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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 & TIME: October 24 and 25, 2002

LOCATION: The Berkeley Marina Radisson Hotel
200 Marina Boulevard
Berkeley, CA 94710

BOARD MEMBERS PRESENT:
John Jones, President
Donald Gubbins, Vice President
Caleb Zia, Treasurer
Dave Fong
Stanley Goldenberg
Clarence Hiura
Steve Litsey
William Powers
John Tilley
Andrea Zinder

STAFF PRESENT:
Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Ron Diedrich, Deputy Attorney General
Dana Winterrowd, Department Legal Counsel

Thursday, October 24, 2002

CALL TO ORDER

President Jones called the meeting to order at 8:30 a.m. on Thursday, October 24, 2002.

CLOSED SESSION

The board moved to closed session pursuant to Government Code Section 111126(c)(3) to deliberate upon disciplinary cases and the petition for reinstatement. The board also moved into closed session to confer with Legal Counsel pursuant to Government Code Section 11126 (e) regarding the following pending litigation: Doumit v Board of Pharmacy, Sacramento Superior Court Case #98A504499.

COMMUNICATIONS AND PUBLIC EDUCATION COMMITTEE

LICENSING COMMITTEE

- Presentation on the Pharmacy Technician Certification Examination – Bruce Wearda, Chair, Certification Council.

  Bruce Wearda, Chair of the Certification Council for the Pharmacy Technician Certification Board presented an overview of the Pharmacy Technician Certification Examination (PTCE) administered by the Pharmacy Technician Certification Board (PTCB). He explained that the PTCB was established in 1995, by four founding organizations, the American Pharmaceutical Association, the American Society of Health –System Pharmacists, the Illinois Council of Health System Pharmacists and the Michigan Pharmacists Association. The PTCB has certified over 100,000 pharmacy technicians nationwide and administered 23 successful examinations. Most recently, the National Association of Boards of Pharmacy (NABP) has joined as partner with the PTCB recognizing the importance of the registration and certification of pharmacy technicians nationwide.

  To qualify for certification, an applicant must have a high school diploma or GED and never been convicted of a felony. The examination is comprised of 140 multiple-choice questions with 15 pre-test, non-operational questions. The examination fee is $120 and it is offered three times a year. Recertification is required every two years. Recertification includes the completion of 20 hours of continuing education that includes one hour on pharmacy law. A certified technician may earn 10 hours of the required 20 hours of CE at the workplace under the direct supervision of a pharmacist.

  The PTCB examination is psychometrically sound and a legally defensible certification process. It is a competency-based examination that meets the 1985 *Standards for Educational and Psychological Testing.* The PTCB uses subject –matter experts to write

the examination questions. In 2000, the PTCB performed a job analysis, which identified the content outline for the examination. It serves as the blueprint for item development, item classification, and test development efforts. The examination pass rate since 1995 is 80 percent. Between 1995-1999, it was 82 percent. It is believed that the recent drop in pass rate is because of a recent Texas mandate that requires certification of all pharmacy technicians. The average pass rate for California is 88 percent and there are 3,000 certified technicians in California.

Mr. Wearda explained that currently there are 32 states that require the registration of pharmacy technicians, and there are 6 states that require the PTCB examination. There are also 4 other states that recognize the PTCB in some form. He also noted that in 2001, 60 percent of the applicants that took the PTCB came from community pharmacy.

- **Report on the Meeting of September 24, 2002**

  Chairman David Fong reported on the meeting of September 24, 2002, that was also attended by committee and board member Clarence Hiura.

- **Review of the Pharmacy Technician Registration and Program Requirements (Business and Professions Code section 4115-4115.5 and the California Code of Regulations section 1793-1793.7)**

  Chairman Fong stated that the original technician registration and program requirements have been in place for over 10 years. Although there have been some program modifications such as technician trainees, ratio increase for the second pharmacist in the community setting, and mandatory registration of all pharmacy technicians, there has not been a major review or update of the program.

  Chairperson Fong stated that the Licensing Committee discussed the current registration and program requirements for pharmacy technicians. There were several suggestions for revising the program. It was recommended that the board accept the PTCB examination as one method for qualifying to be a registered pharmacy technician, but not to allow it as the sole qualifier. That if the board accepts the PTCB, it should also require in addition for registration, some type of education or training. Another suggestion was that the board requires a two-tiered registration process for pharmacy technicians. The first level would be the existing requirement that provides for rapid, minimum training for community pharmacy technicians. The second level of registration would be for the more complex practice of acute care and home infusion pharmacy. It would be an extensive curriculum that would prepare technicians for registration at a more advanced level.

  Another recommendation was to eliminate an applicant's ability to qualify for registration with "clerk-typist" experience. Further, it was encouraged that the board no longer allow an applicant to qualify for registration with an associate degree in biological

sciences, physical sciences and natural sciences. This is because these fields do not prepare an individual for the practice of pharmacy technicians. The associate degree should be in pharmacy technology, which many academic institutions offer.

MOTION: Licensing Committee: Revise the registration and program requirements for pharmacy technicians. Such revisions would require both legislative and regulatory action. The proposed changes are to accept the PTCB as one method to qualify for registration as a pharmacy technician, accept only an associate degree in pharmacy technology and eliminate the other degrees, revise the training requirements and eliminate the "equivalent experience provision for the clerk typist and hospital pharmacy technician that is currently allowed in regulation.

SUPPORT: 9

OPPOSE: 0

- **Proposed Changes to the Supervision of Ancillary Personnel – Pharmacist Interns, Pharmacy Technicians, and Pharmacy Technician Trainees**

Committee Chairman David Fong stated that the Board of Pharmacy supports the ability of the pharmacist-in-charge and the pharmacist on duty to determine the number and combination of ancillary personnel that he/she may supervise. Ancillary personnel as defined would be the pharmacist intern, pharmacy technician and pharmacy technician trainee. Currently, a community pharmacist can supervise one pharmacy technician, one intern, one technician trainee, and one clerk-typist. This is a one to four ratio. However, a second pharmacist in a community pharmacy is allowed to supervise two technicians. And in a hospital inpatient pharmacy and a pharmacy that services long-term care facilities or home health patients, the ratio is one pharmacist to two pharmacy technicians.

Currently, the board's position is to increase the number of interns that a pharmacist can supervise to two, which would require legislation, and to amend its regulation to eliminate the ratio altogether for the clerk-typist. The board agreed to sponsor legislation next year to increase the intern ratio, making it a legislative priority. Additionally, the board has approved the regulation change to eliminate the clerk-typist ratio. This proposed change is with the Legislation and Regulation Committee, which must notice it for a regulation hearing. The committee concluded its discussion that the board would need to consider the appropriate ratio of pharmacists to ancillary personnel that would ensure patient safety.

Shane Gusman, representing United Food and Farm Workers, stated they support the concept but felt that the pharmacist must be protected while exercising his or her

discretion and that the maximum amount of supervised ancillary personnel remain the same.

MOTION: Licensing Committee: Pursue change in statute that allows the pharmacist-in-charge and the pharmacist on duty the discretion to supervise at least four ancillary personnel in any combination.

SUPPORT: 9
OPPOSE: 0

- **Proposed Regulation for Central Fill for Hospital Pharmacies**

Chairperson Fong stated that based on comments received previously, language was drafted that would allow for central fill of orders for hospital pharmacies. There were some suggestions to amend the current CCR 1707.4, which establishes the procedures for central refill for community pharmacies. Draft language to add CCR, Title 16, Section 1707.5 was provided for the board's consideration.

MOTION: Licensing Committee: Move to hearing a proposed CCR, Title 16, Section 1707.5 that would allow the central fill of patient orders for hospital pharmacies.

SUPPORT: 9

OPPOSE: 0

- **Request from Cedars-Sinai Medical Center (CSMC) and Long Beach Memorial Medical Center (LBMC) to Extend its "Technician-Check-Technician" Study for Unit-Dose Cassette Fills in an Inpatient Hospital Pharmacy**

Chairperson Fong stated that in May 1998, the California State Board of Pharmacy granted UCSF, School of Pharmacy, in conjunction with CSMC and LBMMC, a waiver pursuant of CCR 1731, to evaluate pharmacy technicians in the unit does distribution system. At its January 2001 meeting, the board granted an extension of the waiver until December 2002, in anticipation of a regulatory action that would allow technicians to check other technicians filling unit-dose medication cassettes in an inpatient setting. Subsequently, the board decided that the proposed changes would require legislation.

CSMC and LBMMC have reported that technicians functioning in this study have consistently met or exceeded the minimum target of 99 percent accuracy rate as documented by its quarterly reports to the board. Also, the results of the study were published in the June 15, 2002 issue of the American Journal of Health-System Pharmacists. CSMC and LBMMC have reported that their clinical pharmacy programs

as well as patient care have benefited from the use of technicians in this capacity. They have also documented an increase in potential adverse events prevented by pharmacists interventions and have been able to respond to an increase number of requests by physicians to manage drug therapy for inpatients receiving drugs with a narrow therapeutic index.

CSMC and LBMMC are requesting another extension of the study until December 2004. The California Society of Health-Systems Pharmacists is introducing legislation in January 2003 to allow technicians to check technicians filling unit-dose cassettes setting pursuant to a strict quality control program, the CSMC and LBMMC would like to carry on the study during this time so that it can continue collecting the data to support the effectiveness of this program and continue enhanced care to its patients.

The Licensing Committee discussed the importance of this study and enhanced patient benefits. They expressed concern that since the board already approved an extension once, that another extension for two years may not provide the necessary incentive for successful passage of the legislation. The committee recommended that the board consider extending the waiver for another year and if necessary, reconsider another extension next year depending on the status of the legislation.
Rita Shane, Director of Pharmacy at Cedars-Sinai Medical Center, thanked the board for its consideration of the request and added that the board's decision that legislation was needed did not occur until the fourth year into the project. Thus, requiring that they regroup to move forward with legislation.

Kathleen Creason, representing the California Society of Hospital Pharmacists (CSHP), also stated that the CSHP supports the study and has identified this issue as a legislative priority for 2003.

MOTION: Licensing Committee: Extend the waiver for one year to allow technicians to check technicians at Cedar-Sinai Medical Center (CSMC) and Long Beach Memorial Medical Center (LBMMC) as a study with UCSF, School of Pharmacy, while legislation is being pursued to allow this practice.

SUPPORT: 6

OPPOSE: 3

- **Request from Ramona Pharmacy for Waiver of 16 CCR 1717(e) to Deliver Prescriptions to Patients at Julian Medical Clinic**

Chairperson Fong stated that Ramona Pharmacy requested a waiver of CCR section 1717(e) to deliver prescription medications to Julian Medical Clinic. This request was received after the Licensing Committee meeting, but due to the urgency of the request

and consistent with pending regulation, the request has been provided to the board without a Licensing Committee recommendation.

Concern was expressed that the policies and procedures for the delivery of medications were insufficient.

MOTION: Approve the request from Ramona Pharmacy for a waiver of California Code of Regulations, section 1717(e) to deliver prescription medications to the Julian Medical Clinic with the provision that the supervising inspector reviews the policies and procedures for the delivery of the medications.

MSC: POWERS/ZIA

SUPPORT: 9

OPPOSE: 0

- **Feasibility of Offering the California Pharmacist Licensure Examination More than Twice a Year**

Chairperson Fong stated that the Licensing Committee was provided a table summarizing a number of alternatives for providing the pharmacist licensure examination. The table included the adoption of the National Pharmacist Licensure Examination (NAPLEX) and a California jurisprudence examination. This alternative would increase the availability of a licensure examination through the daily computer based administration. Total cost for this alternative would be $250,000, but would require a statue and regulation change to implement. Currently, it costs the board $350,000 annually to administer its examination.

The second alternative would be to give the California examination three times a year instead of twice. This would increase costs by $175,000 and would require a statutory change in order to increase fees to cover the costs. The board would also be required to submit a budget change proposal to increase its pending authority in order to administer the third exam.

The last alternative proposes to transition the California examination to a computer-based test. This option would require a new contract with a testing organization to develop and administer the exam by computer. It would appear that the board could absorb the costs; however, the candidate fee would have to be increased through a regulation change. Also, there would be a new "administration" fee assessed to the candidate.

It was also noted that Governor David signed AB 2165 that requires the Joint Legislative Sunset Review Committee to review the state's shortage of pharmacists and make

recommendations on the course of action to alleviate the shortage, including, but not limited to, a review of the current California pharmacist licensure examination. It is anticipated that this information will be provided to the Joint Legislative Sunset Committee when it performs this review.

- **Requirement for Social Security Numbers as a Condition of Licensure**

  Ms. Herold stated that for years, board licensees have been subject to the provisions aimed at "dead beat parents" from failing to pay their court-ordered child support and yet enjoy the benefits of professional or occupational licensure. This is tracked through the social security number of every applicant. Additionally, the Franchise Tax Board requires the board to obtain a social security number as a condition of issuing a license, for tax-related reasons.

  Therefore, the board is required to have the social security number of all applicants. However, some foreign applicants do not have a social security number and instead use an ITIN number.

  It is difficult for foreign applicants to obtain a social security number until they enter the USA. It is also difficult to enter the country unless a foreign applicant has a job, which in the case of many board applicants requires a board license. This is a Catch 22 situation since one cannot get a social security number until one is in the country, but one cannot enter the country without a job. However, the board cannot issue a license without a social security number.

  The board previously has used ITIN numbers instead of a social security number; however the Legal Office has advised that the board must have the social security number. To prevent the Catch 22 situation, the board will continue to accept applicants from foreign applicants without a social security number. Once all other requirements are complete, the board will send a letter to the applicant advising that the only item missing is a social security number; this will allow the individual to apply to the INS and obtain a visa, and once in the country, the applicant can apply for a social security number. This process is accepted by the INS and is outlined in a letter from them dated November 20, 2001. This process and the letter from INS will be posted on the board's website for foreign applicants.

- **Informational Hearing – Proposed Amendments to Title 16, Section 1732.2(b) of the California Code of Regulations**

  Chairperson Fong stated that previously, the board approved the amendment of this regulation to allow pharmacists to take continuing education that has been approved by other California health boards without petitioning the board for credit. The regulation was amended accordingly and scheduled for an information hearing. Based on

comments, the proposed language was modified. The proposed amended regulation will be noticed to the public for adoption without a regulation hearing unless one is requested.

Mr. Tilley asked the status of regulating the pharmacy benefit manager practice in California.

Ms. Harris responded that as a strategic objective for the Licensing Committee, this would be discussed at the next Licensing Committee scheduled on December 5, 2002.

LUNCH

COMMITTEE REPORTS AND ACTION - Continued

ENFORCEMENT COMMITTEE

- **Proposed Revisions to Complaint Disclosure Policy**

Chairperson Goldenberg reported that during the Enforcement Committee meeting held on September 10, 2002, Kathleen Hamilton, Director of the Department of Consumer Affairs, presented the department's recommended minimum standards for consumer complaint disclosure. She explained that these recently adopted standards were a culmination of consumer forums and cooperative efforts with the regulatory boards to develop guidelines for disclosing information concerning complaints filed by consumers.

Ms. Hamilton requested that the DCA boards review the standards and consider them when determining its own disclosure practices. The conditions of disclosure are when a substantiated consumer transaction has occurred, the business has been provided an opportunity to respond to the complaint, a probable violation of law has occurred or there is a possible risk of harm to the public, and the complaint will be referred to legal action. Ms. Hamilton emphasized the importance that consumers be informed of complaints when these conditions are met. This would also include when a complaint has been referred to the Attorney General's Office for possible disciplinary action.

Based on the guidelines provided by the Department of Consumer Affairs and the requirements of the Public Records Act, the Enforcement Committee is recommending that the board revise its disclosure policy to reflect the information that is available on all licensees.

MOTION: Enforcement Committee: Revise the Board of Pharmacy's Complaint Disclosure Policy as an overview of information that is available regarding licensees in accordance with the Public Records Act.

SUPPORT: 9

OPPOSE: 0

- **Proposal to Grant Continuing Education to Pharmacists for Attending Board Meetings**

  Chairperson Goldenberg stated that the Enforcement Team discussed the value of offering CE credit to pharmacists who attend board meetings. It was expressed that licensees better understand the role and responsibility of the board when they attend these meetings, and by offering CE, more pharmacists may attend the meetings. Some team members recommended that there should be a limitation as to the number of hours a pharmacist could earn in one year attending board meetings. A recommendation on the number of hours that would be granted was not determined.

  Chairperson Goldenberg stated that to implement this policy would not require a regulatory change since the board has the authority to grant continuing education. However, a regulation change may be necessary to establish the parameters for limiting the number of hours annually that a pharmacist could obtain by attending a board meeting.

  It was suggested that the board consider holding evening meetings for a higher public turnout from pharmacists.

  MOTION: Enforcement Committee: Grant continuing education to pharmacists who attend board meetings.

  SUPPORT: 9

  OPPOSE: 0

- **Update on the Citation and Fine Process**

  Chairperson. Goldenberg stated that concerns were raised that the process does not conform with the intent of the regulation, in that it fails to provide the licensee the opportunity to have a hearing before the committee prior to the committee ever having the chance to consider whether or not a citation should be issued.

  In response it was explained that the board, through the Citation and Fine Committee, has put a citation process in place that complies with the plain language and requirements of Business and Professions Code section 125.9; California Code of Regulations, Title 16, section 1775-1775.4; and Government Code section 11500 et seq. It was also explained that the regulatory scheme does not mandate that a hearing be held prior to the issuance of citation.

Mr. Goldenberg also discussed various improvements to the board's investigative processes. The board inspectors will no longer be using the "Notice of Violation" document to advise a licensee of possible violation(s) of law. Inspectors will continue to advise licensees of the violation(s) they believe occurred. However, that notification will be on a new form that also advises the licensee in writing of the opportunity to respond within 14 calendar days to the identified possible violation(s) of pharmacy law. This notification may occur at any time during the investigative process. This advisement is not the board's final or formal determination regarding the matter. It is also neither a citation no is it a disciplinary action.

Chairperson Goldenberg stated that the Enforcement Committee emphasized that the board's overriding mandate is to protect the public. The citation process is a key component of fulfilling that responsibility. It provides a means whereby the board can meet its public protection obligation in a manner that does not require formal disciplinary action be initiated against licensees who have committed relatively minor infractions of pharmacy law. Without the citation process in place, there would be little alternative but to impose formal disciplinary action, up to and including the revocation of their license, on such licensees.

Moreover, the citation and fine process that is in place is both workable and fair to the licensees. The affected licensee is given multiple opportunities to provide the Board's inspector with a written response and/or documentation prior to the matter being submitted to the Citation and Fine Committee. Further, the inspector's report is reviewed at least twice (by the supervising inspector and the executive officer) prior to the matter ever being submitted to the Citation and Fine Committee. This is a rigorous screening process. It appears that less than 3 percent of the last 3,000+ inspections that could have resulted in a referral to the Citation and Fine Committee were actually submitted to the committee.

Chairperson Goldenberg stated that the citation processes used by the Ohio and Pennsylvania Boards of Pharmacy were put forward as models for California to consider. As described to the committee, it appears that in both states, it is the inspector (or similar type personnel) who determines that a violation of law did in fact occur. A notice of that violation is then issued and the licensee must respond within a specified time as to what actions he or she has taken to correct the violation or to prevent future incidents from occurring. If the licensee does not correct the violation or there are repeat violations, then he or she may be subject to a fine or other action.

Based on this suggestion, the Enforcement Committee requested that language be drafted to model the Ohio and Pennsylvania programs. These models would provide the board with additional tools to address non-compliance issues at the administrative level. The draft proposals would do the following:

- **Add Section 4083 – Order of Correction**

Would allow an inspector to issue an order of correction to a licensee directing the licensee to comply with the Pharmacy Law within 30 days, would allow the licensee to contest the order of correction to the executive office for an office conference, would provide for judicial review and would not be considered a public record for purposes of disclosure/

- **Add Section 4315 – Letter of Admonishment**
  Would authorize the executive officer to issue a letter of admonishment to a licensee for failure to comply with Pharmacy law, would allow a licensee ton contest the letter of admonishment to the Board President and/or board member designee, would provide for judicial review and would be conside4red a public record for purposes of disclosure.

- **Add Section 4314 – Issuance of Citations**
  Would allow the board to issue an order of abatement that would require a person or entity to whom a citation has been issued to demonstrate how future compliance with the Pharmacy Law will be accomplished and provides that such demonstration may include, but not be limited to, submission of a corrective action plan, as well as requiring the completion of up to six hours of continuing education courses in subject matter specified in the order of abatement.

Ms. Harris stated that the legislative proposal would require a legislative change and the proposals are provided to the board as information. They will be placed on the agenda for the December 5, 2002, Enforcement Committee Meeting for a discussion and a recommendation will go to the board in January.

Concern was expressed that a recent situation that occurred in a pharmacy where the pharmacist-in-charge was cited and fined for a prescription error that involved a staff pharmacist. Because the PIC was fined $250 for something that the PIC claims was out of his control, he considered stepping down from his PIC position.

It was discussed (without commenting on specifics of a particular case) that the Citation and Fine process has created a clearer understanding of the PIC's responsibility. It is important for all pharmacy personnel to reevaluate the situation and understand the responsibilities of the PIC. Also, the PIC should have the authority to take on the responsibility.

President Jones stated that the Enforcement Committee meetings are open to the public and with the board inspectors attending, the discussions have provided valuable insight into this policy.

John Cronin, representing the California Pharmacist Association, commented that licensees should have closure when a citation is not issued and there is no action. Also,

he asked why the licensee does not have the opportunity to appear before the committee prior to when a citation and fine is issued.

Chairperson Goldenberg stated that a successful evaluation by the committee depends on the licensee or the organization providing additional information to the board within the 14-day time period.

Legal Counsel Ron Diedrich also responded that the licensee has multiple opportunities during the entire process to provide information for consideration by the Cite and Fine Committee. For example, the licensee can provide information at the time of the inspection or to submit information within 14 days. However, the licensee does not have the opportunity to have a quasi hearing before the Cite and Fine Committee or prior to a citation. He added that the Cite and Fine Committee could also request additional information from the licensee.

- **Prescriber Dispensing**

Chairperson Goldenberg stated that Kathleen Hamilton, Director for the Department of Consumer Affairs, requested that the Board of Pharmacy work with the Medical Board of California (MBC) on the issue of prescriber dispensing. This request was the result of a meeting with Ms. Hamilton, Deputy Director Lynn Morris, MBC Executive Director Ron Joseph, Alscripts' representative Pat Leathers, Steve Thompson from the California Medical Association (CMA), attorney Gene Livingston and Executive Officer Patty Harris. The meeting was held September 16, 2002.

The purpose of the meeting was to discuss a recent Court of Appeal decision that concluded that Pharmacy Law does not prohibit a physician from dispensing or selling drugs on a for-profit basis to his or her patients for the condition for which the patient sought treatment. CMA requested that the following issues also be addressed regarding dispensing by physician groups: accountability, ordering of drugs, common storage, and the use of an assistant for dispensing.

It is the board's position that there is no authority for a group of physicians to purchase prescription drugs for communal use, except as specifically authorized by law. There is disagreement with this interpretation and thus the request from CMA to address the commingling of drugs by physician groups.

For background information, the Enforcement Committee drafted a Compliance Guide on prescriber dispensing that was discussed at its public meetings in July 2000 and September 2001. Essentially the Compliance Guide stated that the issue of prescriber dispensing for profit was the jurisdiction of the Medical Board of California and that the dispensing of drugs by physicians groups (where the drugs are commingled) is the practice of pharmacy and falls within the jurisdiction of the Board of Pharmacy. The Board of Pharmacy has yet to take a formal position on this compliance guide.

The director asked that the Board of Pharmacy and MBC to advise her in 60 days the process by which the issue will be mutually addressed. Since the compliance guide originated with the Enforcement Committee, this committee will work with MBC to address the issue of prescriber dispensing.

LEGISLATION AND REGULATION COMMITTEE

Regulation Report and Action

Pending Regulations

- **Adoption of Amendments to 16 CCR 1717 and 1745 – Delivery of Medications and Partial Filling of Schedule II Prescriptions**

Chairperson Litsey reported that in August, the board proposed a regulation to permit the depoting of prescriptions at health care facilities and to extend the time period for the partial filling of Schedule II controlled substance prescriptions to 14 days, matching requirements in California law. The 45-day comment period for this regulation closed on September 16, 2002. The board received neither a request for hearing nor any comments on the proposed regulation.

Under existing law, a pharmacy may only deliver prescriptions directly to the patient or the patient's agent. The board may grant waivers for delivery to a specific location in the absence of the patient or the patient's agent. The board has routinely granted such waiver requests in the past and has proposed this regulation change to permit prescriptions to be delivered to a location where the patient receives health care.

Under existing law, a prescription for a Schedule II controlled substance may be partially filled if the balance of the prescription is filled within seven days. Recent legislation extended the period of time in which a Schedule II prescription may be filled from seven to 14 days, and this regulation conforms the partial filling time restriction to that change.

Dr. Fong expressed support of this recommendation as an effort to improve quality patient care.

MOTION: Legislation and Regulation Committee: Adopt regulations to amend Title 16, Sections 1717 and 1745 of the California Code of Regulations relating to the delivery of medication and the partial filling of Schedule II prescriptions.

SUPPORT: 9

OPPOSE: 0

- **Adoption of Amendments to 16 CCR 1720.1 – Evaluation of Transcripts for Foreign Pharmacist Graduates**

  Chairperson Litsey referred to the board's proposed rulemaking to amend section 1720.1 of Title 16 of the California Code of Regulations. Chairperson Litsey stated that the proposed amendment would allow the board to accept the findings of a foreign credentials evaluation service as evidence that an applicant has satisfied the collegiate equivalency required in Business and Professions Code section 4200(a)(3). This may include authentication, translation and or evaluation of college transcripts. This will remove one possible impediment to graduates of foreign pharmacy schools who are otherwise unable to provide detailed proof of their educations to the board.

  Chairperson Litsey added that the 45-day comment period for this regulation closed on September 16, 2002. The board received neither a request for hearing nor any comments on the proposed regulations.

  Dr. Zia stated expressed concern that universities in Asia do not have Pharm.D. programs, only B.S degrees.

  Ms. Harris stated that a candidate's educational qualifications would be demonstrated by taking the National Foreign Equivalency Examination as well as passing the board's pharmacist licensure examination.

  Ms. Harris stated that this proposed regulation would allow the board to accept the findings of a foreign credentials evaluation service as evidence that an applicant has satisfied the collegiate equivalency required in Business and Professions Code section 4200(a)(3) or 150 semester credits.

  Ms. Harris added that the entrance requirement for the National Foreign Equivalency Examination is a Bachelor of Science. However, the National Association of Boards of Pharmacy, which administers the foreign equivalency examination, has determined that it would not accept any degree less than a Pharm.D. worldwide after 2003 and this would be the national standard. The standard will remain a Bachelor of Science degree for those who graduated before 2003/04.

  MOTION: Legislation and Regulation Committee: Adopt proposed amendments to Title 16, California Code of Regulations section 1720.1 to accept transcripts verified by a credentials evaluation service for candidates who graduated from a foreign pharmacy school.

  SUPPORT: 8

  OPPOSE: 0

ABSTAIN: 1

- **Proposed Regulation Proposals for the 2003 Rulemaking Calendar:**
  - **Revise existing regulations relating to wholesaling to address drug diversion issues,**
  - **Revise existing regulations to eliminate the clerk/typist ratio,**
  - **Revise existing regulations to permit a pharmacist to be pharmacist-in-charge at two pharmacies.**

Chairperson Litsey stated that each year, the board is required to submit a calendar of proposed rulemaking activity to the Office of Administrative Law (OAL). This calendar is not binding, but rather serves to provide OAL with workload information for the coming year. The board has directed staff to proceed with the above rulemaking proposals. Further proposals may be added at the board's discretion.

MOTION: Legislation and Regulation Committee: The Board of Pharmacy will include in its 2003 rulemaking calendar these additional proposals: revise existing regulations relating to wholesaling to address drug diversion issues, revise existing regulations to eliminate the clerk/typist ratio, revise existing regulations to permit a pharmacist to be pharmacist-in-charge at two pharmacies.

SUPPORT: 7

OPPOSE: 0

ABSTAIN: 2

Mr. Mayer referred to the board's "Notice to Consumers" poster and asked about the toll-free 800-telephone number that was not included on the poster because of budget restrictions. Mr. Mayer stated that budget reductions have caused delays in publications of *The Script* and this is an important information source for pharmacists and consumers. He asked Senator Figueroa, who was in attendance, to address these issues as well as staffing.

Senator Figueroa stated that she and her staff have sent letters to the chair of the Budget Committee and sent numerous letters to the Governor to share information on this very serious situation that is detrimental to so many constituents.

Senator Figueroa thanked the board for its hard work and for allowing her and her staff to work with the board on so many important issues. She requested that the board send letters so her office can continue to advocate for the board.

REGULATION HEARING
Proposed amendment to Section 1751 – Regulations for Compounding Sterile Products

President Jones stated that in August, the board proposed a regulation establishing new standards for sterile compounding. These standards are required by Senate Bill 293 (Chapter 827, Statutes 2001). The proposed standards substantially revise existing board regulations regarding "parenteral compounding" based on guidelines adopted by the American Society of Health System Pharmacists and the United States Pharmacopoeia, existing board regulations, and comments received from the public in three separate information hearings.

President Jones stated that board action on the proposed standards is required at this meeting to have the standards in place before the July 1, 2003 implementation date for the licensing of pharmacies compounding sterile injectable drug products. The comment period for the proposed regulation ends on October 14, 2002, and a summary of that comment and any suggested revisions to the standards based on that comment would be provided to the board prior to the board meeting.

Hank Rahe, representing Containment Technology, commended the board on the proposed regulations. He expressed concern about the class 1000 environments within the definitions. He suggested that the board either add more definition or eliminate the definition and add it under the pharmacist's responsibility provision.

Mr. Rahe referred to language in the proposed regulation regarding controlled areas where the board refers to controlled access area but fails to identify components for contamination control:

1. Pressure differential
2. Number of air changes in the environment.
3. Filtration.

Mr. Rahe referred to item 6 under facilities and talked about the potential for contamination in drains. Mr. Rahe stated that there was no mention of "gloving" under category 1. Mr. Rahe added that "gowning" has a potential for contamination if the pharmacist leaves the pharmacy with the gown on.

Mr. Rahe referred to the added section 1751.03 and referred to manipulating products for a long period of time.

Mr. Rahe stated that the basic acceptable technology is a laminar flow hood with no controls around. He added that this has a high potential for contamination.

Mr. Rahe referred to section 1751.04 (protective clothing) and stated that when using a barrier isolator, protective clothing is not necessary because of the positive barrier.

John Cronin, representing the California Pharmacists Association (CPhA), referred to CPhA's comments in a letter dated October 14, 2002.

Mr. Cronin stated that the intent of SB 293 is to improve public safety and to preserve compounding sterile products as an essential health care service. Mr. Cronin expressed concern that the proposed regulations do not meet this objective and that they are too complex. He urged the board to consider the proposal submitted by the CPhA.

Mr. Cronin stated that one area of concern is the potential conflict that the proposed regulations have with the national standards. If the board's proposed regulations were adopted, the board would be required to keep these standards current with the profession but would not be able to enforce these standards because it does not have the resources available to handle out-of-state pharmacies that may be operating under the new or improved USP standards.

He asked how a pharmacist could exercise professional judgment as permitted under 1751.06 without violating the other provisions of the proposed regulation.

Mr. Cronin expressed concern about the cost estimates for remodeling under the business impact provisions and stated that the estimates are too low and do not contain supporting documentation. Also, ongoing costs were not considered.

William Blair, Pharmacy Director of McGuff Pharmaceuticals stated that his company would not be able to comply with the proposed regulations and he asked the board to consider three major areas where this would impact his business:

1. Complying with the record-keeping requirement that this proposed regulation imposes on furnishing for physician's office use.

2. Due to the high cost of remodeling, out-of-state competition will take over California businesses.

3. Temperature controls are not reasonable.

Mr. Blair added that his company supports the CPhA's proposed regulations.

Damon Jones, Vice President and Director of Operations for McGuff Pharmaceuticals (MPI), stated that MPI is a licensed drug manufacturer that co-exists with compounding pharmacies.

Mr. Jones stated that MPI could not comply with the proposed language as written because the practice of compounding sterile products is very dynamic and can differ

based on the products and patient needs. Mr. Jones added that the board's standards must be flexible so that pharmacies can comply in multiple ways.

Mr. Jones referred to the following standards that MPI would not be able to comply with:

1. That compounding is done in a class 10,000 environment.
2. Although the board's regulation attempt to define controlled and critical areas, they do not adequately define critical areas where actual sterile manipulations would actually occur, so where compounding must occur is not clear.

Mr. Jones stated that he supports CPhA's proposed language.

Kathleen Creason, representing the California Society of Health System Pharmacists (CSHP) stated that she is attending the board meeting on behalf Teri Miller who has jury duty.

Ms. Creason thanked the board for addressing the CSHP's previous concerns. She added that many members have submitted additional comments and she encouraged the board to consider them. She added that the CSHP looks forward to working with the board to continue this process. She referred to a letter she submitted to the board.

Don Kaplin, inpatient home health pharmacy practice coordinator for Kaiser Permanente Pharmacy Strategy and Operations, commented:

1. Kaiser Permanente agrees with the CPhA that the board's regulations are not ready for adoption. The cost of remodeling an inpatient pharmacy to meet these proposed regulations would be in excess of $100,000. If an inpatient pharmacy had to be relocated during a remodel, hospitals do not have the additional space needed for this. The timeframe for meeting the compliance deadline is too soon. The proposed regulations are too detailed and too complex for the wide variety of compounding that occurs, particularly in hospital pharmacy.
2. The harm caused by the incident with Doc's Pharmacy that brought about this action occurred with essentially level III products. If the board moves forward with a detailed regulation, it should be limited to a category III product with more general regulations for categories I and II.

Dan Wells, business manager for a compounding pharmacy, expressed concern for testing every product because the only way to make economic sense is to produce large batches. He added that tests will cost $200-$300. If the pharmacy compounds large batches, they become a manufacturer.

Mr. Wells expressed concern with section 1751.04(d) – Aseptic Technique & Product Preparation. Mr. Wells stated that testing would be too costly.

Mr. Wells referred to the labeling section under 1751.02(g)(1)(b) where it states that the names and concentrations of all ingredients in the sterile drug product need to be on the label. He stated that the labels would be too small to include all of this information.

Michael Pastrick stated that most of his pharmacy career has been in the preparation of sterile IV products in the acute-care setting.

Mr. Pastrick referred to his comments in a letter dated October 14, 2002.

Mr. Pastrick expressed concern about the cost of remodeling.

Mr. Pastrick referred to section 1751.02(d)(5) – Aseptic Technique & Product Preparation. He referred to where it states "the compounding process for each preparation must be determined in writing before the compounding begins and be reviewed by the pharmacist," and he commented that this section is not clear.

Rita Shane, Pharm.D. Director of Pharmacy, Cedars-Sinai Medical Center stated that she supports the comments presented and CPhA's position to review the current proposed regulations.

Ms. Shane stated that it would be difficult for Cedars-Sinai Medical Center to meet the standards of the proposed regulations.

Alan Kern, CFO for Med-Mart, stated that the proposed regulations are overly prescriptive, and will prove costly and burdensome and will also disadvantage California pharmacies. If adopted, patients will face increased prices for compounded prescriptions. Mr. Kern added that the board has regulations in place to regulate the sterile compounding practice, particularly as it relates to injectables.

Mr. Kern stated that the proposal underestimates economic impacts on state agencies and private businesses. It also underestimates the economic impact on jobs and small businesses in California. Also, it does not consider alternatives that will enhance the safety of compounded products without adversely affecting the cost or availability.

Mr. Kern requested that the board reconsider all of the costs, including the board's cost.

Mr. Kern stated that out-of-state pharmacies would not have to comply with the regulations, leaving California pharmacies at a disadvantage. He suggested that the board use the American Society of Health System Pharmacist's guidelines.

Mr. Kern referred to his written comments submitted in a letter dated October 15, 2002.

Paul Riches clarified that non-resident pharmacies are subject to the same requirements as California pharmacies under SB 293.

Mr. Riches explained non-resident pharmacies must be licensed in California before they can ship drugs into California.

Because of the concerns raised, the board agreed to use the existing standards for compounding injectable sterile drugs (California Code of Regulations, Title 16, sections 1751-1751.10) to implement the new license requirement for these compounding pharmacies. The board also requested that interested parties attend the Licensing Committee meeting on December 5, 2002, to provide constructive resolution to the concerns that were raised during this regulation hearing.

MOTION: Table the recommendation to adopt regulations adopting standards for the compounding of sterile drug products.

M/S/C: POWERS/ZIA

SUPPORT: 9

OPPOSE: 0

PUBLIC MEETING OF THE LEGISLATION AND REGULATION COMMITTEE

Gail Askew, Department Chair, Pharmacy Technology, Santa Ana College, submitted her letter dated September 20, 2002, addressed to the board's Licensing Committee regarding the proper training and appropriate qualifications for registration for pharmacy technicians.

Legislation Update

Board Sponsored Legislation

Chairperson Litsey reported that the board sponsored AB 2655 (Mathews) to extend the CURES program and move a monitoring program like that in Nevada. The bill was amended to permit practitioner access to CURES data for their patients and to permit the Department of Justice (DOJ) to screen CURES data and send practitioners profiles of their patient(s) when a potential pattern of abuse is indicated by the CURES data. The bill was signed by the Governor on August 31, 2002.

Other Legislation

AB 269 (Correa)
This bill reiterates the board's central function as public protection (as well as all other entities in the department). This bill was signed by the Governor.

AB 2045 (Matthews)
This bill requires the board to consider good faith reporting of violations by a pharmacist-in-charge as a mitigating factor in disciplinary proceedings. Signed by the Governor.

AB 2165 (Strom-Martin)
This bill directs the Joint Legislative Sunset Review Committee to evaluate the use of the national pharmacist examination (NAPLEX) in California during the board's Sunset Review. This bill was signed by the Governor.

SB 2026 (Senate Business and Professions Committee)
This is the annual omnibus bill. This year's bill contains provisions that conforms state controlled substance schedules to recent federal controlled substance schedules and repeals an unused statute that permits the licensing of controlled substance warehouses. This bill was signed by the Governor.

October 25, 2002

COMMITTEE REPORTS AND ACTION -- Continued

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

- **Report on the Meeting of October 21, 2002**

  Chairperson Powers reported on the October 21, 2002, committee meeting.

- ***The Script*** **Update**

  Chairperson Powers reported that the board lost the two most critical staff for this committee – The Script editor and the public outreach coordinator in the 2002/03 budget reductions. The board's management will pursue whatever process is established to restore both positions once the state's and the board's fiscal picture improves.

  Chairperson Powers stated that the board has contracted with Hope Tamraz to produce two issues of *The Script* annually. The next issue is underway and will be the January 2003 issue. Issues are planned for publication in January and July. To reduce printing and postage costs, the board will only mail the newsletter to all pharmacies. Pharmacists and other licensees will be encouraged to download the newsletter from the board's web site. Printing and postage for the January 2002 newsletter was $34,000.

Chairperson Powers stated that the board will make available all new pharmacy laws and regulation on the board's website for those who may not receive a copy of the newsletter informing them of changes. Also, the board will not be printing a 2003 lawbook. However, it will be available on the website as well.

- ***Health Notes* Update**

  Chairperson Powers stated that in late September, the board published and distributed the "Quality Assurance" issue of *Health Notes*. This issue was developed via a contract with UCSF, and the contents of this important issue include items on "best practice" quality assurance programs in different pharmacy settings, communicating errors to patients and prescribers, and using and managing the quality assurance information to improve operations. The board's expenses to produce and mail this issue were $124,520.

  Chairperson Powers stated that the board also contracted with UCSF to develop the 7th *Health Notes* on Geriatrics. These articles have been undergoing final edits by UCSF, and the board should have the final manuscript in November. Because UCSF received outside funding to develop this issue, the board will pay for layout and printing (est. $60,000) and postage (est. $15,000).

- "**Notice to Consumers" Poster**

  Chairperson Powers stated that the revised "Notice to Consumers" regulation was approved by the Office of Administrative Law and took effect on September 8, 2002.

  The board has printed and mailed the redesigned poster to all community pharmacies, at a cost of $30,000.

  Chairperson Powers stated that one change made to the poster was the removal of the toll free telephone number for consumers to contact the board, unfortunately the board lacks the staff and economic resources at this time to absorb this additional workload and expense of an 800 number. Over the last few years, the board has tried repeatedly to establish an 800 number for consumers through the budget change proposal process until the board lost four staff positions due to a substantial tightening of the hiring freeze, and the transfer of the board's reserve to the general fund. However, there is no way the board can absorb the additional workload, and this important outreach effort would have failed due to lack of resources. As such, the notice was published with the board's Sacramento number and website address, but without an 800 number.

  Chairperson Powers stated that the board is translating the notice to consumers in to five languages – Spanish, Vietnamese, Chinese, Korean and Russian. These translations will be converted into the poster's graphic layout and made available in a camera-ready format for pharmacies to distribute to patients. The translations will be available from the board and from our website in an 8.5x11 inch size.

Chairperson Powers stated that the Department of Consumer Affairs distributed a press release to highlight the five questions emphasized on the new "Notice to Consumers" poster and released it during "Know Your Medicines, Know Your Pharmacist" week (October 20-26).

- **Board-Sponsored Seminar Series on "Hot Topics in Pharmacy"**

  The board-sponsored series "Hot Topics in Pharmacy" began with its first seminar on "Antibiotic Use and the Risk of Bacterial Infection" on October 18 in the State Capitol. The board is cosponsoring this series with the UCSF's Center for Consumer Self Care and the Department of Consumer Affairs.

  Chairperson Powers stated that the committee is interested in developing a much-needed consumer educational brochure about purchasing drugs from foreign counties. While the committee acknowledges this practice is illegal, many seniors obtain drugs from foreign countries because the drugs are cheaper. This is a new area of consumer and media interest, and is generating a number of media calls to the board.

  Chairperson Powers stated that a major issue for those who purchase prescription medication from foreign countries is because of costs. Some patients are unable to obtain prescribed medication because of the high cost, while other try to make difficult decisions to balance food or housing expenses versus the purchase of medication.

  Chairperson Powers stated that patients hoping to reduce their drug costs are purchasing medications from outside the U.S., typically from Canada where the costs are less. Whereas such drug purchases are illegal, the FDA is not enforcing restrictions against patients who obtain a 90-day supply for personal use. However, when drugs are purchased from other countries, the FDA cannot guarantee authenticity of prescription drug.

  Board Members discussed the importance of educating patients about the "risks" involved when they purchase prescription medication from foreign countries and that a consumer brochure should be developed.

ORGANIZATIONAL DEVELOPMENT COMMITTEE

Chairperson Gubbins stated that the Organizational Development Committee met on September 26, 2002, in a teleconferenced meeting.

- **Updated on Current Budget (2002/03)**

Chairperson Gubbins reported that $6 million from the board's reserve was transferred as a loan to the state's General Fund. A preliminary fund condition prepared by the department's Budget Office indicates a deficiency in the board's fund in 2003/04.

Chairperson Gubbins stated that the Department of Finance issued a directive that no budget change proposal should be submitted for program expansions or new programs for future years due to the state's economy and fiscal crisis. Therefore the only budget change proposal that was submitted was for $354,059 -- $301,919 for the Attorney General's Office and $52,140 for postage. The Department of Finance disapproved the budget change proposal.

- **Act to increase its fees via a regulation change to the statutory fee maximums beginning July 1, 2003. This will add at least $1.3 million in additional revenue annually**

  For the 2002/03 budget, the board "loaned) $6 million from its fund to the State's Funeral Fund. According to the language from the Budget Act, the Legislature committed to repayment of the loan to ensure that the programs supported by this fund are not adversely affected by the loan through reduction in service or through increased fees. This language would indicate that the board should not have to increase fees; instead the loan will be paid. However, the Department of Consumer Affairs did state that a fee increase through regulation would be allowed.

  Projections for fiscal year start next July 1, 2003, show the board will deplete its fund and will end the fiscal year on June 30, 2004, approximately $275,000 in the red. As such the board (if necessary) needs to take action to increase its fees effective July 1, 2003.

  The board agreed to raise fees to the statutory maximum via regulation should the 6 million loan not be repaid. Even if the board increased its fees through regulation, there would still be a $1.2 million gap between annual revenue and expenditures. Staff will continue to work closely with the Department of Consumer Affairs and the Department of Finance to assure re-payment of the loan and to avoid deficiencies.

- MOTION: Organizational Development Committee**:** To increase its fees via a regulation change to the statutory fee maximums beginning July 1, 2003.
  SUPPORT: 8
  OPPOSE: 1

- **Pursue increases in its statutory maximum fees to the levels of the mid-1980s when adjusted for inflation.**

  Chairperson Gubbins stated that the board might need to raise the statutory maximum fees to the levels of the mid-1980s when adjusted for inflation. If the state's economy makes it difficult for the $6 million loan to be repaid in the next year, the board's huge

gaps between annual revenue and expenditures may require the board to pursue legislation to increase its fee authority above the current maximum. The revenue projections for 2004/05 are $2.8 million less than expenditures. The board cannot reduce expenditures sufficiently without Draconian cuts and possible layoffs to balance its expenditures with revenue. As such, the board will either need to be repaid for its loan or will need to increase fees to new and higher levels than currently authorized in statutes. Staff will work closely with the Department of Consumer Affairs and Department of Finance to assure timely repayment of the loans. However the board may need to consider this option as well. If necessary, the board agreed to pursue legislation to raise the statutory maximum levels of fees.

MOTION: Organizational Development Committee: If necessary, pursue legislation to raise the statutory maximum levels of fees.

SUPPORT: 5

OPPOSE: 4

The board requested that the Department of Consumer Affairs and the Department of Finance be informed of the impact that the loan of the board's fund and loss of vacant positions has had on the board's public protection efforts.

MOTION: Communicate with the Department of Consumer Affairs and the Department of Finance to inform them of the impact that the loan of the board's fund and loss of vacant positions has had on the board's public protection efforts.

M/S/C: POWERS/ZIA

SUPPORT: 9

OPPOSE: 0

- **Communications Team Report**

Lin Hokana, representing the Communications Team reported that the TCT continues to focus on three major functions; communicating issues between staff and management, facilitating the All-Staff Meetings and fundraising for the annual staff picnic.

APPROVAL OF MINUTES

Full Board Minutes
(July 24 and 25, 2002)

President Jones asked if there were any corrections to the minutes. There were none.

MOTION: Approved the July 24 and 25, 2002, minutes.

MSC: POWERS/ZIA

SUPPORT: 9

OPPOSE: 0

PUBLIC COMMENT

Robert Horowitz, asked the board to consider a letter of explanation regarding a disciplinary action taken in connection with Doc's Pharmacy.

Deputy Attorney General Ron Diedrich stated that because a decision was made regarding the case, the board does not have the legal authority to act on additional information submitted. However, the board would accept the letter.

ADJOURNMENT

There being no further business, President Jones adjourned the meeting 11:00 a.m.