

HEALTH CARE REGULATORY AGENCIES

as posted on the Board's Web site. However, at this writing, the most recent newsletter available on the Board's Web site dates back to 1997. According to EO Ollinger, DCA must first approve all Web site postings; apparently the new newsletter was misplaced for some time in DCA bureaucracy, but is now back on track and should be electronically posted in the near future.

At its December 2000 meeting, the Board unanimously reelected Gerald Easton, OD, as Board president and Sheilah

Titus, OD, as vice president. Steven Grant, OD, was selected Board secretary.

Due to its failure to muster a quorum, the Board cancelled its scheduled March 16–17, 2001 meeting in Oakland.

FUTURE MEETINGS

2001: June 8–9 in Orange County; September 7–8 in Sacramento; November 30–December 1 in San Diego.

2002: No meetings have been scheduled at this writing.

Board of Pharmacy

Executive Officer: Patricia Harris ♦ (916) 445-5014 ♦ Internet: www.pharmacy.ca.gov



Pursuant to Business and Professions Code section 4000 *et seq.*, the Board of Pharmacy grants licenses and permits to pharmacists, pharmacy interns, pharmacy technicians, pharmacies, pharmacy corporations, nonresident pharmacies, wholesale drug facilities, veterinary food-animal drug retailers, out-of-state distributors, clinics, and hypodermic needle and syringe distributors. 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 the Pharmacy Law and 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 misconduct substantially related to the practice of pharmacy.

The Board of Pharmacy is a consumer protection agency located within the Department of Consumer Affairs (DCA). The Board consists of eleven members, four of whom are public members. The Governor appoints two public members and the Senate Committee on Rules and the Speaker of the Assembly each appoint one. The remaining members are pharmacists appointed by the Governor, five of whom must be active practitioners. All Board members are appointed for four-year terms.

In March 2000, Governor Davis appointed Donald W. Gubbins, Jr., Pharm.D., to the Board. Dr. Gubbins is Regional Pharmacy Development Manager for RiteAid Corporation.

In June 2000, the Senate Rules Committee named William Powers as a public member of the Board. Powers is legislative director of the Congress of California Seniors and is also Coordinator of the Capital City Task Force for the American Association of Retired Persons (AARP).

MAJOR PROJECTS

State Auditor Critical of Board's Enforcement System

In April 2001, the Bureau of State Audits (BSA) released a report entitled *Investigations of Improper Activities by State Employees: July 2000 Through January 2001*. In a chapter entitled *Board of Pharmacy: Gross Inefficiency in Processing Consumer Complaints and Failure to Record and Pay Overtime*, BSA noted that it received an allegation that the Board had a backlog of consumer complaints and was not doing its job to investigate incoming complaints. BSA investigated and substantiated the allegation. Specifically, BSA found that the Board's established timeframes to resolve complaints—up to 290 days for complex complaints and 140 days for all others—are excessive when compared to the timeframes mandated by law or regulation for other consumer protection agencies.

Second, BSA found that the Board fails to meet its own excessive timeframes. Between January 1, 1994 and March 6, 2000, it took the Board an average of 441 days to close 5,265 complaints. Of those complaints, the Board resolved only 35% of its high-risk complaints within 290 days and only 20% of its less complex cases within its 140-day goal. As of March 6, 2000, the Board had not resolved 770 of 1,552 open complaints within its maximum 290-day goal. Although the Board's goal is to complete the investigation phase of its enforcement process within five months, BSA found that Board staff takes on average nine months to complete investigations after the complaint is assigned to an inspector.

Third, BSA examined the Board's system for prioritizing complaints. Based on the subject matter of complaints, the Board categorizes its high-risk complaints as Priority 1 (urgent-immediate), Priority 2 (rapid), Priority 3 (active investigation), or Priority 4 (standard, consistent turnaround). BSA found that this system "does not ensure that complaints

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involving potential injury are investigated within the maximum allowed time of five months.” BSA found that, regardless of risk, the Board took longer than five months to complete about 60% of its investigations.

Fourth, BSA found that the Board has not maintained adequate staff to ensure timely complaint resolution. The Board is authorized to hire only 19 inspectors and two supervising inspectors (all of whom are pharmacists) to cover the entire state of California. In fiscal year 1999–2000, there was a 35.7% vacancy rate for inspector and supervising inspector positions at the Board; 7.5 of the Board’s 21 inspector positions were vacant. Had those positions been filled, BSA projected that each inspector would have been able to resolve an additional 51 complaints per year and a backlog would not exist. BSA noted that the Board believes that difference in salary paid to public sector pharmacists compared with the private sector hinders its ability to attract qualified applicants for its inspector positions. [17:1 CRLR 66]

Finally, BSA noted that the Board failed to maintain records adequate to ensure that staff were compensated for all overtime hours worked, possibly in violation of the federal Fair Labor Standards Act.

BSA concluded that “these concerns reflect gross inefficiency on the part of the Board. Delays in resolving complaints increase the risk that those violating pharmacy laws will continue to make mistakes that affect the public health, safety, or welfare of California consumers.”

In a written response, the Board agreed it had not investigated and completed cases promptly in the past, and stated that it is taking action to address these concerns. The Board said that it is focusing on clearing away the existing backlog of cases (and is down to 393 pending complaints more than six months old as of March 8, 2001) and will then be better able to prioritize the remaining complaints. The Board noted that it has increased its salaries for pharmacists, hired eight inspectors and one supervising inspector during the seven months prior to January 2001, and expects to fill the remaining three vacant inspector positions soon. The Board also stated it plans to increase consumer awareness by adding a toll-free consumer complaint line and posting this number in every pharmacy later in 2001.

Prevention of Medication Errors: Quality Assurance Program

For several years, the Board has attempted to address the growing incidence of medication errors, which can include any of the following: (1) a prescriber orders an inappropriate

drug for a patient’s condition; (2) a pharmacist enters incorrect information on the label of the prescription container; (3) a prescription is dispensed with the wrong drug or wrong drug dosage; (4) a drug is dispensed that is contraindicated if taken with another drug; or (5) a prescription is filled with a medication whose expiration date has passed. Obviously, a medication error can result in patient injury or death. To prevent such harm, the Board initiated rulemaking in July 1999

to require every licensed pharmacy to develop and implement a quality assurance program (QAP) to document medication errors attributable to the pharmacy or its personnel. After an October 1999 public hearing at which many pharmacists and representatives of pharmacies, retail-

ers, and pharmaceutical companies registered opposition to the QAP requirement, the Board unanimously deferred the issue and remanded it to its Enforcement Committee for further study. [17:1 CRLR 57–58; 16:2 CRLR 55]

Although the Board took no further action with respect to its proposed rulemaking, the issue came to a crux with the Institute of Medicine’s (IOM) November 1999 publication of *To Err Is Human: Building a Safer Health System*, in which IOM reviewed the results of two large studies—one conducted

in Colorado and Utah and the other in New York—and found that up to 98,000 Americans die each year due to medical errors. According to IOM, “medication errors alone, occurring either in or out of the hospital, are estimated to account for over 7,000 deaths annually.” Extrapolated to California, the statistics revealed by IOM indicate that over one million adverse drug reactions occur each year in California on an outpatient basis alone. A great many of these reactions are preventable medication errors that inflict pain, loss of function, and economic loss on consumers. Thus, instead of rulemaking, the Board decided to sponsor legislation, SB 1339 (Figueroa), which was enacted and requires pharmacies to implement a QAP by January 1, 2002 (see 2001 LEGISLATION). Each pharmacy’s QAP must, at minimum, document medication errors attributable in whole or in part to that pharmacy or its personnel. SB 1339 also requires the Board to adopt regulations to implement the program by September 1, 2001.

On February 23, 2001, the Board published notice of its intent to adopt new section 1711, Title 16 of the CCR, to implement SB 1339. Section 1711 would require each pharmacy—effective January 1, 2002—to establish and maintain a QAP designed to prevent medication errors. As published, section 1711(b) would define the term “medication error” to mean “any act or omission in the dispensing process that may cause or lead to patient harm.” It does not include any act or

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omission that is corrected prior to furnishing the drug to the patient or patient's agent. Section 1711(c) would require each pharmacy's QAP to be "described in written policies and procedures maintained in the pharmacy," which must include "directions for communicating the details of the error to the patient, caregiver, prescriber, and other members of the health care team as appropriate. This communication shall also describe methods for correcting the error and/or reducing its negative impact on the patient."

The QAP must be reviewed by the licensee and revised if necessary prior to application for renewal of the pharmacy's license.

As published, section 1711(d) would require each QAP to include a process designed to detect and identify medication errors.

"An investigation of each medication error shall commence as soon as is reasonably possible, but no later than two business days from the date the medication error is discovered. If the investigation indicates that the medication error is attributable, in whole or in part, to the pharmacy or its personnel, a quality assurance review shall be performed." Under proposed section 1711(e), the quality assurance review shall include investigation of the error and completion of an "essential cause examination" of the error (defined in subsection (f) to focus primarily on "systems and processes, not individual performance"). A written record of the quality assurance review, which must be retained in the pharmacy, must include (1) the date of, location, and participants in the quality assurance review conducted; (2) a record of the facts relating to the medication error; (3) the essential cause examination; (4) the findings and determinations generated by the quality assurance review; (5) changes to pharmacy policy or procedure made pursuant to the quality assurance review; and (6) activities undertaken with the patient or other healthcare providers to mitigate the error.

Subsection (g) of the proposed regulation would require pharmacies to keep records relating to activities undertaken as part of a quality assurance review in the pharmacy for at least three years from the date those records were created. The Board may review quality assurance records in an individual pharmacy "as necessary to protect the public health and safety, or if fraud is alleged by a government agency with jurisdiction over the pharmacy." As set forth in SB 1339, proposed section 1711(h) provides for confidentiality of QAP records: "Neither the proceedings nor records of a pharmacy's quality assurance program shall be subject to discovery in any arbitration, civil, or other proceeding" except as provided in subsection (g) as to the Board. Further, "no person in attendance at a meeting of a pharmacy's quality assurance committee shall be required to testify in any arbitration, civil, or other proceeding" as to what transpired at that meeting, except as provided in subsection (g) as to the Board. Subsection (i) provides that a pharmacy's compliance with section

1711 may be considered by the Board as a mitigating factor in its investigation and evaluation of a medication error.

On April 26, 2001, the Board held a public hearing on the proposed QAP regulations. Numerous witnesses representing pharmacists and pharmacies testified that the overall effect of the regulations is punitive rather than educational, and that pharmacy personnel who are already fearful of the Board will not be encouraged to report errors if the result is

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punitive; these witnesses advocated softening of the regulatory language to promote a "blame-free, sanction-free, non-punitive" approach that seeks to avoid repetition of errors. In particular, they complained about the focus on the "essential cause examination," the definition of the term "medi-

cation error," and the length of time that QAP records must be retained in the pharmacy.

Following much testimony, the Board agreed to adopt section 1711 subject to several amendments. First, the Board revised subsection (b)'s definition of the term "medication error" to "any variation from a prescription or drug order not authorized by the prescriber." Under this definition, a "medication error" does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation that is allowed by law (such as form variations contemplated under SB 340 (Speier); see 2001 LEGISLATION). Further, the Board deleted the requirement that the QAP include procedures for communicating the details of the error to the patient, caregiver, prescriber, and other members of the health care team, and substituted language requiring communication about the error with the patient and prescriber only "when a medication error threatens a patient's well-being." The Board also deleted entirely subsection (f) (defining the "essential cause examination"), deleted the requirement in subsection (e) that the quality assurance review include an "essential cause examination," and substituted language requiring the review to include "a determination of the proximate cause of the medication error" and "an evaluation of the systems and processes that may have contributed to the medication error." The Board also reduced the QAP records retention requirement in subsection (g) to one year. The Board agreed to release the modified language of section 1711 for an additional 15-day comment period, and is expected to revisit this proposed regulation at its July 2001 meeting.

Board Revises Disciplinary Guidelines

At its October 2000 meeting, the Board held an informational hearing on proposed changes to its 1997 disciplinary guidelines, which essentially set forth every statute and regulation the violation of which is grounds for disciplinary action by the Board, and identify the Board's preferred penalty for that violation. Like other regulatory agencies, the Board developed disciplinary guidelines to guide licensees, attor-

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neys who prosecute disciplinary cases, administrative law judges who preside over disciplinary hearings, and the Board itself in disciplinary decisionmaking; the intent of the guidelines is to establish consistency in disciplinary penalties for similar offenses on a statewide basis. Prior to its October 2000 meeting, the Board drafted revisions to the 1997 guidelines to correct errors, make changes due to amendments to the Pharmacy Law and the Board's regulations since 1997, and reorder the various sections into a document that is more user-friendly. No comments were submitted or received.

Thus, on December 1, 2000, the Board published its notice of intent to amend section 1760, Title 16 of the CCR, which requires the Board—in reaching a disciplinary decision—to consider its 1997 disciplinary guidelines. The guidelines are not in section 1760; they are simply incorporated by reference. The Board proposed to amend section 1760 to require consideration of the new version of the guidelines (to be dated January 2001) which were the subject of the October 2000 informational hearing.

At its January 2001 meeting, the Board held a public hearing on its proposal to amend section 1760. The California Pharmacists Association, Longs Drug Stores, and an attorney submitted comments. Following the hearing, the Board voted to adopt the revised version of the disciplinary guidelines subject to the following changes: (1) deletion of a provision stating that failure to pay cost recovery is grounds for automatic revocation (with no hearing); (2) a minor change in a provision regarding the tolling of probation; (3) the addition of a provision prohibiting a suspended or revoked pharmacist from performing the duties of a pharmacy technician or an exemptee for any entity licensed by the Board; and (4) deletion of a provision requiring a pharmacy on probation to post a notice of the probation in the pharmacy premises. Subject to those changes to the disciplinary guidelines, the Board adopted the proposed amendment to section 1760. At this writing, DCA is considering the rulemaking file on section 1760; after DCA approves the file, it will be forwarded to the Office of Administrative Law (OAL) for approval.

Self-Assessment of a Pharmacy by the Pharmacist-In-Charge

On December 1, 2000, the Board published its notice of intent to amend section 1715, Title 16 of the CCR, which established a "self-assessment" program effective January 1, 1999, under which pharmacists-in-charge must complete a self-assessment of the pharmacy's compliance with federal and state pharmacy laws by March 31 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance with the law through self-examination and education. The Board developed two forms to guide a pharmacist's self-assessment: Form 17I-29 for community pharmacies, and Form 17I-30 for hospital inpatient pharmacies. [16:1 CRLR 76]

The proposed amendments to section 1715 would move the biennial completion date of the self-assessment process

from March 31 to July 1 of each odd-numbered year, and would incorporate by reference new January 2001 versions of the two forms on which the self-assessment must be conducted.

At its January 2001 meeting, the Board adopted the proposed amendments. As of April 30, 2001, the Board is awaiting approval of the proposed amendments by DCA, and has not yet submitted them to OAL for approval.

Preprinted, Multiple Checkoff Prescription Blanks

On August 25, 2000, the Board published its notice of intent to amend section 1717.3(b), Title 16 of the CCR, which currently prohibits pharmacists from dispensing controlled substances and/or more than one dangerous drug from a "preprinted, multiple checkoff prescription blanks," defined as any form used or intended to be used as a written order for an individual for dangerous drugs which order contains or lists more than one drug for which the name, strength, amount, or quantity has been preprinted on the prescription blank. Under this version of the regulations, a prescriber must use one completed blank for each drug he/she is prescribing for a patient, regardless of whether most or all of the drugs being prescribed are preprinted on the form. This regulation was originally written to assure that patients would not mark additional prescription drugs prior to submitting the prescription document to the pharmacy.

However, the use of preprinted prescription blanks has proven to eliminate confusion as well as reduce potential medication errors. To facilitate the use of preprinted, multiple checkoff prescription blanks by prescribers, the Board proposes to amend section 1717.3(b) to allow a pharmacist to dispense more than one dangerous drug from a preprinted, multiple checkoff prescription blank provided that the prescriber indicates on the form the total number of drugs selected.

The 45-day comment period ended October 9, 2000, and the Board held no public hearing on the proposal. At its January 25, 2001 meeting, the Board adopted the proposed amendment. At this writing, DCA is considering the rulemaking file on section 1717.3(b); once DCA approves the file, it will be forwarded to OAL for approval.

Update on Other Board Rulemaking

The following is an update on recent Board rulemaking proceedings described in detail in Volume 17, No. 1 (Winter 2000) of the *California Regulatory Law Reporter*:

◆ **Citation and Fine Regulations.** In July 1999, the Board amended sections 1775 and 1775.1, Title 16 of the CCR, to expand the list of violations which are grounds for a citation and/or fine to include noncompliance with the Board's continuing education requirements and violation of the Board's regulations, and to update the statutory references in the sections to reflect the 1996 reorganization of the Pharmacy Law. [17:1 CRLR 60] OAL approved the amended regulations on March 1, 2000.

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In the meantime, the Board continued its discussion of staff's proposal to expand its rather narrow citation and fine regulations to permit the issuance of citations and fines for other violations, and to permit the Board's executive officer to issue citations and fines for certain violations. Whereas the executive officers of other DCA agencies are routinely permitted to issue citations and fines, section 1775 limits the issuance of citations and fines to "a board inspector or committee of the board." [17:1 CRLR 60]

On May 12, 2000, the Board published its intent to amend sections 1775 and 1775.2, repeal section 1775.1, and adopt new section 1775.15, Title 16 of the CCR, to expand its use of the citation and fine sanction and to permit its executive officer to issue citations and fines in certain cases. In its initial statement of reasons justifying the proposed regulations, the Board stated that "increasing numbers of complaints against licensees" (a 10% increase since 1995) and "ongoing difficulties in achieving licensee compliance with routine licensure requirements" demonstrate the need for added enforcement options.

In its initial statement of reasons justifying the proposed regulations, the Board stated that "increasing numbers of complaints against licensees" (a 10% increase since 1995) and "ongoing difficulties in achieving licensee compliance with routine licensure requirements" demonstrate the need for added enforcement options.

"Currently, the Board must choose between admonition (*i.e.*, field admonitions by inspectors, office conferences, and compliance committee actions) and formal disciplinary action against a license when imposing sanctions for violations. Current regulations do not provide the Board with appropriate options for violations that warrant more severe sanction than admonition but are not appropriate for formal disciplinary action.... Citation and fine provides the Board with an intermediate sanction to increase compliance and expend limited Board resources more efficiently."

As proposed, section 1775(a) would be amended to eliminate the authority of a Board inspector to issue a citation and/or fine, but authorize a committee of the board to issue citations and fines for any violation of the Pharmacy Law or the Board's regulations. New subsection 1775(d) would require a committee of the board to meet periodically in both the northern and southern portions of the state for the purpose of reviewing alleged violations, including notices of violation issued by the Board, and issuing citations to licensees of the Board.

New subsection 1775(d) would authorize the Board to issue a "request to appear" to individuals before a committee of the board; the "request to appear" must include a summary of alleged violations to be reviewed at the hearing. Under the proposed regulation, "persons or entities may reschedule their appearance before a committee of the board," but the committee may issue a citation and impose a fine in the absence of a person who fails to appear a second time.

The Board also proposed to repeal section 1775.1, which lists the violations subject to citation and fine, as moot (inasmuch as amended section 1775(a) would permit a committee

of the board to issue a citation and fine for any violation of the Pharmacy Law or the Board's regulations).

New section 1775.15(a) would permit the Board's executive officer to issue citations and fines for specified violations of the Pharmacy Law. Under the proposed regulation, the EO is not permitted to issue citations and fines to pharmacies and pharmacists; however, the EO may issue citations and fines to other Board licensees (including wholesalers, manufacturers, and veterinary food-animal drug retailers) and for violations relating to hypodermic needles and syringes, continuing education, and the failure to file a notice of discontinuance of business. These violations generally relate to the administrative requirements of site permits rather than the provision of patient care. Section 1775.15(b) would permit the executive officer to issue citations and fines for violations relating to unlicensed practice under Business and Professions Code section 148.

Section 1775.2 would be amended to conform to the above-described changes, and would require a committee of the board and the executive officer—in assessing the amount of an administrative fine—to consider the number of violations found in the investigation, in addition to other factors already listed in section 1775.2.

On July 25, 2000, and over the opposition of the California Pharmacists Association and Longs Drug Stores, the Board adopted these proposals without change. However, at this writing, the Board has not yet submitted the rulemaking file on the proposed changes to OAL because the State and Consumer Services Agency declined to sign the fiscal impact statement until the Department of Finance approves a budget change proposal (BCP) submitted by the Board to carry out its expanded authority; the BCP was not approved due to the Governor's limit on the size of growth in state government. The final day for submission of this rulemaking file to OAL is May 12, 2001.

Meanwhile, at the Board's December 2000 meeting, the Enforcement Committee recommended that the Board further amend its citation and fine regulations to permit a committee of the board to issue citations and fines for violations of the Confidentiality of Medical Information Act, Civil Code section 56 *et seq.*; and to Internet pharmacies that dispense drugs without a prescription issued pursuant to a good faith examination under SB 1828 (Speier) (Chapter 681, Statutes of 2000) (see 2000 LEGISLATION). At its January 2001 meeting, the Board approved the Enforcement Committee's recommendations; at this writing, the Board has not yet published those regulatory changes for comment.

◆ ***Dangerous Drugs and Devices Exempt From Storage in a Pharmacy.*** SB 1308 (Committee on Business and Professions) (Chapter 655, Statutes of 1999) amended Business and Professions Code section 4057 to remove from stat-

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ute two lists of dangerous drugs and devices that are exempt from the Pharmacy Law's requirements and may be stored outside a pharmacy's licensed premises when furnished to specified licensed individuals or entities. Instead, SB 1308 directs the Board to list these exempt drugs and devices in regulation.

In October 1999, the Board published notice of its intent to adopt section 1714.5, Title 16 of the CCR, to place in regulation two lists of dangerous drugs and devices that are exempt from required storage in a pharmacy, provided they are obtained by a person or entity meeting specified licensure and practice criteria. [17:1 CRLR 60-61] During the 45-day comment period, the Board received several comments which prompted it to substantially revise the proposed regulation and republish it in August 2000.

As republished, new section 1714.5 would list dangerous drugs and devices that are exempt from storage in a pharmacy provided that their sale and furnishing is made to a clinic, hospital, institution, or an establishment holding a currently valid and unrevoked license or permit under Health and Safety Code section 1200 *et seq.* (a hospital, clinic, or other licensed health facility), Welfare and Institutions Code section 3300 *et seq.* (the California Rehabilitation Center of the Department of Corrections), or Welfare and Institutions Code section 6250 *et seq.* (institutions housing individuals who have been judicially committed as mentally disordered sex offenders, sexually violent predators, or mentally retarded). The Board adopted new section 1714.5 at its October 2000 meeting; OAL approved the new section on April 9, 2001, and it became effective on May 9, 2001.

◆ **Offsite Storage of Records.** Under various provisions of the Business and Professions Code, all records of the manufacture, sale, acquisition, or disposition of prescription drugs or devices must be, at all times during business hours, open to inspection by authorized law enforcement officers. Business and Professions Code section 4333 requires pharmacies to preserve these records at the licensed premises for at least three years from the making of the records. However, the Board is authorized to grant a waiver of the requirement that the records be kept on the licensed premises to an applicant who requests a waiver.

At its January 2000 meeting, the Board considered—for the second time—proposed section 1707, Title 16 of the CCR, which would establish criteria for a waiver of the onsite storage requirement, to enable pharmacists to store records at a place other than the licensed premises. [17:1 CRLR 59-60] After discussion at the meeting, the Board modified the language and adopted it subject to a 15-day comment period. Under the modified language, the Board “shall” grant a waiver of the onsite storage requirement to any licensee for offsite storage of the records described in Business and Professions Code subsections 4105(a), (b), and (c) unless the applicant has, within the preceding five years, failed to produce records pursuant to section 4081 or has falsified records covered by section 4081. An entity that is granted a waiver must main-

tain the storage area so that the records are secure (including from unauthorized access) and must be able to produce the records within two business days upon the request of the Board or an authorized law enforcement officer. In the event that a licensee fails to comply with these conditions, the Board may cancel the waiver without a hearing, and the licensee must maintain all records at the licensed premises. Further, even under this waiver, all prescription records for noncontrolled substances must be maintained on the licensed premises for one year from the date of dispensing; and all prescription records for controlled substances must be maintained on the licensed premises for two years from the date of dispensing. Section 1707 also expressly permits licensees to store the records described in subdivisions (a), (b), and (c) of section 4105 of the Business and Professions Code in a storage area at the same address or adjoining the licensed premises without obtaining a waiver from the Board if the records are readily accessible to the pharmacist-in-charge (or other pharmacist on duty, or exemptee) and upon request to the Board or any authorized law enforcement officer, and the storage is maintained so that the records are secure and so that the confidentiality of any patient-related information is maintained. OAL approved the regulation on September 20, 2000; it became effective on October 20, 2000.

◆ **Specialized Refill Pharmacies.** In May 1999, the Board adopted section 1707.4, Title 16 of the CCR, to set standards for a “refill pharmacy,” which prepares refill prescriptions for another pharmacy. New section 1707.4 allows a pharmacy to utilize the services of another pharmacy to provide its refills if it has a contract for these services or has common ownership with the refill pharmacy; specifies the labeling requirements for a prescription refilled at a refill pharmacy, including the name and address of the refill pharmacy and/or the name and address of the pharmacy which receives the refilled prescription for dispensing to the patient, and information as to which pharmacy the patient should contact if he/she has questions (this information may be either on the label or in writing accompanying the medication); specifies the documentation requirements for the originating pharmacy and the refill pharmacy; and allows a pharmacy to operate as a refill pharmacy as well as fill new prescriptions. [17:1 CRLR 61]

OAL disapproved section 1707.4 on January 24, 2000 for technical reasons. On April 7, 2000, the Board mailed a 15-day notice clarifying the steps taken to modify its originally proposed language and resubmitted the modified section for approval. OAL approved section 1707.4 on June 1, 2000; it became effective on July 1, 2000.

◆ **Pharmacy Operations During Temporary Absence of a Pharmacist.** SB 188 (Leslie) (Chapter 900, Statutes of 1999) requires the Board to adopt regulations accommodating the temporary absence of a pharmacist from a pharmacy. SB 188 and the new regulations became necessary after the Governor signed SB 651 (Burton) (Chapter 190, Statutes of 1999), which mandates breaks and lunch periods for pharmacists during the workday. Absent new regulations, the

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combination of SB 651 and the existing Pharmacy Law would have required the closure of a single-pharmacist pharmacy and the removal of all non-pharmacist personnel from the pharmacy area during the pharmacist's breaks and lunch periods.

At its October 20, 1999 meeting, the Board adopted section 1714.1, Title 16 of the CCR, on an emergency basis, to specify security requirements for prescription drugs and the limited functions that non-pharmacist staff, such as pharmacy technicians and assistants, may perform when the pharmacist is temporarily absent from a single-pharmacist pharmacy. [17:1 CRLR 58-59] OAL approved the Board's emergency regulation on December 21, 1999, and it became effective on January 1, 2000.

On November 19, 1999, the Board published notice of its intent to permanently adopt a slightly modified version of section 1714.1. Following a January 26, 2000 public hearing on the proposed regulation, the Board adopted new section 1714.1. The section provides that, in any single-pharmacist pharmacy, the pharmacist may leave the pharmacy temporarily for breaks and meals pursuant to section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy and removing ancillary staff from the pharmacy only if the pharmacist reasonably believes that the security of the dangerous drugs and devices will be maintained in his/her absence. If the pharmacist determines that the pharmacy should close during his/her absence, then the pharmacist must close the pharmacy and remove all ancillary staff (including intern pharmacists, pharmacy technicians, pharmacy technician trainees, and nonlicensed personnel) from the pharmacy during his/her absence. During the pharmacist's temporary absence, no prescription medication may be provided to a patient or a patient's agent unless the prescription medication is a refill medication that the pharmacist has checked, released for furnishing to patients, and does not require a pharmacist's consultation.

During the pharmacist's temporary absence, ancillary staff may continue to perform the non-discretionary duties authorized by the Pharmacy Law. These duties must be reviewed by the pharmacist upon his/her return. During the pharmacist's temporary absence, an intern pharmacist may not perform discretionary duties nor otherwise act as a pharmacist. The temporary absence authorized by section 1714.1 is limited to that authorized by section 512 of the Labor Code, and any meal is limited to 30 minutes. Finally, the pharmacy must have written policies and procedures regarding the operations of the pharmacy during the temporary absence of the pharmacist for breaks and meals; these policies must include the authorized duties of ancillary staff, the pharmacist's responsibility for checking all work performed by ancillary staff, and the pharmacist's responsibility for maintaining the security of the pharmacy. These policies must be open to inspection by the Board at all times during business hours.

At its January 2000 meeting, the Board voted to sponsor a legislative proposal to make the CURES program permanent and to repeal the triplicate prescription program.

OAL approved new section 1714.1 on June 12, 2000 and it became effective the same day.

◆ **Medical Device Retailer Location Restrictions.** In May 1999, the Board adopted new section 1748.3, Title 16 of the CCR, which explicitly prohibits a medical device retailer from conducting business from a private residence and from locating a warehouse, the primary purpose of which is storage of medical devices, at a private residence. [17:1 CRLR 61] OAL approved the regulation on December 17, 1999.

CURES Update

The Controlled Substance Utilization Review and Evaluation System (CURES), established by the Board and the state Department of Justice (DOJ) under Health and Safety Code section 11165, electronically monitors the prescribing and dispensing of Schedule II controlled substances by all practitioners authorized to prescribe or dispense them. Currently, the electronic CURES and the traditional paper-based triplicate prescription system coexist, and their comparative efficiencies are being monitored by the Board and DOJ on a pilot project basis until July 1, 2003. [17:1 CRLR 64; 16:2 CRLR 48-49; 16:1 CRLR 69-70]

At its January 2000 meeting, the Board voted to sponsor a legislative proposal to make the CURES program permanent and to repeal the triplicate prescription program. On February 4, 2000, the Board hosted a CURES conference, formally known as the "Conference on the Monitoring and Regulation of Schedule II Controlled Substances." The idea for the conference originated from a working

group made up of representatives from state regulatory agencies that work on prescription drug diversion cases, and that want to improve the CURES program. The agencies involved include the Board of Pharmacy, the Medical Board, the Dental Board, the Department of Health Services, and DOJ. National experts on pain management, controlled substance monitoring, and drug diversion attended the conference, as well as doctors, patients, law enforcement officials, patient advocates, and legislative staff. Discussion focused on California's monitoring system, which currently includes both the triplicate prescription forms and the electronic monitoring system under CURES. Despite differences of opinion among many who attended, the conference culminated in several agreements, including (1) the need to make the CURES program permanent, (2) the need to add the ability to make patient profile data generated from CURES available to treating physicians, and (3) the need to repeal the triplicate prescription requirement for Schedule II drugs.

The agreements reached at the conference resulted in the Board's sponsorship of AB 2018 (Thomson) in 2000. Under AB 2018 as introduced on February 18, 2000, the triplicate prescription program would end and the CURES electronic

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system of tracking the prescription of Schedule II narcotics would become permanent on July 1, 2003. Despite strong support for the bill by numerous licensing agencies and health care trade associations and organizations, the bill was opposed by the Attorney General's Office, numerous law enforcement agencies, and ultimately the U.S. Department of Justice, all of whom argued that the triplicate prescription program enables law enforcement to monitor the prescribing of dangerous drugs and to minimize the chances of those drugs being diverted into the illegal market. They further contended that the CURES system is not secure—they believe it can be compromised by entering false or incorrect data. Furthermore, the law enforcement community argued that the triplicate prescription program should continue to serve as a check against CURES being compromised. Due to this heavy opposition by law enforcement, AB 2018 was substantially amended in June 2000 in the Senate; as ultimately enacted, it eases some existing restrictions on the prescription and dispensation of Schedule II drugs to "ease the administrative hassle" of the triplicate program for prescribers and pharmacists (see 2000 LEGISLATION).

Currently, the Board supports SB 1000 (Johannessen), which would extend CURES until January 1, 2007, state the legislature's intent that CURES ultimately replace the triplicate program, and require DOJ to prepare a report describing how CURES would have to be modified in order to make it a secure stand-alone electronic monitoring system. SB 1000 would also provide additional funding for CURES (see 2001 LEGISLATION).

Use of NAPLEX Exam

In 2000, the Board considered using the North American Pharmacists Licensure Examination (NAPLEX) of the National Association of Boards of Pharmacy (NABP) as the licensing examination for pharmacists in California; use of this exam, which is administered in every other state, will stimulate reciprocity licensure of out-of-state pharmacists and may help alleviate the pharmacist shortage in California. In October 2000, the Board initiated a review of the NAPLEX by contracting with DCA's Office of Examination Resources (OER) to conduct an audit of the NAPLEX. The OER audit consisted of a psychometric evaluation by a five-member team, including four psychometricians from California, Colorado, Michigan, and Wisconsin. The fifth member was Board member and Licensing Committee Chair Holly Strom. The cost of the audit is projected at approximately \$10,000.

On March 22–23, 2001, the audit team met with NABP representatives in Illinois and reviewed documentation describing the examination validation process undertaken by NABP, including documentation regarding the occupational analysis, test plan (blueprint) examination development process, administration procedures, passing score study, and reliability analyses. At this writing, the next meeting of the audit team is set for May 2–3, 2001. Upon completion of the audit, the team will make recommendations to the Board regarding the legal valid-

ity and defensibility of NAPLEX as a California licensure exam for pharmacists. The team will also prepare a report describing the extent of the relationship of NAPLEX to the 1999 *Standards for Educational and Psychological Testing* of the American Educational Research Association, American Psychological Association, and National Council on Measurement in Education. The final report will be completed by June 30, 2001 and presented to the Board at its July 2001 meeting.

"Notice to Consumers" Poster

At the Board's July 2000 meeting, the Communications and Public Education Committee reported completion of a telephone survey of consumers to measure the effectiveness of the Board's public education program. The survey (which was conducted by an outside contractor and required by the Department of Finance before that agency would approve any further funding for the Board's public education program) measured the public's awareness and opinions about the Board and the importance of medication compliance and consulting with pharmacists about medications. The survey indicated that consumers hold a generally positive view of pharmacists and the role they play in patient care. However, over 75% of those surveyed had never heard of the Board of Pharmacy, although 92% thought such an entity would be useful or essential to protect the public. Of those responding that they had heard of the Board, many believed that the Board represents the interests of pharmacists. Most respondents stated that the Board should place posters and pamphlets directly in pharmacies in order to be more effective in providing consumers with educational information. As a result of this survey, the Board voted to update its "Notice to Consumers" poster that is required to be posted in pharmacies under Business and Professions Code section 4122, to better communicate the Board's role of public protection and education.

At its September 28, 2000 meeting, the Communications and Public Education Committee discussed the contents of the "Notice to Consumers" poster, and noted that it had not been updated since 1993. Because the contents of the poster are contained in section 1707.2(f), Title 16 of the CCR, the Board will need to engage in rulemaking to alter the poster. The Committee decided to recommend that the Board conduct rulemaking in 2001 to update and redesign the poster, and to amend its contents to include questions that consumers should ask their pharmacist about their prescription drug (such as how and when the patient should take a particular drug, for how long, what foods and drinks to avoid while taking the medication, possible side effects, whether the new medication will work safely with other prescription and non-prescription drugs the patient is taking, and whether the pharmacist has written information about the drug in large print and in languages other than English). The Committee also recommended that the Board create a toll-free information number that should be printed on the poster along with the Board's Web site address. At its October 18–19, 2000 meeting, the Board approved the Committee's recommendations.

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At its January 5, 2001 meeting, the Communications and Public Education Committee approved draft language of the revised poster and decided to hold a special informational hearing on the new language at the Board's January 24, 2001 meeting. The draft language began with the following statement: "California law requires the pharmacist personally to discuss your prescription medicine with you at no charge, the first time the medicine is prescribed to you or whenever you have a question....Know these answers before taking any prescription medicine." Thereafter followed a series of questions that consumers are encouraged to ask their pharmacist, along with a statement that pharmacies are required to provide their current price of any medicine without obligation. The draft language also suggested that consumers ask their pharmacist if the pharmacy has written information on any drug dispensed. In response to the survey findings, the draft language also included a statement: "The Board of Pharmacy is a consumer protection agency that licenses pharmacists and pharmacies. If you have questions, please contact us. However, we are not able to help with inquiries involving medicine prices and insurance disputes."

At the January 24, 2001 informational hearing, representatives of the California Pharmacists Association and Kaiser Permanente expressed opposition

to the statement that pharmacists must offer oral consultations on new medications "at no charge." CPhA's John Cronin stated that no law prohibits pharmacists from charging a fee for statutorily-required oral consultations. Kaiser Permanente's Steve Gray stated that many pharmacies have been successful in getting patients as well as insurance companies to pay for oral consultations, and expressed concern that the draft language may lead insurance companies to think they cannot pay for such services.

At its April 12, 2001 meeting, the Committee revised the draft language to delete the "at no charge" language, shorten the number of questions posed by the poster, and delete the suggestion that consumers ask their pharmacists for written information on drugs dispensed. At its April 25-26, 2001 meeting, the full Board approved the Committee's suggested language, and instructed staff to commence the rulemaking proceeding to amend section 1707.2(f), regarding the contents of the "Notice to Consumers" poster, with a public hearing to be held at the Board's July or October 2001 meeting.

Federal Compounding Legislation Invalidated

Throughout 1999, the Board monitored the U.S. Food and Drug Administration's (FDA) implementation of the FDA Modernization Act of 1997 (FDAMA), which became effective in November 1998 and required the FDA to enter into a memorandum of understanding (MOU) with state boards of pharmacy regarding the compounding of drugs. Compounding is the process by which a pharmacist mixes ingredients to

create a specialized medication for an individual patient at the direction of a physician. Section 503A of the FDAMA recognized compounding as an element of the practice of pharmacy that is to be regulated by the states, and distinguished it from "manufacturing" (which falls within the jurisdiction of the FDA). The statute instructed the FDA to utilize the MOU to obtain state agreement on two issues: (1) protocols for the appropriate investigation of complaints relating to compounded drug products shipped out-of-state; and (2) establishment of appropriate restrictions on the amount of compounded drugs shipped in interstate commerce, including "safe harbors" for pharmacists who distribute compounded products in interstate commerce. In January 1999, the FDA published a draft MOU that was the subject of much critical commentary by compounders and state boards; in July 1999, the Board agreed to send a letter to FDA objecting to several aspects of the MOU. [17:1 CRLR 62-63; 16:2 CRLR 51; 16:1 CRLR 71-72]

Before the FDA could finalize the MOU, however, a federal district court and then the U.S. Ninth Circuit Court of

Appeals invalidated provisions of the FDAMA that restrict the right of compounding pharmacies to advertise the kinds and classes of drugs they compound; the court also found that the advertising restrictions are not severable from the other provisions of the

FDAMA, such that the entire statute is unconstitutional (see LITIGATION). As such, pharmacy compounding regulation is in an unsettled state.

2000 LEGISLATION

SB 1339 (Figueroa), as amended August 8, 2000, requires every pharmacy, on and after January 1, 2002, to establish a quality assurance program (QAP) that, at minimum, documents medication errors attributable in whole or in part to that pharmacy or its personnel. This bill provides that records generated and maintained for the QAP are not subject to discovery in arbitration, civil actions, or other proceedings, except as specified. SB 1339 further provides that its provisions shall not prohibit a patient from accessing his/her own prescription records. SB 1339, which also requires the Board to adopt regulations by September 1, 2001 specifying the requirements and implementation of QAPs, was sponsored by the Board (see MAJOR PROJECTS). The Governor signed SB 1339 on September 24, 2000 (Chapter 677, Statutes of 2000).

AB 1496 (Olberg), as amended August 25, 2000, deletes provisions of the Pharmacy Law authorizing the Board to license and regulate medical device retailers, and instead provides for the licensure and regulation of "home medical device retail facilities," as defined, by the state Department of Health Services (DHS) effective July 1, 2001. The Governor signed AB 1496 on September 28, 2000 (Chapter 837, Statutes of 2000).

At the January 24, 2001 informational hearing, representatives of the California Pharmacists Association and Kaiser Permanente expressed opposition to the statement that pharmacists must offer oral consultations on new medications "at no charge."

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SB 1554 (Figueroa), as amended August 22, 2000, permits a pharmacy to provide dangerous drugs or devices to certified emergency medical technicians (EMTs) if they are furnished exclusively for use in conjunction with an ambulance, the dangerous drug or device is within the EMT's scope of practice, and the EMT provides a written request specifying the name and quantity of the dangerous drugs or devices. SB 1554 requires records of these transactions to be maintained by both the pharmacy and EMT for at least three years. [16:2 CRLR 51] The Governor signed SB 1554 on September 28, 2000 (Chapter 836, Statutes of 2000).

AB 751 (Gallegos), as amended June 20, 2000, specifies that an existing misdemeanor provision prohibiting any person from dispensing or furnishing prescription drugs or devices without a license also applies to any item represented as, or presented in lieu of, a prescription drug or device. AB 751 also eliminates a January 1, 2001 sunset date on a provision of law permitting local health officers to take certain actions against persons selling prescription drugs or devices without a license, including closing a business upon the second offense. This bill was sponsored by Los Angeles County and is intended to remedy problems associated with "backroom clinics" and pharmacies that sometimes dispense substances that are illicit counterfeits and contain no active ingredients. Governor Davis signed AB 751 on September 7, 2000 (Chapter 350, Statutes of 2000).

AB 2240 (Bates), as amended May 16, 2000, eliminates a requirement that electronic data transmission prescriptions, as defined, be reduced to writing by the pharmacist, as long as the pharmacy is able to, for a three-year period following the final date that the prescription is dispensed, immediately produce a hard copy report upon request by the Board that includes specified information. AB 2240 also authorizes prescribers, prescribers' agents, and pharmacists to electronically enter prescriptions and orders into a pharmacy's or hospital's computer from an outside location, if permitted by the pharmacy or hospital. With the approval of the Board and the Department of Justice, this bill authorizes a pharmacy or hospital to receive electronic data transmission prescriptions and computer entry prescriptions or orders, for controlled substances in Schedules II through V, if authorized by federal law and in accordance with regulations promulgated by the U.S. Drug Enforcement Administration. The Governor signed AB 2240 on September 1, 2000 (Chapter 293, Statutes of 2000).

AB 2018 (Thomson), as amended August 18, 2000, simplifies the triplicate prescription monitoring system for Schedule II controlled substances and revises the information required in a prescription for a Schedule II controlled substance. Specifically, the bill lifts the cap on the number of triplicate prescriptions that may be issued to physicians; allows physicians to either type the triplicate prescription or have an employee type or write the prescription, so long as the physician signs the prescription; and permits a pharmacist to fill a Schedule II prescription containing error(s) if the pharmacist notifies the prescriber of the error(s), the prescriber approves any corrections, and the

prescriber faxes or mails a corrected prescription within seven days of the prescription being dispensed. The Board sponsored this bill, which—in its original version—would have eliminated the existing triplicate prescription program and made the CURES program permanent (see MAJOR PROJECTS). On September 30, 2000, AB 2018 was enacted into law without the Governor's signature (Chapter 1092, Statutes of 2000).

SB 1828 (Speier), as amended August 11, 2000, adds section 2242.1 to the Business and Professions Code, which prohibits the prescription, dispensation, and furnishing of drugs over the Internet without a prior medical examination, medical indication, and prescription. Violators are subject to a \$25,000 fine. The Governor signed SB 1828 on September 24, 2000 (Chapter 681, Statutes of 2000).

SB 1903 (Speier), as amended August 29, 2000, applies provisions of the existing Confidentiality of Medical Information Act (CMIA), which generally prohibit health care providers and contractors from sharing or selling a patient's medical information, to corporations and their subsidiaries and affiliates; and specifies that any person or entity seeking an individual's medical information, other than those specifically authorized to do so pursuant to the CMIA, must obtain valid authorization for release of the information. SB 1903 was signed by the Governor on September 30, 2000 (Chapter 1066, Statutes of 2000).

AB 2294 (Davis), as amended August 25, 2000, would have prohibited the sale or distribution of any dietary supplement product containing ephedrine, unless the product meets specified requirements; imposed requirements on product labels for dietary supplement products containing ephedrine group alkaloids; imposed requirements on companies that engage in direct marketing of any dietary supplement product containing ephedrine with respect to advertising and promotional literature; and imposed requirements on manufacturers or distributors of dietary supplements containing ephedrine group alkaloids with respect to reports of serious adverse effects. Violation of any of these requirements would be a misdemeanor. On September 29, 2000, Governor Davis vetoed AB 2294, stating that while regulation and labeling of dietary supplements containing ephedrine would seem prudent and in the interest of public safety, "this is a matter of interstate commerce and clearly the responsibility of Congress to regulate, which they have thus far neglected to do."

AB 1791 (Wiggins), as amended August 24, 2000, would have authorized a pharmacy to furnish epinephrine auto-injectors to a school district or county office of education if certain conditions are met; authorized the school district or county office of education to provide emergency epinephrine auto-injectors to trained personnel, and authorized those trained personnel to utilize them to provide emergency medical aid to persons suffering from an anaphylactic reaction. This bill expressly authorized each public and private elementary and secondary school in the state to voluntarily determine whether or not to make emergency epinephrine auto-injectors and trained personnel available at its school, and to designate one or more

school personnel to receive prescribed training regarding epinephrine auto-injectors from individuals in specified positions. On September 28, 2000, Governor Davis vetoed AB 1791. In his veto message, the Governor acknowledged that the administration of epinephrine auto-injectors by medically trained personnel such as school nurses could in certain instances be life-saving. "However, the shortage of school nurses with the knowledge necessary to administer medications would assure that the bulk of school personnel administering epinephrine in emergencies would be lay personnel. While there are training programs for non-licensed persons that must administer medications conducted by schools of nursing, medical schools, and schools that train physicians assistants, such programs require weeks for matriculation and cannot safely be compressed into a few hours. Lay persons cannot receive the necessary background in a limited training program that would provide the essential medical judgement skills required to administer medication in an emergency situation."

SB 550 (Johnston), as amended March 2, 2000, moves the controlled substance dronabinol (an orally taken pharmaceutical form of synthetic medicinal marijuana) from Schedule II to Schedule III, which results in reduced requirements for the written prescription of the drug (including elimination of the need to prepare the prescription in triplicate), and authorizes the oral prescription of the drug. The bill does not change the criminal penalties attached to unlawful transactions involving dronabinol. The Governor signed SB 550 on March 29, 2000 (Chapter 8, Statutes of 2000).

The following bills reported in Volume 17, No. 1 (Winter 2000) of the *Reporter* died in committee or otherwise failed to be enacted in 2000: **AB 660 (Cardenas)**, a Y2K bill authorizing pharmacists to refill prescriptions between November 1, 1999 and February 29, 2000; and **SB 404 (Alpert)**, which would have authorized pharmacists to initiate emergency contraception drug therapy in accordance with protocols established by an authorized prescriber. **AB 141 (Knox)**, as amended March 27, 2000, is no longer relevant to the Board.

2001 LEGISLATION

SB 724 (Committee on Business and Professions), as introduced February 23, 2001, is a DCA omnibus bill that would make numerous technical clean-up changes to the Pharmacy Law. Among other things, the bill would revise the definition of the term "manufacturer"; authorize the Board to establish a list of dangerous devices that may only be maintained, dispensed, sold, or furnished by a pharmacist in a pharmacy; and revise the Board's authority to issue a temporary permit to conduct a pharmacy. SB 724 would also provide that it is a misdemeanor for a wholesaler or any other person to permit the furnishing of dangerous drugs or dangerous devices except by a pharmacist or exemptee. The Board is sponsoring these provisions of SB 724. [*S. Appr*]

AB 809 (Salinas), as amended April 17, 2001, would authorize the installation of secure automated drug delivery systems (ADDS) in specified clinics licensed by the Board and

located in areas with a pharmacist shortage; these ADDS would be controlled by pharmacists who may remotely operate these systems to dispense prescription medication. The bill would require a pharmacist to review the prescription and the patient profile, authorize the release of the prescriptions drugs or devices from the automated drug delivery system, and consult with the patient via a telecommunications link with two-way audio and video capabilities. AB 809 would further require a pharmacist to perform the stocking, inventory maintenance, and review of the operation and maintenance of the system, and require the Board to adopt regulations specifying other activities in which a pharmacist operating an ADDS may engage. AB 809 is sponsored by the Board. [*A. Appr*]

AB 826 (Cohn). Existing law generally restricts pharmacists to initiating prescriptions and providing clinical advice in a pharmacy premises; however, under Business and Professions Code sections 4051 and 4052, a pharmacist is permitted to provide certain services in licensed acute care hospitals, health care facilities, home health agencies, or hospice settings. As introduced February 22, 2001, AB 826 would eliminate restrictions on where a pharmacist is permitted to provide clinical advice, information, or patient consultation by removing the language restricting these services to patients in licensed acute care hospitals, health care facilities, home health agencies, or hospice settings. The Board is sponsoring AB 826. [*A. Appr*]

SB 340 (Speier). Existing law authorizes a pharmacist filling a prescription order for a drug product prescribed by the trade or brand name to substitute a generic drug product, subject to specified requirements. As amended April 17, 2001, SB 340 would additionally authorize a pharmacist to substitute a drug product with a different form of medication having the same active chemical ingredients of equivalent strength and duration of therapy as the prescribed drug product, if the change is in the patient's best interests and unless the prescriber indicates no substitution may be made. SB 340 would require that the patient be notified of the substitution.

The Pharmacy Law authorizes specified nonprofit and free clinics licensed by the Board of Pharmacy to purchase drugs at wholesale for administration or dispensing to patients registered for care at the clinic. SB 340 would authorize specified entities—so-called "340B entities" as defined in federal law—to contract with a pharmacy to provide pharmacy-related services to patients of the entity. SB 340 would authorize a pharmacy to dispense preferentially priced drugs obtained pursuant to federal law, require that those drugs be segregated from the pharmacy's other drug stock, and require excess drug stock to be returned to the distributor. SB 340 would also require pharmacy records of acquisition and disposition of these drugs to be kept separate from other records. This bill would exclude 340B entities and pharmacies from the requirement that they obtain a wholesaler's license for actions necessary to participate in the drug purchase program. SB 340 would also provide that it is unprofessional conduct for any person licensed under the Pharmacy Law to sell, trade, transfer, or furnish, drugs obtained pur-

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suant to federal law to any person the licensee knows or reasonably should know is not a patient of a 340B entity, as defined by federal law. This bill is sponsored by the Board. [*S. Appr*]

SB 1000 (Johannessen), as amended April 26, 2001, would state the legislature's intent to eliminate the triplicate prescription requirement for Schedule II controlled substances when a secure stand-alone electronic monitoring system is in place. This bill would direct the Attorney General to prepare a report describing how the existing CURES would have to be modified in order to make it a secure stand-alone electronic monitoring system (see MAJOR PROJECTS), and require DOJ to dedicate two employees with peace officer status to investigate persons who improperly prescribe Schedule II controlled substances. The Board supports SB 1000. [*S. Appr*]

AB 1589 (Simitian), as amended April 30, 2001, would require the Medical Board to consult with the Board of Pharmacy and commission a study that evaluates the electronic transmission of prescriptions by physicians and report its results to the legislature by January 1, 2003. The bill would require MBC's report to include recommendations to encourage physicians to use this method to transmit prescriptions and identify systems to protect patients, including the issuance of a digital certification, as defined. [*A. Appr*]

AB 536 (Bates). Existing law provides that the ratio of pharmacy technicians to pharmacists shall not exceed one to one when the pharmacy technician is assisting the pharmacist by the performance of nondiscretionary tasks. As amended April 18, 2001, AB 536 would increase the maximum ratio of pharmacy technicians performing specified non-clerical functions under the direct supervision and control of a pharmacist to two technicians for each additional pharmacist in those pharmacies with more than one pharmacist. This ratio is applicable to outpatient practice settings. AB 536 would also allow a pharmacist assigned to supervise a second pharmacy technician to refuse to supervise the technician in specified circumstances, and would prohibit an employer from discharging, disciplining, or discriminating against a pharmacist for doing so. The Board supports AB 536. [*A. Appr*]

AB 269 (Correa), as amended April 5, 2001, would create the Division of Enforcement Oversight within DCA. Under the direction of the DCA Director, the Division would monitor and evaluate the consumer complaint and discipline system of each DCA board (including the Board). Further, the bill would require the executive officer of each DCA board to be appointed by a three-member panel comprised of a representative of the board, the DCA Director, and the Governor's appointments secretary. [*A. B&P*]

AB 207 (Matthews) as amended April 17, 2001, would require certain health plans and disability insurers that offer coverage for prescription drug benefits and that issue identification cards to enrollees and insureds to issue a card containing uniform information necessary to process claims for prescription drug benefits. [*A. Appr*]

AB 108 (Strom-Martin), as amended March 14, 2001, would require the Board to issue a pharmacy license to au-

thorize the operation of a pharmacy located on Indian trust lands held by a federally recognized Indian tribe under certain conditions, including provisions for licensure by the Board of a pharmacist to be employed by the pharmacy who is licensed by another state or territory of the United States. This bill would authorize the Board and a recognized Indian tribe to enter into a memorandum of agreement concerning their obligations. AB 108 would also provide that all of the benefits and obligations of licensure by the Board would apply to these pharmacies. The Board opposes this legislation (see RECENT MEETINGS). [*A. Health*]

AB 258 (La Suer). Under existing law, controlled substances are categorized into five schedules; the greatest restrictions and penalties are placed on those substances contained in Schedule I, which are deemed by law to have no accepted medical use. The controlled substance gamma-hydroxybutyrate (GHB)—the so-called "date rape drug"—is classified as a Schedule II drug. AB 258 would reclassify GHB from a Schedule II controlled substance to a Schedule I controlled substance, thereby making unlawful the possession, possession for sale, and sale of GHB punishable under Health and Safety Code sections 11350(a), 11351, and 11352. The Board supports AB 258. [*A. Appr*]

AB 559 (Wiggins), as introduced February 21, 2001, is Assemblymember Wiggins' reintroduction of AB 1791, which was vetoed in 2000 (see above). AB 559 would permit school districts or county offices of education to provide emergency epinephrine auto-injectors to trained personnel, and permits trained personnel to utilize these auto-injectors to provide emergency medical aid to persons suffering from an anaphylactic reaction. The bill would also require the Superintendent of Public Instruction to establish minimum training standards for the administration of epinephrine auto-injectors; authorize school nurses or, if a school does not have a nurse, a person who has received training regarding epinephrine auto-injectors, to obtain prescriptions for epinephrine auto-injectors and to immediately administer an epinephrine auto-injector under certain circumstances; require those individuals to initiate emergency medical services or other appropriate medical follow-up in accordance with written training materials; and require any school district or county office of education electing to utilize epinephrine auto-injectors for emergency medical aid to create a plan to address specified issues. The Board supports AB 559. [*A. Appr*]

SB 633 (Sher), as amended April 19, 2001, the California Mercury Reduction Act of 2001, would make findings that mercury is a serious threat to public health and the environment and make several legislative changes aimed at restricting the amount of mercury added to the environment. To reduce the amount of mercury added to the environment by broken and discarded fever thermometers, this bill would ban the manufacture, sale, or supply of mercury fever thermometers except when the thermometer is supplied to a consumer or patient by written prescription. Any thermometer supplied under prescription must be accompanied by adequate instructions concern-

ing proper handling and cleanup in case of breakage. [*S. Appr*]

SB 696 (Speier). Existing federal law establishes the Medicare program, a national health insurance program for people 65 years and older; Medicare does not cover outpatient prescription drugs. To fill this void, and consistent with the law in 14 other states, SB 696 would enact—contingent on federal approvals—a voluntary Medicare drug rate program providing prescription drugs at reduced prices to Medicare beneficiaries.

As amended April 17, 2001, SB 696 would enact the Golden Bear State Pharmacy Assistance Program, participation in which would be voluntary for Medicare beneficiaries, pharmacies, and drug manufacturers. The bill would permit DHS to negotiate rebate amounts with drug manufacturers, contingent upon sufficient participation by the drug manufacturers. SB 696 would require pharmacies to charge prices based on specified components, including rebates to be negotiated with drug manufacturers, and would require DHS to pay pharmacies an amount based on these rebates. It would further require rebate amounts paid by DHS with respect to a manufacturer's drug to also be paid by the manufacturer to DHS.

SB 696 would require moneys received from drug manufacturers pursuant to the bill to be deposited into the Golden Bear State Pharmacy Assistance Program Rebate Fund, which would be created by the bill. The fund would be continuously appropriated to DHS without regard to fiscal year for implementation of the bill. SB 696 would be implemented only upon the receipt of all necessary federal approvals and if DHS is able to negotiate a sufficient number of rebate agreements. SB 696 would appropriate \$1,000,000 from the general fund to DHS in the form of a loan, for startup costs for implementation of the bill. [*S. Appr*]

LITIGATION

On February 6, 2001, in *Western States Medical Center v. Shalala*, 283 F.3d 1090, the U.S. Ninth Circuit Court of Appeals held that certain subsections of the Food and Drug Administration Modernization Act of 1997 (FDAMA) that restrict the advertising of compounded drugs violate first amendment commercial speech rights. Further, the court held that the advertising restrictions are not severable from the remaining provisions of the statute and, therefore, the entire statute is unconstitutional—thrusting pharmacy compounding regulation into uncertainty (see MAJOR PROJECTS).

Compounding is the process by which a pharmacist combines, mixes, or alters ingredients to specialize a medication for a patient at the direction of a physician. One provision of the FDAMA, 21 U.S.C. section 353a, recognized compounding as an element of the practice of pharmacy that is to be regulated by the states, and distinguished it from “manufacturing” (which falls within the jurisdiction of the FDA). The 1997 legislation exempted compounding from certain requirements of the federal Food, Drug and Cosmetic Act, but only under certain conditions. Under the FDAMA, pharmacists may advertise to the public that they offer general compound-

ing services, but may not advertise that they compound particular drugs. In this case, plaintiffs—a group of licensed pharmacies—sought to enjoin enforcement of 21 U.S.C. sections 353a(a) and (c), arguing that a restriction on pharmacists' ability to advertise particular compounded drugs violates the first amendment.

In order to meet the test for acceptable government regulation of commercial speech, as set forth in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980), a regulation must satisfy a four-part test. The court must determine whether: (1) the regulated speech is misleading or concerns unlawful activity; (2) the government has asserted a “substantial” interest in restricting the speech; (3) the government has demonstrated that the regulation “directly advances” the asserted interest; and (4) the restriction is not more extensive than necessary to achieve the asserted governmental interest.

As to factor (1), the court found that the pharmacies' advertising is not untruthful or misleading. On factor (2), the Ninth Circuit agreed that the government has a substantial interest protecting the public health and safety and preserving the integrity of the drug approval process. As to factor (3), the government argued that the advertising restrictions are necessary to prevent an increase in the demand for compounded drugs that would be injurious to the public health. Here, the Ninth Circuit held that the government failed to offer evidence or arguments to explain sufficiently why those restrictions will reduce the type of consumption of compounded drugs that is harmful. The court noted that other safeguards exist to protect the public—for example, the requirement of a valid physician's prescription, limitations on the substances that can be used to fashion a compounded drug, and a prohibition on the compounding of drugs that are essentially copies of commercially available drug products.

Further, the court said that “FDAMA is so riddled with exceptions that it is unlikely that the speech restrictions would actually succeed in depressing the volume of compounded drugs. The exceptions also demonstrate that the restrictions do not directly advance the government's interest in maintaining the integrity of the drug approval process. Under the statute, pharmacists can advertise their compounding services and promote their skills at medical trade events so long as they do not promote the compounding of any *particular* drug. It seems obvious that advertising that informs physicians that a pharmacy is available to compound drugs is likely to increase demand for compounding. Moreover, even with the ban on specific advertising, FDAMA provides significant incentives for pharmacies to increase their drug compounding business. The statute allows compounded drugs to constitute up to five percent of a pharmacy's interstate drug distributions and 100 percent of its intrastate drug distributions. If a pharmacy has a Memorandum of Understanding with the Secretary of Health and Human Services, up to twenty percent of its interstate drug distributions can be in the form of compounded drugs....Under FDAMA, a pharmacist can call

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a physician and recommend a drug compound when a patient comes in with a prescription for a commercial drug and provides information to the pharmacist that indicates that the patient might require a compounded product. When exemptions and inconsistencies counteract the alleged purpose of a speech restriction, the restriction fails the direct advancement test" (emphasis original; citation omitted).

The court went on to find that the restrictions also fail the fourth *Central Hudson* factor because they are more extensive than necessary to achieve the asserted government interest. The court noted that the government could have required disclaimers on compounded drugs saying that they had not been subject to FDA approval or could require safety reviews similar to those required for manufactured drugs in order to meet safety concerns.

Finally, the Ninth Circuit held that the challenged subsections could not be severed from the rest of the statute because Congress would not have enacted the remaining provisions of the FDAMA absent the advertising restrictions; thus the entire statute is invalid. At this writing, the federal government plans to petition the U.S. Supreme Court for review of the Ninth Circuit's decision.

In December 2000, a Sacramento County Superior Court jury awarded former Board supervising inspector Labib Doumit \$3 million in damages in *Doumit v. Board of Pharmacy, et al.*, No. 98AS04499. Doumit alleged that he was harassed by Board Executive Officer Patricia Harris after he reported to federal authorities his suspicions that his supervisors had mishandled evidence and mismanaged a joint state-federal investigation into Medi-Cal fraud. Further, he claimed that Harris and Assistant Executive Officer Virginia Herold came to his home and removed computer equipment, office supplies, and a Board van—an incident that allegedly caused him angina for which he was hospitalized and subsequently took a medical leave. Doumit claimed this treatment came in retaliation for reporting his suspicions to the U.S. Attorney's Office. Following a trial, the jury awarded Doumit \$1.4 million for past and future lost wages, \$850,000 for lost pension benefits, \$250,000 for invasion of privacy, and \$500,000 for emotional distress.

At the Board's January 2001 meeting, Board President Robert Elsner stated that "the Board stands firmly behind its managers, Executive Officer Patricia Harris and Assistant Executive Officer Virginia Herold, who made every effort to act lawfully and to be fair and cordial in their relationship with Mr. Doumit throughout his employment....The Board of Pharmacy will appeal the jury's verdict and seek review of the legal basis for the damages awarded in this case. The Board disagrees with the jury's decision and continues to support its management."

RECENT MEETINGS

At its April 13, 2000 meeting, the Board elected Robert Elsner as President, Steven Litsey as Vice-President, and Caleb Zia as Treasurer.

At its July 25–26, 2000 meeting, the Board voted to acknowledge the existence of a pharmacist shortage in Califor-

nia, and directed its Licensing Committee to work with industry in an effort to find solutions. At its October 2000 meeting, the Board convened a task force to seek solutions to the pharmacist shortage. The task force will consist of the two Licensing Committee members and approximately 15 members as recommended by the Committee and appointed by the Board President and Vice-President.

In October 1998, the Board's counsel recommended that the Board consider proposed legislation that would authorize the Board to issue "site" permits to pharmacies owned by a limited liability company (LLC). [16:1 CRLR 70–71] At that time, the Board accepted this recommendation and initiated efforts to introduce legislation but never obtained an author. At its October 2000 meeting, the Board took the opposite stance and unanimously voted not to license any pharmacy as an LLC.

At the Board's January 2001 meeting, Board member Holly Strom reported on a longstanding request of the Hoopa Indian Tribe for a waiver of the Board's licensure requirements so that a pharmacy could be located on tribal ground to serve both members of the tribe and California residents from outside the tribe. Although a pharmacy operated on tribal lands is not required to comply with California pharmacy law for the purpose of serving residents of the reservation, a California license is required if the pharmacy also serves other California residents. The Hoopa Tribe has been unable to hire a California-licensed pharmacist, and has sought a waiver of the requirement for a California pharmacist-in-charge under Business and Professions Code section 4118; however, the Board believes it is not authorized to waive that particular requirement. Strom noted the pendency of AB 108 (Strom-Martin), which would authorize the Board to issue a license to a pharmacy with a pharmacist-in-charge who is licensed in another state (see 2001 LEGISLATION). Under AB 108, the Hoopa Tribe would be able to hire non-licensed pharmacists. Board members expressed concern that if such a waiver were allowed, the Board would not have jurisdiction over the non-licensed pharmacists, and would be unable to take action against violations committed by these pharmacists. In view of these concerns, the Board voted unanimously to oppose AB 108.

At its April 25–26, 2001 meeting, the Board said farewell to Deputy Attorney General Bill Marcus, its longtime liaison with the AG's Office; due to health problems, Marcus retired after a long and distinguished career in state service. Also in April, the Board elected Steven Litsey as President, John Jones as Vice-President, and Caleb Zia as Treasurer.

FUTURE MEETINGS

2001: July 25–26 in San Diego; October 15–16 in San Francisco.

2002: January 23–23 in Los Angeles; April 24–26 in Sacramento; July 24–25 in San Diego; October 23–24 in San Francisco.

2003: January 22–23 in Los Angeles; April 9–10 in Sacramento; July 21–22 in San Diego; October 29–30 in San Francisco.