



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: October 18, 19, 2000

TIME: 9:00 a.m. - 5:00 p.m.

LOCATION: Embassy Suites Hotel
San Francisco Airport
150 Anza Boulevard
Burlingame, CA 94010

BOARD MEMBERS

PRESENT: Robert Elsner, President
Steven Litsey, Vice President
Caleb Zia - Treasurer
Darlene Fujimoto
Richard Mazzoni
Andrea Zinder
John Jones
Donald Gubbins
William Powers (October 18, 2000, only)

BOARD MEMBERS

ABSENT: Holly Strom

STAFF

PRESENT: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
William Marcus, Deputy Attorney General
LaVonne Powell, Department Legal Counsel

CALL TO ORDER

President Elsner called the meeting to order at 9:00 a.m. on Wednesday, October 18, 2000.

COMMITTEE REPORTS AND ACTION

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Chairperson Zia reported that the Communication and Public Education Committee met in a teleconference meeting on September 28, 2000. He stated that committee members include Board Member William Powers and himself with assistance from Assistant Executive Officer Virginia Herold and board staff Hope Tamraz.

Chairperson Zia reported that because senior citizens take a large number of the nation's prescription drugs, the UCSF has suggested that a future *Health Notes* publication on pharmaceutical care for geriatric patients be developed. Whereas UCSF is seeking federal funding for this project, it has asked if the board would be willing to fund the project if federal funding cannot be obtained. The Communication and Public Education Committee supports the development of such an issue.

Lorie Rice, Associate Dean, External Affairs, University of California, San Francisco, appeared before the board and thanked the board for its consideration.

The following are prior published issues of *Health Notes* available on the board's website and in print:

- Care of Children and Adults with Developmental Disabilities, 2000
- Anticoagulation, 1999
- Women's Health, 1999
- Pain Management, 1997/98

Dr. Fujimoto requested feedback from the publications of *Health Notes* to assure its usefulness. She added that there are many publications on the subject of geriatrics and asked if this publication would incorporate consumer education. Dr. Fujimoto requested that the committee review the effectiveness of continuing education awarded from *Health Notes* – essentially how many pharmacies are pursuing this.

Ms. Harris stated that in the past, the board extracted articles from *Health Notes* into consumer columns through a national association publisher. Also, the board has received numerous requests for the *Health Notes* issue on Care of Children and Adults with Developmental Disabilities and this was distributed to many providers. She added that during a meeting with the Consumer Services Agency, considerable interest was expressed for the issue dealing with alternative medicine planned for publication in late 2000.

Deputy Attorney General William Marcus stated that the first publication of *Health Notes* on pain management was written with a dual purpose to educate practicing pharmacists about pain treatment and to provide useful information to consumers.

Ms. Harris added that the board plans a *Health Notes* on quality assurance programs for prescription errors that is required by SB 1339. Topics will include preventing errors, board requirements for pharmacies and models of quality assurance programs that pharmacies can use to establish their own programs. The board has requested supplemental funding for this issue as a fiscal impact of enactment of the legislation.

MOTION: Approve the Communication and Public Education Committee's recommendation to develop a *Health Notes* on geriatric issues, and contract with UCSF to develop this if federal funding is not obtained by UCSF.

SUPPORT: 7 OPPOSE: 0

Chairperson Zia reported that the Communication and Public Education Committee is initiating the revision and redesign of the Notice to Consumers poster that must be posted in every pharmacy.

Chairperson Zia also noted that the committee suggested that the questions patients should understand before taking medications, recommended by the National Council on Patient Education and Education, be added. The committee is likely to include questions similar to these:

1. What is the name of the medication and what is it supposed to do? Is this the brand or generic name?
2. How and when do I take it – and for how long?
3. Are any monitoring tests required (for example, to check for liver or kidney functions)?
4. What foods, drinks other medicines or activities should I avoid while taking this medicine?
5. What are the possible side effects and what do I do if they occur?
6. Will this new prescription work safely with the other prescription nonprescription and herbal medicines I am taking?
7. Is there any written information available in large print or in a language other than English?

Chairperson Zia stated that the committee will draft proposed language for the Notice to Consumers poster for comment at the January 2001 public meeting of the committee. The text will need to be adopted by the board at a later meeting as a regulation, and the poster itself, once the text is finalized, will be redesigned and distributed to the state's pharmacies. The committee recommends that it be translated into other languages as well. The 800 consumer telephone line of the board (not yet in place) will be included on the poster as well as the board's website address.

MOTION: Approve the Communication and Public Education Committee's recommendation to revise the "Notice to Consumers" to include questions patients should understand before taking medications.

SUPPORT: 7 OPPOSE: 0

Chairperson Zia reported that the board will have its lawbook reprinted later this year. The lawbook and a CD version of the lawbook will again be distributed to all California pharmacies by January 2001. The cost for this mailing will be about \$65,000.

MOTION: Approve the Communication and Public Education Committee's recommendation to reprint and mail *the 2001 California Pharmacy Lawbook* to all California pharmacies.

SUPPORT: 7 OPPOSE: 0

Mr. Cronin, California Pharmacists Association, stated that the board should provide more information on the board's website. Chairperson Zia expressed concern for the many people that do not have access to computers and the need to provide them with information in a different venue.

LICENSING COMMITTEE REPORT

President Elsner reported that Chairperson Holly Strom was absent from the board meeting due to a family illness. As such, Don Gubbins would provide the Licensing Committee report.

Dr. Gubbins reported on the October 3, 2000, Licensing Committee Meeting.

- Use of Automated Dispensing Machines at "Remote Pharmacies"

Dr. Gubbins stated that the committee directed staff to draft statutory language that would authorize a pharmacy to use an automated dispensing device to dispense medications from a remote pharmacy site without a pharmacist physically present. The committee reviewed the proposed language that defines an "automated dispensing device," and authorizes a "remote pharmacy site" to use an automated dispensing device under specified conditions. These conditions are: the remote site is licensed as a pharmacy and is located in a Health Professional Shortage area as designated by the federal government, permits pharmacist consultation via a two-way audio and video device, a technician or licensed health care provider may provide the dispensed medication, and the pharmacist can access the dispensing device outside the pharmacy premise and is responsible for stocking the device.

Board Member Andrea Zinder requested staff to clarify "Health Professional Shortage" area.

Bruce Young, California Retailers Association, stated that they had concerns with the vague definition of Automated Dispensing Device. He added that if the board moves forward with this language, language should include that consultation will be provided from a licensed pharmacist and a licensed pharmacy. Mr. Young stated that this legislation could provide a means for others to move this activity away from licensed pharmacists and pharmacies.

Dr. Fujimoto stated that she would not want this to be linked to a federal definition and she wants the board to have the ability to evaluate and consider other criteria to decide what is appropriate for the use of remote pharmacies.

Robert LaWinter, Telepharmacy Solutions, stated that Telepharmacy Solutions has 11 automated remote dispensing sites in California with the Veterans Administration where they dispense from their outpatient clinics and hospitals to remote sites. They have been in California for approximately two years. He added that they have over 50 installations of these remote devices around the country, fully controlled by the pharmacists. Mr. LaWinter urged the board to move cautiously in this area. He suggested that the board assure that safeguards for patient consultation are established. He supported postponement until the next board meeting.

Mr. Mazzoni suggested that a demonstration project be presented to the board as a study project.

MOTION: Postpone the recommendation by the Licensing Committee to sponsor legislation that authorizes the use of an "automated dispensing device" from a "remote pharmacy site."

M/S/C: MAZZONI/FUJIMOTO

SUPPORT: 7 OPPOSE: 0

John Jones stated that an important goal of the legislation is that pharmacies that have shortages would have a means to resolve the shortage.

Board Member William Powers arrived at the board meeting.

Mr. LaWinter referred to a grant provided by another state agency for St. Joseph's Hospital in Stockton that was funded for a remote system in an area without a pharmacy within 40 miles.

Ms. Harris clarified that the board does not have statutory authority to permit the hospital to do this. She added that the way the legislation is written, the pharmacists can dispense as they do in skilled nursing facilities or from home (telecommuting), but they have to be present to make sure that the supply is stocked properly and that consultation is provided. She added that the law restricts the use of this technology.

Steve Gray, Kaiser Permanente, recommended a pilot project to demonstrate the utility of this technology.

Rose Deleonardis, President, California Employee Pharmacists Association stated that they are against remote controlled pharmacies.

MOTION: The Licensing Committee will explore a demonstration project on automated dispensing machines at remote pharmacies in an area documented as a pharmacist shortage area and evaluate the impact on operations and consumer access.

M/S/C: MAZZONI/ZIA

SUPPORT: 7 OPPOSE: 0 ABSTAIN: 1

- Implementation of Pharmacist Manpower Task Force

Dr. Gubbins stated that at the July meeting, the Board of Pharmacy adopted a motion that identified the shortage of pharmacists as a priority for strategic objective and directed that a task force be appointed to seek solutions.

Dr. Gubbins stated that the Licensing Committee identified 15 potential task force members. A representative from each of the following pharmacy groups will be asked to participate: the California Retailers Association, the California Pharmacists Association, the California Society of Health Systems Pharmacists, the Pharmacists Planning Service, Inc., the four pharmacy schools, managed care, state government, United Food and Commercial Workers, and the Guild for Professional Pharmacists. In addition, a consumer will be asked to participate.

Bruce Young stated that by the end of the year, the federal government will have a national study that will further document the pharmacy shortage.

President Elsner stated that the first meeting of the task force is set for January 23, 2001, and will be open to the public.

Dr. Fujimoto recommended that this committee establish goals and objectives at its first meeting to ensure a focus for the discussion.

Ken Caldwell, Texas Board of Pharmacy, expressed support of the board's efforts to address the pharmacist shortage issue. He suggested that the board review this issue in broad terms by examining other avenues such as expanding the ratio of technicians to pharmacists and expanding the duties of the clerk typists.

Rose Deleonardis, California Employee Pharmacists Association, added that some of the reasons contributing to the pharmacist shortage is that pharmacists are retiring early and

refusing to work weekend and evening shifts. She added that pharmacists often seek other career paths for better working conditions.

MOTION: Adopt the Licensing Committee's recommendation to form a task force to seek solutions to the pharmacist shortage comprised of approximately 15 members.

SUPPORT: 8 OPPOSE: 0

- Request for Long Beach Memorial Hospital to Extend UCSF Study on Technicians checking Technicians

Dr. Gubbins reported that in May 1998, the Board of Pharmacy granted a waiver pursuant to California Code of Regulation section 1731, to the UCSF, School of Pharmacy in conjunction with Long Beach Memorial Medical Center and Cedars-Sinai Medical Center, to evaluate technicians in a unit-dose drug distribution system to check the work of other technicians. The waiver is granted until November 1, 2000.

Dr. Gubbins stated that the UCSF will be submitting a report on the study at its conclusion, to be considered by the board at its January 2001 meeting. At that time, UCSF, Long Beach Memorial Medical Center and Cedars-Sinai Medical may request that the board amend its regulations to allow pharmacy technicians to check pharmacy technicians in an inpatient hospital pharmacy since the board has the authority to do this by regulation.

Dr. Fujimoto asked why the study has taken so long to complete.

Ms. Harris explained that the study was originally set for two years and now because USCF has technicians trained to check technicians, they want to continue.

Mr. Cronin expressed concern that UCSF wants to continue with this study simply to continue as they have been under the waiver.

Steve Gray stated that it is problematic to have a system in place for two years without the manpower in place to return to a prior system.

Teresa Miller, California Society of Health System Pharmacists, stated that the intent of this study was to provide current data that demonstrates that technicians checking technicians in such a system is safe.

Ms. Harris stated that once the board is presented with the study, the UCSF likely will request the board to move forward with a proposal for a regulation change. At that point, the board would make a determination.

MOTION: Extend the UCSF, School of Pharmacy study on technicians checking technicians in a hospital pharmacy until February 1, 2001.

M/S/C: CALEB/JONES

SUPPORT: 8 OPPOSE: 0

- Licensure of Limited Liability Companies as Owners of Board of Pharmacy Licensed Sites

Dr. Gubbins reported that Business and Professions Code section 4201 authorizes the board to issue permits for a pharmacy, wholesaler, medical device retailer, and veterinary food-animal drug retailer to several types of legal entities, including partnerships, corporations, or other unincorporated associations. This section was amended in 1994 to include limited liability companies (LLCs). As such, the original interpretation of this section was for an LLC to operate a pharmacy or other licensed pharmaceutical "business." However, the board's legal counsel researched the issue and concluded that an LLC is ineligible for any license or permit issued by the board. This analysis was provided to the board in March 1998.

In October 1998, the board's counsel recommended that the board consider proposed legislation that would authorize the board to issue "site" permits to an LLC. He based this recommendation on the fact that current law already authorized the board to issue "site" permits to corporations, which have the same liability shields as an LLC, and that the proposed legislation would not adversely affect consumer protections.

The board accepted the recommendation and initiated efforts to have the legislation introduced; however, an author was never obtained.

In a recent court decision (the Mann case), the Court of Appeals gives guidance as to what constitutes "professional services." In essence, the question is what licenses are professional versus business, occupation, or vocational. Essentially the criterion is whether any education or experience is required before the agency will issue a license.

Although no education or experience is required to issue a pharmacy license, the license does require a qualifier. The qualifier is a professional licensee who is legally responsible for professional acts of the business entity. In the board's case, this is a licensed pharmacist referred to as the pharmacist-in-charge. The pharmacist must be licensed in California and must possess a degree, pass the California licensure examination, and have successfully completed an internship.

The committee determined that pharmacies are licensed for the primary purpose of "delivering a pharmacist's professional services" and therefore, does not meet the criteria of a business license.

MOTION: Unless legislation is passed that clarifies the law, the Board of Pharmacy should not license any pharmacy as an LLC.

SUPPORT: 8 OPPOSE: 0

- Preferentially Priced 340B Drug Dispensing

The 340B Drug Pricing Program was established federally in response to the passage of section 340B of Public Law 102-585, the Veterans Health Care Act of 1992. Section 340B of this law limits the cost of drugs sold to federal purchasers and to certain grantees of federal agencies such as clinics. Entities that participate in this program benefit from significant savings on pharmaceuticals which allows them to provide in-house pharmacy services to the rural or under-served population that would have otherwise not received such services.

Under this federal program “covered entities” such as clinics can access statutory established drug prices and then contract with a licensed pharmacy to dispense those drugs to covered patients. The board has received requests from clinics to contract with pharmacies to dispense 340B drugs to their under-served patients.

Staff Counsel LaVonne Powell researched this issue and she concluded that clinics acting in such a fashion would be wholesaling pursuant to Business and Professions Code section 4043, and would be required to be a licensed wholesaler.

The committee discussed that under current state pharmacy law, clinics do not have the authority to provide 340B drugs to pharmacies to dispense. This would require statutory change. Moreover, federal law authorizes a “covered entity” to participate in the program; however, the definition of “covered entity” is unclear. Further, clinics licensed by the board pursuant to Business and Professions Code section 4180 and 4190, have the authority to dispense to patients without a pharmacist being present. While the committee agreed that the intent of the federal legislation is good and a benefit to the under-served population, there is no authority to allow 340B drugs to be dispensed through pharmacies.

Mr. Marcus clarified that the issue is not that California cannot permit covered entities and contracting pharmacies to be licensed as wholesalers but, unless they have the proper licenses, California law does not permit them to make these arrangements even if the federal government supports this.

Ms. Harris stated that the issue becomes whether a clinic can have dual licensure as a clinic and a wholesaler at the same time and still meet the requirements.

Mr. Powers asked if the board could initiate legislation to resolve this issue.

MOTION: To direct legal counsel to draft language to allow this type of relationship under California law for, consideration at the January 2001, board meeting.

M/S/C: POWERS/ZIA

SUPPORT: 7 OPPOSE: 1

MOTION: Authorize the Executive Officer to use a spot bill or seek author to meet the legislative deadline.

M/S/C: POWERS/ZIA

SUPPORT: 7 OPPOSE: 1

- Request to Accept the Certified Geriatric Pharmacist Credential as Meeting CE Requirements

Dr. Gubbins stated that the Commission for Certification in Geriatric Pharmacy requested that the Board of Pharmacy recognize the Certified Geriatric Pharmacist credential to meet California's continuing education requirement. The CGP requires candidates to be knowledgeable about the principles of geriatric pharmacotherapy and the provisions of pharmaceutical care to the elderly.

The committee discussed the merits of this credential; however, since legislation is required to implement the request, the Commission for Certification in Geriatric Pharmacy should pursue the legislation.

MOTION: Advise the Commission for Certification in Geriatric Pharmacy that it does not have the authority to accept the certification as meeting the requirements for continuing education.

SUPPORT: 6 OPPOSE: 0 ABSTAINED: 2

- Competency Committee Report – June 2000 Pharmacist Licensure Examination

Steve Litsey referred to the Competency Committee Report that included the statistical report for the June 2000 examination. He stated that the June 2000 exam had a 58.4 percent pass rate.

Ms. Herold referred to the concern expressed at the last board meeting that the board would be unable to issue permits timely following release of exam results. She reported that there were a number of walk-in candidates who wanted to be licensed immediately and staff not only issued all permits at that time (providing all requirements were met), they were able to issue wall certificates as well. She noted that most candidates, who were licensed by mail, were issued licenses within 24 hours.

- Implementation of Live-Scan for Fingerprint Clearances

Dr. Gubbins reported that the Department of Justice is now ready to automate much of the fingerprint review process. On January 1, 2001, all California-residing applicants will be directed to go to a site where they can submit prints directly through LiveScan, an automated system for checking prior convictions. A list of sites will be available on line (due to constant changes in providers) as well as on a list attached to board applications. The cost of LiveScan fingerprint analysis will reduce the fingerprint-processing fee to \$32, and the board will receive a clearance or conviction history for the applicant via fax typically in three days. Simultaneously, the board will begin federal fingerprint analysis of all applicants, which will cost \$24 more.

- Strategic Plan Modification Suggested

Dr. Litsey suggested that the board include in the Strategic Objectives for the Licensing Committee, language for electronic-signature. Currently, the Board of Pharmacy cannot accept credit cards for renewal purposes. He suggested that the committee make suggestions to the board. Further, the committee should address the technology as it relates to electronic transfer of prescriptions. At the same time, the board can look at ways to protect consumers and improve our systems and reduce costs.

ENFORCEMENT COMMITTEE REPORT

- Compliance Policy on Prescriber Dispensing

Dr. Fujimoto stated that the Compliance Policy was released at the Enforcement Committee Public Meeting during the July board meeting and subsequently discussed by the Enforcement Team at its last meeting. There was discussion at the public meeting that the board needs to take a more active role in regulating the dispensing of drugs from a prescriber's office. The board lacks the resources and refers the matter to the Medical Board of California to obtain compliance of its licensees. If adopted, the policy will be published in the board's newsletter and on the board's website.

Mr. Cronin stated that there was considerable disagreement with this policy in July and he stated that the board should not adopt such a policy now. He referred to litigation occurring in July that would be impacted by this policy guide. He urged the board not to adopt this policy statement.

Ms. Harris asked Mr. Cronin to clarify any inconsistencies or inaccuracies in the document.

Mr. Cronin stated that he was not prepared to present any information to the board. He stated that he opposes the guidelines and that the Board of Pharmacy and the Medical Board have essentially dodged the issue.

Ms. Harris stated that based on legal counsel assessment, the issue of dispensing and reimbursement is an issue for the Medical Board. She added that the board's concern is whether the drugs have been commingled and if they are dispensing from a common stock without a clinic license.

Mr. Jones asked if the board would like to have another forum to discuss this further.

Dr. Fujimoto stated that this is an open board meeting and the board is providing the opportunity for discussion. Mr. Cronin has stated that he is not ready. She expressed concern about delaying this just because someone is not prepared to discuss it.

Mr. Marcus stated that whether the board decides to defer further consideration of adoption of this proposal until March, it should not be based on the litigation that Mr. Cronin mentioned.

Mr. Mazzone stated that he remained opposed to a postponement.

MOTION: Refer the Compliance Policy on Prescriber Dispensing for consideration at the Enforcement Committee's public meeting in March.

M/S/C: JONES/POWERS

SUPPORT: 8 OPPOSE: 0

- Compliance Policy on Expiration Dates

Dr. Fujimoto stated that this Compliance Policy was also discussed at the public meeting of the Enforcement Committee. It was revised to include the expiration dates for the repackaging of unit dose medications. The Enforcement Committee's direction to inspectors is to enforce violations of law when pharmacies dispense expired drugs.

Dr. Fujimoto stated that there are further issues to add to the guideline before it is ready for board evaluation and action.

- Delegation of Authority to Board President for Petitions to Compel Psychiatric Evaluations

Dr. Fujimoto stated that if the board has reason to believe that a licensee is unable to practice due to a mental or physical illness that affects his or her competency, it may order the licensee to undergo an examination by a physician or psychologist, pursuant to Business and Professions Code section 820.

If this decision is made, the deputy attorney general prepares a Petition for Order Compelling Psychiatric Examination. This order is sent to board members to vote on. If the board affirms the order, then the licensee is ordered to undergo a psychiatric examination. If the examination confirms the licensee's inability to practice or requires that he or she practice in a restricted manner, then the board can take appropriate administrative action.

It is staff counsel's recommendation that the board delegate to the board president or in his or her absence, the vice president, the authority to order the psychiatric examination.

This is a process followed by other boards. This procedure expedites the process.

MOTION: Delegate to the board president (in his or her absence, the vice president) the authority to order a psychiatric or physical evaluation pursuant to Business and Professions Code section 820.

SUPPORT: 8 OPPOSE: 0

- Compliance with SB 393 – Providing Medi-Cal Price Quotes for Medicare Patients

Dr. Fujimoto reported that on February 1, California implemented a law that requires pharmacies to sell prescription medication to Medicare patients at Medi-Cal prices, if the patients are paying for medication themselves and if the pharmacy is a Medi-Cal provider. These provisions were enacted by SB 393 (Speier, Chapter 496), and will remain in effect until January 1, 2003.

During deliberations in the Legislature on SB 393, concern was raised that failure to sell the drugs at the Medi-Cal prices would become a disciplinary action against the pharmacy. The resolution that the sanction for failing to sell medication to eligible patients at the Medi-Cal prices would be loss of provider status with the Medi-Cal program, which rests with, the Department of Health Services.

However, a new problem has appeared; one that was not deliberated during enactment of SB 393. Pharmacies are required by California law and regulations to provide price quotes to consumers, without obligation to purchase the medication. Business and Professions Code section 4122 requires a pharmacist or his or her employee to give the retail price of up to five drugs, and regulation section 1707.2 reiterates this requirement. For Medicare patients, the retail price is the Medi-Cal price.

According to Department of Health Services, some pharmacies are not providing price information to these patients, and will not provide the price information unless the prescription is actually filled. Moreover, DHS states that it will not enforce the price quote requirements as part of its implementation of SB 393, and that the board must enforce this requirement. They state that any DHS-imposed sanctions will be solely based upon failure to actually sell the drug to eligible patients.

The team discussed that the core of the legal requirements for price quotes is an important consumer issue—patients should be able to know how much they will be charged for a drug before they actually purchase the drug. SB 393 was intended to lower the drug costs for Medicare recipients, but if price comparisons are not possible unless the patient purchases the drug, this undermines much of the consumer value of SB 393.

MOTION: The Board of Pharmacy will mediate consumer complaints against pharmacies for failure to provide a Medi-Cal price quote to Medicare patients.

SUPPORT: 8 OPPOSE: 0

MOTION: Encourage the Department of Health Services to establish on their website a list of Medi-Cal price quotes.

M/S/C: POWERS/ZIA

SUPPORT: 8 OPPOSE: 0

- Report on Aging Case Data

Dr. Fujimoto referred to data on the status of pending cases over one year old provided from the Enforcement Committee meeting. She added that although inspector positions have been vacant, inspectors and enforcement analysts have made tremendous progress over the last six months to resolve these cases.

Supervising Inspector Ratcliff stated that the current concern is for cases that are in excess of one year old. He stated that these cases are tracked from the date the complaint is received by the board and not the date received by the inspector. He acknowledged the efforts by board staff to clear up these cases in spite of heavy caseloads. He referred to the progress made so far and stated that the goal is to have no cases in excess of one year by the end of this year.

Mr. Jones applauded the efforts of supervising inspectors and inspectors in resolving the aging cases.

Dr. Fujimoto stated that the Enforcement Committee would like to hold more open public meetings in the future to receive information. She added that the board is addressing ways to promote greater public attendance at future board meetings.

CLOSED SESSION

The board moved into closed session pursuant to Government Code section 11126(c)(3) and 11126(e)(2)(A) to deliberate upon disciplinary cases and to confer with legal counsel regarding the following pending litigation: Doumit v. Board of Pharmacy, Sacramento Superior Court Case #98A504499 and Gonzalez v. Board of Pharmacy, Sacramento Superior Court Case #99AS01990.

ANNOUNCEMENT

President Elsner acknowledged Judi Nurse, the board's new supervising inspector, who was in attendance.

LEGISLATION AND REGULATION COMMITTEE

Mr. Mazzone reported that the Legislation and Regulation Committee met on September 20, 2000.

Regulations: Action

- Dangerous Drugs Exempt from Storage in a Pharmacy – Adopt Section 1714.5

Business and Professions Code section 4057 was amended last year through board-sponsored legislation to remove the list of dangerous drugs and devices that can be stored in non-pharmacy areas of a hospital or by licensed practitioners. Instead, this list will be maintained in section 1714.5 of the California Code of Regulations.

At its July meeting the board approved moving forward with a 45-day notice for the language proposed by the affected parties. The notice of proposed action was published on August 25, 2000. The 45-day comment period ends on October 9, 2000. No hearing was scheduled.

The board received a comment letter from Steven Gray of Kaiser Permanente supporting the board's proposal.

MOTION: The Legislation and Regulation Committee recommends that the board adopt the proposed amendments of California Code of Regulations section 1714.5 to place in regulation a listing of dangerous drugs and devices that can be stored in non-pharmacy areas.

SUPPORT: 8 OPPOSE: 0

Pending Regulations

- Citation and Fine – Amend Section 1775 et seq.

Ms. Herold stated that these regulations were adopted by the board at its last board meeting earlier this year. Before the regulation is submitted to the Office of Administrative Law, the board has to compile a rulemaking file with all of the comments received during the regulation hearing. The board also has to provide a fiscal impact statement that the Department of Finance has reviewed. Currently, the board does not have the fiscal impact statement signed.

Ms. Herold reported that the board submitted a budget change proposal to implement the cite and fine program that was not approved due to the Governor's limit on the size of growth in state government. So, the board will have to absorb the additional workload without adding staff.

- Quality Assurance Programs – Adopt Section 1711

Mr. Mazzone reported that the information hearing on the draft regulation is scheduled for the January 2001 Board Meeting. The regulation will establish components for quality assurance programs that pharmacies must establish to evaluate prescription errors.

Bruce Young, California Retailers Association, thanked the board and staff for efforts to draft this regulation.

Approved

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

Steve Gray, Kaiser Permanente, asked how the standards for off-site storage of specified records will be issued when a waiver is granted.

This regulation will permit licensed sites to store records elsewhere if the board issues a waiver. The regulation was approved and will take effect October 20, 2000.

Ms. Herold stated that the standards will be outlined in the board's newsletter scheduled for release in January 2001.

INFORMATIONAL HEARING – Proposed Revisions to Disciplinary Guidelines (1760)

Mr. Mazzone announced that this portion of the meeting is an informational hearing on a proposed revision of the board's Disciplinary Guidelines. He noted that this is the same document that the board moved to release public notice at the July meeting. There were no comments made.

Mr. Mazzone stated that this document will be submitted for adoption through the rulemaking process.

Legislative Report

1. Board-Sponsored Legislation for 2001

Mr. Mazzone reported that during the September 20, 2000, Legislation and Regulation Committee meeting, the committee put together the following legislative proposals for 2001, resulting from input from board staff, components from the board's strategic plan, and comments provided from the regulated community:

1. Conforming federal and state controlled substance schedules
2. Conforming with the federal definition of wholesaling
3. Remote controlled pharmacies
4. Repackaging pursuant to patient request
5. Temporary pharmacy license
6. Controlled substances act clean-up
7. Fee schedule clean-up

8. Medi-Cal fraud provision
9. Consulting pharmacists
10. Program flexibility

President Elsner asked for comments on any of these proposals.

John Cronin requested that item number two be extracted.

Steve Gray, Kaiser Permanent, requested that item number five be extracted.

President Elsner asked that the board decide whether to move forward the remaining proposals.

MOTION: Seek introduced legislation in 2001 as recommended by the Legislation and Regulation Committee on the following:

1. Conforming controlled substance schedules
2. Remote controlled pharmacies
3. Repackaging pursuant to patient request
4. Controlled substances act clean-up
5. Fee schedule clean-up
6. Medi-Cal fraud provision

7. Consulting pharmacists
8. Program flexibility

SUPPORT: 8 OPPOSE: 0

Conforming with Federal Definition of Wholesaling

Mr. Marcus referred to the proposals to conform California law with the federal definition of wholesaling and he stated that he has not had the chance to compare it to the federal definition that it is supposed to conform to. He added that if this conforms to the federal definition, the board is bound to it any way.

Ms. Harris stated that this is an enforcement issue. She added that there are many cases where pharmacies buy drugs and then wholesale them, and this practice is secondary sourcing. It is the board's intent to clarify the law concerning a pharmacy and clarify that it cannot be wholesaler too. Mr. Cronin asked the board to assure that the language does not conflict with authority granted to pharmacies to act as refill pharmacies.

MOTION: Conforming California law with the federal definition of wholesaling – clarify by either regulation change or seek introduced legislation in 2001.

M/S/C: POWERS/JONES

SUPPORT: 8 OPPOSE: 0

- Temporary Pharmacy License

Steve Gray stated that an amendment to this section would permit an opportunity to correct a problem that occurs when a pharmacy is opened for only a few months to handle peak demand for pharmacy services. Current law states that a pharmacy must be open one day a week within a 120-day period.

Mr. Mazzone suggested that Mr. Gray bring these concerns to the public committee meeting later in the afternoon.

MOTION: Seek amendments to permit the board to issue temporary pharmacy licenses.

SUPPORT: 8 OPPOSE: 0

2. 2000 Enacted Legislation

Mr. Mazzone stated that the following legislative bills were enacted:

AB 1496 (Olberg)

This law expands the Medical Device Retailer licensing requirements to include entities that sell specified non-prescription medical equipment and services and transfers the program from the board to the Department of Health Services effective July 1, 2001. The board supported this legislation. Revenue loss to the board is projected at \$268,000 annually.

AB 2240 (Bates)

This law permits the electronic transmission of a prescription without requiring the pharmacist to reduce it to writing. The board supported this legislation. The board has submitted a fiscal impact of \$40,000 to train board staff and retain technology consultants for investigations involving licensees' failure to provide this.

SB 1828 (Speier)

This law allows the board to issue fines for up to \$25,000 for Internet dispensing violations. The board supported this legislation. The board has submitted a fiscal impact approaching \$1 million to fund six staff to conduct Internet investigations, fund covert drug purchases and additional Attorney General costs.

SB 1903 (Speier)

This law requires affiliated or subsidiaries of a corporation to obtain patient consent before sharing medical information kept electronically. The board had an oppose unless amended position on this legislation.

SB 2018 (Thomson)

Paul Riches, board legislative analyst, reported that this bill became law without the Governor's signature on September 30, 2000. This bill amends requirements for Schedule II drugs so that the entire triplicate prescription need not be written in the prescriber's hand, it simply requires the prescriber sign the prescription. The bill eliminates the cap on the number of triplicates that may be ordered. The bill permits pharmacists to make a correction to the triplicate provided that the pharmacist consult with the prescriber before dispensing and the prescriber follows up within seven days with a correction.

Mr. Riches stated that initially this bill would have ended the triplicate program and established CURES as a full-time program. This bill no longer addresses the CURES system. Because these provisions were deleted from the bill, CURES will end January 1, 2003. However, existing board funding for CURES ends January 1, 2002.

President Elsner acknowledged all of Mr. Riches' efforts and hard work regarding legislation.

Ms. Harris referred the board to a letter from Assemblywoman Helen MacLeod Thomson, acknowledging Mr. Riches' efforts on AB 2018.

SB 1339 (Figueroa)

This law, which was sponsored by the Board of Pharmacy, requires pharmacies to establish quality assurance programs for prescription errors. The board is required to promulgate regulations to specify these requirements.

Mr. Mazzone referred to the Governor's message in signing SB 1339 where it states: "I would encourage the Board of Pharmacy to use as a model for their regulatory program some of the more successful quality control programs already being used voluntarily by pharmacies." Mr. Mazzone stated that the board has been directed to carefully examine issues before making regulatory changes.

Other Bills Inacted

Ms. Herold advised the board of three additional bills that were enacted that impact the practice of pharmacy.

The first bill expands the drugs that optometrists can prescribe. She added that the board's January newsletter will list these drugs so that pharmacists are aware of them.

The second bill establishes in the Department of Consumer Affairs a Patient Privacy Board to deal with issues relating to confidentiality and privacy. The department has a two-year time period to establish this board.

Ms. Herold stated that occupational therapists now have an exemption from MDR law to obtain legend devices. Additionally they will be licensed under a new board within the Department of Consumer Affairs.

Federal Legislation "Electronic Signatures in Global and National Commerce Act" or "E-Sign"

Deputy Attorney General William Marcus referred the board to his analysis of the federal act signed by President Clinton.

Mr. Marcus stated that the act was intended to give electronic transactions, records, documents, and signatures the same weight as written, printed or typed original documents or an original signature.

Mr. Marcus reported that a recent legal analysis by Law Watch stated that the federal legislation eliminated federal and state requirements for retention of paper documents and handwritten signatures. The analysis stated that "E-Sign" would eliminate triplicate prescription requirements, among other requirements of written records, as well as any state requirement that a prescription be written.

Mr. Marcus stated that California law requires that the original triplicate be submitted to the Bureau of Narcotic Enforcement. He added that the state agency can continue to demand that applications, affidavits and other items be submitted in writing. He added that the Board of Pharmacy virtually has no problems in this area because it has been in the forefront of recognizing and encouraging electronic transactions for prescriptions for over 10 years.

Mr. Marcus stated that in his opinion, this act does not eliminate triplicates and it was not intended to do so.

Mr. Marcus noted that the problem is that some board licensees may attempt to accept and fill electronically transmitted prescriptions for Schedule II controlled substances or electronic data transmission orders for Schedule IIIs, IVs, and Vs, despite the fact it violates current DEA regulations. He added that the board should continue to treat this as a violation of enforceable law.

- Status Report on Committee Goals 2000-2001

Mr. Mazzoni stated that the board has made significant progress on its board-sponsored legislation and regulations over the last year and he acknowledged the staffs' efforts for a job well done.

- Drug Importation Law Changes

Mr. Marcus reported that HR 5426 was introduced on October 6, 2000. The Agriculture Rural Development Food and Drug Administration and Related Agencies Appropriations Act of 2001 has one provision that is important to pharmacy. The secretary of Health and Human Services is required, in consultation with United States Trade Representatives and the Commissioner of Customs, to promulgate regulations permitting wholesalers to import prescription drugs into the United States. Mr. Marcus noted that the stated intent is to help lower the cost of prescription drugs by allowing U.S. pharmacies and wholesalers to buy these drugs, which are usually exported at deep discounts from the price available for drugs sold by manufacturers within the US. These drugs can then be used to fill in the U.S. at a lower cost.

LEGISLATION AND REGULATION COMMITTEE - PUBLIC MEETING

Pharmacists Shortage

Bruce Young representing the California Retailers Association stated that in a meeting with the National Association of Chain Drug Stores, seven ideas were developed to address the pharmacist shortage issue. He added that working pharmacists from various chain drug stores are in attendance from Northern California to present their ideas.

Mr. Young stated that this testimony will address the pharmacist shortage issue as well as attempt to convey problems pharmacists are faced with.

1. Allow Reciprocity and NABPEX

It was recognized that the pharmacy shortage is a nationwide problem. It was recommended that the board consider license reciprocity and NABLEX to alleviate the manpower shortage to bring more qualified pharmacists to California. It was also noted that California could add its specific concerns regarding testing requirements to the NABLEX exam.

The California Retailers Association submitted a proposed regulation to the board that would allow for reciprocity.

2. Make the Exam Multiple Choice, Available On-Line and Offer it Three Times a Year

Comments included making the California Pharmacist exam a multiple-choice exam to speed up the grading process and allow pharmacists to be hired more quickly. This would also allow for more frequent exams. Also, a multiple-choice exam would more accurately test the knowledge of candidates.

3. Allow Central Processing

The model language provided by the NABP would allow central processing pharmacies to be established to perform functions for multiple pharmacies.

4. Eliminate the Clerk-Typist from the Ratio and Expand Their Duties

Comments in this area included: pharmacists are performing more non-discretionary pharmacy work and by reconsidering the clerk typist/technician/pharmacist ratio, would benefit the consumer and the pharmacy staff. Because third-party insurance has placed additional demands on pharmacists' time, these types of tasks prevent lost opportunities in providing patient consultation. Expanding the ratio of clerk to pharmacist would allow more opportunity for the pharmacist to interact with customers.

Another suggestion was to eliminate registration of technicians in California. Reference was made to the standardized national test for technicians that other states recognize. Further, another comment was made that the requirement for technicians to complete 1500 hours is a good requirement but not necessary to learn certain activities in the pharmacy.

The proposed language would eliminate the clerk-typist from the ration and expand their duties by allowing them to prepare and type prescription labels, contact the physician's office to clarify prescriptions if directed by the pharmacist, and handle third party claims related task.

5. Revise Requirements for Technician Training

The proposed language submitted to the board would revise existing language to include passing the Pharmacy Technician Certification Board examination as part of the experience criteria. It also adds community pharmacy setting to the experience criteria.

6. Allow Pharmacist-In-Charge to Supervise More Than One Pharmacy

Language was provided by the California Retailers Association that would allow for the pharmacist-in-charge to serve in two pharmacies.

7. Adopt Regulations to Expand Pharmacy Technicians Duties

Proposed language was submitted to add duties for technicians.

Additional Comments

Comments from others at the board meeting included Bob LeWinter who stated that too many pharmacies are being opened, and the board should limit the number of pharmacy licenses it issues. The Guild for Professional Pharmacists stated that the board should not take action that will increase speed at the expense of safety.

There being no further business, the public meeting of the Legislation and Regulation Committee adjourned.

October 19, 2000

ORGANIZATIONAL DEVELOPMENT COMMITTEE

Dr. Litsey reported that the Organizational Development Committee met on September 20, 2000. He referred to the following recommendations made by the committee:

1. Modify the board's 2000/01 strategic plan:
 - a) To reflect board policy regarding membership on the board's strategic plan committees and the ability of the board president to make committee assignments. The proposed change to the strategic plan is:

Each of the ~~first four~~ five committees is comprised of two board members and at least two ~~to~~ or three staff members, who provide technical and administrative input and support. The committees are an important venue for ensuring that staff and board members share information and perspectives in crafting and implementing strategic objectives.

One of the two board members is designated as the chairperson to coordinate the committee's work and ensure progress toward the board's

priorities. Committee terms are preferred to be for two years, although ~~and~~ the board president is empowered to assign committee members to any committee, so the terms may be other than for two years. Depending on board member interest, each committee may have a public board member.

Dr. Litsey stated that the board president has made modifications to the board member composition of the strategic plan committees to fit the interests of board members and to refill vacancies on committees caused by departing board members so that membership on these committees is less than one year. The strategic plan contains language that is inconsistent with this practice, which has been board practice for years and was ratified when it adopted the Board Member Procedure manual.

MOTION: Modify the board's 2000/01 strategic plan as proposed by the Organizational Development Committee regarding committee assignments.

SUPPORT: 7 OPPOSE: 0

b) To modify the strategic goals of the Organizational Development Committee to add:

Manage the board's financial resources to ensure fiscal viability and program integrity

Dr. Litsey stated that the committee strongly believes that the committee must consistently review the financial condition of the board. Where deficits or problems are noted, action needs to be taken immediately to correct the problem.

MOTION: Manage the board's financial resources to ensure fiscal viability and program integrity.

SUPPORT: 7 OPPOSE: 0

2. Approve the board's 2000/01 Strategic Plan.

Dr. Litsey stated that the plan includes the ongoing and strategic objectives of each committee that have been separately approved by the board; there are no changes to these sections unless already approved by the board. This plan now includes the environmental scan performed during the April 2000 board meeting.

The Organizational Development Committee believes that this plan will be more than adequate to guide the board through the next several years, although each committee will need to review and revise its strategic objectives next spring.

MOTION: Approve the board's 2000/01 Strategic Plan

SUPPORT: 7 OPPOSE: 0

3. Modify the Policy and Procedure Manual for Board Members to reference a videotape and related materials on the Bagley Keene Open Meeting act now available from the board.

Dr. Litsey noted the specific change to the procedure manual:

Board meetings are subject to the provision of the Bagley-Keene Open Meeting Act. This act governs meetings of the state regulatory boards and meetings of committees of those boards where the committee consists of more than two members. It specifies meeting notice and agenda requirements and prohibits discussing or taking action on matters not included on the agenda. A videotape and written manual on the Open Meeting Act are available from the board, and all members are encouraged to review these materials.

MOTION: Include reference materials on the Bagley-Keene Open Meeting Act in the Policy and Procedures Manual for Board Members

SUPPORT: 7 OPPOSE: 0

Dr. Litsey reported on the status of the office move. Ms. Harris stated that it will be mid-November before the board is up and running.

Executive Officer's Report

Ms. Harris reported that she attended the National Association of Boards of Pharmacy District 7 and 8 meeting as well as the American Association College of Pharmacy that was held September 21-24, 2000, in Tucson, Arizona. She added that board members Rich Mazzoni and Darlene Fujimoto attended the meeting as well. The primary theme was integrated medicine, and dietary supplements and how pharmacists can be involved in that role. Presentations also included manpower shortage issues and technology and electronic prescribing.

Last week the health boards were invited to meet with the Secretary for State and Consumer Services Agency. Virginia Herold attended on behalf of the board, and stated that the board's activities in a number of areas were well-received including revisions planned for the Notice to Consumers and the board's *Health Notes*.

Personnel Update

Ms Harris reported that Barbara Shelton retired from the board in August. Ms. Shelton was an analyst with the board and had worked for the board since 1994. For much of this time, Ms. Shelton provided support to the executive office and board members.

Ms. Harris stated that the board hired Yolanda Barnes as a new office technician who will work processing pharmacist exam applications and in licensing pharmacists. Ms. Barnes formerly worked with the Department of Fair Employment and Housing and the State Contractors License Board, and began work for the board in late September.

Inspectors

Ms. Harris reported that effective September 1, Judi Nurse was appointed as the new supervising inspector. Supervising Inspector Nurse has been an inspector with the board since 1994, and prior to that was a pharmacist in both the hospital and community settings.

She added that the board currently has eight inspector vacancies, and 15 pharmacists working for the board. Interviews with 12 applicants for inspector positions took place in mid September, and seven job offers were made. Six of the seven have so far accepted the positions and will start in November and December.

The application deadline for interested pharmacists to be interviewed for placement on the hiring list for inspector was October 1, and qualification interviews are planned for late November.

BUDGET REPORT

1. 1999/00 Budget Year

Revenue: \$6,005,840

Ms. Harris reported that the budget figures for the year are nearly final (small adjustments will continue as the department's disencumbers unspent money and deducts invoices and other expenses not paid that were incurred during the fiscal year).

Ms. Harris noted that the licensing fee revenue was about 10 percent higher than projected for the year. Fee reductions taking effect July 1, 1999, reduced annual revenue by what was then estimated as \$1,125,125.

Actual Through
June 30, 2000

Licensing Fees:	\$5,132,969
Interest:	627,840
Cite & Fine:	57,750
Cost Recovery:	152,304
Misc.:	34,977
Total:	\$6,005,840

Ms. Harris stated that the board does not add cost recovery or cite and fine fees into revenue projections for the year, but does report such revenue when it actually collected.

<u>Expenditures Authorized:</u>	\$6,157,921
<i>CURES</i>	466,345
<i>Actual Expenditures:</i>	6,518,730

Ms. Harris stated that according to the department's Budget Office, the board had an unspent reversion of two percent (\$139,299) back to the board's fund at the end of the year.

She noted that last year the board overspent its AG appropriation by nearly \$310,000. A major portion of this funding was redirected from salary savings from unfilled inspector positions.

1. 2000/01 Budget Year

Projected Revenue: \$6,594,982

Revenue is projected to be comprised of \$4,868,360 in license fees and \$513,622 in interest on the board's fund. Also, the board is expected to receive the final repayment of the money borrowed nine years ago to help assist with the state's fiscal crisis. This \$1,213,000 is included in the above figure.

Authorized Expenditures: \$6,457,000

The board did receive \$260,000 for increased rent and for construction expenses for the board's expanded Sacramento office (which is under construction). Not included in the expenditures is a projected \$384,000 deficit in the AG line item. The board has submitted a BCP to augment this year's budget to permit continued AG work.

Fund Condition: \$10,232,244

The board is projected to have 19 months remaining in its fund on June 30, 2001, at current authorized level of expenditures.

2. Budget Change Proposals

At the April and July board meetings, the board approved the Organizational Development Committee's recommendations on the development of budget augments on enhance programs in a number of areas described below. (All the items identified below would increase expenditures by about \$1.09 million annually, and add 10 permanent staff positions.)

a) BCP for 2000/01 (to be pursued as a "current year" augment)

Attorney General's Office - \$383,000 requested to obtain increased AG hours to work the record number of board cases awaiting board action.

b) BCPs for 2000/01

Enforcement:

Consumer Complaint/Mediation Unit -- \$189,000 requested augment

- Make permanent the two staff services analyst positions currently filled as temporary positions and add one new position for unit support. A toll free number for consumers to reach the board will be added to the unit as well.

Citation and Fine Program -- \$134,000 requested augment

- Create one staff services analyst position and clerical support for the proposed expansion in the cite and fine program (triggered by a regulation adopted by the board at the July 2000 board meeting to cite and fine for all violations of pharmacy law).

Attorney General's Office – obtain a one-year augment of \$541,000 and \$371,000 ongoing to work the backlog of cases awaiting board action and to more immediately complete cases referred there each year.

Licensing:

- Add one office technician position to assist with processing applications for individual licenses (the pharmacist, pharmacy technician, foreign graduate and intern programs for audit control, and to back up during periods of high workload) -- \$65,000 augment requested.
- Establish as a permanent position the office technician position for the wholesaler desk currently filled limited term basis – \$68,000 augment requested.
- Establish one office technician position for keeping current pharmacist-in-charge transactions required for all pharmacies -- \$68,000 augment requested.

Communication and Public Education:

- Establish an associate analyst position to oversee the public education program --\$87,000 requested.

Organizational Development:

- Establish in the department's Legal Office, one full-time attorney position dedicated solely to the Board of Pharmacy -- \$119,000 requested.

Funding for these proposals

According to estimates prepared by the department: the board's fund condition at the end of 1999/00 was 18.3 months or \$10.1 million. Without any changes in the board's expenditures, by the end of 2000/01, the board is estimated to have approximately 19 months of expenditures in its fund.

If all of these BCPs are approved at the specified amounts (and if fees are kept at their current level), the board's fund will decrease to 17.3 months at the end of 2000/01, and then over the next three years will decrease to 11.8 months, 8.4 months and 4.6 months by June 30, 2004.

The revenue figures also do not include any cost recovery or cite and fine revenue that may be collected.

3. Office Expansion

Construction began in August to double the size of the board's office to provide more space. The construction should be complete in November.

APPROVAL OF MINUTES

Full Board Minutes – July 25, 26, 2000

MOTION: Approve the minutes as corrected.

M/S/C: FUJIMOTO/MAZZONI

SUPPORT: 7 OPPOSE: 0

Southern Compliance Committee Minutes – July 18, 2000

MOTION: Approve the minutes as corrected

M/S/C: MAZZONI/JONES

SUPPORT: 7 OPPOSE: 0

Northern Compliance Committee Minutes – September 6, 2000

MOTION: Approve the minutes as corrected

M/S/C: GUBBINS/JONES

SUPPORT: 7 OPPOSE: 0

ADJOURNMENT

There being no new business, President Elsner adjourned the meeting at 10:00 a.m.

CLOSED SESSION

The board moved into closed session pursuant to Government Code section 11126(c)(3) to consider the Petition for Reinstatement.