



Roger Valine, the insurer agreed to discontinue its policy "to avoid long and expensive litigation with the Justice Department that could easily have cost thousands and maybe millions in legal fees."

RECENT MEETINGS

At its October 14 meeting, the Board unanimously accepted DCA's recommendation to abolish its existing Examination Committee made up of non-Board members, and to reestablish the Examination Committee as an integral part of the Board with a member of the Board serving as chair of the Committee.

At the Board's December 1-2 meeting, President John Anthony, OD, announced that he will be appointing a Sunset Review Committee to prepare the Board for its upcoming "sunset" review before the legislature; SB 2036 (McCorquodale) (Chapter 908, Statutes of 1994) created a sunset review process for occupational licensing boards within DCA, requiring each to be comprehensively reviewed every four years. SB 2036 imposes an initial sunset date of July 1, 1999 for the Board; approximately one year prior to the Board's sunset date, a Joint Legislative Sunset Review Committee will review the Board's performance in several areas and make a recommendation to the legislature on whether the Board should be abolished, restructured, or redirected in terms of its statutory authority and priorities. The legislature may then either allow the sunset date to pass (in which case the Board would cease to exist and its powers and duties would transfer to DCA) or pass legislation extending the sunset date for another four years. [14:4 CRLR 89]

Also in December, the Board reviewed the request of Akorn, Inc., for approval of its product, AK-T-caine, as a topical pharmaceutical agent (TPA) which may be used by optometrists in their examination of patients in California. Following discussion, the Board agreed to approve the product and to (1) seek the Medical Board's approval as required by Business and Professions Code section 3041(e), and (2) schedule rulemaking hearings to amend section 1560, Title 16 of the CCR, to add AK-T-caine to the list of approved TPAs in California.

Also at the December meeting, the Board re-elected John Anthony, OD, to serve as president, and selected Robert Dager, OD, as vice-president and Mona Tawatao as secretary for 1995.

FUTURE MEETINGS

March 9-10 in Sacramento.
May 22-23 in San Francisco.
August 24-25 in Sacramento.
December 1-2 in Orange County.

BOARD OF PHARMACY

*Executive Officer: Patricia Harris
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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.

In January 1994, public member Herb Stoecklein resigned from the Board; at this writing, he has not yet been replaced.

MAJOR PROJECTS

Board Publishes Scaled-Back Version of Citation and Fine Regulations.

On November 4, the Board republished notice of its intent to adopt new Article 9.5, commencing with section 1775, to Title 16 of the CCR. For years, the Business and Professions Code has authorized the Board to adopt regulations to implement a system of issuing citations and fines to its licensees and to others who unlawfully provide services for which a license is required; however, the Board has never implemented this authority. Currently, when a licensee fails to comply with a statute or regulation, the Board is limited to seeking suspension, revocation, license probation, or judicial relief through actions by the Attorney General or a district attorney to enforce compliance. These processes are time-consuming, expensive, and allow illegal activities to continue throughout the process. In addition, many violations of laws regulating the practice of pharmacy do not warrant such severe discipline. These regulations, if adopted, would establish a citation and fine program to deal with some of these violations.

The proposed regulations represent an extremely scaled-back version of the citation and fine regulations proposed by the Board in 1993. [14:4 CRLR 91-92; 14:2&3 CRLR 95; 14:1 CRLR 73]

Proposed new section 1775 would provide that a Board inspector or committee may issue citations containing orders of abatement and/or fines for violations of the statutes referred to in section 1775.1. Each citation must be in writing and must describe the nature and facts of the violation, including a reference to the statute or regulation alleged to have been violated, and the citation must be served upon the individual personally or by certified mail. Section 1775 would also require that a citation inform the person or entity that if a hearing to contest the finding of a violation is desired, the hearing must be requested by written notice to the Board within thirty days of the issuance of the citation.

Proposed new section 1775.1 would list the Business and Professions Code violations for which the Board inspector or committee may issue a citation and fine or order of abatement. At this time, the listed sections which justify the issuance of a citation and/or fine pertain only to the unlicensed practice of pharmacy or related activities and violation of the pharmacist's duty to provide oral consultations before dispensing medication.

Section 1775.2 would set forth the criteria which must be considered when determining the amount of an administrative fine (when a fine is assessed with a citation). As proposed, this regulation provides that in no event shall the fine exceed \$2,500 for violations of the Code sections set forth in section 1775.1; a Board inspector or committee, in his/her/its discretion, may issue an order to cease the violation without charging a fine. In assessing the amount of an administrative fine, section 1775.2 would require the Board inspector or committee to consider, among other things, the gravity of the violation, the good or bad faith of the cited person or entity, the history of previous violations, evidence that the violation was or was not willful, and the extent to which the cited person or entity has mitigated or attempted to mitigate any damage or injury caused by the violation.

New section 1775.3, as proposed, would provide that an order of abatement shall either be personally served or mailed by certified mail; the time allowed for the correction of a violation begins when the order of abatement is final and has been served or received. If a cited person or entity who has been issued an order of abatement is unable to complete the cor-



rection in the time given because of condition beyond his/her/its control after the exercise of reasonable diligence, the person or entity may request an extension of time to complete the correction; such a request must be in writing and made within the time set forth for abatement. Failure to comply with an order of abatement shall constitute grounds for revocation or suspension of the license, permit, or registration. This section would also provide that the failure of a person or entity cited to pay a fine within thirty days of the date of assessment, unless the citation is being appealed, may result in disciplinary action by the Board; when a citation is not contested and a fine is not paid, the full amount of the fine shall be added to the fee for renewal of the license and the license shall not be renewed without payment of the renewal fee and fine.

Proposed new section 1775.4 would provide that any person or entity served with a citation may contest the citation by appealing to the Board in writing within thirty days of the issuance of the citation. In addition to requesting a hearing as provided in Business and Professions Code section 125.9, the person or entity may also request an office conference within fourteen calendar days after service of a citation; the office conference would be conducted by the Board's Executive Officer, a supervising inspector, or Board member(s). The person or entity may have legal counsel or an authorized representative present at the office conference. At the conclusion of the office conference, the Executive Officer, supervising inspector, or Board member(s) may affirm, modify, or dismiss the citation, including any fine or order of abatement issued; the reasons for the action must be stated in writing and a copy must be served or sent by certified mail to the person or entity cited within fourteen calendar days of the date of the office conference. The decision shall be deemed a final order with regard to the citation issued. The right to request a hearing to contest a citation is not waived by requesting an office conference after which the citation is affirmed; if the citation is dismissed at the office conference, the request for a hearing will be deemed withdrawn. If the citation is modified at the office conference, the citation originally issued shall be deemed withdrawn and a new citation issued; a request for a hearing on the subsequent citation shall be made within thirty days of the subsequent issuance.

At this writing, the Board is scheduled to hold a public hearing on the proposed adoption of new sections 1775, 1775.1, 1775.2, 1775.3, and 1775.4 on January 25 in Los Angeles.

Fee Increases Proposed. Also on November 4, the Board published notice of its intent to amend sections 1749 and 1793.5, Title 16 of the CCR, which specify the schedule of fees and penalties for the licenses, permits, and registrations issued by the Board. The proposed amendments would increase specified fees to ensure that the Board's reserve fund is restored and maintained at a prudent level for conducting ongoing operations. Currently, Business and Professions Code section 4415(r) directs the Board to maintain a reserve fund equal to approximately one year's worth of operating expenditures; however, fiscal policy in the Department of Finance has identified three months' worth of operating expenditures as the appropriate amount to be maintained as a reserve fund. A fiscal analysis of the Board's current reserve, its expected income from fees at current levels, and the Board's expectation of increased expenditures for consumer awareness programs, recent increases in staff, and the continuing efforts toward automation indicates that by the end of fiscal year 1995-96, the Board will have a budget deficit of \$797,064, which will grow to \$2.2 million by the end of fiscal year 1996-97. Consequently, the Board has proposed to increase its fees beginning July 1, 1995 to protect its reserve fund.

The amendments to section 1749 would, among other things, increase the fee for the issuance of a permit to conduct a pharmacy from \$340 to \$400; increase the annual permit renewal fee from \$175 to \$250; increase the penalty for failure to renew from \$87.50 to \$125; and increase the fee for the biennial renewal of a pharmacist's license from \$115 to \$150. The amendments to section 1793.5 would increase the fee for registration as a pharmacy technician from \$25 to \$50. Although these changes would eliminate the danger of a deficit in the Board's reserve fund, the increased income will not provide the Board with a reserve equal to three months' operating expenditures; accordingly, the Board may sponsor legislation which would allow it to impose further fee increases.

At this writing, the Board is scheduled to hold a public hearing on the proposed amendments to sections 1749 and 1793.5 on January 25 in Los Angeles.

Electronic Transmission of Prescriptions. AB 1807 (Bronshvag) (Chapter 26, Statutes of 1994) revised the definition of the term "prescription" to include prescriptions for controlled substances that are electronically transmitted, and specified the information gathering and storage requirements for a valid prescription

transmitted electronically. [14:4 CRLR 89; 14:2&3 CRLR 98] However, the Board's existing regulations do not contain the provisions necessary to implement these amendments. On November 4, the Board published notice of its intent to add new section 1717.4, Title 16 of the CCR, to authorize the electronic transmission of prescriptions by prescribers to pharmacies while assuring the security and confidentiality of electronically transmitted prescriptions.

As proposed, this regulation would provide that, except as otherwise prohibited by law, prescriptions may be transmitted by electronic means from the prescriber to the pharmacy. An electronically transmitted prescription shall include the name and address of the prescriber, a telephone number for verbal confirmation, date of transmission, and the identity of the recipient, as well as any other information required by federal or state law. An electronically transmitted prescription shall be transmitted only to the pharmacy of the patient's choice; the pharmacy receiving the electronic transmission must either receive or have the capacity to retrieve the prescription in hard copy form; and any hard copy of a prescription shall be maintained on paper of permanent quality. The regulation also provides for an "interim storage device," which is an electronic file into which a prescription is entered for later retrieval by an authorized individual; any interim storage device shall record and maintain the date of entry and/or receipt of the prescription order, date of transmission from the interim storage device, and identity of the recipient of such transmission, as well as other specified information. The interim storage device must be maintained so as to prevent unauthorized access and use of prescription information, including dispensing information. The regulation would further require that any person who transmits, maintains, or receives any prescription or prescription refill orally, in writing, or electronically shall ensure the security, integrity, and confidentiality of the prescription and any information contained therein.

At its October meeting, Deputy Attorney General William Marcus again discussed the extremely complex overlap between state and federal law on the issue of electronic prescription transmission. [14:4 CRLR 90] He noted that even though electronic transmission of prescriptions would be allowed if this regulation takes effect, a triplicate form signed by the prescriber is still necessary for prescriptions for Schedule II controlled substances, according to California state law. Where an inter-



mediate health care facility, licensed skilled nursing facility, or licensed home health agency is involved, a triplicate form must be prepared by the pharmacy prior to dispensing (except in certain limited circumstances). If there is only a partial filling of a prescription, the pharmacy must prepare a triplicate form and have it signed by the person receiving the drugs at the facility for each partial filling.

At this writing, the Board is scheduled to hold a public hearing on the proposed addition of section 1717.4 on January 25 in Los Angeles.

Automation of the Triplicate Program.

The Board's Oversight Committee on the Automation of the Triplicate Program met several times throughout the fall to discuss the progress of the study being carried out to develop a way to implement an automated statewide monitoring system for tracking controlled substance prescriptions as an alternative to the current paper-intensive triplicate system. [14:4 CRLR 90] The goal of the automation study is to have an online, real-time system containing 100% of the triplicate prescription information on record and current so that it may be accessed by prescribers, pharmacies, and eventually others such as regulatory boards. The study has involved interviews of various individuals and organizations as well as the consideration of other electronic monitoring systems in place in Oklahoma and Hawaii and the Statewide Integrated Narcotics System (SINS) used in California and other states to monitor narcotics. The Feasibility Study Report (FSR) that will summarize the study's findings was to be completed by December 1 and finalized by February 1995. However, due to a delay in completing the draft FSR, the January 4, 1995 meeting of the Oversight Committee to discuss the draft was cancelled; the meeting will be rescheduled as soon as the draft is completed. Copies of the draft FSR will be made available to interested parties prior to the meeting.

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

• After its adoption of new sections 1751.11 and 1751.12, Title 16 of the CCR, in May 1994, the Board submitted the rulemaking file to the Department of Consumer Affairs (DCA). Section 1751.11 would establish a list of dangerous drugs which may be furnished by a pharmacist to a home health agency or licensed hospice and stored in transportable, tamper-proof, sealed storage containers; it would also create inventory and recordkeeping requirements. Section 1751.12 would provide that a pharmacy shall not issue porta-

ble containers unless the home health agency or licensed hospice complies with the provisions of section 1751.11. [14:4 CRLR 91; 14:2&3 CRLR 95-96; 14:1 CRLR 73] DCA approved the proposed regulations on December 9, and forwarded them to the Office of Administrative Law (OAL) on December 19; at this writing, the regulations are still awaiting approval by OAL.

• In November, DCA approved the Board's proposed amendments to section 1724, Title 16 of the CCR, which would require candidates taking the California pharmacist licensure examination to pass both sections of the exam (essay and multiple choice) at the same time; a candidate who fails the multiple choice section of the exam will be given a failing grade for the entire exam and will have to take the entire exam again at another time. This change was made to streamline the examination and grading process by reducing the time and cost for expert graders and travel expenses. [14:4 CRLR 91; 14:2&3 CRLR 96; 14:1 CRLR 74] On December 5, OAL approved the changes, which become effective on February 1, 1995 and will apply to the California pharmacist licensure examination in June.

• At its October 24 meeting, the Board resumed its discussion of proposed amendments to section 1707.2, Title 16 of the CCR, which would apply the same requirements and standards for oral consultation to out-of-state pharmacies which ship, mail, or deliver prescriptions to California residents as are applied to in-state pharmacies. As proposed, the regulation would provide, among other things, that any resident or non-resident pharmacy that ships, mails, or delivers any controlled substances or dangerous drugs or devices shall make a reasonable attempt to contact the patient or his/her agent and provide oral consultation over the telephone. The regulation would also specify alternatives to oral consultation over the telephone before dispensing the medication in cases where the patient cannot be reached for oral consultation and further attempts would cause unnecessary delay in the patient receiving the medication; such alternative written consultations must notify the patient of his/her right to an oral consultation and must include directions for use and storage and any precautions and relevant warnings. [14:4 CRLR 90-91; 14:2&3 CRLR 95]

At the October meeting, the Board stated that it has received many comments supporting and opposing the proposed changes and, as a result, unanimously decided to delay adoption of the amendments until 1995 to allow for further study and discussion of all information. Al-

though most Board members support the concept of the amendments because of their importance to consumer safety, they also want to discuss the issue further with mail-order company representatives; as a result, the Board directed Executive Officer Patricia Harris to arrange a meeting with mail-order representatives. DCA also announced plans to host an open forum for the Board and those concerned about consultation by out-of-state pharmacies to continue discussion on the issue of consultation requirements; the forum is a public meeting but will involve about two dozen "major stakeholders" participating in a discussion of the issues, problems, and solutions. At this writing, the forum—which will be facilitated by Rob Eskridge of Growth Management Center USA—is scheduled for February 9 in Sacramento.

■ LEGISLATION

Future Legislation. At its October meeting, the Board agreed to sponsor three legislative changes during 1995; at this writing, however, the Board has not yet found authors for any of the proposals.

The first proposal approved by the Board would amend Business and Professions Code section 4085, which specifies the requirements an individual must meet in order to be licensed by the Board. The amendment would repeal a part of the section describing qualifications of foreign-educated applicants; according to the Board, it no longer uses this provision to qualify such applicants for the California pharmacist licensure examination. Currently, the statute provides that an applicant who was a nonresident of the United States for at least five of the ten years prior to enrollment in a foreign pharmacy school, and who has graduated from a foreign pharmacy school, must have either successfully completed coursework established by the Board as being equivalent to that required for domestic graduates, or received a grade satisfactory to the Board on an examination designed to measure the equivalency of foreign pharmacy education with that required of domestic graduates in order to be registered as a pharmacist. The proposed legislative amendment would repeal the first option and instead provide that if the applicant has graduated from a foreign pharmacy school, he/she also must have received a satisfactory grade on an examination designed to measure the equivalency of foreign pharmacy education with that required of domestic graduates. The Board has recognized only the latter option, which requires that foreign graduates take and pass the Foreign Pharmacy Graduate Equivalency Examination, since March 1992.



The Board also agreed to pursue an amendment to Business and Professions Code section 4052, in order to allow recognized schools of nursing to obtain dangerous drugs and devices needed for training. Existing statutory law contains no specific provision authorizing provision of dangerous drugs and devices to nursing schools for training purposes. Currently, the Board's supervising inspectors approve "orders for use" for nursing schools to obtain dangerous drugs and devices; however, the Board would like to add a statutory provision to allow schools of nursing recognized as training facilities by the Board of Registered Nursing to obtain dangerous drugs and devices, not including controlled substances, for training purposes.

The Board will also seek to add new section 4227.4 to the Business and Professions Code in order to provide statutory authority that would implement Title 21, Code of Federal Regulations, section 1301.28, which permits controlled substances to be provided to the masters of ocean vessels so long as "such activity is authorized by state law..." In the past, pharmacies have furnished controlled and non-controlled dangerous drugs to ocean vessels under the condition that the drugs were delivered in a sealed container on board the vessel and the container could not be opened until the vessel entered international waters; however, there is no provision in state law authorizing this practice. The proposed section would permit a pharmacy or wholesaler to furnish dangerous drugs to a master or first officer of an ocean vessel pursuant to a written requisition; the dangerous drugs would have to be delivered in a sealed container, and the wholesalers or pharmacies engaging in such activities would be required to give notice to the Board within thirty days of undertaking such activity.

■ RECENT MEETINGS

At its October 23-25 meeting, the Board completed its strategic planning sessions with facilitator Michael Dues by finalizing its purpose, vision, goals, and objectives for the next five years. [14:4 CRLR 93] According to its mission statement, the purpose of the Board is to protect the health, safety, and welfare of the people of California with integrity and honesty; advocate the highest quality of affordable pharmaceutical care; and promote education, wellness, and quality of life. The Board identified nine general areas in which it has established goals, including enhancing the role of the pharmacist, communication and public education, advocacy, standards of practice, con-

sultant education, automation, customer service, enforcement, and disciplinary guidelines. Within each of these goal areas, the Board further established specific objectives to pursue in the next five years; at the end of the session, the Board adopted the goals and mission statement.

Also at the October meeting, the Board briefly discussed the funding of its proposed "Ask Your Pharmacist" public education program, which would inform consumers about the benefits of the new oral consultation requirement. [14:4 CRLR 94] Although the Board submitted a budget change proposal to fund the program, the Department of Finance disapproved it. Thus, the program would have to be funded via a fee increase; however, the Board's current proposal to increase fees is required to maintain the Board's reserve fund. As a result, the consumer education program is effectively on hold until the Board's funding issues are resolved.

Also in October, the Board again discussed the issue of prescription drug sample distribution. [14:4 CRLR 93-94] Deputy Attorney General William Marcus clarified that restrictions on the distribution and possession of drug samples would require legislative action; the Board could seek authority to do anything from restricting drug sampling to banning it altogether. The Board considered a motion to seek legislation to ban the distribution of drug samples; however, the vote was divided with four Board members in favor of the motion, three against, and one abstaining. The four members who did not vote in favor of the motion felt there should be more discussion about the advantages of samples, the use of "starter packs" which are not defined as samples, and the items which could be used to replace samples. The Board agreed to convene an informational session on this issue.

Also in October, the Board approved the closure of its Los Angeles branch office to take place on January 1, 1995; the Board's decision was based on its establishment of a strong administrative component and a complaint unit in Sacramento, the consolidation of the probation monitoring and interim committee meeting processing into the Sacramento office, and the imminent ability of all inspectors to use computer modems to send documents and itineraries to and from the Sacramento office. Only one office assistant and one secretary position will be moved to the Sacramento office; all inspector and supervising inspector positions will remain in southern California as field positions. The Los Angeles telephone number will be routed to Sacramento and the Board hopes to establish an 800 number

for consumers to call with complaints. Hearings of the Southern Interim Committee (SIC), which handles disciplinary matters in southern California, will continue to be held in southern California so that practitioners and inspectors required to appear are not inconvenienced; meetings of the SIC and office conferences for inspectors will be held at some public site to be selected or possibly at the offices of another state agency, such as the Medical Board, which is willing to occasionally share its facilities.

Also at the October meeting, the Board discussed a letter from the California Retailers Association (CRA) regarding the growing problem of prescription illegibility; the letter described how illegible prescriptions cause pharmacists to spend excessive time deciphering them and are sometimes the cause of mistakes in the dispensing of medications. The letter referred to an American Medical Association report recognizing this issue and requested the Pharmacy Board and the Medical Board to address the problem of prescription legibility. CRA suggested that the Board adopt a requirement that prescriptions be typed or printed; however, the Board noted that such a requirement could only be created by legislation and opined that such a step may not be necessary. The Board acknowledged the problem and directed Executive Officer Patricia Harris to contact the Medical Board and the Board of Dental Examiners in order to seek solutions to this issue.

■ FUTURE MEETINGS

January 25-26 in Los Angeles.
 March 29-30 in Sacramento.
 May 24-25 in Sacramento.
 July 26-27 in San Diego.
 October 25-26 in San Francisco.

BOARD OF REGISTRATION FOR PROFESSIONAL ENGINEERS AND LAND SURVEYORS

Executive Officer:
 Harold L. Turner
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The Board of Registration for Professional Engineers and Land Surveyors (PELS) regulates the practice of engineering and land surveying through its administration of the Professional Engineers Act, sections 6700 through 6799 of the Business and Professions Code, and the Profes-