California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814-6237
Phone (916) 445-5014
Fax (916) 327-6308
www.pharmacy.ca.gov

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 AND TIME: October 15 and 16, 2001

LOCATION: The Embassy Suites Hotel
(San Francisco Airport)
150 Anza Blvd.
San Francisco, CA 94010

BOARD MEMBERS PRESENT:
Steven Litsey, President
John Jones, Vice President
Robert Elsner
Stanley Goldenberg
Donald Gubbins
Clarence Hiura
William Powers
Holly Strom
Andrea Zinder

BOARD MEMBERS ABSENT:
Caleb Zia, Treasurer
John Tilley

STAFF PRESENT:
Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Ron Diedrich, Deputy Attorney General
LaVonne Powell, Department Legal Counsel (October 16 only)

CALL TO ORDER

President Litsey called the meeting to order at 1:05 p.m. on Monday, October 15, 2001.

COMMITTEE REPORTS AND ACTION

LEGISLATION AND REGULATION COMMITTEE

Regulation Report and Action

Regulations Approved in 2001

Ms. Zinder updated the board on the status of regulations adopted during the year as follows:

- **Disciplinary Guidelines (1760)** – which revises and reorganizes the board's disciplinary guidelines was approved by the Office of Administrative Law on (date) and will become effective on (date).

- **Exempt Dangerous Drugs and Dangerous Devices (1714.5)** – which was approved by the Office of Administrative Law on April 9, 2001, and became effective May 9, 2001.

- **Citations and Fines (1775 et seq.)** – which broadens the board's ability to cite and fine for violations of pharmacy law, was approved by the Office of Administrative Law on June 22, 2001, and became effective July 22, 2001.

- **Self-Assessment (1715)** – which updates the board's self-assessment forms for community and in-patient pharmacies and changes from March to July of every odd-numbered year as the time for the required biennial assessment (unless there is a change in the pharmacist-in-charge), was approved by the Office of Administrative Law on August 23, 2001, and became effective September 23, 2001.

- **Preprinted, Multiple Check-off Prescription Blanks (1717.3)** – Which permits pharmacies to dispense more than one drug prescribed from a preprinted prescription form if designated by the prescriber, was approved by the Office of Administrative Law on August 1, 2001, and became effective August 31, 2001.

Pending Regulations

- **Quality Assurance Programs (1711) –** which establishes specifications for quality assurance programs for pharmacies to evaluate, study and prevent medication errors, completed its final 15-day comment period on August 22, 2001. The comments submitted question the board's authority to adopt the regulation or essentially restate

comments on the regulation considered by the board during the July 2001 Board Meeting when the board adopted the regulation with modifications that were noticed in August. As such and consistent with board direction, the board's staff will compile the rulemaking file for submission to the Department of Consumer Affairs and the Office of Administrative Law.

- **Patient Privacy and Internet Dispensing (1777 et seq.) –** which will permit the board to issue citations and fines authority as granted to the board by the provisions of Senate Bill 19 (Chapter 526, Statutes of 1999) and Senate Bill 1828 (Chapter 681, Statutes of 200). This regulation was the subject of an informational hearing at the July 2001 Board Meeting. The notice of proposed action was published on September 14, 2001, and the 45-day comment period closes on October 29, 2001.

Other Proposed Regulations on the Board's Calendar for 2001:

- **Section 1706.3 – Privacy of Financial Records -- this proposed regulation will specify that financial records submitted to the board as part of a site license application are confidential, and cannot be subpoenaed.

- **Section 1707.2 – Notice to Consumers --** this proposed regulation would substantially revise the "notice to consumers" that must be displayed in pharmacies so that the notice contains improved consumer information.

- **Sections 1717.4 and 1717.2 – Electronic Prescriptions and Electronic Records --** this regulation will make changes needed to conform board regulations conform with Assembly Bill 2240 (Statutes of 2000) to require that pharmacists confirm the authenticity of any electronic prescription in which there is any uncertainty or ambiguity, and repeal section 1717.2. (The notice to consumers required by this section has been superseded by amendments to California law that substantially strengthened privacy protections).

- **Section 1720.4 – Foreign Graduates --** this regulation will specify a procedure for foreign graduates who cannot obtain verifiable transcripts to become eligible to take the pharmacist license exam.

- **Sections 1793.7 and 1793.8 – Technician Checking Technician --** this regulation will permit technicians to check the work of other technicians filling unit dose medication cassettes in hospitals.

- **"Section 100" Changes --** this submission will make technical corrections to existing regulations that have been made obsolete (or conflict with) recent legislation. For example, consistent with Assembly Bill 1496, corrections are needed to repeal sections dealing with medical device retailers (which since July 1, 2001, the board no

- longer regulates). There are a number of other technical (and non-substantive) changes that are needed to board regulations.

President Litsey provided the opportunity for public comments on the regulation report. There were no comments. He added that later in the day's meeting, the Legislation and Regulation Committee would hold a public meeting where additional comments may be provided.

Legislation Report

- **Board Sponsored**

AB 802 (Salinas)
Chairperson Zinder stated that this bill permits clinics licensed by the board to use automated dispensing devices controlled by a pharmacist. This bill was chaptered.

AB 826 (Cohn)

This bill permits pharmacists to provide consulting services in unlicensed care settings. This bill also permits pharmacists to initiate prescriptions under protocol in outpatient settings. This bill was chaptered.

SB 293 (Torlakson)

This bill requires pharmacies engaging in sterile compounding to obtain an additional license from the board. This bill requires that sterile compounding be performed in a manner consistent with guidelines adopted by the board. Exempts pharmacies licensed either by the board or by the Department of Health Services and accredited by the Joint Commission on the Accreditation of Health Care Organizations from the licensing requirement in this bill. This bill was chaptered.

SB 340 (Speier)

This bill permits non-profit clinics to contract with pharmacies to distribute drugs purchased in the 340B drug discount program. The bill also contains a provision permitting pharmacists to make dosage form changes that is not sponsored by the board. This bill was chaptered.

SB 724 (Business and Professions) – Omnibus Bill

This bill contains numerous technical corrections to the pharmacy law including clarifying provisions for manufacturers, the retired pharmacist license provisions and and amendments to the provision of when temporary permits can be issued. This bill was chaptered.

Other Legislation

AB 108 (Strom-Martin)

This bill permits pharmacists not licensed in California to practice in pharmacies located on Indian land. The bill was amended on August 23, 2001 to remove its prior provisions and now contains language adopting the NAPLEX in California and providing for license transfer consistent with the board position adopted at the July 25, 2001 meeting. The board supports the bill as amended August 23. This bill is a two-year bill that is pending.

AB 207 (Mathews)

This bill requires standard drug benefit information to be on any health insurance identification card. The board has a support position on this bill. This bill was chaptered.

AB 225 (Washington)

This bill expands unprofessional conduct by a pharmacist to include dispensing psychotropic medication to a minor who is a ward of the court without a court order. The board has an oppose unless amended position on this bill. The bill is a two-year bill and is pending until 2002.

AB 258 (La Suer)

This bill conforms California's controlled substance schedules with recent federal action on GHB. The board supported this bill, which was signed by the Governor.

AB 394 (Maddox)

This bill would have increased penalties for backroom clinic offenses to being prosecuted either as a felony or a misdemeanor. The board
The board supported this bill, which is dead.

AB 536 (Bates)

This bill increases the ratio of pharmacy technicians to pharmacists in community pharmacies under specific circumstances. The board supported this bill, which has signed by Governor Davis and will take effect January 1, 2002.

AB 559 (Wiggins)

This bill permits schools to purchase epinephrine auto-injectors for administration by school staff. The board supported this bill that was signed by Governor Davis.

AB 586 – (Nation)

This bill clarifies existing law relating to pharmacists performing clinical laboratory tests. The board supported position this bill that was signed by Governor Davis and will take effect January 1, 2002.

AB 1292 (Aroner)

This bill would require hypodermic needles and syringes to be purchased only from a pharmacist, and would eliminate the prescription requirement for hypodermics. The board supports this bill, which is a two-year bill.

AB 1589 (Simitian)

This bill requires the Medical Board, in consultation with the Board of Pharmacy, to study how to increase the use of electronic prescriptions.
The board supported this bill, which was signed by the Governor.

AB 1622 (Cardenas)

This bill was amended late in the session to prohibit the board from adopting a regulation permitting technician-checking technician. The board has no position on this bill, which is a two-year bill.

SB 119 (Haynes)

This bill would require pharmacists to report all prescriptions of psychotropic medications to minors to the board. The board opposed this bill, which is a two-year bill.

SB 633 (Sher)

This bill requires all retail outlets (including licensed pharmacies) selling mercury fever thermometers to obtain a hypodermic needle and syringe license. The board opposed this bill unless it was amended. Governor Davis signed this bill.

SB 696 (Speier)

This bill establishes a subsidized drug purchase program for seniors.
The board has an oppose unless amended position on this bill. This bill was chaptered.

SB 1000 (Johannessen)

This bill would have modified the CURES (Controlled Substances Utilization Review and Evaluation) program. This bill would have provided General Fund support to pay for CURES and permitted prescribers and pharmacists to obtain CURES data regarding their patients. The board supported this bill.

Mr. Riches stated that the Governor's veto message focused on the program evaluation for CURES that required the Department of Justice to go through a program analysis. The Governor's veto message concludes that there is already review required as part of the annual reports to the Legislature. The board has a support position on this bill. The Governor vetoed this bill.

SB 1169 (Alpert)

This bill permits pharmacists to dispense emergency contraceptive drugs to patients under protocol and requires the board to develop a patient education brochure. The board supported this bill, which was chaptered and will take effect January 1, 2002.

Bills for Consideration in the 2002 Legislative Session

NAPLEX – Mr. Riches stated that Assemblywoman Virginia Strom-Martin amended AB 108 consistent with the board's position on adopting NAPLEX established at the July 25, 2001, Board Meeting. Assemblywoman Strom-Martin's office has indicated a strong desire to move such legislation forward in 2002.

The NAPLEX proposal has been submitted to the Department of Consumer Affairs for consideration as part of the department's legislative program for 2002. The department has urged the board to consider adopting the national exam and has been supportive of the board's efforts in evaluating the NAPLEX.

Omnibus Provision – Staff of the Department of Health Services (DHS) requested that the DHS receive authorization to administer the exemptee program for manufacturers. The board currently administers the exemptee program for manufacturers licensed by the Food and Drug Administration or the DHS.

- **Report on the Meeting of September 20, 2001**

Chairperson Zinder reported on the teleconference meeting held on September 20, 2001. She added that the focus of the meeting was the public information hearing on pending board regulations that will be heard as the next agenda item. The pending regulations include proposed requirements involving privacy of financial records, common electronic pharmacy records, foreign graduates, partial filling of Schedule II prescriptions, distinction of a wholesaler from a pharmacy, and technicians-checking-technicians.

President Litsey stated that the board sponsored five legislative proposals this year, and that all were signed. He commended staff for this effort, and noted that this represents a significant achievement. He additionally commended Paul Riches on his efforts.

John Cronin, representing the California Pharmacists Association, also acknowledged the significant legislative achievement made by the board. He added that it would be helpful for board inspectors to make themselves available to interpret the new laws and determine how they will effect pharmacists.

Theresa Miller, representing the California Society of Health System Pharmacists, also acknowledged the board's efforts and stated that the bill information is available on the CSHP website for review. She added that she looks forward to working with the board and asked if the board plans to discuss new regulations regarding technician ratios in diverse practice settings, specifically skilled nursing facilities.

Ms. Harris responded that the board has had the authority to establish ratios within the inpatient setting for pharmacies that service skilled nursing facilities and the board set the regulation for a 1 to 2 ratio.

President Litsey adjourned the public board meeting at 1:15 p.m.

PUBLIC MEETING OF THE LEGISLATION AND REGULATION COMMITTEE

President Litsey (Chairperson of the Legislation and Regulation Committee) called the meeting to order at 1:30 p.m., noting that copies of the proposed regulations were available in the meeting room.

Rulemaking Proposals

- Section 1706.3 – Privacy of Financial Records

  President Litsey stated that this regulation is required to assure the privacy of financial records that are provided as a portion of a license application. He added that this regulation is being sought on the advice of counsel. The board previously approved pursuing this regulation as part of the rulemaking calendar for 2001. President Litsey asked if there were public comments. There were none.

- Section 1717.2 – Common Electronic Records

  President Litsey stated that this regulation needs amendment because it is no longer consistent with the law governing the disclosure of confidential medical information. The board previously approved pursuing this regulation as part of the rulemaking calendar for 2001.

Steve Gray, representing Kaiser Permanente, stated that when this regulation was initially adopted, few people understand how common electronic files would work. He added that some patients do not want their records to be accessible to staff from other pharmacies even within the same chain in efforts to hide their drug use. For example, Kaiser found that there was a disproportionate number of patients who were getting triplicate prescriptions and who would opt out of this practice. This meant that the pharmacist and sometimes the prescriber would not have the information available to determine if a patient was inappropriately seeking drugs.

Mr. Gray recommended that the regulation be repealed because there is privacy protection in California already in the Civil Code's Medical Confidentiality Information Act and under the federal HIPAA regulations.

- Section 1720.1 - Foreign Graduates

  President Litsey stated that this regulation is being sought to clarify the process for certifying the college equivalence of foreign graduates. The board previously approved pursuing this regulation as part of the rulemaking calendar for 2001. President Litsey asked if there were any comments regarding this regulation. There were none.

- Section 1745 – Partial Filling of Schedule II Prescriptions

  President Litsey stated that this regulation will make the partial fill regulation consistent with recent statutory changes to Schedule II prescription requirements. President Litsey asked if there were comments to this proposed amendment. There were none.

- Adopt Section 1784 – Definition of Wholesaling

  President Litsey stated that this regulation would establish a definition of when a pharmacy is wholesaling drugs and thus must be licensed as a wholesaler. John Cronin, representing the California Pharmacists Association, stated that there is a definition of wholesaling in the Prescription Drug Marketing Act and he asked why this regulation, which is inconsistent with the PDMA, is necessary in California. He added that the PDMA, in dealing with wholesaling, is much more detailed and exempts a lot of activity.

  Mr. Riches stated that there have been cases when the board has encountered secondary sourcing for gray market drugs and judges have not been willing to move forward with an accusation against a respondent based on the provisions in federal guidelines without specific state requirements.

  Ms. Harris stated that an enforcement problem that the board encounters is when a pharmacy owns a wholesale facility. The pharmacy purchases its drug inventory

at preferential prices and then transfers the drugs to its wholesale facility. The pharmacy obtains these drugs at special prices for dispensing to patients in skilled nursing facilities. But this does not occur. The pharmacy does not maintain records of the transfers which exceeds hundreds of thousands dollars worth of drugs. The wholesaler then wholesales these drugs to other pharmacies at a substantial profit.

Steve Gray, representing Kaiser Permanente, stated that Kaiser is concerned about how the definition would impact federal law. He added that the problem is that the DEA regulations for wholesalers are dramatically different than for pharmacies. Every pharmacy that is considered a wholesaler and a pharmacy would have to keep the Schedule IIs items in a vault. He suggested that this definition be modified to make it clear that the board has no intent of changing the status of the pharmacy as it applies to the Federal Control Substance Act or the DEA regulation. He asked why current law does not satisfy the need for accountability of drugs as discussed earlier. Further, as far as the tracking of drugs that are purchased at preferential prices, there are already statutes that deal with that as a violation of statute. He expressed concern that this would add a level of complexity that is not necessary.

- Technician Checking Technician – Proposed Regulation Section 1793.8

  President Elsner stated that in May 1998, the board granted a waiver pursuant to board regulations to the University of California School of Pharmacy in conjunction with Long Beach Memorial Medical Center and Cedars-Sinai Medical Center to permit a study of technicians to check technicians for unit-dose medication cassette distribution system in the inpatient setting. The waiver was initially granted until November 1, 2000, and has been extended until September 1, 2002.

  The study includes a baseline check for accuracy of pharmacists and an accuracy study with the technicians who were involved in the study following their certification as having successfully completed didactic and practical training. To become a certified technician"checker," a technician had to have an overall accuracy rate of at least 99.8 percent.

  At the board's January 2001 meeting, a report on the pilot project was provided to the board. Forty-one technicians participated in the study with 39 completing all of the certification training required to become certified technician checkers. The combined institution (total) average accuracy for pharmacist checkers was 99.52 percent. In comparison, the combined-institution average accuracy for technician checkers was 99.88 percent.

  As a result, the board voted at the January meeting to proceed with legislation or a regulation change to allow technicians to check technicians in inpatient settings if

there is a quality assurance program in place, certification, audit review, and ongoing checking.

In late August 2001, the board published a notice for an informational hearing on a tech-check-tech regulation at its October 2001 board meeting. Subsequent to that notice, the California Pharmacists Association and the United Food and Commercial Workers sponsored legislation (AB 1622) to prohibit the board from adopting a tech check tech regulation. That legislation is currently pending on the Senate floor.

Support:

President Litsey asked those who wished to testify in support to begin.

Peter Ambrose, University of California, San Francisco, School of Pharmacy, provided the board with basic background information on the tech-check-tech study.

Mr. Ambrose stated that the basis for the experimental study was to evaluate the accuracy range of having trained registered pharmacy technicians fill unit dose medication cassettes and compare their accuracy rates with licensed pharmacists.

Mr. Ambrose stated that the study began in 1998 over a two-year span. He added that the study was submitted to the board in January 2001.

Mr. Ambrose stated that the study included 29 pharmacists and 41 technicians. He added that all of the technicians met the 99.8 percent accuracy rate to become certified.

Ms. Strom asked Mr. Ambrose if they continue to collect data.

Mr. Ambrose stated that they continue to do periodic audits of the technicians.

Frank Saya, president of the California Society of Health Systems Pharmacists and manager of inpatient pharmacy services at Cedars-Sinai Medical Center, added that the board has supported this policy twice and has approved and supported the policy of supporting technicians checking technicians in the inpatient setting for unit does purposes for card fill. He added that he fully supports the proposed language of the regulation.

Rita Shane, Director of Pharmacy Services, Cedars-Sinai Medical Center, stated that this regulation is critical for patient care.

Ms. Shane stated that the scientific study was conducted using an ongoing quality assurance program and it was their intent that it would be a critical and essential component of any program that wished to adopt technicians checking technicians.

Ms. Shane referred to the Institute of Medicine's report of November 1999 demonstrating the increased concern about medication safety, particularly in health systems.

Ms. Shane expressed concern for the current need for patient safety in hospitals. She added that patient populations and medications require the ongoing ability of pharmacists to be within patient care areas, evaluating orders, being a resource to the nurses and physicians, managing drug therapies upon request and preventing prescribing errors. She added that pharmacists are the safety net for medical staff and nursing staff dependent on the medication use process. She added that if pharmacists have to perform non-discretionary tasks, they would not be able to take care of patients.

She added that in the hospital setting, factors that complicate the medicine use process include: an increase of very highly technological drugs that sometimes require significant monitoring, patient populations that are critically ill, and most recently with drugs that are removed from the market by the FDA as a result of toxicity. She added that these situations occur in outpatient settings but more frequently in inpatient settings because of the number of medications patients receive. Complicating patient care this factor is the nursing shortage and the pharmacist shortage in hospitals, which is at 21 percent nationally as reported by the American Hospital Association. In the retail sector, the same report cites a 6 percent vacancy rate in pharmacists nationally.

Ms. Shane added that there are significant drug shortages that prompt many calls for support of alternative therapies for patients. Also, the hospitals see ongoing increases in requests for management of therapies by pharmacists from physicians.

Mr. Goldenberg asked about the involvement with the pharmacist within the quality assurance program.

Ms. Shane explained that the pharmacist is involved in the quality assurance program and an ongoing audit is performed.

Ms. Strom referred to quality assurance when a technician checking a technician finds an error and a correction needs to be made. She asked who checks the technicians. Ms. Shane responded that the pharmacist checks the technician.

Steve Gray, Kaiser Permanente, asked about the ability to recruit technicians and pharmacists in terms of quality, quantity and job satisfaction.

Ms. Shane responded that the pharmacists and technicians enjoy having a

diversity of roles and responsibilities. She added that for pharmacists, it provides an opportunity to use skills developed through training to support the medication use process and manage drug therapy under protocol through the medical staff and being requested by physicians to do something they take great pride in.

Bruce Young, California Retailers Association, asked how the responsibilities of a hospital pharmacist differ from a community pharmacist. He added that in the community pharmacy, it is inconceivable for a technician to check a technician.

Ms. Shane responded that hospital pharmacists have responsibilities for assuring that all drug orders are appropriate in the context of the patient. She added that pharmacists have access to all of the medical information including progress notes, lab results, etc. She added that hospitalized patients generally have more drug orders and if used incorrectly or if dosed incorrectly, could result in immediate patient harm. Further, the number of medications available to hospital patients is far more than in the outpatient setting. There is also a host of medications given to hospital patients that require very careful dosing administration and monitoring these drugs do not exist in the outpatient setting, including drugs issued in the ICUs and drugs that are only available in parenteral form that require extensive monitoring.

Ms. Shane noted that the specific tasks that the technicians perform occur only after the pharmacist has verified the order. Ms. Shane stated that they have scientific data over the course of a couple of years that demonstrate the safety of their practice and they have evidence about clinical pharmacy services and its impact on patient care.

Ms. Shane noted that this type of practice only occurs for non-discretionary tasks with evidence demonstrating a superior outcome with ongoing quality assurance to ensure the safety of medications in the hospital setting.

John Cronin, representing CPhA, referred to the chart provided by Cedars-Sinai Medical Center titled Potential Adverse Drug Events Prevented by Pharmacist Intervention and asked for clarification.

Ms. Shane responded that at the July 2001 board meeting, Cedars-Sinai Medical Center presented data that reflected how pharmacists used the extra time freed up by ancillary staff. She added that there are two major areas that they are involved in. One is responding to requests for assistance by physicians that need support in dosing therapies or need support. The other is preventing adverse events that are due to prescribing errors. The Institute of Medicine Report and it states that there are two preventable adverse drug events per 100 admissions that due predominantly to prescribing errors.

Larry Lovett, Long Beach Memorial, stated that he is a community pharmacist

and as such he is the last line of defense for patients and the last line of defense in the hospital is the nurse. So the best efforts of the pharmacist in the hospital setting is spent making sure the patient has the right kind of medicine ordered and the right kind of dose. He added that in the hospital setting, you cannot have a pharmacist on each floor dispensing medications.

Sandy Tan, Pharmacy Manager overseeing the Technician Program at Cedars-Sinai Medical Center, commented on the unit dose medication dispensing process at Cedars-Sianai Medical Center.

Ms. Tan explained that the pharmacist receives an order written by a physician, he or she will do the necessary review of every order that is received and check for allergies, drug/drug interactions, necessary dose adjustment and check with the lab to see if the appropriate order is written. If an order needs to be changed, the pharmacist will contact the physician and make sure the order is changed with the physician's approval. After the pharmacist has reviewed and approved the order, he or she will then verify the order in the pharmacy computer system and fill a 24-hour supply of medications with the new order for the patient. Once each night, a fill list will be generated that provides a list of all the medications that have been reviewed, approved and verified by a pharmacist. The fill list has the drug needed, the dosage form and necessary information.

Ms. Tan added that with this information, the technician will fill a 24-hour supply of unit dose. Each unit dose will have appropriate labeling, expiration date, drug number and lot number. This will be placed in the patient's specific cassette with the room number and patient name. The technician that is certified to check doses will use the same fill list and make sure the dose that is filled is appropriate in terms of quantity, the actual drug and dosage and make sure that it was put in the right cassette for the right patient. The medication cassettes are delivered to the nursing stations and exchanged from the previous day and replaced with the new cassette to be used for the next 24 hours. The nurse will pick-up the dose medication and verify that the drug matches what is printed on the "MER."

Mr. Goldenberg asked Ms. Tan to describe how the systems can be assured of a more continuous quality improvement that occurs more frequently than quarterly.

Ms. Tan responded that all certified technicians have to be audited monthly for the first three months and meet the 99.8 percent accuracy rate. After three consecutive months of accuracy, they can be certified quarterly. She added that at the same time, they have ongoing programs in the department, quality assurance programs and filler audits.

Mr. Goldenberg stated that he wants to focus more on the quality assurance of the technicians actually filling the daily cassettes. He asked what assurance is there in place, beyond tech-check-tech, that the system is working.

Ms. Tan responded that a filler audit is performed on a quarterly rotation bases by the pharmacist who checks the filler for accuracy.

Mr. Goldenberg asked if there was additional participation by the pharmacist to oversee the systems and possibly challenge them to insure that a shorter time frame exists other than monthly or quarterly. He stated that he felt that the expectation, not only from the consumer but possibly the nurses is that pharmacies do not make mistakes. He added that he understands that there is a tremendous amount of benefit for the consumer due to pharmacist involvement in clinical areas, but that routine systems should be established that would shorten the time frame of errors or problems within a system.

Ms. Shane stated that the Board of Pharmacy did approve their quality assurance process based on results from other states in the country that had been through a year's worth of monthly audits.

Mr. Ambrose stated that before technicians become certified, they are audited everyday for 3,500 consecutive doses. If they do not pass with a 99.8 percent accuracy, they will not become certified. He added that the unit dose packet is already labeled and so all the technician is doing is reading and not labeling. He added that in a community pharmacy, you are assuring that the medication is what is in the bottle. The technician reads what is needed and places that medication in.

Mr. Goldenberg stated that there is concern that tech-check-tech in the inpatient environment may lead to tech-check-tech in other environments. He expressed the need for the pharmacist to be responsible for the system of dispensing without physically being involved in the system of dispensing so the pharmacist's time can be spent in more critical issues that he or she is trained for.

Ms. Tan responded that the focus of the study is strictly in the inpatient setting. She added that they do not circumvent the pharmacist intervention in this process and the pharmacist is very much involved. All orders are reviewed by a pharmacist before they are approved.

Mr. Ambrose stated that there are three other states that allow this procedure in the inpatient setting. He added that he is not aware of problems associated with this in the other states.

Bruce Young asked if this would be applicable to all hospitals?

Theresa Miller, representing the California Society of Health Systems Pharmacists, responded that the regulation requires that any hospital inpatient facility that is doing tech-check-tech to have a clinical pharmacy program in place

and that the program operates under the direct supervision of the pharmacist.

Ms. Shane responded that the tech-check-tech process does not involve initial orders; a pharmacist checks all initial orders. This only refers to initial orders after they have been checked by the pharmacist for the next day. She added that the pharmacist gets the order, evaluates the order is appropriateness, intervenes if necessary and makes sure that the initial dose is correct.

Ms. Harris stated that you can only have technicians on duty when a pharmacist in on duty.

Doug Douglas, staff inpatient clinical pharmacist at Cedars-Sinai stated that his first duty in the morning is to review those orders that were written the night before. He also reviews the lab computer for those patients that he is monitoring for the day. Further, physicians will also call during the day to ask for input on various drug dosing. He reviews medication orders and evaluates them for the patient's age, renal function and makes dose adjustments based on these and other factors. Mr. Douglas added that if he had to take an hour out of the day to check cassettes, it would compromise patient care. He added that some of the medications are so critical that if you do not intervene on the lab results as soon as they are available, serious consequences could occur to the patient. He added that the tech-check-tech program would benefit the patient. He added that there are many new medications that physicians are not aware of, and these physicians constantly call for information regarding how to dose the medication, the appropriate use of the drug or if there are alternatives.

Mr. Douglas expressed the need for tech-check-tech especially during a pharmacist shortage and the difficulty in hiring enough pharmacists. It would place a burden on pharmacists to have to check the cassettes. He referred to the board's publication *Health Notes* and the possible cognitive functions that a pharmacist can do but without the time to do these functions, it is very frustrating on the front line. He encouraged the board to continue this program.

Steve Thompson, Director of Pharmacy at Torrance Memorial Medical Center, stated that his facility did not have the opportunity to participate in the study and the timesavings for the pharmacist would benefit their hospital as well as the patients.

Teri Miller, representing the California Society of Health System Pharmacists (CSHP), stated that the CSHP has supported the tech-check-tech program for eight years. She reiterated that the proposed regulations are specific to the inpatient setting for the filling of unit dose carts and ward stock only. She added that that this is not in the community practice setting and it is not outpatient pharmacy. The regulations proposed by the board specifically state that compounded or repackaged products must first be checked by a pharmacist. It

also requires that any institution inpatient facility that want to use tech-check-tech to have a clinical pharmacy program in place. The intent is clearly to improve patient care. Also, the board has built in another safeguard that requires technicians participating in the program to have passed a national technician certification board exam. This is a nationally accepted exam that is designed to measure the level of competency of technicians.

Ms. Miller stated that the tech-check-tech program must be within the supervision of the pharmacist and must have quality assurance perimeters built into it that requires that the technicians involved in the program receive training, they are audited and they perform ongoing evaluation of the program. She added that this is clearly designed to improve patient care.

Ms. Miller noted that the Manpower Task Force members voted last week to support the board's proposed regulation. She added that the Manpower Task Force represented 15 different pharmacy organizations in the state. Ms. Miller added that SB 1622 was recently amended to preclude the board from adopting rules and regulations to allow technicians to dispense a drug without a pharmacist checking and reviewing the drug.

Ms. Miller urged the board to support and move forward with the regulations.

Gail Askew, Department Chair for the Pharmacy Technology Program at Santa Ana College and a practicing pharmacist with both hospital and retail experience, stated that the technicians who have been through a formal training program are learning to do drug distribution in an inpatient setting with a unit dose cassette type of system. She added that a lot of quality assurance testing is also included. She added that there are many safeguards in place that would allow the tech-check-tech regulation as it is written to be very successful.

Oppose:

Board Member Andrea Zinder stated that there is legislation pending that will determine if it is appropriate for the board to move forward with this regulation or whether this proposal should move forward only in the legislative process. She added that because this is pending legislation, she felt in was not appropriate for the board to consider this issue at this time. She suggested that the board wait until the legislation has gone through the process.

Ms. Zinder commended Cedars-Sinai for the program that they had in place during the experimental period. She expressed concern that the board may not be able to monitor the kind of quality assurance that was in place during the experimental period in other practices.

Mr. Elsner stated he disagreed with the premise that the board should not move

forward with a regulation because of pending legislation.

Mr. Ambrose stated that institutions have quality assurance programs already in place so the tech-check-tech quality assurance program would not add a great burden.

Shane Gusman, representing the United Food and Commercial Workers, stated that they are opposed to the regulation and have the same concerns mentioned by Ms. Zinder. He commented that any board has limitations in its authority that is specifically spelled out in statute. One is that the regulation or proposed rule cannot be inconsistent with state law. The other law is that the regulation or rule must be necessary to protect the public. He did not feel that it was beneficial to consumers to move forward with this proposal.

Mr. Gusman stated that there are several sections in the Business and Professions Code that deal with pharmacy technicians and this proposal would be inconsistent with those statutes. He added that section 4115 (a)(b) dealing with non-discretionary tasks performed by the pharmacy technician states that the task must be performed under the direct supervision and control of the pharmacist. He added that the proposed regulation conflicts with the law.

Mr. Gusman added that this was reaffirmed in 1999. The same section was amended to add breaks and meals for pharmacists and for the temporary absence of the pharmacist. He added that the Legislature made it clear in several sections that the pharmacist must remain in supervision of the pharmacy technicians. He added that within section 4115 there is an exemption for some activities within the inpatient setting, however, the exemption does not apply to subsections (a) and (b).

Mr. Gusman stated that there are also a number of other sections that make the pharmacist responsible for what occurs in the pharmacy. If there is a mistake made, it is the pharmacist's responsibility.

Mr. Gusman added that when notice was received that the board was going forward with regulation, several interested parities approached the Legislature with concern that the board was exceeding its authority. Mr. Gusman added that this is the reason why the bill was introduced. He added that during a policy hearing in the Senate Business and Professions Committee, the bill was passed on a bipartisan basis and it is now on the Senate floor.

Ms. Shane stated that Cedars-Sinai presented evidence demonstrating that technicians checking technicians are significantly better at accuracy than pharmacists. Moreover, it permits pharmacists to perform other duties that ensure medication safety in inpatient settings for a number of reasons.

Mr. Goldenberg stated that the concern is for consumer safety and it appears that tech-check-tech will free up pharmacists in a setting other than retail to perform functions that will ultimately benefit the consumer.

Mr. Gusman stated that the board does not have the authority to move forward with this particular regulation but the board could introduce a board-sponsored bill in the Legislature in January to authorize tech-check-tech.

Ms. Miller asked what position the USCW has on the proposed regulation.

Mr. Gusman responded that they have an oppose position on the regulation.

Mr. Jones asked about the legality of the proposed regulation.

Ms. Harris responded that this issue was raised many times before, especially in 1995. If the Office of Administrative Law does not approve the regulation, the only recourse would be for the board to seek legislation.

Ron Diedrich, Attorney General liaison counsel for the board, added that the board cannot pass a regulation in excess of its statutory authority. However, the Office of Administrative Law ultimately makes the decision. He added that in any event, the board has to make its own decision as to what its policy should be regarding tech-check-tech.

Mr. Gusman stated that there is concern that the tech-check-tech issue would expand to the community setting. He added that another issue is how this would work in a different type of hospital setting.

Mr. Cronin referred to former Deputy Attorney General William Marcus' opinion that the board does not have the authority to do this.

Mr. Diedrich stated that there has not been a formal Attorney General's opinion on this issue. He noted that a deputy attorney general's comment is not considered an official opinion issued by the Office of Attorney General.

Mr. Cronin stated that in 1995, the board considered this issue by way of regulation. He added that on behalf of the CPhA, he had drafted comments for the board. He added that the questions that were raised at that time still remain unanswered. He commended those who testified on behalf of the regulation and he encouraged them to bring their comments to the Legislature.

Mr. Cronin stated that another issue is the need for statutory change regarding liability. He referred to the error count by technicians in the Cedars Sinai study, and noted that they may have made 106 errors.

Ms. Shane stated that based on performance statistics, technicians would introduce 106 errors, however due to the lower accuracy of pharmacists on the same number of doses, the pharmacists would have introduced 512 errors. She added that the pharmacists who have been involved in this project and the pharmacists that she represents in her department are willing to take the responsibility for overseeing technicians checking technicians. She added that this study was initiated based on a waiver approved by the board with the UCSF School of Pharmacy because the pharmacists were supportive of the ability to use technicians for non-discretionary tasks in order to protect patients.

Ms. Shane stated that the other liability issues that the hospital experiences represent a lot more direct potential harm to patients than the liability associated with this particular regulatory issue.

Ms. Shane added that the current environment is such that without this regulation, it will cripple the ability of Long Beach Memorial, Cedars Sinai as well as other hospitals to ensure the safety of the medications being prescribed for patients.

Mr. Goldenberg made recommendation to seek a regulation and legislation to address all of the concerns.

Richard Hall, representing Consumer Federation of California (CFC), stated that the CFC is a coalition that consisting of consumer groups, senior citizens and family advocates, labor organization and environmental organizations. Mr. Hall added that this proposed regulation exceeds the board's authority because pharmacy technicians cannot supervise pharmacy technicians in dispensing medications and filling prescriptions.

Mr. Hall referred to the study and asked where it was published and what kind of peer review resulted. He added that the study appears to include a small sample of participants and that it was conducted under extremely rigorous conditions that are not found in the proposed regulations.

Mr. Hall referred to the pharmacist shortage issue and he expressed concern that this is an example of employers attempting to "de-skill" their workforce with the motivation in hearings such as this is patient protection.

Mr. Hall stated that legislation is the way to address the issue.

Mr. Ambrose responded that Cedars Sinai has submitted a manuscript for publication and it is undergoing peer review now. He noted that the study mimics other published studies regarding the rate of accuracy used and the study design. He added that they also submitted a study methology to the Board of Pharmacy in May 1998 and it was reviewed and approved. He added that in response to the comment regarding the small sampling used in the study, several hundred

thousand doses have been evaluated in two different major medical centers.

Mr. Hall clarified that the regulation states that a pharmacy technician may perform packaging, manipulative repetitive or other non-discretionary tasks only while assisting and only under the direct supervision of the pharmacist.

Bruce Young, representing the California Retailers Association, stated that if the board allows this regulation to go forward, the CRA would move forward in the Legislature to give the same considerations to community pharmacists.

Mr. Young stated that the issue of technicians checking technicians is discretionary and the board should have licensure and standards commensurate with these duties. He added that it is unfair for a pharmacist to have his or her license in jeopardy to be responsible for the duties performed by technicians.

Mr. Young stated that the CRA believes that the process already in place is appropriate, and that the pharmacist should be the start and the end of all prescriptions and should not delegate this to non-licensed personnel.

LEGISLATION AND REGULATION COMMITTEE – Continued

Legislation Report and Action

- Bills for Consideration in the 2002 Legislative Session

  NAPLEX – Adopt the North American Pharmacists Licensure Examination as the board's licensing examination and require the passage of a California State Jurisprudence Examination for pharmacist licensure. And an implementation of license transfer provision for pharmacists.

  President Litsey asked if there were any comments. There were none.

- Public Requests for Legislative and Regulatory Changes

  President Litsey asked if anyone would like to testify.

  Steve Gray, representing Kaiser Permanente, commended the board and staff on all of the legislative accomplishments made during the year. He suggested that there be a general clean-up of the law. He referred to references between the Business and Professions Code and the Health and Safety Code that are inconsistent and he suggested that the Legislative Committee and the board go through these carefully. He referred to section 4180 of the Business and Professions Code, and stated that this section refers to a Health and Safety Code section that does not exist. He stated that other sections refer to the illegality of people to possess controlled substances, unless prescribed by a physician, dentist

or vet. He added that this section excludes other individuals who are now authorized to write prescriptions for controlled substances.

Ms. Herold requested that Mr. Gray submit a written request to the board, outlining Kaiser's specific concerns.

ADJOURNMENT

President Litsey adjourned the public meeting of the Legislation and Regulation Committee at 4:45 p.m.

October 16, 2001

CLOSED SESSION

The board moved into Closed Session at 8:00 a.m. pursuant to Governor Code Section 11126(c)(3) to deliberate upon disciplinary cases. The board will also confer with Legal Counsel pursuant to Government Code Section 11126(e) regarding the following pending litigation: Gonzalez v Board of Pharmacy, Sacramento Superior Court Case #99AS01990.

CALL TO ORDER

President Litsey called the board meeting to order at 9:05 a.m. on October 16, 2001.

Committee Reports and Action – Continued

Legislation and Regulation Committee – Continued

- Proposed Regulation section 1793.8 – Technician Checking Technician Action to Determine Whether or Not to Pursue a Regulation Hearing Based on Testimony during the Information Hearing

  President Litsey stated that the board needs to determine whether to proceed with a regulation based on the testimony heard yesterday during the public meeting technicians checking technicians.

  Mr. Jones questioned whether the board could accomplish its goals through legislation instead of a regulation.

  Ms. Zinder stated that she believed that legislation was needed.

  The board discussed whether regulations or statutory changes were needed. Ms. Harris stated that general parameters for a regulation would allow a pharmacy technician to check another pharmacy technician filling unit-dose

cassettes in an inpatient hospital pharmacy. She added that if legislation is pursued, the hospital inpatient pharmacy could be required to apply to the board for a special waiver that would be renewed annually. The criteria for the waiver would be specified in legislation and would include: the hospital has a clinical pharmacy program, the "checking" technician has specialized training and is PTCB certified, the pharmacy has an ongoing quality assurance review and the board performs an annual inspection of the pharmacy prior to renewing the waiver.

Mr. Goldenberg recommended that the board seek counsel's opinion on the board's authority to promulgate a regulation allowing technicians to check technicians and to move forward with legislation and regulation. He stated that the legislation also should remove the liability issue for pharmacists working in tech-check-tech environments.

Mr. Powers stated that the board needs to determine if it has the authority to promulgate a regulation.

Ms. Strom encouraged help from the interested groups in achieving a legislative change.

Ms. Harris asked if the liability issue should be a focus of the board.

Mr. Diedrich stated that the board could make a policy decision to focus on liability or determine not to proceed in this area.

Ms. Zinder stated that she opposes board-sponsored legislation for tech-check-tech due to the limited resources of the board. She added that the board's resources should be directed to those areas where the consumers' best interests lay.

Mr. Goldenberg stated that he feels very strongly that this proposal would be in the interests of the consumers.

Ms. Miller stated that that the CSHP board will soon meet and will discuss the possibility of introducing legislation on tech-chech-tech in the hospital setting with specific parameters. She stated that the CSHP would like to work with the Board of Pharmacy's Legislative Committee to draft legislation and to address some of the board's concerns.

MOTION: The board will work with interested parties to achieve introduction of appropriate legislation.

GOLDENBERG/STROM

SUPPORT: 6 OPPOSE: 2

President Litsey asked for additional public comment. There was none.

PUBLIC EDUCATION AND COMMUNICATIONS COMMITTEE

Mr. Powers reported that the Public Education and Communications Committee met on October 3, 2001, via teleconference.

- Publications and Public Outreach Coordinator Position Created

  Mr. Powers stated that within the board's 2001/02 budget is a newly created position to prepare consumer education materials, coordinate public outreach activities and respond to press inquiries. The board has been actively recruiting for this position since late August, and hopes to select the individual by November.

- *Health Notes* "Alternative Medicines" Distributed

  Mr. Powers stated that this issue, developed under contract with UCSF, was published and distributed in July 2001.

- *Health Notes* "Quality Assurance Programs" Under Development

  Mr. Powers stated that since June, the board has been trying to obtain approval to release a request for proposals to develop a *Health Notes* to aid pharmacies in complying with the requirements to establish quality assurance programs for prescription errors. The board expects to complete this process this month and select the contractor by the end of the calendar year. The goal is to develop and publish this issue this fiscal year. The board received a one-time appropriation of $100,000 to develop, publish and distribute this issue.

- *Health Notes* "Geriatrics"

  Mr. Powers reported that UCSF has obtained outside funding to develop this manuscript, which the board will publish and distribute as a *Health Notes*. The publication of this issue is likely to occur next fiscal year.

- "Notice to Consumers" Poster

  Mr. Powers reported that the board is awaiting a signed contract with a graphic artist to develop three draft versions of a new "Notice to Consumers" poster. In April, the board directed the committee to finalize a poster when it approved the wording for the poster, the text of which must be adopted by the board as a regulation. By the January 2002 board meeting, the committee should have selected the design and wording for the new poster, and after the January meeting, will release the regulation

for the required 45-day comment period. The poster will include an 800 number for consumers with inquiries to contact the board, and will be translated into several other languages.

- Public Outreach Activities

  Mr. Powers reported that concurrent with the October board meeting is a "Health Aging 2001" conference in Sacramento on October 15 and 16. He added that although the board does not have staff to send to this event, it did send a number of its consumer educational materials. In the future, the board hopes to be able to provide at least one person to attend these major events, a function of the newly created position.

Ms. Strom thanked Mr. Powers for his vigorous efforts in securing the staff position for the public education analyst. She also thanked Mr. Powers for providing a clear voice in the direction of public education that the board so desperately needed.

President Litsey asked for public comment. There was none.

LICENSING COMMITTEE

Chairperson Strom reported on the Licensing Committee meeting held on October 4, 2001, and referred the board to minutes provided in the board packet.

- Proposed Amendment to CCR 1717(e) to Allow the Delivery of Prescriptions to Non-Pharmacy Locations where the Patient is Not Present

  Ms. Strom reported that over the last two years, the board has received many requests from pharmacies to deliver prescription medications to non-pharmacy locations where a patient receives health care; however, the patient is not present at the time of delivery. If the patient is not present, then regulation section 1717(e) permits a waiver if approved by the board to allow the delivery and depoting of the prescriptions until the patient picks them up. The board has been granting these waivers consistently because it makes sense that delivery to the non-pharmacy location where the patient receives health care ensures that the patient receives the needed medication, which then increases patient compliance. Therefore, the Licensing Committee is recommending that the regulation be amended to allow for the delivery to non-pharmacy location where a patient receives health care without requiring that the pharmacy request a separate waiver from the board.

  President Litsey asked if there were any comments from the board.

  Mr. Hiura asked if there had been discussions about where the medications would be stored.

Ms. Strom stated that when the board moves forward with the regulation, the board could specify the details of where the medications would be stored.

John Cronin, representing the California Pharmacists Association, stated that in reading the proposal, he could see a lot of unintended consequences. He asked how burdensome is it to use the current waiver process and whether moving forward with this regulation would be wise.

Ms. Strom stated that at every Licensing Committee meeting, the committee has approximately three waivers to review and this takes time. She added that the same process is required of everyone requests a waiver. Further, this will allow the board to put the requirements for waivers in regulation.

Steve Gray, representing Kaiser Permanente, encouraged the board to move forward with regulation because it would allow the pharmacy to get involved in compounding, and preparing and delivering medication to physicians' office. Mr. Gray stated this would benefit many patients.

Mr. Elsner stated that a simple change in the proposed regulation stating "where the patient receives health services" is unlikely to open the door for abuse. If the board later finds later that the regulation needs to be amended, it can always move forward with an amendment. He added that he supports the committee's recommendation.

MOTION: Licensing Committee: Amend California Code of Regulations section 1717(e) to allow a pharmacy to deliver prescriptions to a non-pharmacy location where the patient receives health care if the patient is not present to receive the prescription at the time of delivery.

SUPPORT: 8 OPPOSE: 0

- Pharmacy Manpower Task Force – A working group to ensure patient access to pharmacists' care and prescription services.

  Chairperson Strom reported that the September 14 meeting of the task force was cancelled due to the terrorist attack on the United States. She added that the task force met on October 10 in Sacramento. Ms. Strom reported that during that meeting, the task force completed review of all of the proposed solutions and voted on all of the items that were presented to the task force. She noted that the conclusion and summary of the results of the task force would be submitted in a report prepared by Lindle Hatton, the task force meeting facilitator. She reported that the final report would be submitted to the board at the January 2002 board meeting.

Ms. Strom reported that she will present the manpower task force report at the January board meeting. She added that it is her intent for the board to use the report. One use will be to integrate this into the board's strategic planning session in April 2002 for those solutions put forward by the task force that the board wishes to pursue and prioritize.

- Status Report on the Use of NAPLEX in California

Chairperson Strom reported that at its July 2001 meeting, the board voted to support the use of the North American Pharmacist Licensure Examination (NAPLEX) and a California Multi-State Jurisprudence Pharmacy Examination (MPJE). This decision was based on an independent audit that concluded that the NAPLEX is a valid measure of competencies essential for entry-level pharmacist practice and that it meets relevant psychometric standards. Legislation is required to implement the use of NAPLEX and MPJE in California.

Ms. Strom reported that since the board meeting, AB 108 was amended to incorporate language to authorize the use of NAPLEX and the MPJE. However, the bill is a two-year bill and if passed, would not become effective until January 2003.

Ms. Strom stated that staff has been working with the National Association of Boards of Pharmacy (NABP) to draft a letter of agreement between California and the NABP regarding the use of the national examination and the development of the California MPJE should legislation be enacted.

Ms. Strom added that the Licensing Committee reviewed the draft agreement and made suggestions. The draft incorporated many of the recommendations from the independent audit. It also includes participation of California representatives from the board's Competency Committee (subject matter experts) on the various NAPLEX review committees that develop the exam.

- Competency Committee Report to the Board Members
  Report on the January 2002 Examination

Chairperson Strom reported that on January 8 and 9, 2002, the board will administer its January 2002 pharmacist licensure examination at the Hyatt Regency San Francisco Airport Hotel.

Ms. Strom stated that grading for this exam will be conducted in Sacramento on a date to be determined by the Competency Committee. Board member graders may be needed and are encouraged for this exam.

Report on the June 2001 Examination

Ms. Strom reported that approximately 1200 candidates took the June 2001 exam. She added that the USC School of Pharmacy had the highest pass rate of 92.6 while the other California schools that were in the mid 70 percentages for their pass rate.

Mr. Elsner asked if lowering the pass rate from 75 to 70 percent has ever been considered. He added that a number of California graduates would have been affected favorably if the pass rate would have been 70 percent.

Ms. Strom stated that the passing score on the exam is determined by the Competency Committee, which evaluates every single question based on whether a minimally competent practitioner would be able to answer the question correctly. She added that the pass rate cannot be lowered arbitrarily, it is a clear issue of knowing the material, as a minimally competent pharmacist.

John Cronin, representing the California Pharmacists Association, stated that the whole issue of NAPLEX and reciprocity is very controversial. Mr. Cronin added that a bill has been introduced but it is not a board-sponsored bill. He added that the CPhA has policy opposing reciprocity. He stated that this legislation would undergo a significant legislative battle. Further, it is important for other entities that are interested in the issue to have very open communications with the board on all matters relating to the exam, particularly the memorandum of understanding with the NABP. He added that the reciprocity issue will be much more controversial.

Ms. Strom stated that the language from the board for AB 108 does not address reciprocity but rather establishes a process to transfer a pharmacist's license to California, yet still will require the California jurisprudence exam.

Ms. Miller stated that the CSHP has policy that the Board of Pharmacy should be the sole entity granting licenses in California. Another related policy is that the CSHP feels that there should be no decrease in the level of competency required of pharmacists who are being licensed in California. She added that her organization has had many discussions about the issue. She added that this is an emotional issue like tech-check-tech, and her organization is split in supporting it. She added that educational efforts are made to advise the organization of the Board of Pharmacy's activity.

Ms. Miller stated that the CSHP is having an open forum in Santa Clara from 3 – 5:00 p.m. and this may be the major topic. She invited President Litsey as well as other board members to discuss the board's position on the NAPLEX.

Ms. Miller requested that the Licensing Committee reconsider the issue of charging pharmacists for the evaluation of continuing education programs that are not ACPE provider approved. She stated that the CSHP's house of delegates actually took action on this issue last year, although a formal request to the board has not been made. She added that many of their members attend medical meetings in order to improve their understanding of different drug therapies that are mainly directed to physicians and specialists in those areas and may not have a large number of pharmacists attending yet many of their members do this routinely. Based on the board's policy, these pharmacists have to pay $40 per hour for an evaluation of the program they attended to increase their knowledge as practitioners to protect patients of California. Sam Shimada, representing Western University of Health Science College of Pharmacy, stated that many of their students are asking about when the board will make the switch to the NAPLEX and he requested that the board give students advance notice about when this will start. He added that he has heard that the new NAPLEX exam will be as difficult as the current California exam.

Ms. Strom responded that legislation must be enacted before there is a timetable. Some adjustments will need to made to the board's incorporation of its current multiple choice item pool because the NAPLEX has a 5-choice multiple choice item pool and the board has a 4-choice item pool. She added that the board would have California representatives that help develop the NABP exam.

ENFORCEMENT COMMITTEE

Chairperson John Jones announced that the Enforcement Committee held a public meeting on September 25, 2001. He thanked those who were present at the public meeting as it proved to be valuable and useful. He added that later in the day the board held a team meeting with board enforcement staff. Minutes for these meetings are in the board packet.

- Proposed Procedures for Implementation of the Cite and Fine and Quality Assurance Regulations

Chairperson Jones reported that the Enforcement Committee developed procedures to implement the cite and fine regulations. These regulations expand the board's authority to cite and fine for any violation of pharmacy law. The board has the authority through its compliance committee (NCC/SCC) to issue a citation and fine. The board's regulations delegates to the executive officer the authority to cite and fine for unlicensed activity, failure by a pharmacist to comply with the continuing education requirements, failure by a pharmacy to file a discontinuance of business form and to board non-pharmacy facilities (wholesalers, hypodermic needle and syringe distributors, clinics and veterinary food-animal retailers).

Mr. Jones stated that the committee also developed procedures for implementing the quality assurance regulation that is expected to be in effect by January 1, 2002. This regulation has a major consumer protection impact.

Mr. Jones stated that the Enforcement Committee discussed the draft procedures during its public meeting held September 25, 2001. Based on the discussion, the committee added an introduction to the procedures that will provide direction to licensees on how the board plans to implement the quality assurance regulation during the first six months.

Ms. Powell referred to the Citation and Fine Quality Assurance Program procedures and suggested several changes.

Board Member John Jones stated that the whole concept of the quality assurance regulations is to establish a blameless environment and to encourage programs to be created and used.

Steve Gray representing Kaiser Permanente, stated that they fully support the concept of the pharmacy quality assurance program.

He referred to paragraph one regarding prescription errors that are discovered because there is a complaint. He stated that this will discourage recording errors.

He suggested a change to paragraph 3 and not to cite and fine for errors found during peer review.

Bob Ratcliff discussed how the inspectors might handle prescription error complaints reported to the board and how they would review and investigate the matters and then review the quality assurance programs.

Ms. Harris explained that when the board first implemented the authority to cite and fine, it only decided to pursue regulations to do this for patient consultation at board member level review.

Mr. Ratcliff added that the inspectors understand the importance of the quality assurance program and that during quality assurance reviews the inspectors are not on a fishing expedition beyond a specific area of a complaint. Although, the inspectors will review whether there is actually an effort being made to comply with the quality assurance review of complaints.

Mr. Jones stated that the public meeting of the Enforcement Committee was held with all of the inspectors present so they would understand the public's concern and for the board members to emphasize that this is an educational effort over the first 6-months. He added that the inspectors were positive.

Mr. Gubbins stated that it was a great meeting and the message was conveyed and will be followed through professionally by the inspectors.

MOTION: Enforcement Committee: Approve the procedures.

SUPPORT: 8 OPPOSE: 0

- Proposed Complaint Disclosure Policy for the Department of Consumer Affairs and the Board of Pharmacy

Mr. Jones stated that for over 15 years, the Board of Pharmacy's complaint disclosure policy has included the release of information regarding all substantiated complaints. Recently, the Department of Consumer Affairs proposed a policy that encourages the disclosure of all complaints as early as when a supervisor determines that a probable violation of law has occurred or there is a possible risk of harm to the public.

The board substantiates a complaint after mediation makes this determination through mediation of investigation of a complaint. The Enforcement Committee recommends that the board slightly modify its existing complaint disclosure policy. This modification would include the disclosure of routine compliance inspections performed within the last five years and a summary of any "corrections ordered" during the inspection. Corrections ordered are minor violations of pharmacy law.

Ms. Powell stated that of all her boards, the Board of Pharmacy's complaint disclosure policy is most in line with the Department of Consumer Affairs' policy.

Ms. Herold stated that in the broadening of the board's policy to include items listed on an inspection report, the board is using the expertise of its staff of pharmacist inspectors, since the board is required by law to have only a pharmacist inspect those pharmacies.

Ms. Harris added that other boards only disclose information after an accusation has been filed with the A.G.'s Office.

Cookie Quandt, Longs Drugs, Inc., asked about the five-year retention and whether this is a DCA requirement. She stated that procedures can change a lot in five years.

Ms. Harris stated that this is the board's retention schedule.

Ms. Powell clarified that the board cannot suddenly declare that something is no longer a public record. The only way the board cannot disclose a record is to destroy the record. Another issue is that consumers should be given credit for their ability to review the complaints and make decisions on there own behalf.

MOTION: Enforcement Committee: Approve the board's Complaint Disclosure Policy to include a summary disclosure of routine compliance inspections.

SUPPORT: 8 OPPOSE: 0

- Enforcement Team Meeting Summary

Mr. Jones stated that The Enforcement Committee held a public meeting on September 25, 2001. Many items were discussed including prescriber dispensing and the Pharmacists Recovery Program (RRP). About a year ago, the enforcement Committee developed a compliance guide on prescriber dispensing. This was in response to inquiries received from pharmacists complaining about prescribers dispensing drugs for profit. Many believe that California law does not allow prescribers to dispense for profit and therefore such prescribers are operating a pharmacy in violation of pharmacy law.

Mr. Jones stated that the Enforcement Committee discussed the compliance guide at its March enforcement meeting and again in September. Based on the discussion, the committee asked its liaison counsel deputy Attorney General Ron Diedrich to review the additional materials.

Mr. Jones reported that at the July board meeting, there was a presentation by the CPhA on suggested improvements to the board's Pharmacists Recovery Program (PRP). It was suggested that the board consider using diversion evaluation committees to develop and monitor the treatment plan for pharmacists in the program. This is a model currently used by the Dental and Nursing Boards.
At the September Enforcement meeting staff prepared an overview of the board's program and discussed the methods by which treatment contracts are developed and participants monitored. The committee discussed the recommendations and advised the California Pharmacists Association that should it decide to move forward with legislation to change the PRP, then the committee would consider whether sufficient data to support has been provided to warrant the change in the PRP.

Mr. Jones referred to the enforcement statistics for investigation of complaints and stated that the statistics continue to improve and reflect shorter investigation time frames. He added that the board is very close to the 90-day performance standard to investigate complaints. He commended the inspectors for their enthusiasm and efforts.

John Cronin, California Pharmacists Association thanked the Enforcement Committee for the increase in open meetings and the format that allows interested parties to submit questions regarding the law. He encouraged other committees of the board to do the same.

ORGANIZATIONAL DEVELOPMENT

- **President's Report**

  President Litsey reported that he attended the National Association of Boards of Pharmacy District 7 and 8 meeting last weekend. He added that John Jones in working with staff to prepare a resolution that was introduced at the meeting regarding quality assurance programs.

  Mr. Jones stated that one of the limitations of the quality assurance program was that although pharmacies have protection from civil discovery within California, companies that have multi-state operations might not be so protected under the federal court. He added that Steve Gray from Kaiser Permanente provided comments that there were national organizations that were coordinating efforts to achieve federal legislation that would protect quality assurance programs from discovery in federal court.

  Mr. Jones stated that the resolution was provided to the NABP to seek support from them for federal legislation that would protect from discovery any information that is in place in a quality assurance program.

- Report on the Meeting of September 20, 2001

  Chairperson Elsner reported on the Organizational Development Meeting held via teleconference on September 20, 2001.

- Strategic Plan Update

  Chairperson Elsner stated that the committee reviewed its strategic and ongoing goals for 2001/02.

  Mr. Elsner stated that the committee noted that during the April 2001 Board Meeting, a consultant will lead the board in revamping its strategic plan. An extra day will be added to the meeting (April 26). The committee will hire and work with the consultant in advance of the April meeting to prepare for this session.

- Personnel Update

  Ms. Harris provided an update on personnel action. She reported that the board was able to reclassify a position to that of a manager for the Sacramento office, a position greatly needed to reduce the span of control of 1 supervisor to 16 staff. In the past, creation of any supervisory position was an extremely difficult task to accomplish. She added that Anne Sodergren, who has been with the board since 1990, has been promoted into this manager position.

Ms. Harris noted that the board's staff had submitted a budget change proposal for 2002/03 aimed at correcting the board's imbalance of supervisors to staff that results in an inadequate span of control. The budget change proposal would establish an office services supervisor over the clerical staff, two additional supervising inspectors (creating a ratio of 5 inspectors to one supervisor) and one chief of enforcement over all enforcement functions. However, because the Governor does not want to expand the size of state government, approval of this budget change proposal, although vitally necessary, will be difficult to secure. Total annual costs for these positions would be $433,000.

The board has (re)hired Linda Alderman for the budget analyst position and Vicki Almes, currently the board's public information analyst, has transferred to the board's citation and fine desk.

Patricia Walker, who has been the board's cashier for 2.5 years, is transferring to another position with the Contractors State License Board.

Cindy Figgins, who has been an office technician in the Complaint Unit with the board for several years, transferred to another office technician position with the Department of Health Services at the end of September.

Ms. Harris reported that the board received two new positions with the 2001/02 state budget: a complaint analyst and a full-time associate analyst position, who will prepare public education materials, handle press calls, coordinate public outreach events and coordinate *Health Notes*. The board has been seeking the creation of this associate analyst position for five years, and gained it after Board Member Bill Powers successfully lobbied the Legislature and Administration during budget negotiations on the 2001/02 budget.

Ms. Harris stated that the board currently has three inspector vacancies and 19 employed pharmacists. She added that on September 5, the board completed interviews of new inspector applicants, and hopes to fill the remaining vacancies by December.

Vacancies

Ms. Harris reported that the board has the following vacancies: three inspector vacancies, two associate analyst positions, one analyst position, and two office technicians.

The board's managers (its executive and assistance executive officers, two supervising inspectors and two managers) recently began a yearlong training called "Bullet Proof Manager." This training is a four-hour per month video and classroom session of 24 modules, led by a facilitator. The board's managers then become trained so that they can present the modules to staff (the videos are

provided to the managers as are the handouts). Board managers did this successfully in 1998 in the initial series of this course; the 2002 course is a second level.

- Budget Update

Ms. Harris provided an overview of the board's budget.

2000/01 Budget Year

Revenue: $7,392.165

Ms. Harris reported that revenue was comprised of $5,405,988 in license fees and $547,415 in interest on the board's fund. Also, the board received the final repayment of the money borrowed nine years ago to help assist with the state's fiscal crisis. This $1,213,500 in included in the above figure.

Expenditures: $6,822,480

Ms. Harris reported that the board had a reversion (or unspent balance) in its budget at the end of the last fiscal year of $28,482 (0.4 percent of its budget).

She reported that the board received a $143,000 augmentation for legal services from the Attorney General's Office in May 2001. However, the board spent about $915,000 for the year for AG services; nearly $350,000 more than its initial budget of $555,000.

The board redirected other unspent money from other budget areas to cover the AG deficiency. This included:

- stopping the printing and distribution of "Alternative Medicines" *Health Notes* until the next fiscal year -- $78,000
- stopping the printing and distribution of June's *The Script* -- $45,000
- stopping the purchase of computers for the Sacramento office staff $70,000
- stopping the AG referral of all but the most critical cases (12 cases were held until July 2001)
- directing the Attorney General's Office to limit the hours they would work on board cases in May and June.

Fund Condition: $10,232,244

Ms. Harris stated that according to the Department of Consumer Affairs'

Budget Office, the board had 24 months of operating expenses remaining in its fund on June 30, 2001. Projections are that this will be reduced to 17.7 months at the end of 2001/02.

2. 2001/02 Budget Year

Ms. Harris stated that the 2001/02 fiscal year started July 1, 2001.

Projected Revenue: $5,452, 708

Revenue is estimated to be comprised of $4,831,760 in licensing fees and $621,000 in interest on the board's contingency reserve fund.

Projected Expenditures: $7,205,000

The board received the following budget augmentations to its budget:

- Consumer Complaint/Mediation Unit – approved 1 new staff analyst position for $58,000 for resolving and mediating consumer complaints.
- Attorney General's Office – one-year augmentation of $541,000 for 2001/02 (and $135,000 ongoing years) to work the backlog of cases awaiting board action and to complete cases referred there each year more immediately.
- Health Notes -- $100,000 to develop, publish and distribute a special issue on quality assurance programs and medication errors (legislative BCP for SB 1339).
- Computer consultants -- $40,000 for computer consultants to train board staff and assist inspectors in obtaining computer records from pharmacies (legislative BCP for AB 2240).
- Public Education -- $67,000 for one associate analyst to oversee the board's public education program.

3. Budget change Proposals for 2002/03

At the April board meeting, the board authorized staff to develop budget change proposals in a number of areas. However, once the data for specific workload for each budget change proposal was prepared and given the Department of Finance's directive that the Governor does not want to increase the size of government, the board submitted only the most supportable and most needed budget change proposals:

Organizational Development:

1. budget realignment to provide funding to budget areas under-funded in prior years (including the AG's budget), but which were partially funded from salary savings from unfilled inspector positions or redirected from

other budget areas ($847,000)

2. management reorganization: to establish two additional supervising inspectors, one chief of enforcement, and one attendance supervisor for the office who will also handle recruitment for vacant positions (4 staff positions, $433,000)
3. Enforcement: one analyst and one clerical person for the Complaint Unit to process complaints timely and monitor the status of complaints and investigation cases, and meet increased workload expected from establishing an 800 line for consumers (2 staff positions, $130,000).

Ms. Harris stated that under the Governor's directive, agencies were asked to take a 15 percent cut. She added that because the board is special funded, it has not been asked to do this but if the board is asked to make a 15 percent reduction in expenditures, it will amount to a 25 percent reduction in denial of the budget alignment. Budget change proposal is also considered.

Ms. Harris stated that legislation was enacted requiring hypodermic permits for any firm selling mercury thermometers (SB 633). The board will have to do a legislative budget change proposal for this bill because it will impact board workload.

Ms. Harris stated that a specific appropriation to the board in the compounding bill (SB 293) was removed from the bill late in the legislative session. However, there is also a provision that unless the board receives the resources to implement the bill, the legislation will not take effect.

She added that the board has five days from the time the Governor signs the bill to submit a legislative budget change proposal to develop and distribute a brochure.

She also stated that a budget change proposal is needed for the emergency contraceptive bill.

- Communications Team Report

  Stephanie Jones, a member of The Communications Team (TCT) reported on the October 5, 2001, meeting.

  Ms. Jones stated that the team had two meetings since the last board meeting. The seven issues that were pending at the last board meeting have all been presented to management for resolution. TCT has had one new issue that was presented to management and resolved at the last staff meeting.

  Ms. Jones stated that after the staff picnic, the TCT realized that it had set a high standard. Moreover, it was out of funds and still had debts, which the board members reimbursed. On behalf of the staff, the TCT thanked the board members for their contributions.

The team has also implemented a new team building idea for the quarterly staff meetings where each meeting will have a theme.

APPROVAL OF MINUTES

Full Board Minutes
(July 25, 2001)

President Litsey asked if there were any comments. There were none.

MOTION: Approve the July 25, 2001, Board Meeting minutes.

MSC: POWERS/ELSNER

SUPPORT: 8 OPPOSE: 0

NEW BUSINESS ITEMS

Cookie Quandt representing Longs Drugs, Inc., asked the board to discuss the process for approving a pharmacist in charge (PIC) for a new pharmacy. She suggested that a PIC be designated immediately before the new pharmacy will open, thereby permitting the proposed PIC to work as a PIC elsewhere until the new pharmacy is ready to open.

Ms. Miller requested, in light of the recent events, that the board consider ways to educate or help patients deal with disasters or emergencies as they evolve, for example, regarding anthrax.

Ms. Powell stated that the Office of Emergency Services was working with the department on this for awhile. The Board of Registered Nursing is starting to work with the department on this issue regarding licensure status of nurses during national emergencies.

President Litsey thanked the board and the public for attending the meeting as well as the feedback and comments received. He also thanked staff and counsel for their participation.

He announced that the next Board of Pharmacy meeting will be held on January 23 and 24, 2002, in Los Angeles.

ADJOURNMENT

President Litsey adjourned the meeting at 11:55 a.m.