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: July 28, 1999

TIME: 8:00 a.m. - 5:00 p.m.

LOCATION: Embassy Suites
150 Anza Boulevard
Burlingame, CA 93010

BOARD MEMBER PRESENT:
Richard Mazzoni, President
Robert Elsner, Vice President
Darlene Fujimoto
Marilyn Shreve
Andrea Zinder
John Jones
Steven Litsey
Holly Strom
Caleb Zia

BOARD MEMBER ABSENT:
Thomas Nelson
Sandra Bauer

STAFF PRESENT:
Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Ruta Arellano, Associate Analyst
Robert Ratcliff, Supervising Inspector
Gilbert Castillo, Supervising Inspector
William Marcus, Deputy Attorney General
Lavone Powell, Department Legal Counsel
Cassandra Kearney, Enforcement Technician

CALL TO ORDER

President Mazzoni called the meeting to order at 8:00 a.m. on July 28, 1999.

INTRODUCTIONS/ANNOUNCEMENTS/ACKNOWLEDGEMENTS

President Mazzoni introduced Lavone Powell, Department of Consumer Affairs Legal Counsel, and advised the board that former staff counsel Christopher Grossgart recently transferred to CAL OSHA.

COMMITTEE REPORTS AND ACTION

ORGANIZATIONAL DEVELOPMENT

President's Report

President Mazzoni announced new committee appointments to board committees. Holly Strom will continue as the chairperson of the Licensing Committee, with Sandra Bauer as committee member. Darlene Fujimoto will remain chairperson of the Enforcement Committee, with John Jones as committee member. Marilyn Shreve will remain as chairperson for the Public Education Committee, with Caleb Zia as committee member. Thomas Nelson will be the chairperson for Legislation and Regulation Committee, with Andrea Zinder as committee member. Robert Elsner will be the chairperson for the Organizational Development Committee, with Steve Litsey as committee member.

In August the National Association of Chain Drug Stores (NACDS) is having its annual meeting. President Mazzoni stated that he and Ms. Harris would be participating on panels to address regulatory matters.

President Mazzoni stated that the request for out-of-state travel for attending meetings during this current fiscal year is still pending approval.

Thomas Nelson, Darlene Fujimoto, Holly Strom, and Patricia Harris attended the National association Board of Pharmacy (NABP) annual meeting. At this meeting the NABP gave an update on competency testing for pharmacists, computerized testing and the proposed FDA regulations on compounding. There were also special "break-out" sessions on the electronic monitoring of scheduled drugs, central refill pharmacies and workload issues.

Ms. Strom NABP also previewed its Verified Internet Pharmacy Practice Site (VIPPS). NABP has developed criteria for pharmacy Web sites to obtain VIPPS certification, similar to a “Good Housekeeping” seal of approval. However to be effective the public will need to be educated to know to look for this certification.

President Mazzoni outlined his goals for the coming year. He explained his philosophy of "less is more" with regards to regulation and meeting the board’s public protection mandate, and assuring patients receive pharmacists care in the new millennium. The board needs to allow the natural evolution of pharmacy practice, while balancing the needs of the consumer. The board must embrace and fully promote use of technology and automation, and there impact on pharmacy practice for the benefit of patients.

President Mazzoni added that the board must continue its efforts to strive for salary parity for its inspectors. The board cannot fill the vacancies that it has with quality pharmacists when the gap between the private sector and our inspector salaries continues to widen. This will be a charge given to staff and the board to work on this year.

Lastly President Mazzoni stated the board must continue to look at alternative practice, Internet pharmacies, and alternative therapies. The board must acknowledge them as forces in health care, integrate them into whatever we do, and protect the consumer's interest for those who use these services and therapies.

President Mazzoni ended his report by sharing this quote, "Those who say it can't be done, should not interrupt those that are doing it."

Executive Officer’s Report

Personnel Update

Ms. Harris reported on new staff and recent departures of staff. Board Inspector Wayne Batalo retired from state service in July, after five years with the board. Board Inspector Roger Toevs also resigned from the board in July. Mr. Toevs was with the board for three and one half years.

This leaves 10 of 19 inspector positions vacant. Ms. Harris and Supervising Inspector Robert Ratcliff conducted employment interviews in early July. In addition there are 32 applicants for qualifications assessment interviews, to be scheduled by the department in September.

Budget Update

1. 1998/99 Budget Year

Ms. Harris reported that end of the fiscal year was June 30th. This is the first year in many that the state has gone into July 1 with a signed budget. Final fiscal year data for the year is typically available in August. The following are estimates for both revenue and expenditures. The final fiscal year report of the year will be presented at the October board meeting.

Revenue projected: $10,460,694

Revenue projected for the year includes $5,960,574 in revenue from licensing fees, $443,000 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 3/5 repayment, only 1/5 of the $5.4 million transferred - or $1.14 million with interest - remains unpaid). There has been a $70,200 reduction in this year's revenue due to the $75 rebate that was paid to 2,300 pharmacies that submitted data to CURES by July 18, 1998. There also has been $169.689 in cost recovery paid to the board through May 31, 1999.

Expenditures projected: $6,092.208

This 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.

Final expenditures for the year are provided in August. Projections for the fiscal year indicate a $50,000 surplus. Since the March Board Meeting, expenditures at the AG's Office have continued at higher levels than seen in previous years, and the board will expend more than the full AG budget ($645,000 for the year). Nevertheless the $50,000 surplus in the board's annual budget already includes a redirected $130,000 to the AG's estimated annual expenditures for a total of $645,000.

Fund Condition Projection: $9,972,500

There was projected to be 19 months of operating expenses in the board's fund at current expenditure levels on June 30, 1999.

2. 1999/00 Budget Year

Revenue Projected: $4,820.669

The board decreased 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: $6,136,513

The state began the budget year on July 1 with a budget in place. This is the first time in years that state government has had a budget in place at the start of the year.

The board has been authorized $5,755,000 in baseline expenditures.

- Included in this amount is 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 was added to the board's baseline budget by budget change proposals that allocate $238,000 for the public education program, create an associate 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. The public education program has been funded for only one year, during which time the board is directed to establish an effectiveness assessment of the program.

The board received authority for a supplemental augment for Y2K issues of $381,513. Thus maximum expenditure authority for the year is $6,136,513 ($5,755,000 plus $381,513).

Fund Condition: $8,304,365

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

3. 2000/01 Budget Year

Expected Revenue: $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.

Projected Expenditures: $6,155,564

The board is currently developing two budget change proposals to augment the board's budget beginning July 1, 2000. We are seeking two augments: $300,000 for an ongoing public education program, staffed with one associated analyst (duplicating the BCP we submitted for 1999/00, which was funded for only one year) and $125,000 for staff development and an associate analyst to coordinate the training programs of staff (resubmitting a BCP which was denied this year by the Department of Finance). The amount listed as the projected expenditures include these BCP in the estimate.

Fund Condition $8,098,665

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 as projected.

4. Additional Budget Issues

1. Y2K Issues

This year (1999/00) the board will receive the long-awaited Y2K supplemental funding that has been expected for two years.

- Also coming this year is a new phone system with computerized components, one that is Y2K compliant. We will replace the phones in the next few months so a new system is in place before the end of the year.

2. Additional Office Space

Ms. Harris explained that she learned just before the May Board Meeting that the board may soon gain an additional 5,000 sq. feet of office space contiguous to its current office location at 400 R Street. This additional space is sorely needed to accommodate program growth since 1991 and to add a conference room a sufficient size to hold staff meetings. The new space may be available to the board by January 2000. The board will prepare a BCP to pay for construction and ongoing increase in rent.

3 Communication Team Report

Cassandra Kearney provided The Communications Team update. On June 29, 1999, The Communication Team (TCT) held the second quarter's staff meeting. Staff meeting ground rules were reviewed and adopted. A question and answer session has been added to encourage communication among staff about procedural issues within the board.

To date, the TCT has held eight team meetings. A total of three issues have been brought to the TCT. Two of the issues have been resolved and one issue is pending. The status of TCT and activities will be presented to the board at the October Board Meeting.

PUBLIC COMMENTS ON MATTERS NOT ON THE AGENDA

Bruce Young, representing the California Retailers Association, encouraged the board to take prompt action to support SB#651 (Burton, Chapter-Statutes of 1999. He stated that there is another legislative proposal to authorize pharmacists to take required breaks without closing the pharmacy. He requested that the board have policies in place by January 1, 2000, to ensure that pharmacies can continue to operate while pharmacists take the required breaks.

Ralph Duff, representing the California Employee Pharmacists Association (CEPA) expressed his personal observation that either the board is out of step with the profession or the profession is out of step with the board. He added that part of the reason that the board cannot obtain inspectors is because the board does not have the profession of pharmacy at heart.

Licensing Committee Report

Ms. Strom reported on July 28, 1999, Licensing Committee meeting. She provided a summary on the following licensing issues that were addressed.

Review of California Code of Regulations 1732.2

This regulation authorizes the board to accept continuing education (CE) from non-recognized providers as long as the board reviews and approves the CE. The fee for this review is $40 per hour of credit. This provision also applies to CE provided by other health professions. Prior to April 1999, the board only charged non-recognized providers a fee for the review of CE coursework. In January, the board changed its policy and now charges a fee to the petitioner whether it is the provider and or the pharmacist who seek approval for non-recognized CE.

Several pharmacists had concerns with the board's new policy, so the committee reviewed how other health professional boards (Nursing, Dental and Medical) approve CE and if any allowances are provided to accept CE from other disciplines. No allowances are provided by any of these boards. Each licensing board for the profession must approve all CE. Many pharmacists take CE offered by other health professional associations that benefit may them as practicing pharmacists, and the board did acknowledge the importance of pharmacists choosing CE that necessary to maintain their competence; however the committee reaffirmed its position that pharmacists should take CE approved by this board and pay the cost for this review.

The committee recommended no change in its current policy to require pharmacists to petition for approval of CE at a review fee of $40 per unit.

The California Society of Health System pharmacists stated its concerns regarding the limits of this policy and its impact on pharmacists.

FDA Memorandum of Understanding MOU on Pharmacy Compounding

In 1997, the President signed into law the Federal Food and Drug Administration Modernization Act of 1997. The act includes a provision regulating the practice of pharmacy compounding and provided for specific parameters for compounding practice. The specific parameters were to be provided in proposed regulations issued by the Federal Food and Drug Administration (FDA) in January 1999. Specifically, the regulations establish the parameters of the memorandum of

understanding (MOU) that each state must sign in order for pharmacies to compound and ship these compounded drugs interstate in quantities greater than 5 percent of prescription orders.

The Licensing Committee reviewed the proposed regulations and recommended that the board sign the agreement once the regulations were final. The board did not submit comments to the FDA.

At the time the board reviewed the proposed FDA regulations, its understanding of the proposal was that absent a MOU with the FDA, a pharmacy was limited to the amount of compounded prescription medications that it could distribute interstate. This limit would be less than 5 percent of its total prescription orders. However, the board did not discuss the fact that although a pharmacy could distribute compounded prescription products beyond the 5 percent it could not dispense more than 20 percent. If a pharmacy distributed more that 20 percent, then it would have to be licensed as a manufacturer.

Morton Leiter, owner of Leiter's Park Avenue Pharmacy, presented to the board his concerns regarding the MOU and its limitations on pharmacies such as his that compound prescription medications. Mr. Leiter stated that the 20 percent limitation would not allow his pharmacy to remain financially viable, nor serve those patients that benefit from his specialized practice from throughout the country.

John Cronin, representing the California Pharmacists' Association, stated that all state boards would have a 5 percent limit unless they signed a MOU with the FDA. However the board can develop its own MOU making whatever changes it sees fit, including setting any limit it wishes, and then submit the modified MOU to the FDA.

Ron Miller, a compounding pharmacist, stated that he only fills prescriptions for compounded medications. He fills 20 to 25 prescriptions per day, and 40 percent to 50 percent of those prescriptions are from out-of-state. His out-of-state patients do not have access to a compounding pharmacy in their area.

Steve Feldman, a compounding pharmacist, requested that the board oppose the memorandum, because of the percentage limit, and the limits to a 50-mile radius for dispensing the products.

Steve Gray, speaking on behalf of himself, as a pharmacist, stated that as the volume of compounded medications becomes higher, it is reasonable for the FDA to want greater assurances of quality. He suggested that the FDA may want to approach this issue by requiring pharmacies who compound large volumes to register as manufactures to ensure that quality controls and standards are met, but not require NDA applications which call for lengthy and expensive drug trials.

MOTION:	Send a letter to the FDA stating the board's objections to the limitations proposed to limit both the percentage and geographically distribution of compounded products. Also include a copy of CCR 1716.2.				
M/S/C:	Shreve/Elsner				
SUPPORT:	8	OPPOSE:	0	ABSTAIN	0

Pharmacy Manpower - Open Forum (September 16, 1999)

The Licensing Committee will have an open forum on September 16, 1999, to solicit comments from the profession regarding pharmacy personnel issues in the workforce and possible solutions. There is concern from employers regarding a shortage of pharmacists and the Licensing Committee is interested in finding solutions to address this concern, The forum is open to the public and will be noticed in the board's newsletter.

Automation, Technology, and Innovation - Public Meeting

Ms. Strom stated that the Licensing Committee held its public meeting on July 27th on issues involving of automation, technology, and innovation and the practice of pharmacy. Also discussed was the management of a patient's drug therapy being preformed by a pharmacist who not in a licensed pharmacy or facility.

A presentation on Internet pharmacy was provided. One item noted was that when a cash-paying patient has a prescription filled at an Internet pharmacy, there is nothing to prevent the patient from taking the original prescription to another pharmacy to be filled again.

Enforcement Committee Report

Dr. Fujimoto reported on July 28, 1999, Enforcement Committee meeting. She provided a summary on the following enforcement issues that were addressed.

CURES Report to the Legislature

The Department of Justice completed its report on CURES and submitted it to the legislation. At this time the board is the creator of legislation to extend the program for another three years. The board will continue its funding of the program from the original $1 million appropriation made in 1996. During the next three years the Enforcement Committee will develop a task force to establish parameters and guidelines for reviewing the data, evaluate the effectiveness of the program and to make a recommendation to the board on the continued use of the triplicate. The department of Justice will also need to seek a permanent legislative solution to the tracking of schedule II controlled drugs.

NCC/SCC Meeting Guidelines

The Enforcement Committee provided NCC/SCC Meeting Guidelines for board members. The purpose of these guidelines is to standardize the meetings and provide consistency.

Request to Amend CCR 1716 Regarding the Dispensing of Cyclosporine Drugs

Dr. Fujimoto stated that the board has received a request from the National Kidney Foundation and Novartis Pharmaceutical Corporation to amend CCR 1716 that would require a pharmacist to know which formulation of cyclosporine drug is being prescribed before the drug is dispensing.

Deputy Attorney General William Marcus was asked to review this request. It is Mr. Marcus's opinion that section 1761 (a) is sufficient to require that a pharmacist contact a physician when generic cyclosporine is written on a prescription. He also stated that a prescription written to encompass multiple configurations of the drug product that are not bioequivalent is a classic form of an uncertain prescription. Further if the board was to amend its regulations to specify orders which be checked with the prescriber, the board will face other such requests which could become unmanageable on both the board and on the profession. The board could, as an alternative, add "unclear" to section 1761 (a).

Dr. Fujimoto stated that the Enforcement Committee recommends that CCR 1761 (a) is sufficient to address those instances when a pharmacist receives uncertain prescriptions written for cyclosporine. In addition to alert pharmacists to the concerns raised by Novartis and the National Kidney Foundation, a Script article on this general issue will be written.

Jim Morgan, representing Novartis Pharmaceuticals, stated that he authored one of the letters in the packet, and agreed with the recommendation of the Enforcement Committee.

Minutes of the Enforcement Committee Meeting - May 19, 1999

The enforcement committee also discussed CCR 1707.3, regarding drug utilization review and the use of technology to perform such a review. The Enforcement Team reviewed the comments of staff and is considering the development of guidelines in this area.

Regulation Update

Ms. Harris provided the board with an update on regulations.

A. Awaiting Notice

- Pharmacy Without Drugs - Adopt Section 1707.5

  The expanding practice of pharmacy was addressed during the public meeting of the Licensing Committee on July 27, 1999. Among the topic areas was a discussion on whether there is a need to license a pharmacy without drugs. Such pharmacies could include call centers, a pharmacy practice for management of drug therapy, etc. A regulatory proposal may come from the meeting.

- Dangerous Drugs Exempt from Storage in Hospital Pharmacy - Adopt section 1714.5

  Business and Professions Code section 4057 is being amended through board-sponsored legislation to remove the list of dangerous drugs and devices that can be stored in non-pharmacy areas of a hospital. This list instead will be maintained in proposed section 1714.5 of the California Code of Regulations.

- Graduates of Foreign Schools - Amend Section 1720.1

The proposed amendment would specify that the evaluation of a foreign pharmacy school graduate's education for equivalency with the requirement for 150 semesters of collegiate study may be performed by a service outside the board in instances when the applicant is unable to provide the board with adequate background information to complete the evaluation.

B. Pending

- Procedures for refill pharmacy - Adopt Section 1707.4

The proposal would allow a pharmacy to use the services of another pharmacy to provide refills if the pharmacy has a contract for these services or the pharmacies have common ownership.

At its May meeting the board conducted a public hearing in the matter, and modifications were made to the originally proposed language the board then adopted the regulation.

The modified language was sent out for a 15-day comment period from June 3 through June 21, 1999. The board directed that the proposal would stand adopted as modified absent any comments relevant to the action taken that might be received during the 15-day comment period. The two comments received during the 15-day comment period did not affect the adoption of the proposed modified language.

The regulation proposal will be submitted to the Department of Consumer Affairs for the director's review by the end of August. Once the proposal is submitted, the department will have 30 days in which to complete its review, then the file will be submitted to the Office of Administrative law.

- Medication Errors: Quality Assurance Programs - Adopt Section 1717.5

This proposal would provide pharmacists with proactive methods 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’s policies and procedures manual.

The notice for this proposal will be published on July 30, 1999. The close of the 45-day comment period will be on September 13, 1999. A hearing in the matter is scheduled for October 20, 1999.

- Medical Device Retailer Location - 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.

At its May meeting the board adopted the regulation as noticed. The regulation file will be submitted to the Department of Consumer Affairs for the director's review and approval at the end of July.

- Citation and Fines - Amend Sections 1775 and 1775.1

This proposal would make technical amendments to 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 board received comments during the 45-day comment period. These comments were from the California Pharmacists Association and the California Trade and Commerce agency. In response to the comments received regarding the legal citations, the board added "Section 1732.5" to its proposal and issued a 15-day notice to all persons on the board's regulations notification mailing list.

MOTION:		Adopt the language as stated in the packet for cite and fine.			
M/S/C:		Elsner/Zia			
SUPPORT:	8	OPPOSE:	0	ABSTAIN	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 (e.g., a delivery person) 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. Additionally, individuals not licensed by the board to conduct a pharmacy have set up pharmacies with phooey owners for the purpose of diverting drugs purchased at a discount.

At its May meeting the board adopted the regulation as noticed. The regulation file was approved by the director of the Department of Consumer Affairs on July 12, 1999. The file was submitted to Office of Administrative Law for final review and approval on July 15, 1999. The OAL has until August 26, 1999, to complete its review.

Regulation Hearing

Virginia Herold, Assistant Executive Officer reported on the following legislation introduced ion 1999.

Regulation Hearing - Waiver Requirements for Off-Site Storage of Records
(Adopt section 1707 of Division 17 of Title 16 of the California Code of Regulations)

President Mazzoni stated that this regulation hearing is to consider the adoption of section 1707 of Division 17 of Title 16 of the California Code of Regulations. This regulation would establish the standards for a waiver of the board's records storage requirements 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. Further, this proposal would establish the eligibility requirements for granting such a waiver.

Bruce Young, representing the California Retailers' Association, offered testimony regarding the two-hour requirement for retrieving records from storage. Mr. Young suggested that a more reasonable time limit be considered in light of potential traffic delays, etc.

John Cronin, representing the California Pharmacists Association (CPhA), offered testimony in opposition to the board's proposal. Dr. Cronin stated that the regulation does not have a real need and could be expensive for pharmacies. He recounted elements of the legislative history for the provision for off-site storage of records. Dr. Cronin stated that his recollection was that the original intent was to grant a waiver routinely

rather than have to qualify for a waiver. Also, he stated that it was CPhA's position that the requirements for storage of records are excessive. Dr. Cronin asked the board to consider granting a waiver automatically.

Lastly, Dr. Cronin quoted a news clipping he had provided to the board that outlines the complexity of pharmacy law. He equated compliance with the board's proposal as being a highly complex law.

Board Member Darlene Fujimoto asked Dr. Cronin for clarification of the past requirements he had made reference to in his testimony. She asked how the board's proposal would inhibit off-site storage of records. In addition Dr. Fujimoto stated that as an enforcement agency the board must be able to access the records of its licensees.

Dr. Cronin stated that it would be very difficult to meet the requirements, e.g., being on probation would not necessarily preclude one from being issued a waiver, retrieving files within two hours. He concluded that the proposal would need more discussion and modification.

A discussion regarding possible modifications followed. The time frame for retrieving records was of particular concern to those present. Dr. Cronin stated that there might be several ways to interpret "retrievable."

Steven Gray, representing Kaiser Permanente (Kaiser), offered testimony in opposition to the board's proposal as noticed. Mr. Gray stated that many hospitals around the state do not have the physical space dedicated to record storage. He explained that in the past there had been different interpretations of the storage requirements which led to space planning that did not include the amount of space that is needed to accommodate the records generated by a hospital. Kaiser's records are stored in two centers where a pharmacist is not in charge. Rather, the storage is maintained by a "professional" storage manager.

Mr. Gray summarized his comments by suggesting that modification is needed with regard to the time allowed for record retrieval. He noted that the Drug Enforcement Agency (DEA) allows more time to access records than is provided in the proposed regulation. In addition he stated that the summary cancellation of a waiver by an inspector without benefit of appeal would have serious financial repercussions for a hospital.

Board Member Fujimoto stated that the law revision committee had the input from Kaiser when the statute was written. She suggested that the matter regarding record storage should be resolved.

Cooky Quandt, representing Longs Drugs (Longs), offered their support to the proposed modification to the proposal that would allow for automatic storage adjacent to the licensed premises. Ms. Quandt stated that Longs has concerns regarding the two-hour retrieval period. She suggested conforming to the DEA 72-hour requirement. In addition

Ms. Quandt asked that the board consider an automatic waiver provision rather than qualification for the waiver.

After all interested parties were heard, no other individuals wished to submit testimony and the issue stood submitted.

The board members discussed modifying several elements of the proposal including the time for retrieval of records and the types of records that should be maintained at the licensed premises.

MOTION: Amend the proposal to allow 48 hours for retrieval of records that are stored off-site.

M/S/C: Elsner/Zinder

SUPPORT: 7 OPPOSE: 0 ABSTAIN: 1

Board Member Fujimoto asked for clarification of other proposed modifications. Mr. Marcus read potential amendments to the board members. A discussion of the time for storage of records on the licensed premises followed. Consideration was made to conform with the DEA requirements.

The board members discussed the comments specifically related to the time required to retrieve the records. Mr. Marcus provided revisions to the language.

1707 Waiver Requirements for Off-Site Storage of Records

(a) Pursuant to subdivision (e) of Section 4105 of the Business and Professions Code and subdivision (c) of Section 4333 of the Business and Professions Code, a waiver shall be granted to any entity licensed by the board for off-site storage of the records described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code unless the applicant has, within the preceding five years, failed to produce records pursuant to Section 4081 of the Business and Professions Code or has falsified records covered by Section 4081 of the Business and Professions Code.

(b) An entity that is granted a waiver pursuant to subdivision (a) shall:

(1) maintain the storage area so that the records are secure, including from unauthorized access; and

(2) be able to produce the records within 48 hours upon the request of the board or an authorized officer of the law.

(c) In the event that a licensee fails to comply with the conditions set forth in subdivision (b), the board may cancel the waiver without a hearing. Upon notification by the board of cancellation of the waiver, the licensee shall maintain all records at the licensed premises.

(d) A licensee whose waiver has been cancelled pursuant to the provisions set forth in subsection (c) may reapply to the board when compliance with the conditions set forth in subsection (b) can be confirmed by the board.

(e) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records shall be maintained on the licensed premises for a period of two years from the date of dispensing.

(f) Notwithstanding the requirements of this section, any entity licensed by the board may store the records described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code in a storage

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4105 and 4333, Business and Professions Code.

MOTION: Adopt the proposal as modified. (Text appears below.)

M/S/C: Zia/Strom

SUPPORT: 7 OPPOSE: 0 ABSTAIN: 1

LaVonne Powell, DCA legal counsel, advised the board members that they would not have to reconsider the matter at the close of comment. The board delegated to Ms. Harris the authority to make changes to the adopted language necessitated by comments received during the 45-day notice period. These changes would be sent out for a 15-day notice period.

Legislation Report and Action

AB #141 (Knox)

This bill would require the board to conduct and fund a prescription error study. At the last meeting, the board agreed to appropriate $1.24 million for the study ($1 million for the study itself, and $240,000 for an associate analyst for three years to provide support for the program and undertake a review of staffing ratios and prescriptions dispensed on the days the prescription errors have been reported to the board). The bill has been

amended to extend the period within which the study can be conducted from three to five years, and funding is currently at $600.000 in the bill. The Department of Consumer Affairs has stated that the existing language in AB141 is insufficient to actually make the appropriation. The board has requested amendments to make these changes, but the bill is in suspense file of the Senate Appropriation s Committee

AB #261 (Lempert)

This bill, sponsored by the California Pharmacists Association, would permit individual 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.

As amended on July 7, 1999, the bill would require that a pharmacist function as part of a multidisciplinary group including physicians and direct care registered nurses, when providing services for an individual physician as well as those groups listed in Business and Professions Code section 4052 (a) (5).

In addition, the patient's medical records would have to be available to both the prescriber and pharmacist, and the pharmacist could only treat patients for a condition for which a physician has already seen the patient.

At the March Board Meeting the board took a position of "Support."

Amendments have been proposed for this bill. The amendments would be made to section 4115 and 4116 of the Business and Professions Code. These amendments would direct that the board undertake rulemaking proceeding to establish parameters for periods of time within which a pharmacist may be temporarily absent from a pharmacy for lunch periods and for breaks without closing the pharmacy. The board would flush out the details in regulations. The board would probably have to do this under emergency rulemaking procedures and take action during the October board meeting. There is currently no proposed regulation language for these changes at this time.

AB#1430 (Bates)

This bill makes multiple changes in pharmacy law.

- First, it permits groups of prescribers, to purchase and store prescription drugs for "use: by the group.

- The bill would also permit prescribers or designated prescribers' agents to electronically submit prescription information for a patient and access a pharmacy's files - which could indicate contraindications immediately to the proposed prescribed

drug. However, before any drug is dispensed by the pharmacy, the pharmacist would continue to review the record.

- The bill would establish requirements for pharmacies that do not printout electronically or faxed prescriptions, including that the prescription information must be retained and immediately retrievable upon board request.

- Lastly, the bill would permit the board to authorize a pharmacy to permit the electronic submission of prescriptions for Schedule II drugs if the pharmacy has obtained a DEA exemption or the act complies with federal law.

At the May Board Meeting, the board deliberated the provisions in the bill for a considerable length of time. Since the May meeting, staff produced a set of amendments to incorporate the changes supported by the board and which would meet the sponsor's goals. These amendments were provided to Kaiser in mid June.

However, when the bill was amended on July 2, 1999, the bill did not contain the amendments submitted by the board. The language of several of the sections differed substantially from the language submitted by the board. Since this amendment occurred immediately before the final policy committee hearing in the Senate Business and Professional Committee on July 12, there was little time to resolve the matter. A letter was sent to the committee, and numerous discussions with the sponsor were initiated. Meanwhile President Mazzoni authorized a position of oppose on AB 1430 unless certain provisions were amended.

As a result, several amendments were made during the committee meeting on July 12. And following the meeting additional amendments were developed by the board to conform the bill to the policies agreed to by the board during the May meeting. These amendments were provided to Kaiser on July 16, which may or may not be incorporated into the bill.

However, there is a significant amendment in the July 2 version of the bill that needs the board's deliberation. The provision would permit groups of prescribers to purchase drugs for "dispensing and administration" to patients - permitting the establishment of pharmacies without pharmacists from which prescribers could commingle drugs, and administer and dispense full treatment regimens without any pharmacist involvement. Currently, individual physicians may order drugs for office use or for dispensing to patients - by purchase of the drugs by the individual prescriber, for which the prescriber is responsible. Alternatively, groups can purchase drugs under a clinic license. There is no other process in law by which groups of prescribers can purchase drugs collectively (and there are statutory prohibitions against prescriber ownership of pharmacies).

According to Kaiser Permanente, the ability of groups of prescribers to purchase drugs collectively for administration and dispensing to patients is strongly supported by the CMA and AllScripts (a vendor of automated drug dispensing systems), and they are not inclined to limit the group purchase of drugs by prescribers only to administration by any

prescriber in the group. Existing ways for prescribers to purchase drugs for such use (purchased by individual prescriber, or obtain a clinic license to permit commingling of drugs) are not acceptable.
At the May meeting, the board agreed to authorize groups of prescribers to purchase and store medications for administration to patients, but not to permit dispensing to patients.

At the July meeting, the board needs to re-evaluate its position on AB#1430 (currently support with amendments), and whether it wishes to authorize groups of prescribers to purchase and commingle drugs for dispensing to patients.

Steve Gray representing Kaiser Permanente, explained Kaiser's intent was to have medication on hand for the physician to begin therapy immediately or emergency dispensing only, but new limits should be established on prescriber dispensing. The board discussed the concerns it had with this section. This bill would authorize a group of physicians to dispense which blurs the line as to whether these groups of physicians are "pharmacies," which California Pharmacy Law prohibits physicians from owning. Moreover this is a major policy issue that has not been debated by the Legislature.

MOTION:	Oppose AB#1430 unless amended to restrict unlimited dispensing. Especially in the pretext that physician's are owning and operating a pharmacy.				
M/S/C:	Jones/Elsner				
SUPPORT:	7	OPPOSE:	0	ABSTAIN	0

Board Member Steve Litsey recused himself from this discussion, and left the room.

AB#1496 (Olberg)

This bill would expand the board's medical device retailer program to regulate "home medical equipment suppliers" with a jurisdiction broader than just dangerous devices. In addition, the bill was amended on June 28 to require the board to regulate "disposable medical supplies" when prescribed and delivered to patients at home (so the board would regulate diapers, bandages and numerous other over-the-counter supplies). In addition, the board would be required to enforce provisions currently administered by the Bureau of Home Furnishings regarding sterilization of upholstered items (mattresses, wheelchairs).

The board has a position of oppose unless amended on the bill, with the amendment being moving 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.

MOTION: Oppose AB#1496.

M/S/C: Strom/Fujimoto

SUPPORT: 8 OPPOSE: 0 ABSTAIN 0

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. The bill has been amended to include amendments desired by the board: 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 bill 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 not pharmacy open within 30 miles or 30 minutes of the hospital

According to the sponsor, the definition of rural hospital included in the bill would limit to 12 hospitals (all in non-urban areas) the authority to provide drugs to outpatients.

MOTION: Change the board's position to support

M/S/C: Strom/Jones

SUPPORT: 8 OPPOSE: 0 ABSTAIN 0

AB#724 (Dutra)

The author of this bill is personally interested in this subject and his office has worked closely with any entity expressing opposition. In the area of prescription medication, drug manufacturers and some wholesalers have opposed this bill. The board strongly opposed the July 2 version of the bill, which would have required pharmacists to refill any remaining refills indicated on the initial prescription upon request of the patient when made between December 1, 1999, and February 1, 2000. Such a requirement could have resulted in patients receiving more than a 60-day supply of medication, which could have let to drug stockpiling as well as create a loophole for drug diversion for Schedule III and IV drugs where refills were indicated.

The board worked with the author's office on language to reduce opposition. Whereas the board advocated 7 day's supply for any Y2K-related refill, this was not acceptable to the author's office. The board alternatively developed language does not alter existing refill authority for pharmacists (in Business and Professions Code section 4064) to refill medication when a prescriber is unavailable. A new section with a sunset provision of February 1, 2000, was developed to restate the pharmacist's need to exercise professional judgement in refilling medication, limits specialized Y2K refills to those where refills have been indicated and upon patient request, permits early refills during the period December 1, 1999, through February 1, 2000, if the prescriber is not available. President Mazzoni approved these amendments as sufficient to remove the board's opposition.

MOTION: Ratify the board's position that was recommended by Board President Mazzoni and take a position of watch with regards to the bill.

M/S/C: Strom/Elsner

SUPPORT: 8 OPPOSE: 0 ABSTAIN 0

AB#1545 (Correa)

This bill would amend Business and Profession Code sections 4040 and 4060 to add nurse practitioners and physician assistant to the group of prescribers who may issue prescriptions. This bill would also amend section 4061 to allow nurse practitioners and physician assistants to accept and request drug samples directly form manufacturers, and provide them to patients. The bill would also amend section 4076 to authorize the name of the physician assistant or nurse practitioner to be used on a prescription label as the prescriber. The bill would amend sections 4077 and 4078 (allowing prescribers to furnish drugs from their offices and possess dispensing devices and ownership of the drugs) to include nurse practitioners and physicians assistants. The bill would allow nurse practitioners and physician assistants to "prescribe" schedule III-V controlled drugs.

According to the sponsor, this bill is intended to permit physician assistants and nurse practitioners to sign for drug samples ordered by prescribers, who are usually with patients and are not readily available to sign for them. However, the language in the bill is broader. The sponsor is seemingly willing to incorporate an amendment offered by the board to clarify this. This amendment should be provided to the sponsor before the board meeting.

The board has a position of oppose unless amended on the bill, to seek amendments to prohibit nurse practitioners and physicians assistants from ordering drug samples, and to add pharmacists to the provisions that direct that the names of nurse practitioners and

physicians assistants appear on prescription labels when they order a drug for a patient under protocol.

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 thus may obtain DEA registration numbers to prescribe. The bill would change the definition of prescription in pharmacy law (section 4040) to include physician assistants and nurse practitioners to the group of providers who my issue "delegated prescriptions." The bill also would add nurse practitioners and physician assistants to the group who may have stock containers of controlled drugs (section 4060). The bill would allow nurse practitioners and physician assistants to "prescribe" schedule II-V controlled drugs. The bill contains language that it is not intended to expand the scope of practice of nurse practitioners or physician assistants.

The sponsor is willing to consider board amendments to add pharmacists to this group who may issue orders, and to restrict the ordering of stock supplies.

The board has an oppose unless amended position on the bill to add pharmacists to the provisions authorizing nurse practitioners and physician assistants to obtain DEA numbers and to prohibit nurse practitioners and physician assistants from ordering and owning their own drug stock. It may be too late in the year to achieve the former amendments

AB#1063 (Anaestad)

This bill would provide that nurse practitioners and physician assistants who furnish medications are preparing prescriptions, and may register with the DEA as prescribers. The bill is now a two-year bill.

SB#838 (Figueroa)

This bill is now statutory law and authorizes the board to issue nonresident pharmacy permits to pharmacies organized as limited liability companies in the state where they are located. The bill was introduced to assure these pharmacies could be licensed as nonresident pharmacies, even though California pharmacies cannot be organized as limited liability companies. However, at the time the bill was amended to contain these provisions (April 28), then Board Counsel Chris Grossgart completed an opinion that the board could issue nonresident pharmacy permits to companies organized as limited liability companies.

AB#60 (Knox)

This bill has been passed by Legislature and is awaiting action by the Governor. The bill deals with overtime issues in the work place.

SB#651 (Burton)

This bill has been passed by the Legislature and is awaiting Governor Davis' action. The bill would direct that pharmacists earn overtime salary for time worked longer than 8 hours per day or 10 hours if on an alternate workweek.

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Marilyn Shreve reported that a committee meeting has not been held since the last board meeting; however, the following is a report on various committee activities.

Health Notes

The anticoagulant issue of Health Notes was distributed in June. It was mailed to all California licensed pharmacists and pharmacies. In addition it was mailed to all state boards of pharmacy, NABP and deans of the schools of pharmacy.

The articles for the fourth Health Notes on the care of children and adults with developmental disabilities are in the process of being prepared.

The July issue of the Script newsletter is at the printers.

Consumer Columns

Three consumer columns from the Women's Health Notes will be developed. The articles will be on breast cancer, osteoporosis, and coronary heart disease. The article on breast cancer has been completed.

A consumer column on "Learning the ABC's of Asthma Prevention" has been released. Preliminary market research data show that the article reached 8 million readers. Recent market research results on the consumer column "Asking Questions May Save Your Life" indicate 20 million readers have been reached.

Mr. Elsner reported on his work with the Senior Medication Awareness and Training Program (SMART) Coalition. At the next SMART Coalition meeting, they will be working on the October senior medication awareness month. SMART's message for the month will be "Be SMART about your medication." Senator Joe Bacca is working with

SMART on this, and has offered to present a resolution declaring October as senior medication awareness month. There will be a proclamation also coming from the Governor.

Medication Information Technology Task Force

The task force held its second meeting on July 7, 1999. Ms. Shreve presented information about the task force's activities at the Licensing Committee public meeting on technology. The task force will examine patient confidentiality laws and patient medication compliance programs.

Proposal from UCSF, School of Pharmacy - Alternative Medicines

Associate Dean Lorie Rice from UCSF, School of Pharmacy presented an outreach proposal to the board on alternative medicines. UCSF would like to join in a partnership with the Board of Pharmacy to provide consumer education to the public. The purpose of the proposal is to create an outreach program for pharmacists and consumers on alternative medicines, funded by the board.

Ms. Rice stated that it is UCSF's goal to make pharmacists more knowledgeable when responding to consumer questions regarding herbs and nutritional supplements, which has become a multi-million dollar industry. UCSF has developed knowledge in this area.

Dr. Candy Tsourounis explained how large the herbal medication industry has become, and listed the top 20 herbs on the market today. She also shared her personal experiences as a pharmacist about how misinformed the general public is in taking herbal medications.

MOTION: Support the concept, as long as such a project can be performed within the budget allocation for this committee.

M/S/C: Strom/Elsner

SUPPORT: 8 OPPOSE: 0 ABSTAIN 0

Approval of Minutes

Full Board Minutes - May 19-20, 1999

MOTION: Approve minutes.

M/S/C: Jones/Zia

SUPPORT: 8 OPPOSE: 0 ABSTAIN 0

Northern Compliance Minutes - June 2, 1999

MOTION: Approve as corrected.

M/S/C: Elsner/Zia

SUPPORT: 8 OPPOSE: 0 ABSTAIN 0

Southern Compliance Minutes - June 15, 1999

MOTION: Approve

M/S/C: Zia/Fujimoto

SUPPORT: 8 OPPOSE: 0 ABSTAIN 0

NEW BUSINESS/AGENDA ITEMS FOR FUTURE MEETINGS

Ms. Strom requested that the video conferencing units be discussed as a future item. This issue can first be discussed in the licensing committee.

There were no additional comments from the board or the public.

ADJOURNMENT

President Mazzoni adjourned the meeting at 5 p.m.