



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

ACTION ITEMS – July 2005 BOARD MEETING

The board meeting materials are on the Web site.

ORGANIZATIONAL DEVELOPMENT COMMITTEE

The board:

- Announced the committee assignments for 2005/06:
Organizational Development: President Goldenberg and Ruth Conroy
Communication and Public Education Committee: Andrea Zinder (Chair), Richard Benson, William Powers, and Kenneth Schell
Subcommittee on Medicare Drug Benefit Plans: Stanley Goldenberg (Chair), William Powers, John Jones, and Andrea Zinder
Enforcement Committee: William Powers (Chair), Marian Balay, David Fong, and Stanley Goldenberg
Legislation and Regulation Committee: John Jones (Chair), David Fong, Kenneth Schell, and Andrea Zinder
Licensing Committee: Ruth Conroy (Chair), Richard Benson, Clarence Hiura, and John Jones
Competency Committee: Kenneth Schell
- Recognized 486 pharmacists who have been licensed for 50 years. These pharmacists were mailed an award certificate with a congratulatory letter. The board publicly acknowledged three pharmacists who attended the board meeting. The recognition will also be published in the board's newsletter, along with a list of recipients.
- Announced the board meeting dates for 2006: January 24 & 25, April 26 & 27, July 19 & 20 and October 25 & 26.
- Reported on its participation in a newly formed pharmacy leadership council that also includes the membership of the California professional associations and schools of pharmacy.
- Reported that the board received repayment of \$3 million for the new fiscal year. This repayment is for the \$6 million loaned to the General Fund to offset the state budget crisis four years ago.
- Approved the minutes of the April 27 & 28, 2005 board meeting.

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

The board:

- Reported on the first subcommittee meeting on the Medicare Drug Benefit Plans. The purpose of the meeting was to discuss the implementation of the Medication Prescription Drug Act, and specifically the Part D Benefit for prescription drugs. The changes, which will begin January 1, 2006, represent an enormous change in the Medicare benefit program. The changes affect Medicare beneficiaries, their

families and caregiver as well as pharmacists, physicians, nurses and patient advocates. The goal is for the regulatory agencies of professional licensees take a strong lead in educating their licensees about the new provisions. Patients and their families will seek information from their health care providers, and lack of knowledge by the health care providers will place additional strains on patients and health care advocates to obtain and provide this information. The next meeting is October 14th in Sacramento.

- Approved the proposal to develop a joint web site with the Center for Consumer Self Care at UCSF to house consumer fact sheet series under development by both agencies.
- Announced that the California Health Communication Partnership will be launching its third coordinated project. The third project will be on cancer screening. The Center for Consumer Self Care has obtained funding for a consumer column to be distributed nationwide through the NAPS distribution system. Public service announcements encouraging mammograms and prostate cancer screening also have been developed.
- Reported that staff is working on publishing a new *Health Notes on Pain Management*. This new issue will contain new pain management therapies and the new prescribing and dispensing requirements for controlled drugs enacted by SB 151 (Burton, Chapter 406), which took place in 2005. The goal is to have this publication available for distribution in the Fall 2005. The next *Health Notes* publication that the board agreed to produce will be on pharmacy emergency response to patients in a declared disaster area.
- Reported that articles for the next *Script* have been written. The next issue should be published in Fall 2005.
- Reported that during 2004/05, members and staff have participated in at least 17 public education fairs or outreach events and more than 56 forums to educate the profession or other healthcare providers and law enforcement staff.

LICENSING COMMITTEE

The board:

- Approved the proposed statutory changes to the clinic requirements. These provisions will be submitted to the Legislature as omnibus provisions for 2006.
- Received an interim report on the UCSF School of Pharmacy and Cedars-Sinai Medical Center (CSMC) study on the evaluation of the impact of pharmacists in the prevention of medication errors in the hospital setting. This study is evaluating the impact of pharmacists in prevention of medication errors associated with prescribing and administering of medications as a result of pharmacist being re-deployed from unit-dose medication cassette checking to more clinical and professional functions. This study is a sequel to the experimental program that evaluated technicians checking technicians in a unit-dose distribution system in a hospital setting. The study will end April 21, 2006.
- Reported on the development of a proposal for pharmacists performing drug utilization review (DUR), medication therapy management (MTM), pharmacist call centers and the central processing of prescriptions for California patients. This proposal will be the subject of the future roundtable discussions at the Licensing Committee meetings. The next meeting is set for September 21st in Oakland.
- Noted that the board is seeking assurance that the Drug Enforcement Administration (DEA) will issue DEA mid-level practitioner numbers to pharmacists who practice in community pharmacy settings as well as to those in hospital settings.

- Reported that President Goldenberg appointed 8 new members to the Competency Committee. This committee is responsible for the development of the California Pharmacist Jurisprudence Examination (CPJE).
- Completed its job analysis of the pharmacist profession to maintain the validity of the CPJE. A new content outline for the CPJE should be in place by the end of 2005, at which time it will be released publicly. The new content outline will be used for the Spring 2006 administration of the CPJE.
- Reported that the CPJE is administered through Experior Assessments, LLC, at test centers statewide. Experior also administers California examinations for many other boards and programs of the Department of Consumer Affairs. The master contract expires November 30, 2005. Currently, the department is in the contracting process for a new vendor. The new contract should be awarded by October, leaving four months to transition to a new vendor before the end of the current contract (which can be automatically extended to February 2006). It was noted that delays in the process could impact of applicants to take the CPJE after February 2006.

ENFORCEMENT COMMITTEE

The board:

- Discussed the use of automated storage devices in clinics as authorized by Bus. & Prof. Code, § 4181.
- Approved the repeal of 16 CCR § 1717.2 – Notice of Common Electronic Prescription Files. To repeal this regulation, the board must provide a 45-day notice and adopt the change at a future board meeting.
- Granted a waiver of CCR, title 16, sec. 1717(e) to authorize White Cross Drug Store to install and use an automated self-service delivery unit in its pharmacy that allows a patient to access his or her filled prescriptions. A patient will be allowed to access the delivery unit when the pharmacy is open or closed. The board granted the waiver with the condition that the device is for refilled prescriptions only; however, the pharmacist is not to use the device to dispense refilled prescriptions if the pharmacist determines that the patient requires consultation pursuant to section 1707.2(a)(2). The device must be located in reasonable proximity to the licensed pharmacy premise. The device must have the means to identify the patient and only release that patient's prescriptions. The device is secure from access and removal by unauthorized individuals. The pharmacy must provide a means for the patient to obtain consultation with a pharmacist if requested, and the pharmacy is responsible for the prescriptions stored in the device. The patient must choose to use this device. In conjunction with the waiver, the pharmacy has agreed to participate in the UCSD Skaggs School of Pharmacy and Pharmaceutical Sciences research study on the impact of this technology to pharmacy and patients.
- Granted a similar waiver to Walgreens to install and use an automated self-service delivery unit in its pharmacies that allows a patient to access his or her filled prescriptions. The waiver was granted based on the same conditions as stated above.
- Received an update from UCSD Skaggs School of Pharmacy and Pharmaceutical Sciences on its research study regarding the use of an automated self-service drug delivery system and the impact of this technology to pharmacy and patients. It is anticipated that the study will be completed and the final outcome reported to the board by February 2007.
- Reviewed the requirements for petitions for reconsideration and reaffirmed its current policy of reviewing all petitions for reconsideration that are received timely, and delegating to the board president the authority to review those petitions not received timely. For petitions not received timely, the board president may (a)

stay the effective date of the disciplinary order to allow the board to consider the petition, or (b) not take any action and consider the petition denied.

- Clarified pharmacy laws related to intern pharmacists, orally and electronically transmitted prescriptions and the filing of non-security prescription forms. This information will be included in a board newsletter.

LEGISLATION AND REGULATION COMMITTEE

The board:

- Held an informational hearing on a proposed regulation change to add 16 CCR § 1727.1 that would exempt an intern pharmacist’s address from being available on an interactive communication system such as the “World Wide Web” and “Internet.” This regulation will be released for public comment soon to initiate the rulemaking process.
- Reported that the following regulations changes adopted by the board are pending review by the Office of Administrative Law. The regulations are:
 1. Adoption of Amendment to CCR, title 16, sec. 1706.1 – Abandonment of Application Files
 2. Adoption of CCR, title 16, sec. 1712 – Use of Pharmacist Identifier
 3. Adoption of Amendment to CCR, title, 16, sec. 1715 – Self-Assessment of a Pharmacy by the Pharmacist-in-Charge (PIC)
 4. Adoption of Amendment to CCR, title 16, sec. 1717 – Pharmacy Practice
 5. Adoption of Amendment to CCR, title 16, sec. 1719 – Recognized Schools of Pharmacy
 6. Adoption of Amendment to CCR, title 16, sec. 1720 – Application for Pharmacist Examination and Licensure
 7. Adoption of Amendment to CCR, title 16, sec. 1720.1 – Graduates of Foreign Pharmacy Schools
 8. Adoption of Amendment to CCR, title 16, sec. 1725 – Acceptable Pharmacy Coursework for Examination Candidates with Four Failed Attempts
 9. Adoption of Amendment to CCR, title 16, sec. 1726 – Supervision of Intern Pharmacists
 10. Adoption of Amendment to Repeal CCR, title 16, sec. 1727 – Intern Pharmacist
 11. Adoption of Amendment to CCR, title 16, sec. 1728 – Requirements for Examination
 12. Adoption of Amendment to CCR, title 16, sec. 1732 – 1732.7 – Continuing Education
 13. Adoption of Amendment to CCR, title 16, sec. 1745 – Partial Filling of Schedule II Prescriptions
 14. Adoption of Amendment to CCR, title 16, sec. 1749 – Fee Schedule
 15. Adoption of Amendment to Repeal CCR, title 16, sec. 1750 – Fee Schedule – Health and Safety Code
- Reviewed pending legislation and changed positions on three bills that are identified with an asterisk.

*AB 21	Levine	Allows a pharmacist to decline on ethical, moral, or religious grounds to dispense a drug pursuant to a lawful request only if he or she satisfies certain conditions.	Oppose
AB 225	Negrete McLeod	Allows health care professionals to receive nonmonetary remuneration, in the form of hardware, software, or information technology and training services, necessary and used solely to receive and transmit electronic prescription information. Requires freedom of choice to transfer a prescription to a	Support if Amended

		pharmacy of the patient's choice.	
AB 283	Koretz	Limits the access to ephedrine and pseudoephedrine products by requiring the products be placed in a locked cabinet.	No Position
AB 446	Negrete McLeod	Prohibits "regulatory gag clauses" in malpractice settlements.	Support
AB 497	Negrete McLeod	Revises the nonresident wholesaler license requirement to require an applicant to submit only one surety bond of \$100,000, or an equivalent means of security, regardless of how many individual sites are licensed.	Support
AB 522	Plescia	Clean-up language for AB 2184 (Chapter 342, Statutes of 2004), Automated Dispensing Devices.	Support if Amended
AB 595	Negrete McLeod	Defines compounding of a prescription drug for the purposes of the Pharmacy Law and establishes requirements for pharmacists that compound drugs.	Board Sponsored/ Support
AB 657	Karnette	Revise the prescription-labeling requirement to require a container to be labeled with the "intended purpose" for which the drug was prescribed essentially an "opt out" process instead of an "opt-in" process already in law.	Oppose
SB 152	Speier	Requires pseudoephedrine products to be sold in a pharmacy by a pharmacist or pharmacy technician and for pharmacists and pharmacy techs to document purchase of products.	Neutral
*SB 401	Ortiz	Define marketing to include written communication that is provided by a pharmacy to a patient about a different drug or treatment than that being dispensed by the pharmacy and that is paid for, or sponsored by a manufacturer.	Oppose Unless Amended
SB 592	Aanestad	Permits pharmacy technicians to check the work of other pharmacy technicians filling unit dose medication cassettes for hospital patients.	Support
SB 644	Ortiz	Require a health care licentiate to dispense drugs and devices pursuant to a lawful prescription or order except in specified circumstances, including on ethical, moral, or religious grounds asserted by the licentiate.	Support
SB 734	Torlakson	Clean-up changes to facilitate the effective operation of the CURES, the prescribing and dispensing of controlled substances, and the program duties of the Bureau of Narcotics Enforcement.	Oppose Unless Amended
*SB 798	Simitian	Authorizes a county to establish, by local ordinance, a repository and distribution program for purposes of distributing surplus unused medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies.	Oppose Unless Amended
SB 1111	Senate B&P Com	Annual omnibus bill with technical and non-controversial changes to pharmacy law.	Support