



At its December meeting, the Board vote for President resulted in a tie between John Anthony, OD, and Pamela Miller, OD, JD. Because of the tie, existing president Thomas Nagy, OD, will continue to serve as president until a new vote is taken at the March meeting. The committee chairs will also remain the same until March, as they are selected by the President.

### ■ FUTURE MEETINGS

March 11-12 in Long Beach.  
May 19-20 in San Diego (tentative).

### BOARD OF PHARMACY

*Executive Officer: Patricia Harris*  
(916) 445-5014

Pursuant to Business and Professions Code section 4000 *et seq.*, the Board of Pharmacy grants licenses and permits to pharmacists, pharmacies, drug manufacturers, wholesalers, and sellers of hypodermic needles. It regulates all sales of dangerous drugs, controlled substances, and poisons. The Board is authorized to adopt regulations, which are codified in Division 17, Title 16 of the California Code of Regulations (CCR). To enforce its regulations, the Board employs full-time inspectors who investigate complaints received by the Board. Investigations may be conducted openly or covertly as the situation demands.

The Board conducts fact-finding and disciplinary hearings and is authorized by law to suspend or revoke licenses or permits for a variety of reasons, including professional misconduct and any acts substantially related to the practice of pharmacy.

The Board consists of ten members, three of whom are nonlicensees. The remaining members are pharmacists, five of whom must be active practitioners. All are appointed for four-year terms.

At the Board's October 6 meeting, President Raffi Simonian introduced new Board members Holly Ann Strom and Gary Dreyfus, appointed by Governor Wilson on August 19. Strom is drug education coordinator for Kaiser Permanente in West Los Angeles; Dreyfus is president of Moulton Plaza Pharmacy in Laguna Hills, and has fourteen years of experience as a self-employed pharmacist.

### ■ MAJOR PROJECTS

**Board Proposes Regulation on Furnishing to Home Health Agencies.** On December 10, the Board published notice of its intent to adopt new section 1751.11,

Title 16 of the CCR, to establish a list of dangerous drugs which may be furnished by a pharmacist to a licensed home health agency and stored in transportable, tamper-proof, sealed storage containers. [13:4 CRLR 82] According to the Board, the drugs on the list are used in parenteral therapy and do not include controlled substances; the sealed storage container would be issued by a licensed pharmacy to a home health agency registered nurse, who could bring a portable container with him/her during home care visits to patients. Under the proposed regulation, drugs could be furnished by the home health agency registered nurse from the portable container to patients pursuant to a prescription or an oral order for emergency treatment or adjustment of parenteral drug therapy; specific administration protocols would be established regarding the furnishing of any dangerous drug from the portable container by the registered nurse.

Among other things, the regulation would establish inventory and record-keeping requirements for the pharmacy that prepares the containers; require the home health agency to keep additional records regarding furnishing; set requirements for the home health agency regarding orally transmitted orders from licensed prescribers to the registered nurse to authorize furnishing drugs from the containers; and establish storage requirements to assure that the container is not exposed to excessive heat or cold which could damage the contents.

At this writing, the Board is scheduled to conduct a public hearing on the proposed adoption of section 1751.11 on January 26 in Sacramento.

**Citation and Fine Program.** On October 6, the Board held a public hearing on the proposed adoption of new Article 9.5, commencing with section 1775, Title 16 of the CCR; the new article would implement Business and Professions Code section 125.9 and authorize the Board's Executive Officer to issue citations and fines for specified violations of law. [13:4 CRLR 79] At the hearing, several individuals and representatives of professional groups and private pharmacies expressed opposition to the proposed regulations, claiming that they fail to provide adequate due process; delegate powers which only the Board should exercise; create an adversarial atmosphere between pharmacists and the Board; make it difficult to determine who to fine (employee or supervisor); lack a statistical showing of need; provide too broad a range of discretionary fines; cost too much; do not affect major violators; present too large a potential to

clog the system with appeals; preclude further use of facts if stronger disciplinary action is needed; and could potentially be used against a licensee in a civil action.

The Board received other comments in support of the proposal from individuals who contended that many of the above issues could be addressed through modified regulatory language; the legislature enacted the citation and fine program to enable agencies to deal with mid-level problems that do not justify the filing of an accusation and, although the specific facts could not be used for further discipline, further action would not be contemplated unless further evidence becomes available; under the proposed regulations, licensees would continue to have the full Administrative Procedure Act appeal process available; the Board could consider an informal appeal process to the Executive Officer; and the program does not include an admission of guilt on the pharmacist's part. Retired Board Supervising Inspector Ken Sain noted that the citation and fine mechanism is an excellent tool for stopping unlicensed activity, which often goes unaddressed by district attorney's offices and other law enforcement agencies which must handle higher-priority matters.

Following discussion, the Board unanimously deferred action on the proposed regulations and referred the matter to its Enforcement Committee for further review; specifically, the Board directed the Enforcement Committee to closely reexamine the proposed regulations, suggest alternative ways to pursue a citation and fine program, and—if appropriate—develop the necessary language. The Committee is expected to present its findings to the Board at a future meeting.

**Fee Increases Postponed.** Last August, the Board published notice of its intent to amend sections 1749 and 1793.5, Title 16 of the CCR, to increase specified license fees; according to the Board, the fee increases are necessary to restore the Board's reserve fund and maintain it at a prudent level to enable it to conduct ongoing operations. [13:4 CRLR 79] At the Board's October 6 meeting, Executive Officer Patricia Harris reported new budget information which indicates that a fee increase will not be needed until July 1995, and that an increase in fees to the maximum allowed by statute would result in too high a surplus. Although Department of Consumer Affairs staff counsel Robert Miller noted that the Board could consider adopting the changes with a delayed effective date, the Board unanimously voted to indefinitely table the proposed fee increases.



**Rulemaking Update.** The following is a status update on other Board rulemaking proposals discussed in detail in previous issues of the *Reporter*:

• In July 1993, the Board adopted a proposed amendment to section 1732.3, Title 16 of the CCR, regarding the duration of its approval of continuing education (CE) courses. Specifically, the proposed change would provide that a recognized Board provider's coursework shall be valid for three years following the initial Board approval; currently, such coursework is valid for two years following initial Board approval. This change would conform the Board's CE course validity period to that used by the American Council on Pharmaceutical Education. [13:4 CRLR 79; 13:2&3 CRLR 101] This change still awaits review and approval by the Office of Administrative Law.

• Also in July 1993, the Board conducted a public hearing on its proposal to amend section 1717(a), Title 16 of the CCR, which provides that—with specified exceptions—no medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia; the Board's proposed amendment would allow pharmacists to refill a prescription for non-liquid oral products in a clean, safe container previously provided to the same patient for the same drug, provided a new label is securely attached to the container. During the hearing, staff noted a comment submitted by the U.S. Consumer Product Safety Commission (CPSC) stating that federal law does not allow the reuse of child-resistant packaging or containers. Following discussion, the Board agreed to defer the regulation until its October meeting pending further research regarding the limitation of federal law and regulations. However, the Board modified the proposed language to provide that a pharmacy may, at the request of the patient or his/her agent, reuse prescription containers under the circumstances described above, provided the container is not a child-resistant container; the Board directed staff to release the modified language for an additional fifteen-day public comment period. [13:4 CRLR 80; 13:2&3 CRLR 101]

At the Board's October 6 meeting, Executive Officer Patricia Harris reported that staff had asked CPSC for clarification of its position regarding the proposed regulations; in response, CPSC stated that any rule allowing the reuse of child-resistant containers would conflict with 16 C.F.R. Part 1700.15(a), and that the prohibition against the reuse of child-resistant containers makes no exceptions, even if

requested by the patient. According to CPSC Western Region Senior Compliance Officer Albert Limberg, "[l]ogic dictates that neither the pharmacist nor the patient would be in any reasonable position to establish the effectiveness of the returned container, the number of reuses it has been subjected to or its remaining useful life." Further, Limberg counseled the Board to "forget the whole idea," contending that if environmental and recycling issues are the principal concern of the Board, a cost-benefit analysis indicates that the cost would be borne mainly "by the poisoning victim should a reuse rule be written." The California Employee Pharmacist Association voiced similar concerns about the safety of reused containers. Following discussion, the Board unanimously voted to indefinitely table the proposed regulatory action.

**Future Rulemaking.** At its October 6 meeting, the Board agreed to pursue rulemaking to modify section 1724, Title 16 of the CCR, regarding the procedure for scoring and grading the pharmacist licensure examination. The Board will propose to repeal section 1724(b), which currently provides that a candidate achieving a score of less than 75 on one section of the exam may retake only that one section at the next scheduled exam; if a candidate exercises this option and fails to achieve a score of 75 or more, the candidate must take the entire examination upon the next application. Under the modified proposal, staff will grade the multiple-choice portion of the exam first; if a candidate fails that section, staff will not grade his/her essay exam, thus eliminating the need to grade approximately 30% of the essays submitted for each exam administration. At this writing, the proposal has not been published in the *California Regulatory Notice Register*.

## ■ LEGISLATION

**SB 1048 (Watson)**, as introduced March 5, would establish the Clean Needle and Syringe Exchange Pilot Project, and authorize pharmacists, physicians, and certain other persons to furnish hypodermic needles and syringes without a prescription or permit as prescribed through the pilot project. Governor Wilson vetoed a similar bill, AB 260 (W. Brown), last October. [S. Floor]

**AB 667 (Boland)**. The Pharmacy Law regulates the use, sale, and furnishing of dangerous drugs and devices, as defined; the law prohibits a person from furnishing any dangerous device, except upon the prescription of a physician, dentist, podiatrist, or veterinarian. However, existing law provides that this prohibition does not

apply to the furnishing of any dangerous device by a manufacturer, wholesaler, or pharmacy to each other or to a physician, dentist, podiatrist, veterinarian, or physical therapist acting within the scope of his/her license under sales and purchase records that correctly give the date, the names and addresses of the supplier and the buyer, the device, and its quantity. As amended March 29, this bill would provide that the prohibition also does not apply to the furnishing of any dangerous device by a manufacturer, wholesaler, or pharmacy to a chiropractor acting within the scope of his/her license.

Existing law authorizes a medical device retailer to dispense, furnish, transfer, or sell a dangerous device only to another medical device retailer, a pharmacy, a licensed physician, a licensed health care facility, a licensed physical therapist, or a patient or his/her personal representative. This bill would additionally authorize a medical device retailer to dispense, furnish, transfer, or sell a dangerous device to a licensed chiropractor. [A. Health]

**SB 849 (Bergeson)**. Under the Pharmacy Law, a "hospital pharmacy" means and includes a pharmacy licensed by the Board of Pharmacy located within any hospital, institution, or establishment that maintains and operates organized inpatient facilities for the diagnosis, care, and treatment of human illnesses in accordance with certain requirements. Existing law requires the Department of Health Services to issue a single consolidated license to a general acute care hospital that meets certain requirements. As amended June 1, this bill would instead define a "hospital pharmacy" to mean a pharmacy licensed by the Board and located either within the physical plant of a general acute care hospital, as defined, acute psychiatric hospital, as defined, or special hospital, as defined, or outside of the hospital in another physical plant that is regulated under the hospital's single consolidated license, in accordance with certain requirements. [A. Health]

**AB 1807 (Bronshvag)**, as amended September 8, would provide that, notwithstanding specified security measures, a medical device retailer could establish a locked facility for furnishing dangerous devices in emergencies or after working hours, and would allow the Board to authorize revisions in the security measures pertaining to the delivery of dangerous devices from locked storage to patients.

Existing law defines the term "prescription" for the purposes of existing law relating to licensure of pharmacists, regulation of pharmacies, and regulation of controlled substances. This bill would re-



vise the definition of the term prescription, for those purposes, to also include electronically transmitted prescriptions, as defined. [13:2&3 CRLR 100-01]

This bill would also provide that any order for a Schedule II controlled substance in a licensed skilled nursing facility, intermediate health care facility, or a licensed home health agency providing hospice care may be dispensed upon an oral or electronically transmitted prescription; and would require these facilities to forward to the dispensing pharmacist a copy of any signed telephone order, chart order, or related documentation substantiating each oral prescription transaction. [A. Inactive File]

**AB 2020 (Isenberg)**, as amended June 17, would, among other things, authorize optometrists to use, prescribe, and dispense specified pharmaceutical compounds to a patient; provide that any use, prescribing, or dispensing of a pharmaceutical agent to a patient by an optometrist pursuant to these provisions is limited to that which is incidental to the practice of optometry; specify that dispensing by the optometrist to a patient be without charge; and make it a misdemeanor for any person licensed as an optometrist to refer a patient to a pharmacy that is owned by that licensee or in which the licensee has proprietary interest. [S. B&P]

## LITIGATION

In *Huggins v. Longs Drug Stores California, Inc.*, 6 Cal. 4th 124 (Nov. 18, 1993), the California Supreme Court reversed the Fifth District Court of Appeal's ruling that a pharmacist's provision of incorrect dosage amounts for a prescription which the pharmacist knew or should have known would be administered to an infant by the infant's parents constitutes negligent action by the pharmacist directed at the parent caregivers, which may allow the parent caregivers to state a claim as direct victims and recover damages for negligent infliction of emotional distress. [13:4 CRLR 81-82; 13:1 CRLR 63]

In reversing the Fifth District's decision, the Supreme Court acknowledged that it has allowed recovery for parental emotional distress resulting from professional mistreatment of a child by health care providers who were concurrently treating the parents as patients. However, where the plaintiff (here, the parent) is not the patient of the defendant caregiver (here, the pharmacist), courts have not extended the direct victim cause of action to emotional distress which is derived solely from a reaction to another's injury. The court found that the duty the Fifth District's ruling would impose upon phar-

macists would inevitably enlarge the potential liability of practically all providers of medical goods and services obtained by parents solely for the treatment of their children, or by other caregivers solely for the treatment of dependent family members; according to the court, that expansion of potential liability "not only would increase medical malpractice insurance costs but also would tend to 'inject undesirable self-protective reservations' impairing the provision of optimal care to the patient."

Justices Stanley Mosk and Joyce Kennard wrote dissenting opinions critical of the majority decision. Mosk opined that he "fail[s] to see how the imposition of liability here would be any novelty; a statutory duty to provide accurate instructions was breached and the persons to whom the instructions were directed seek compensation." Kennard contended that "[i]t is difficult to imagine just what 'undesirable self-protective reservations' a pharmacist under a duty to provide accurate instructions for the use of medicines might have that would impair patient care as a result of allowing parents to recover in the circumstances of this case. Allowing parents to recover against pharmacists as direct victims when they have personally administered medication causing serious injury to their children would rationally tend to assure that the pharmacist's legal duty to consult with the patient or the patient's agent is *more*, not less, effectively fulfilled" (emphasis original).

On October 27, the Second District Court of Appeal upheld the trial court's decision in *Californians for Safe Prescriptions v. California State Board of Pharmacy*, 19 Cal. App. 4th 1136, finding that the Board complied with the Administrative Procedure Act in promulgating and adopting its pharmacy technician regulations which authorize the use of pharmacy technicians in nondiscretionary tasks associated with dispensing drugs. [13:4 CRLR 82; 13:1 CRLR 62]

## RECENT MEETINGS

At its October meeting, the Board discussed the Drug Enforcement Agency's (DEA) response to its request for clarification of 21 C.F.R. Part 1304.04, which requires pharmacists to stamp a red "C" on the hard copy of controlled substance prescriptions; recognizing the increasing computerization of pharmacies, the Board asked DEA to allow pharmacies to either maintain a separate electronic file of Schedule III-V controlled substances, or maintain a separate physical file of Schedule III-V controlled substances, or mark all Schedule III-V controlled substance

prescriptions with a red "C." [13:4 CRLR 82] In its response, DEA offered two options for pharmacies: a pharmacy may either keep controlled substance prescriptions physically separate from other prescriptions, or commingle these and other prescriptions, in which case a red "C" must be stamped on controlled substance prescriptions. Existing DEA regulations do not address the electronic maintenance of prescriptions. Some Board members opined that DEA's regulations seriously affect computerization, and that computerization enhances enforcement efforts by offering easier inspection capabilities. The Board directed Deputy Attorney General William Marcus to write to DEA requesting reconsideration of the issue in light of the increased use of electronic prescription maintenance.

Also on October 6, the Board discussed whether to propose legislation which would require one Board member to be a pharmacist who dispenses prescriptions in the outpatient or community pharmacy setting. Instead of pursuing the change at this time, the Board directed staff to draft a letter to the Governor's Appointment Secretary expressing the Board's desire to have members who are actively practicing in the community setting.

Also at its October meeting, the Board discussed the response from Department of Health Services (DHS) to its letter requesting DHS to permit an increase in the number of different oral drugs which may be stored in the emergency drug supply of a licensed skilled nursing facility. Currently, DHS permits six drugs and allows flexibility for up to twelve drugs; on the recommendation of its Long-Term Care Committee, the Board requested that DHS allow flexibility for up to 24 drugs. Board President Raffi Simonian reported that DHS declined the Board's request, but agreed to consider further requests on a case-by-case basis. A representative from the California Pharmacists Association (CPhA) inquired whether the twelve drugs could vary from nursing station to nursing station within the facility. Because the Board understands its role on this issue as advisory—with DHS approving what actually goes into the kit, the Board asked CPhA to seek this clarification from DHS and report back at the next Board meeting regarding DHS' response.

## FUTURE MEETINGS

March 30-31 in Los Angeles.  
May 25-26 in Sacramento.