



ACTION ITEMS – APRIL 2003 BOARD MEETING

The board packet materials for this meeting are available on the board's website.

LICENSING COMMITTEE

The board:

- Approved the Accreditation Commission on Healthcare (ACHC) as an accreditation agency for pharmacies that compound injectable sterile drug products. ACHC accredited pharmacies are exempt from licensure pursuant to Business and Professions Code section 4127.1(d). The board granted this approval for three years.
- Developed criteria to be used as a guide when evaluating and approving accreditation agencies pursuant to Business and Professions Code section 4127.1(d).
- Reported on the implementation of the licensure and inspection program for pharmacies that compound injectable sterile drug products. The application and a self-assessment forms are available on the board's website.
- Reported on the meeting of the Ad Hoc Committee on Pharmaceutical Benefit Managers (PBMs) Regulation. The next meeting is scheduled for June 4, 2003. The meeting summary is available on the board's website.

ENFORCEMENT COMMITTEE

The board:

- Considered the request from the California Society of Health-System Pharmacists to amend CCR 1771(c) regarding the notification of the patient and prescriber when a prescription error has occurred. This matter was returned to the Enforcement Committee with direction to the stakeholders to develop language to address those situations when a patient has not ingested the medication.
- Took testimony from seniors, consumer groups and the profession regarding the importation of prescriptions drugs from Canada through storefront operations in California. The board has the responsibility as a consumer protection agency to explore all aspects of the issue such as the health and safety concerns of obtaining prescriptions drugs.
- Discussed the implementation of the federal Health Insurance Portability and Accountability Act (HIPAA) that went into effect April 14, 2003. The Office of Civil Rights (the federal agency responsible for the implementation of HIPAA) noted that an inspector's review of a patient's protected health information during an inspection is disclosure of the protected health information and must be disclosed if requested by the patient. Upon completion of a routine inspection, the board inspector will provide to the licensee those patient records that were reviewed so that the licensee can make a proper accounting of the disclosure. When the

inspector is performing an investigation, either the inspector will provide a medical release, an investigative subpoena, or an investigative demand. An investigative demand will include a statement of facts demonstrating why the information is relevant and why de-identified information cannot reasonably be used. To account for the disclosure, the licensee can use the receipt that the inspector provides for the records.

- Noted that the Medical Board of California has appointed two members to serve on a joint task force with the board on prescriber dispensing. Any meetings will be publicly noticed, once scheduled.

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

The board:

- Approved a consumer brochure on purchasing drugs from foreign countries. The brochure is broken down into three parts: purchasing drugs from foreign countries, ways for consumers to reduce their expenses for prescription drugs and discount programs for prescription drugs available to the public.
- Reported that the March 2003 edition of *The Script* was printed and mailed to all California pharmacies and placed on the board's website. The next issue will be produced in the summer of 2003. The California Pharmacists Association (CPhA) Education Foundation is printing and mailing the March 2003 issue to all licensed pharmacists, if sufficient funding is found.
- Reported that *Health Notes #7* on Drug Therapy Considerations for Older Americans was printed and mailed to all pharmacies and pharmacists. The University of California, San Francisco, School of Pharmacy received outside funding to develop this issue, and the California Society of Health-Systems Pharmacists received a grant to assist with the printing.
- Reported that three more series of the Hot Topics in Pharmacy were presented in Sacramento. The seminars are co-sponsored by the Department of Consumer Affairs, the UCSF Center for Consumer Self-Care and the Board of Pharmacy. The seminars were What Everyone Needs to Know About Managing Pain Effectively, Direct-to-Consumer Advertising of Prescription Medications and Current Issues in Tobacco Cessation. The last series on Deciding on Hormonal Options for Menopause will be held May 16, 2003.
- Reported that the board's continuing education course on the Board of Pharmacy, its enforcement, licensing, and legislative activities was developed and presented three times since January 2003. Over 130 pharmacists and 50 students have taken this course.

LEGISLATION AND REGULATION COMMITTEE

The board:

- Adopted amendments to CCR 1775 et seq. These amendments will change the board's citation and fine process by delegating to the executive officer or designee the authority to issue a citation and fine. The Office of Administrative Law (OAL) must approve the proposed regulation changes before they become effective.

- Adopted amendments to CCR 1751 et seq. regarding the compounding of injectable sterile products. The board adopted the amendments with modifications that will be noticed for a 15-day comment period. Then the regulations will be submitted to OAL for approval.
- Reported that OAL approved the following regulations that became effective March 12, 2003. They were: CCR 1717(e) – delivery of medications to a location where a patient receives healthcare; CCR 1720.4 – acceptance of transcripts if verified by a credentials evaluation service for candidates who graduated from a foreign pharmacy school; and section 1745 – extension to 14 days in which a partially-filled Schedule II prescription may be completely filled.
- Took positions on the following legislative bills:
 - AB 103 (Reyes) Oppose unless amended
 - AB 261 (Maddox) Support
 - AB 521 (Diaz) No position
 - AB 746 (Matthews) Support
 - AB 1363 (Berg) Support
 - AB 1460 (Nation) Support
 - SB 151 (Burton) Support
 - SB 175 (Kuel) Support if amended
 - SB 292 (Speier) No position
 - SB 361 (Figueroa) Support
 - SB 393 (Aanestad) Support if amended
 - SB 490 (Alpert) Support
 - SB 506 (Sher) Oppose
 - SB 545 (Speier) Oppose
 - SB 774 (Vasconcellos) Support with amendments
- Voted to sponsor a provision (in the annual omnibus bill) to allow printouts from the board’s website to serve as license verification.

ORGANIZATIONAL DEVELOPMENT COMMITTEE

The board:

- Reported on the Sunset Review process. On April 2, 2003, the Joint Legislative Sunset Review Committee (JLSRC) held its hearing on its staff recommendations for the board. Incorporated into these recommendations were draft recommendations from the Department of Consumer Affairs. On April 7, 2003, the JLSRC adopted the following recommendations:
 - **The licensing and regulation of the pharmacy profession should be continued and a board structure should be maintained.**
 - **Add two public members to the board.**
 - **Make all committee meeting of the board public meetings.**
 - **The board should adopt NAPLEX.**

- **Modify the citation and fine program to exclude the involvement of board members and delegate to the executive officer the authority to issue citations and fines.**
- **The board should not require all its inspectors to be pharmacists.**
- **The board should use the department's online consumer complaint form.**
- **The board should expand its consumer outreach and education, and work with the department to develop additional materials.**
- **The board should establish a reliable method of communicating and surveying those who have filed complaints, and revise its survey instrument to provide meaningful data.**
- **The board should work with the department's Office of Privacy Protection on ensuring patient privacy.**
- Reported that the sunset recommendations and omnibus provisions are contained in SB 361.
- Provided a copy of the Legislative Counsel's opinion of what constitutes "actively engaged" within in the meaning of Business and Professions Code section 4001 regarding the appointment of professional members to the board.
- Reported the findings of the Department of Consumer Affairs' Internal Audits Office on its operational audit of the board.
- Reported that the board has won the Fred T. Mahaffey Award from NABP for its Quality Assurance program for prescription errors.
- Reported that board members and designated staff must complete ethics training by December 2003.
- Began awarding 6 hours of continuing education to pharmacists for attending board meetings.
- Reported on a number of cost containment controls that have been placed on state agencies in addition to the current hiring freeze and elimination of positions. The board's in-state travel budget was cut by 35 percent (\$52,200) and all training requests, contracts and purchases must under go additional review and approval.
- Reported that the Administration directed state agencies to identify cuts in their personnel services budgets of 10 percent for 2003/04 and prepare a list of surplus employees for layoff. This will amount to a \$353,000 reduction for the board, the elimination of all vacant positions (two inspectors, two analysts, and one clerical), overtime, and board member honoraria. The board does not anticipate staff layoffs should it be directed to implement the 10 percent reduction.
- Reported that it is working with the department and the Department of Finance to assure repayment of the \$6 million loan (to the state's general fund) before the board has a deficit.
- Agreed to submit a deficiency augmentation request to maintain ongoing access to legal services from the Attorney General's Office and funding for a job analysis in 2004 for the pharmacist licensure examination.
- Reported that Inspectors Joan Coyne and Dennis Ming were promoted to Supervising Inspectors.
- Held its annual strategic planning session and adopted its strategic plan for 2003/04.
- Reaffirmed its meeting dates for 2003 and established meeting dates for 2004. They are:

- July 21-22, San Diego
 - October 29-30, San Francisco
- 2004
- January 21-22, Orange County
 - April 21-22, Sacramento
 - July 21-22, San Diego
 - October 20-21, San Francisco
- Elected John Jones – President, Don Gubbins – Vice-President, and John Tilley – Treasurer.
 - Approved the minutes of the January 22 and 23, 2003 board meeting.