the Licensing Committee.

#### FDA/NABP Study on Useful Written Prescription Information

FDA asked the board to participate in a nationwide study of medication information that is distributed to patients with each prescription. Participation required the board to coordinate the gathering of the written information by having prescriptions filled at 40 pharmacies throughout California.

Ms. Harris reported that she has been working with the University of Wisconsin to coordinate their efforts; however, based on its STP analysis, it would cost approximately \$15,000 for the board to coordinate the project. The Communication and Public Education Committee does not have a

recommendation as to whether the board should participate and referred the matter to an executive committee of the board. However, through considerable discussions with the principal investigators at the University of Wisconsin, it was clear that additional funds would not be available to reimburse the board for the state coordinator. It was the assumption of the FDA and the University of Wisconsin that the state boards of Pharmacy participating in this project would absorb costs through the use of inspector staff. The board will continue to work with the University of Wisconsin; however, they will take on the role of the state coordinator for California.

### Licensing Committee Report

Ms. Strom reported on the April 27, 1999, Licensing Committee meeting. She provided a summary on the following licensing issues that were addressed:

#### Recycling of Nursing Home Drugs

The committee is recommending that the board adopt a new regulation that would authorize a pharmacy to accept drugs from licensed skilled facilities for reuse pursuant to specified conditions. If the board accepts the committee's recommendation, the proposed regulation will be referred to the Legislation and Regulation Committee to be placed on the "awaiting notice" list. The proposed language will be noticed for at least one board meeting (for public comment) prior to setting it for a regulation hearing.

Ms. Fujimoto expressed concern that the proposal would allow for the reuse with multiple drugs in one bubble pack. She felt this was a problem because drugs from different patients and different places are being packaged together and records are not being kept.

Ms. Strom stated that in skilled nursing facilities multiple drugs are not packaged in one bubble pack; however, in assisted living facilities they do often package multiple drugs in one bubble pack. She added that in the proposed regulation specify health facilities as defined and assisted living facilities are not in this section.

John Cronin commented that if the drugs are not recycled, it is considered medical waste and the disposal of the drugs is an additional cost. He added that this issue needs to be addressed by the FDA.

The board recommended that the licensing committee research this proposal to determine if there are federal regulations that govern this issue.

#### Examination Requirements for Non-pharmacist Pharmacy Owners

The committee is recommending that the board not pursue a statutory change that would require non-pharmacist pharmacy owners to take and pass a law examination prior to obtaining a pharmacy permit. Staff research enforcement data to determine how many non-pharmacist pharmacy owners that the board has disciplined over the last five years. The enforcement data did not support the need for such an examination.

#### Restocking of Ambulances

The Licensing Committee has been working with the State Emergency Medical Services Authority (EMS) to draft statutory authority for the restocking of ambulances. EMS has requested that the board withdraw its efforts because of opposition from the fire districts. At this time the committee is not making a recommendation.

Several public comments were made identifying a need to resolve this issue. Ms. Strom responded that the committee will continue its efforts.

#### Dangerous Drugs Exempt from Storage in Hospital Pharmacies

The board is amending Business and Professions Code section 4057 to place in regulation those dangerous drugs and devices that are currently in section (b), and which are exempt from storage in a hospital pharmacy. The committee solicited comments from the various professional associations for a revision to this current list. The committee recommended moving to regulation hearing those drugs that are currently exempt in statute.

#### Home Health Agency Emergency Kits

The committee reviewed suggested revisions to California Code 1751.11 regarding home health agency emergency kits. The committee recommended the suggested revisions be placed on hold temporarily until Mr. Nelson contacted hospice programs to determine their emergency kit needs. Mr. Nelson reported that he spoke with the director at the hospice at Sutter and their primary need is for schedule II drugs. Therefore, this revision is not necessary.

#### Request for waiver of 1717(e)

Chief Pharmacist Allan Mandell spoke on behalf of San Diego County, Health and Human Services Agency requesting a waiver of 1717(e) regarding the depoting of prescriptions to its county clinics.

Pharmacist Mandell explained these patients are indigent and mentally ill requiring psycho-pharmacotherapeutic intervention. Travel to the pharmacy to pick up these medications is a financial burden and complicated for mentally ill patients. He explained that these patients are required to come to the clinics monthly in order to have their prescriptions refilled.

He stated that the prescription would be stored in a locked area in the clinic. The clinic manager and lead nurse would possess the keys to the locked area. Prescriptions not picked up at the clinic will be returned to the San Diego County Pharmacy.

MOTION: Approve the waiver.

M/S/C: Elsner/Strom

SUPPORT: 9 OPPOSE: 0

Competency Committee Report

Ms. Strom reported that the board's June examination will be administered on June 15 & 16, 1999, at the Oakland Convention Center in Oakland. There were 404 candidates ready to be scheduled for the exam as of April 26, 1999. The final cutoff for scheduling will occur the first week of June.

**REGULATION HEARING**

Board President Tom Nelson opened the regulation hearing to adopt section 1707.4 of Chapter 17 of Title 16 of the California Code of Regulations and take oral testimony and/or documentary evidence by any person interested in the regulation.

The proposed regulation would allow a pharmacy to utilize the services of another pharmacy to provide its refills provided that they have a contact for these services or have common ownership.

Further, this proposal would specify the labeling requirements for a prescription refilled at a refill pharmacy including the name of the refill pharmacy and which pharmacy to contact if the patient has questions. This information may be either on the label or in writing accompanying the medication.

In addition, this proposal would specify the documentation requirements for the originating pharmacy and the refill pharmacy.

Lastly, this action would not prohibit a refill pharmacy from filling new prescriptions.

Oral and Written Testimony:

**THIS INFORMATION WILL BE PROVIDED BY RUTA AND SANDI.**

Enforcement Committee Report

Dr. Fujimoto reported on the committee meeting held May 10, 1999, with all enforcement staff.

- **Quality Improvement Efforts**

The leads from the Compliance, Drug Diversion/Fraud, and Pharmacist Recovery Program (PRP)/Probationer teams reported on their activities from the last Enforcement Team meeting. Each team provided information on the team's workload, significant accomplishments and presentations to outside organizations.

Inspector Joan Coyne and Inspector Judi Nurse designed and presented a program on Commonly Abused Pharmaceuticals and Illegal Imports and Exports. This presentation included a 40-page reference handbook. Their presentation was at the Drug Evaluation and Classification Program sponsored by the Los Angeles Police Department and was attended by approximately 100 law enforcement agency coordinators from California. Ms. Fujimoto commended them on their handbook. The handbook will be distributed to all of the board members.

- **Tracking of Prescription Errors**

Staff provided a status report on the tracking of patient harm arising from prescription error complaints filed with the board. The inspector will report this information on the case action summary form, which is completed for all closed reports.

- **CURES**

Barbara Shelton is temporarily assigned the responsibility to determine those pharmacies not in compliance with the CURES reporting requirements. Once this is done, a "warning" letter will be sent to those pharmacies not in compliance.

**ADJOURNMENT**

President Nelson adjourned the meeting at 2:45 p.m. to go into the Public Enforcement Committee Meeting.

### **CALL TO ORDER**

President Nelson called the meeting to order at 8:00 a.m. on May 20, 1999.

### **CLOSED SESSION**

The board went into closed session pursuant to Government Code Section 11126(a) regarding personnel matters to perform the evaluation of the Executive Officer and to review cases.

### **COMMITTEE REPORTS AND ACTIONS (CONT.)**

#### Legislation and Regulation Committee

##### Regulation Update

##### Approved Regulations

##### Fee Schedule – Adopt Section 1749 and Amend Section 1749.1

The board adopted its amendments to the fee regulations contained in section 1749 and 1749.1 at the January 1999 board meeting. The fee audit report presented at the meeting documented that the fee charged for a pharmacy technician registration is well below the cost to the board for processing. Therefore, the board withdrew its proposed amendments to section 1793.5 which would have reduced technician fees from \$50 to \$25.

The OAL approved this regulation action on April 20, 1999. The reduced fees will be reflected in the renewals for July 1999.

##### Regulations Awaiting Notice

##### Medication Errors: Quality Assurance Programs – Adopt Section 1717.5

This proposal would provide pharmacists with a proactive method for determining the origins of medication errors. Each pharmacy would be required to develop and implement a quality assurance program for inclusion in the pharmacy policies and procedures manual.

The Enforcement Committee has identified medication errors as a practice area in need of proactive measures. In January, the committee recommended that the board adopt a regulation that addresses this issue. The committee submitted the proposed regulation for the board's review. The board reviewed the draft language at the March board meeting. A notice will be published in July and the hearing will be scheduled for the October board meeting.

#### Regulations Pending

##### Waiver Requirement for Off-Site Storage of Records – Adopt Section 1707

This proposal would establish the standards for a waiver of the board's records storage requirement so that permit holders who wish to store records off-site will do so in a manner that assures the security, patient confidentiality and accessibility of these records. The board reviewed the proposed language at the March board meeting.

The notice will be published May 21, 1999. The comment period will close July 5, 1999. Unless requested, a hearing is not scheduled.

##### Citation and Fines – Amend Sections 1775 and 1775.1

This proposal would amend section 1775 and add a violation of Business and Professions Code section 4231 to the list of violations subject to citation and fine listed in section 1775.1

The committee recommended to the board that continuing education violations be added to the board's citation and fine authority. The board accepted this recommendation at its January meeting. At its March meeting, the board reviewed the proposed language.

The notice will be published May 21, 1999. The comment period will close July 5, 1999. Unless requested, a regulatory hearing is not scheduled.

##### Medical Device Retailer Location Restriction – Adopt Section 1748.3

This adoption would prohibit a medical device retailer from conducting business from a private residence. In addition, a medical device retailer would be prohibited from using a private residence as a warehouse for a medical device retailer.

The notice was published on March 19, 1999. The comment period closed on May 3, 1999.

MOTION: Adopt proposed section 1748.3 that would prohibit a medical device retailer business from being located in a private residence.

M/S/C: Legislation and Regulation Committee

SUPPORT: 9                      OPPOSE: 0

Furnishing to Authorized Persons – Manufacturers and Wholesalers – Adopt Section 1783

This proposal would specify who is an authorized person within the meaning of section 4163. The board has encountered numerous situations where an individual who is not the owner of record of a pharmacy has taken shipment of drugs from a manufacturer or wholesaler and, in turn, resold these drugs illegally.

The notice was published on March 19, 1999. The comment period closed on May 3, 1999. The board has not scheduled a hearing in this matter.

MOTION: Adopt proposed section 1783 that would specify who is an authorized person for the purpose of receiving dangerous drugs or devices from a wholesaler or manufacturer.

M/S/C: Legislation and Regulation Committee

SUPPORT: 9                      OPPOSE: 0

1999 Legislation Introduced Relevant to the Practice of Pharmacy

Board – Sponsored Legislation

The Board of Pharmacy supports SB 1308, which is authored by the Senate Business and Professions Committee. The board's provisions were amended in SB 1308 on April 14.

• **Pharmacy Technicians**

Require that applicants for pharmacy technicians registration possess a high school education or GED – reintroducing language contained in last year's SB 2239 (Section 52 – amend B&P Code Section 4202).

Regarding pharmacy technician trainees - extend the period of time allowed for practical experience in a pharmacy from six months to one year for pharmacy technician trainees enrolled in training programs run by private or public schools. The board's Licensing Committee also supports this change (Section 50.5 – amend B&P Code Section 4115.5).



- **Pharmacist’s Care**

Amend B&P Code section 4102 to specify that pharmacists may perform skin puncture to assist in managing a patient’s drug therapy (Section 50 – amend B&P Code Section 4102).

- **Entities/Facilities Licensing**

Amend B&P Code sections 4043 and create section 4040.5 to clarify that “reverse distributors” and brokers must be licensed by the board. While the board currently licenses these facilities as wholesalers, the Licensing committee recommended that the law be clarified by amending and referred the matter to this committee for action.

Amend B&P Code section 4057 to remove a specific list of dangerous drugs and devices that can be stored in non-pharmacy areas of a hospital, and move the list of dangerous drugs and devices to board regulations so that only one list exists and it can be kept current through the regulatory process.

- **Prescriptions**

Amend B&P Code section 4022 to reflect the federal definition of dangerous drugs.

Amend B&P Code section 4078 to permit the labeling of prescription in double blind studies or special situations when famous patients or key prosecution witnesses are admitted to hospitals under assumed names.

- **Board of Pharmacy**

Establish a statutory link of the salaries of the board’s pharmacist-inspectors with the salaries paid to pharmacists at the University of California.

Modify requirements for those seeking a retired pharmacist’s license so that they do not need to surrender their original wall certificate to the board to retire their licenses.

Modify requirements that cancel all licenses by operation of law (except pharmacists) that are not renewed within 60 days after their expiration.

- **CURES**

Extend CURES which will sunset on July 1, 2000. The board wishes to continue the program; therefore, legislation action must be taken in order to extend it.

#### Other Bills Impacting the Practice of Pharmacy

##### AB 141 (Knox)

This bill would require the board to conduct and fund a prescription error study. The board took a “Support Concept/Develop Amendment” position on the bill at the March board meeting. The board and Barry Broad, United Food and Commercial Workers (sponsor of the bill) have developed amendments.

The board estimates the cost for the study at \$1.24 million. This would provide \$1 million for the study and \$240,000 to fund an associate analyst position at the board for three years to provide support to the program.

If the board specifies who shall perform the study, it would save time in establishing a contract, but it may cost more for the study because no competitive bids would be available to evaluate.

During the March board meeting, the board asked that amendments be developed to provide an exemption to discovery in civil cases, data reported to a pharmacy’s Quality Assurance Program.

Barry Broad, United Food and Commercial Workers (sponsor of the bill) stated that the study will be outsourced and the amendments including the appropriations have been submitted to the Appropriations Committee. He added that the Department of Finance has taken a neutral position on the bill. Mr. Broad added that the intent is to have a scientifically valid study that would include “test” prescriptions and incorporate drug utilization review used to prevent errors. The determining factor of the extent of the study is how much funding is appropriated.

##### AB 261 (Lempert)

This bill will permit physicians to enter into protocols with pharmacists to adjust patients’ drug therapy. Pharmacists can currently do this in specified practice settings and for home health care and patients covered by managed care plans.

At the March board meeting, the board took a position of “Support”. The Assembly Health Committee passed the bill on May 12, 1999.

### AB 1496 (Olberg)

The bill would expand the board's medical device retailer program to regulate "home medical equipment suppliers" which is a jurisdiction broader than just dangerous drugs.

At the March board meeting, the board took a position of "Oppose unless amended", with the amendment being to move the full program to the Department of Health Services.

The Department of Health Services and Department of Consumer Affairs do not have a position on the bill. However, according to the DHS, the bill would not address the greatest fraud problem it has with medical equipment suppliers – those who provide adult diapers or rubber sheets for bedding. These items are currently excluded from the bill. Unless the bill is amended, the board would have to promulgate regulations to add these products to the list of products that trigger the firm to be licensed with the board.

The Assembly Health Committee passed AB 1496 in April on a 10-0 vote. The bill passed the Assembly Appropriations Committee and is at the Senate.

The board's position on the bill is still "oppose unless amended" with the amendment being to move the full program to the Department of Health Services.

### Bills for Possible Action

#### AB 1430 (Bates)

Ms Harris reported that this bill would alter provisions regarding the shipping and delivery of drugs, the electronic transmission of prescriptions, and change the manner in which the state regulates controlled drugs.

Amendments are being worked on; however, all concerns have not been worked out, and so the board needs to take a position on the bill. Kaiser has agreed to incorporate several amendments, but they are not in the bill yet.

Steve Gray from Kaiser (sponsor of the bill) did a presentation on AB 1430 for the board.

The board discussed the merits of the bill and its support conceptionally to the goals. They expressed their concerns and requested that the bill be amended as follows: to allow for centralized shipments of drugs to a group of prescribers as long as the group of prescribers is defined and accountability for the drugs is established; not require pharmacies to print a hard copy of the electronic prescription as long as the data cannot be altered including relational data and if the record is corrected, that information is recorded and specify that violation of this section would be subject to cite and fine; allow a prescriber or prescriber's agent to directly access the pharmacy's computer record as long as the "agent" is a licensed health professional and the pharmacist must "initiate" the order; grant the board the ability to grant a waiver to a pharmacy if a waiver has been granted by DEA.

MOTION: Support if amended as stated.

M/S/C: Elsner/Zia

SUPPORT: 8 OPPOSE: 0 ABSTAIN: 1

SB 188 (Leslie)

This bill would allow "exempt hospitals" (those with a pharmacy but without a pharmacist present in the pharmacy) to dispense drugs to patients in rural settings if no community pharmacy is open. Ms. Herold has been working with the sponsor on amendments that accomplish the sponsor's goals – to assure outpatients in rural settings who may appear at these hospitals to receive a limited amount of medication if a community pharmacy is not available. The author and sponsor have agreed to the proposed amendments, but they are not yet in print. A copy of the amendments was provided.

The amendments would restrict such outpatient dispensing from these hospitals to rural hospitals, where the physician personally must provide the medication, the quantity of drugs is limited to a 72-hour supply and there is no pharmacy open within 30 miles or 30 minutes of the hospital. According to the sponsor, these amendments would limit to only 12 hospitals (all in non-urban areas) the authority to provide drugs to outpatients.

MOTION: Support if amended.

M/S/C: Strom/Shreve

SUPPORT: 8 OPPOSE: 0

AB 660 (Cardenas)

Ms. Harris reported on AB 660 & AB 724. This bill was introduced as an urgency bill by the author to assure that in the event that pharmacies' computers are disrupted on January 1, 2000, that patients will be able to receive their medication refills even if a pharmacist cannot access the computerized record. The bill would be operative November 1, 1999 through February 29, 2000.

Current law in section 4064 authorizes pharmacists to refill prescriptions when the prescriber cannot be reached for verification under specific conditions. This bill would limit the ability of pharmacists to refill prescriptions from November 1, 1999 through February 29, 2000 to those events where the prescriber cannot be contacted due to Y2K computer problems.

Mr. Nelson is concerned that this bill will be misconstrued by the public in that patients will demand a refill and only pay their co-pay. Mr. Nelson sent the author suggested language that if a Y2K problem occurs, patients may get the refill but pay the usual charge of the pharmacy and request reimbursement from their insurance carrier at a later date.

Mr. Jones stated that patients need to make sure they have an adequate supply of their prescriptions and not to wait until the prescription is completely empty. He added that he agrees with Mr. Nelson with regards to the patient being responsible for paying for the prescription and requesting reimbursement from the insurance carrier at a later date.

AB 724 (Dutra)

This bill is similar to AB 660. It would create section 4052.5 to allow pharmacists, from December 1, 1999 through February 29, 2000, to refill a 60-day supply if refills have been authorized by the prescriber and (1) patient requests the refill, or (2) the pharmacist determines the patient needs the refill if there might be Y2K failure.

MOTION: Oppose AB 660 and AB 724 and educate the public regarding this issue.

M/S/C: Shreve/Fujimoto

SUPPORT: 9                      OPPOSE: 0

Clarification of Furnishing DEA Numbers

Ms. Harris reported on three bills that were introduced to clarify the furnishing of Drug Enforcement Agency (DEA) numbers to mid-level practitioners. Currently the DEA denies registration numbers to nurse practitioners and physician assistants because California law distinguishes between prescribers (physicians, dentists, veterinarians) and furnishers (nurse practitioners, physician assistants, and pharmacists). Moreover the DEA does not allow the delegating/supervising physician's DEA number to be used by either the nurse practitioner or physician assistant, and has cited pharmacies that have used the physician's DEA number on a transmittal order issued by a physician assistant or a order furnished by nurse practitioners. This interpretation prevents them from furnishing controlled substances.

The following three bills are in the Legislature to correct this for nurse practitioners and physician assistants, but none of the bills include pharmacists, who are equally empowered by California law to furnish medications under protocols with physicians.

SB 816 (Escutia)

This bill would provide that physician assistants and nurse practitioners, who are authorized by their practice acts to furnish medications under protocols with physicians, are empowered by California law to include controlled substances within this authority, and may obtain DEA registration numbers to prescribe. The bill would also allow nurse practitioners and physician assistants to “prescribe” schedule II – V controlled drugs.

MOTION: Oppose SB 816.

M/S/C: Zia/ Mazzoni

SUPPORT: 9                      OPPOSE: 0

AB 1545 (Correa)

This bill would be amended to add nurse practitioners and physician assistants to the group who may issue prescriptions. This bill would also be amended to allow nurse practitioners and physician assistants to accept and request drug samples directly from manufacturers, and provide them to patients. The bill would also authorize the name of the physician assistant or nurse practitioner to be used on a prescription label as the prescriber. The bill would also allow nurse practitioners and physician assistants to “prescribe” schedule III – V controlled drugs.

MOTION: Oppose AB 1545.

M/S/C: Zia/ Mazzoni

SUPPORT: 9                      OPPOSE: 0

AB 1063 (Aanestad)

This bill would provide that nurse practitioners and physician assistants who furnish medications are preparing prescriptions, and may register with the DEA as prescribers.

MOTION: Oppose unless amended to add pharmacists to the bill.

M/S/C: Zia/ Mazzoni

SUPPORT: 9                      OPPOSE: 0

AB 229 (Baldwin)

This bill would authorize the board to register as pharmacies and wholesalers, companies organized as limited liability companies (LLC's). Currently, state law prohibits LLC's from offering professional services for which a license is required.

The board's Licensing Committee recommended sponsorship of a similar proposal when it initially learned of the prohibition. The board declined to proceed with its own bill due to controversy regarding the limitation in liability provisions.

The bill failed the assembly judiciary committee. Reconsideration was granted.

SB 838 (Figueroa)

This bill would authorize the board to issue nonresident pharmacy permits to pharmacies organized as limited liability companies in the state where they are located. This bill was introduced to assure these pharmacies could be licensed as non-resident pharmacies, even if California pharmacies cannot be organized as limited liability companies. Board counsel completed an opinion that the board could license LLC's as non-resident pharmacies.

Bills for Information

SB 651 (Burton)

This bill would exempt pharmacists from being classified as a group exempt from being eligible to earn overtime.

**APPROVAL OF MINUTES**

Full Board Minutes – March 24-25, 1999

MOTION: Approve minutes as corrected.

M/S/C: Fujimoto/Shreve

SUPPORT: 9                      OPPOSE: 0

Northern Compliance Committee Minutes – April 13, 1999

MOTION: Approve minutes.

M/S/C: Elsner/Shreve

SUPPORT: 9                      OPPOSE: 0

Southern Compliance Committee Minutes – February 16, 1999

MOTION: Approve minutes.

M/S/C: Elsner/Mazzoni

SUPPORT: 9                      OPPOSE: 0

**APPROVAL OF 1999/2000 BOARD MEETING DATES**

1999 Meeting Dates (all dates are Wednesdays and Thursdays):

July 28-29, 1999      Burlingame (Public Licensing Committee will be held on July 27)

October 20-21, 1999      Sacramento

2000 Meeting Dates and Locations

January 26-27, 2000      Orange County



April 12-13, 2000 Sacramento

July 26-27, 2000 San Diego

October 18-19, 2000 San Francisco

The above dates/times may be subject to change.

**NEW BUSINESS/AGENDA ITEMS FOR FUTURE MEETINGS**

Mr. Jones requested that Y2K be discussed at a future meeting.

**ELECTION OF OFFICERS**

MOTION: Nominate Richard Mazzoni as President

M/S/C: Nelson/Fujimoto

SUPPORT: 10 OPPOSE: 0

MOTION: Nominate Robert Elsner as Vice President

M/S/C: Shreve/Mazzoni

SUPPORT: 10 OPPOSE: 0

MOTION: Nominate Caleb Zia as Treasurer

M/S/C: Mazzoni/Shreve

SUPPORT: 10 OPPOSE: 0

**ADJOURNMENT**

President Nelson adjourned the meeting at 1:00 p.m.