

## Board of Pharmacy

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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, medical device retailers, 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, which meets five times per year, consists of eleven members, four of whom are nonlicensees. The remaining members are pharmacists, five of whom must be active practitioners. All Board members are appointed for four-year terms.

On May 21, Assembly Speaker Antonio Villaraigosa appointed Andrea Zinder as the Board's newest public member; Zinder replaces Kenneth Tait. Zinder is currently an executive assistant to the President of the United Food and Commercial Workers Union Local 324, where she has worked since 1984. While working at UFCW, she has represented retail workers and drugstore employees, including pharmacists, in contract negotiations.

### MAJOR PROJECTS

#### **Prevention of Medication Errors: Quality Assurance Program Regulations**

The Board's primary responsibility is to protect the public health, safety, and welfare of California's patients. The Board has become increasingly concerned about the growing incidence of medication errors [16:2 CRLR 55], which can include any of the following: (1) the prescriber orders an inappropriate drug for a patient's condition; (2) incorrect infor-

mation is entered 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. Consistent problems contributing to prescription errors are the absence or presence of computerized placeholders that are zeroes before and after the decimal point in the dosage of a medication; misinterpreted abbreviations and incomplete medications; poor communication (including illegible prescriber handwriting [15:1 CRLR 87]); similarities in product names; ambiguities in directions for use or medical abbreviations; unclear labeling; and poor pharmacy procedures or techniques. Some pharmacists complain that their workload—the number of prescriptions to be filled with insufficient staffing—may also cause prescription errors.

Obviously, a medication error can result in patient injury or death. To prevent such harm, the Board on July 30 published notice of its intent to adopt new section 1717.5, Title 16 of the CCR, which would require every licensed pharmacy to develop and implement a quality assurance program (QAP) to document medication errors attributable to a pharmacy or its personnel. The primary purpose of the QAP is not punitive; rather, it is to document and analyze medication errors in order to enable the pharmacy to take appropriate action to prevent a recurrence. For purposes of the required QAP, section 1717.5 would define the term "medication

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error" as "any preventable event that may cause or lead to, or that has caused or led to, inappropriate medication use or patient harm while the medication is in the possession of or under the control of the pharmacy, another health care professional, or the patient or consumer. The circumstances or activities that may lead to or create a medication error include, but are not limited to: receipt and use of health care products, including drugs and devices; receipt of prescriptions, including communication, interpretation, and evaluation of an order; drug selection, compounding and dispensing, including direction and supervision of pharmacy personnel; provision to patients, including selection, preparation and labeling of the prescription container, use of patient profiles, prescriber contacts, and patient consultation and education; patient use, including dispensing and use of refills and monitoring of patient use; general pharmacy administration, procedures, and systems; professional pharmacy practice."

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Section 1717.5 would require every pharmacy to describe its QAP in its policies and procedures manual, and would specify the required contents of the QAP. At minimum, the QAP analysis of medication errors must consider workplace conditions, including general working conditions, peak workload periods, and workplace design and operation; the use of technology; and training and ongoing evaluation of staff, including adequacy of training and evaluation to protect public health and safety. Section 1717.5 would require each pharmacy to document in its QAP, for each medication

error, the fact that a QAP was conducted; the findings and determinations made by the pharmacy; and remedial efforts undertaken, if any, including communication to pharmacy personnel responsible for the error and to pharmacy personnel in general. The pharmacy must maintain records of all activities undertaken as part of its QAP for at least three years, and make those records accessible to the Board during normal business hours. The section would also specify that compliance with the QAP requirement may be considered by the Board as a mitigating factor in an investigation and evaluation of any medication errors.

On October 20, the Board held a public hearing on proposed section 1717.5. Numerous pharmacists and representatives of pharmacies, retailers, and pharmaceutical companies registered opposition to the QAP requirement. Although many agreed with the concept of a QAP as an internal educational tool to analyze the circumstances and reasons for errors, opponents argued that the provision's definition of "medication error" is far too broad and expressed concern about the discoverability of a pharmacy's QAP by plaintiff attorneys. Several witnesses stated that the discoverability of a QAP in civil litigation would discourage the reporting of errors, and argued that a pharmacy's QAP should be immune from discovery in civil actions. Many opponents stated that the focus should be on preventing errors instead of reporting and investigating them after they occur; these opponents argued that errors that are caught by pharmacy personnel before medication is dispensed to a consumer should not have to be reported in the QAP. The California Pharmacists Association (CPhA) also argued that the Board should reevaluate the fiscal impact of this proposal on pharmacies subject to the QAP requirement.

After much debate and testimony at the October 20 hearing, the Board unanimously deferred adoption of section 1717.5's current language and remanded this matter to its Enforcement Committee for further study.

## **Emergency Regulations to Implement SB 188 (Leslie): Pharmacy Operations During Temporary Absence of a Pharmacist**

At its October 20 meeting, the Board considered the emergency adoption of new section 1714.1, Title 16 of the CCR, to implement SB 188 (Leslie) (Chapter 900, Statutes of 1999). SB 188 was amended late in the legislative year to require 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), which mandates breaks and lunch periods for pharmacists during the workday (see LEGISLATION). Absent new regulations, the combination of SB 651 and the existing Pharmacy Law will require the closure of a pharmacy and the removal of all non-pharmacist personnel from the pharmacy area during pharmacist breaks and lunch periods when SB 651 takes effect on January 1, 2000.

As drafted by the Board's Legislation and Regulation Committee, emergency section 1714.1 would state that in pharmacies staffed by a single pharmacist, the pharmacist may leave the pharmacy temporarily for breaks and meal periods without closing the pharmacy and removing ancillary staff "if the pharmacist reasonably believes that the security of the dangerous drugs and devices will be maintained in his or her

absence." If not, the pharmacy area (the area in which prescription drugs and devices are kept) must be closed and non-pharmacist employees must be removed during the pharmacist's absence. Section 1714.1 would also state that during the pharmacist's absence, no prescription medication may be provided to a patient or to a patient's agent unless the prescription medication is a refill that the pharmacist has checked, released for furnishing to the patient, and was determined not to require the consultation of a pharmacist.

Under the draft regulation, ancillary staff (including pharmacy technicians and intern pharmacists) may continue to perform nondiscretionary duties authorized by law during the temporary absence of a pharmacist, but the pharmacist must review any duty performed by ancillary staff upon his/her return to the pharmacy. The proposal also states that in pharmacies where two or more pharmacists are on duty, the pharmacists must stagger their breaks and meal periods to ensure that the pharmacy is not left without a pharmacist for a temporary period. Finally, section 1714.1 would require pharmacies to draft written policies and procedures regarding the

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operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods.

Following its receipt of a number of comments from pharmacist and labor organizations, the Board modified the language of section 1714.1 to add a provision stating that "a pharmacist who takes a break in compliance with this section shall not be subject to California State Board of Pharmacy disciplinary action or citation for acts that he or she did not authorize and that he or she, by the exercise of reasonable care, could not have prevented during his or her absence." The Board adopted section 1714.1 as modified, and instructed staff to forward the proposed emergency regulation to DCA and the Office of Administrative Law (OAL) for approval. At this writing, staff is preparing the rulemaking file on section 1714.1; if approved by OAL, the emergency regulation will be effective on January 1, 2000 for 120 days.

## **Waiver Requirements for Offsite Storage of Drug Records**

Business and Professions Code section 4081 requires Board licensees to make available for Board inspection during business hours all records of the manufacture, sale, acquisition, or disposition of prescription drugs or devices. Additionally, section 4105 requires "all records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the Board...[to] be retained on the licensed premises in a readily retrievable form," and section 4333 requires pharmacies to keep records of all prescriptions filled on pharmacy premises and available for inspection by Board personnel and other authorized law enforcement officers for at least three years. However, subsections 4105(e) and 4333(c)(1) authorize the Board to waive the onsite storage requirement upon written request.

In recent years, the Board has received an increasing number of applications for waiver of the onsite storage requirement, but has not granted any of them. However, the Board realizes that it is not always feasible or practical for a business to maintain all of its records on the licensed premises, and seeks to adopt regulations codifying standard criteria by which it would determine which license holders might be granted a waiver, and ensuring that it is able to pursue disciplinary action should a licensee violate its duties regarding records storage.

Thus, on May 21, the Board published notice of its intent to adopt new section 1707, Title 16 of the CCR. Under the proposed section, a waiver authorizing offsite storage of drug records may be granted to a Board licensee if the licensee has no history of failure to produce records upon the request of the Board or other law enforcement officer, no history of violations related to recordkeeping, and the licensee

is not on probation with the Board. Further, the storage area must be maintained so that records are secure and the confidentiality of any patient-related information is maintained; the address of the site and the key to the storage area must be maintained on the licensed premises by an employee licensed by the Board, and must be immediately accessible to the pharmacist-in-charge and upon request to the Board or other law enforcement officer; and the records in storage must be retrievable within two hours and at all times open to inspection during business hours upon the request of the Board or other law enforcement officer. Under the proposal, in the event that a licensee fails to comply with the above provisions, the Board may cancel the waiver without a hearing, at which time the licensee must maintain all records at the licensed premises. The proposal also specifies the method of reapplying for a waiver in the event one has been canceled by the Board.

In its May 21 notice, the Board did not schedule a public hearing on proposed section 1707, but several licensees requested a hearing under Government Code section 11346.8(a). On June 22, the Board issued a notice stating that it would hold a public hearing on section 1707 at its July 28 meeting in Burlingame. On July 7, the Board released a modified version of section 1707, in which it added a new subsection to the provision. The new language states that "notwithstanding the requirements of this section, any entity licensed by the Board may 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 following conditions are met: (1) 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 officer of the law; and (2) the storage is maintained so that the records are secure and so that the confidentiality of any patient-related information is maintained."

At the July 28 hearing, the California Retailers' Association and Longs Drugs objected to the two-hour requirement for records retrieval, arguing that the Board should consider a more reasonable time limit in light of potential traffic and other delays; Longs stated that the U.S. Drug Enforcement Administration (DEA) requires offsite records to be retrievable within 72 hours. CPhA objected to the regulations as unnecessary and expensive for pharmacies; the trade association asserted that the legislative history of the statutory waiver provisions was intended to permit routine waivers of the onsite storage requirement, not to require pharmacies to qualify for a waiver. CPhA called for fairly automatic waivers upon request, and substantial simplification of the regulatory language. Kaiser Permanente also objected to the Board's proposal, noting that many hospitals

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do not have sufficient physical space for records storage. Kaiser's records are stored in two centers where a pharmacist is not in charge; rather, the records are maintained by a "professional storage manager." Following the hearing, the Board decided to substantially modify the language of section 1707 and to republish the section with its modifications.

On August 20, the Board published a revised version of section 1707, Title 16 of the CCR. Under the August 20 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. However, even under this waiver, all prescription records must be maintained on the licensed premises for a period of two years from the date of dispensing. Any licensee granted a waiver must maintain the offsite storage area so that the records are secure, including from unauthorized access, and must be able to produce the records within 48 hours upon the request of the Board or other authorized law enforcement officer. The proposed regulation states that if a licensee fails to comply with these conditions, its waiver will be canceled without a hearing (such that all records must be maintained at the licensed premises), and provides a method of reapplying for another waiver. Proposed 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 officer of the law, and the storage is maintained so that the records are secure and so that the confidentiality of any patient-related information is maintained.

The Board did not schedule another public hearing on the revised language of section 1707, but accepted written comments until October 4. At its October 20 meeting, the Board discussed a comment received from Kaiser Permanente calling for additional modifications to the language. The Board took no action on section 1707 at its October meeting, and is expected to revisit the proposal at its January 2000 meeting.

## **Citation and Fine Regulations**

On May 21, the Board published notice of its intent to amend section 1775 and 1775.1, Title 16 of the CCR, which implement the Board's citation and fine authority under Business and Professions Code sections 125.9 and 148. The purposes of the amendments are to expand the listing of violations

subject to citation and fine to include noncompliance with the Board's continuing education requirement, add violation of the Board's regulations as a justification for the issuance of a citation and/or fine, and update the statutory references in the sections to reflect the 1996 reorganization of the Pharmacy Law.

The Board did not hold a public hearing on these proposed amendments, but accepted written comments until July 5. At its July 28 meeting, the Board considered several comments that it had received, and adopted the regulatory changes subject to several minor revisions. The Board directed staff to release the revised version of sections 1775 and 1775.1 for an additional 15-day comment period, and then submit the rulemaking file on the proposed changes to DCA and OAL for approval.

In a related matter, at its October 20 meeting the Board discussed staff's proposal to substantially expand its rather narrow citation and fine regulations to permit the issuance of citations and/or fines for violations such as abandonment of a pharmacy, failure to produce records when requested by

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the Board, absence of a pharmacist from a pharmacy, failure to notify the Board of a change of address, license lapse of pharmacy technicians, and other relatively minor violations. Deputy Attorney General Bill Marcus noted that other occupational licensing boards have used the citation and fine remedy expansively for minor offenses, and the result is fewer cases being referred to the Attorney General's Office for full-blown adjudication (and reduced enforcement costs for such boards). Following discussion, the Board approved staff's proposal; at this writing, staff is drafting more expansive citation and fine regulations for public notice and comment in the future.

## **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 statute 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.

Thus, on October 29, 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. Specifically, the section would set forth a list of drugs and devices which need not be stored in a licensed pharmacy so long as they have been sold or furnished to a physician, dentist, podiatrist, pharmacist, medi-

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cal technician, medical technologist, optometrist, or chiropractor holding a currently valid and unrevoked license and acting within the scope of his/her practice, or to a clinic, hospital, institution, or establishment holding a currently valid and unrevoked license or permit under specified sections of the Health and Safety Code or the Welfare and Institutions Code. Proposed section 1714.5 would also set forth a separate list of drugs and devices which need not be stored in a licensed pharmacy when a licensed home health agency or hospice purchases, stores, furnishes, or transports them.

At this writing, the Board does not intend to hold a public hearing on section 1714.5; however, it is accepting written comments until December 13.

## Update on Other Board Rulemaking

The following is an update on recent Board rulemaking proceedings described in detail in Volume 16, No. 2 (Summer 1999) of the *California Regulatory Law Reporter*:

◆ **Refill Pharmacy Regulations.** Recently, many new pharmacy operations and concepts have begun to emerge. One such concept is a refill pharmacy, which prepares refill prescriptions for another pharmacy. While the Board has licensed such pharmacies in the past, it has determined that labeling and documentation requirements should be established to assure that patients can readily determine where the prescription was filled. Thus, in February 1999, the Board published notice of its intent to adopt section 1707.4, Title 16 of the CCR, to address its concerns about the use of refill pharmacies. The purpose of the Board's proposal is to (1) allow a pharmacy to utilize the services of another pharmacy to provide refills if it has a contract for these services or has common ownership; (2) specify the labeling requirements for a prescription refilled at a refill pharmacy, including the name of the refill pharmacy and 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); (3) specify the documentation requirements for the originating pharmacy and the refill pharmacy; and (4) allow a pharmacy to operate as a refill pharmacy as well as fill new prescriptions. [16:2 CRLR 50]

On May 19, the Board held a public hearing on its proposed adoption of section 1707.4. Most witnesses favored the proposal, although Steve Gray from Kaiser Permanente clarified that three pharmacies may be involved in a refill transaction—the pharmacy that receives the refill request, the pharmacy that refills the prescription, and the pharmacy that gives the refilled prescription to the patient. He recommended that the language of section 1707.4 be modified to require that only the name and address of the pharmacy that refills the prescription appear on the prescription container label. Following public comment mostly in support of the proposal, the Board adopted the section

subject to several minor modifications. Specifically, the Board amended the section to require the prescription container to be clearly labeled with all information required by Business and Professions Code section 4076, plus the name and address of the pharmacy refilling the prescription and/or the name and address of the pharmacy that receives the refilled prescription for dispensing to the patient.

On June 3, Board staff released the modified version of section 1707.4 for an additional 15-day comment period ending June 21. At this writing, DCA is considering the rulemaking file on section 1707.4; after DCA approves the file, it will be forwarded to OAL for approval.

◆ **Medical Device Retailer Location Restrictions.** On May 20, 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. Under Business and Professions Code section 4132(f), medical device retailers are required to make their records of sale, purchase, and disposition of dangerous devices available, at all times during business hours, for inspection by authorized law enforcement officers. When persons conduct a medical device retail business from their home or the home of someone else, Pharmacy Board inspectors and authorized law enforcement officers have encountered problems gaining access to records because of residential privacy issues. The new regulatory section eliminates this problem. [16:2 CRLR 50] At this writing, DCA is considering the rulemaking file on section 1748.3; after DCA approves the file, it will be forwarded to OAL for approval.

◆ **Furnishing of Drugs and Devices by Wholesalers and Manufacturers.** On May 20, the Board adopted new section 1783, Title 16 of the CCR, to clarify the identity of "authorized persons" to whom drug manufacturers and wholesalers may furnish dangerous drugs and devices under Business and Professions Code section 4163. [16:2 CRLR 50-51] Under section 1783, the term "authorized person" means a person to whom the Board has issued a permit which enables the permit holder to purchase dangerous drugs or devices

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for use within the scope of its permit. "Authorized person" also means any person in California or in another jurisdiction within the United States to the extent such furnishing is authorized by the law of this state, any applicable federal law, and the law of the jurisdiction in which that person is located. The manufacturer or wholesaler furnishing to such a person shall, prior to furnishing the dangerous drugs and devices, establish that the intended recipient is legally authorized to receive the dangerous drugs or devices. The section is intended to eliminate any confusion on the part of drug wholesalers and manufacturers regarding with whom they may make

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arrangements for the purchase and delivery of drugs, and to ensure that these drugs are maintained at all times by licensees or their designated agents. OAL approved the new section on August 25.

## **Pharmacy Practice on the Internet**

At its October 20 meeting, the Board discussed draft legislation to address the recent and potentially dangerous proliferation of pharmacy practice activity on the Internet. Although the Pharmacy Law requires an Internet pharmacy which offers to compound, dispense, or refill a prescription for a resident of California to be licensed by the Board as a non-resident pharmacy (such that the Board has disciplinary jurisdiction over it), enforcement of that requirement in the Internet environment is difficult. Although the Board's Licensing Committee has requested that the Board sponsor legislation to regulate Internet pharmacy practice and Deputy Attorney General Bill Marcus has attempted a draft, the Committee's study thus far has resulted in conclusions similar to those reached by the Medical Board's Committee on Internet Prescribing: Internet practice is a global problem, far bigger than any state licensing board or even federal agency can address. Perhaps the most any state agency can do is educate consumers to exercise extreme caution when purchasing dangerous drugs or devices over the Internet (see agency report on MEDICAL BOARD OF CALIFORNIA for related discussion).

The legislation drafted by Marcus and considered by the Board in October would establish the following requirements for an out-of-state Internet pharmacy dispensing prescription drugs to California residents: (1) it must be licensed by the Board as a nonresident pharmacy, and must be licensed as a pharmacy in its home state; (2) it may not be foreign-based or owned by prescribers; (3) it may not offer prescribing-based sites where the prescriber issues a prescription to a consumer based upon an online questionnaire; (4) it may only accept a faxed prescription from a prescriber (it may also receive a faxed prescription from a patient, but must receive the original prescription from the patient prior to filling the prescription); (5) it must disclose on its homepage its name, location, toll-free number, and California license number; and (6) it must be registered with the Verified Internet Pharmacy Practice Site (VIPPS) program administered by the National Association of Boards of Pharmacy. NABP has developed the VIPPS program to certify Internet pharmacy sites if they meet certain criteria, similar to a "Good Housekeeping" seal

of approval. Further, Marcus' draft statutory language would provide the Board with the ability to impose civil penalties against Internet pharmacies that do not comply with this legislation.

The Board acknowledges that many consumers prefer to purchase prescription drugs over the Internet because of the convenience, access, and occasional cost savings. Some Internet pharmacy sites are safe, secure, and run by responsible pharmacists who abide by the Board's laws and regulations, and the Board realizes that it must proceed cautiously so as not to impede lawful commerce by these entrepreneurs.

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However, other pharmacy sites are seeking only to make a quick profit, and can easily shut down (and reopen almost instantly under another address) if any government agency seeks to investigate them. The VIPPS program may enable consumers to tell the difference; however, consumers must be educated to expect and demand such information. Thus,

the industry and the Board must educate consumers about how to safely use the Internet to purchase drugs. Following discussion, the Board agreed that its Licensing Committee and its Legislation and Regulation Committee should take another look at the proposed legislation, circulate it to interested parties, and incorporate appropriate changes before any decision is reached on its introduction.

## **Implementation of the FDA Modernization Act of 1997**

The FDA Modernization Act of 1997, which became effective in November 1998, requires the U.S. Food & Drug Administration (FDA) and the fifty states to enter into a memorandum of understanding (MOU) regarding the com-

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pounding of drugs. 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. Section 503A of the Act recognizes compounding as an element of the practice of pharmacy that is to be regulated by the states, and distinguishes it from "manufacturing" which falls within the jurisdiction of the FDA. The purpose of the section is "to ensure continued availability of compounded drug products as a component of individualized therapy, while limiting the scope of compounding so as to prevent manufacturing under the guise of compounding." The purpose of the MOU is to address the interstate distribution of "inordinate amounts" of compounded drug products and the related issue of state investigations of complaints regarding this distribution.

The law instructs the FDA to promulgate regulations establishing the parameters of the MOU, and to consult with the National Association of Boards of Pharmacy (NABP) to develop a standard MOU for state boards. The goal of the MOU is 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. Pharmacies located in a state that did not sign an MOU by the law's effective date (November 21, 1998) are subject to FDA's "safe harbor" provision, whereby compounded products may not exceed 5% of the total prescription orders dispensed or distributed by that pharmacy. [16:2 CRLR 51; 16:1 CRLR 71-72]

In January 1999, FDA published draft regulations and a draft MOU which have been greeted by opposition from compounders and state boards alike. Among other things, the draft MOU requires the Board to agree to take action against a pharmacy that engages in the interstate distribution of compounded drugs under either of the following circumstances: (1) the number of compounded prescriptions dispensed or distributed interstate annually by the pharmacy is equal to or greater than 20% of the total number of prescriptions dispensed or distributed (including both intrastate and interstate) by that pharmacy; or (2) the number of compounded prescriptions dispensed or distributed interstate annually by a pharmacy is less than 20% of the total number of prescriptions dispensed or distributed (including both intrastate and interstate) by that pharmacy, but prescriptions for one or more individual compounded drug products (including various strengths of the same active ingredient) dispensed or distributed interstate constitute more than 5% of the total number of prescriptions dispensed or distributed. Compounded drugs that are distributed interstate but "locally" are excluded from the calculation to determine the number of compounded prescriptions dispensed or distributed annually by a pharmacy, but the MOU defines the term "locally" to mean distribution by a pharmacy to patients located within 50 miles of the pharmacy (notwithstanding that such patients live in another state)—thus requiring compounding pharmacies to keep close track of the mileage between their address and the address of their patients. Apparently, pharmacies that exceed the 20% limit must be licensed by FDA as manufacturers.

At its July 28 meeting, the Board heard extensive public comment from compounding pharmacies and reviewed other written comments that national compounding associations have submitted to FDA. The compounding phar-

macies, largely small specialist pharmacies, complained that both the 5% "safe harbor" and the 20% "inordinate" limits are arbitrary, and that the 20% limit will not allow their pharmacies to remain financially viable or serve patients who benefit from their specialized practices. These compounding pharmacies also noted that the MOU has no effect on chain pharmacies with outlets in multiple states; the compounding pharmacies contended that, because of their many locations and large volume of prescriptions orders, interstate chain pharmacies are being granted a monopoly on compounded drugs.

Following public comment and discussion, the Board decided to write a letter to FDA objecting to both the 20% annual limitation on compounded drugs distributed interstate and the 50-mile geographic restriction. The Board stressed that the MOU should focus on what the compounding pharmacy does and how it does it, not how much it does; in other words, the regulations should focus on the quality of the pharmaceutical products compounded, not the quantity. At this writing, the FDA has neither adopted final implementing regulations nor released a final MOU; once FDA releases the MOU, the Board must decide whether to sign it.

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## LEGISLATION

**SB 1308 (Committee on Business and Professions)**, as amended September 2, enacts various technical changes affecting licensing boards within DCA. Several of the bill's provisions amend the Pharmacy Act in the Business and Professions Code, including the following:

- The bill amends section 4022 to revise the definition of "dangerous drug or device" to include drugs or devices bearing the statement "Rx only." This change conforms California's definition of "dangerous drug or device" to the federal definition.
- SB 1308 amends section 4043 and adds section 4040.5 to the Code to clarify that "reverse distributors" (companies that remove outdated/non-saleable drug products from pharmacies for disposal) and brokers (those who arrange for the sale of drugs but may not take actual possession of the drugs) must be licensed as drug wholesalers by the Board.
- The bill amends section 4057 to permit the Board to control through regulations (rather than statute) two lists of dangerous drugs and devices that may be stored outside a pharmacy's licensed premises when dispensed or furnished to specific licensed individuals or entities. The Board is already engaged in rulemaking to adopt regulations containing these lists (see MAJOR PROJECTS).
- SB 1308 amends section 4078 to permit a pharmacist to place a false label on a prescription if the labeling is a necessary part of a clinical or investigational drug program approved by the FDA or a legitimate investigational drug

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project involving a drug previously approved by the FDA. The bill also permits false labeling in situations where, in the medical judgment of the prescriber, the labeling is necessary for the proper treatment of the patient.

- The bill amends section 4102 to specify that a pharmacist may perform skin puncture in the course of routine patient assessment procedures.

- SB 1308 amends section 4115.5 to extend the period of time allowed for practical experience in a pharmacy from six months to one year for pharmacy technician trainees enrolled in training programs run by private or public schools.

- The bill amends section 4200.5 to clarify that those seeking a retired pharmacist's license need not surrender their original wall certificate to the Board in order to retire their license.

- SB 1308 also amends section 4202 to require an applicant for registration as a pharmacy technician to be a high school graduate or to possess a general education development equivalent.

- The bill amends section 4402 to provide that the Board may cancel any license that is not renewed within 60 days after its expiration.

- Finally, SB 1308 amends section 11165 of the Health and Safety Code to expand the Controlled Substance Utilization Review and Evaluation System (CURES) program to include statistical analysis, education, and research, and extend CURES until July 1, 2003. CURES was created in 1997 as a three-year pilot project to electronically monitor the prescribing and dispensing of Schedule II controlled substances by all practitioners authorized to prescribe or dispense them. CURES will eventually replace the paper-intensive "triplicate" system currently used to track the prescription and dispensing of Schedule II narcotics. While still in the pilot project phase, CURES

is being administered concurrently with the existing triplicate system, to examine the comparative efficiencies between the two systems. [16:2 CRLR 48-49; 16:1 CRLR 69-70] SB 1308 also requires the Department of Justice, in consultation with the Board, to submit reports to the legislature on the effectiveness of the CURES program on January 1, 2000, 2001, and 2002.

SB 1308 was signed by the Governor on October 6 (Chapter 655, Statutes of 1999).

**AB 261 (Lempert).** Existing law authorizes a pharmacist to perform certain patient management functions (e.g., ordering or performing routine patient assessment procedures such as temperature, pulse, and respiration; ordering drug therapy-related laboratory tests; administering drugs and biologicals by injection; and adjusting the drug regimen of a patient) as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic, or a provider under contract with a health care service plan, in accor-

dance with written policies, procedures, or protocols of that facility, home health agency, licensed clinic, or health care service plan. As amended July 7, AB 261 additionally authorizes a pharmacist to perform those procedures or functions in any setting in accordance with the policies, procedures, or protocols of a physician. The bill also revises the standards for those policies, procedures, and protocols to require that, at a minimum, they require that the medical records of the patient be available to both the patient's prescriber and the pharmacist, and that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

AB 261 was sponsored by CPhA and supported by the Board. The California Medical Association originally opposed the bill, but CPhA worked with CMA to amend the bill to resolve its concerns. Governor Davis signed AB 261 on September 15 (Chapter 375, Statutes of 1999).

**SB 651 (Burton),** as amended June 22, provides that a person employed in the practice of pharmacy is not exempt from the coverage of the orders of the Industrial Welfare Commission unless he/she individually meets the criteria established for exemption as an executive or administrative employee. The bill further provides that no person employed in the practice of pharmacy may be subject to any exemption from the coverage of the orders of the Industrial Welfare Commission established for professional employees.

Prior to this bill, pharmacists were considered "professional" employees and were exempt from IWC orders requiring mandatory breaks and lunch periods for employees. The proponents of SB 651 argued that the exemption imposed significant hardship on pharmacists, who routinely work twelve-hour days and are frequently denied breaks or lunch periods, simply because they are licensed by the State of California. Under SB 651,

**Under SB 651, pharmacists are no longer exempt as "professional" employees, and must be afforded breaks and lunch periods unless they are specifically exempt as "administrative" or "executive" staff.**

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Without additional changes to existing law, the passage of SB 651 would have required the physical closing of pharmacies (at least the area in which prescription medications are kept), as well as the removal of all non-pharmacist staff, during these temporary absences of a licensed pharmacist. Thus, the enactment of SB 651 prompted amendments to SB 188 (Leslie), which now requires the Board to adopt regulations governing the functioning of a pharmacy and the work of pharmacy technicians while a pharmacist is temporarily absent from the licensed premises (see below). Governor Davis signed SB 651 on July 26 (Chapter 190, Statutes of 1999).

**SB 188 (Leslie).** Existing law authorizes a pharmacy technician to perform nondiscretionary tasks only while assisting



and while under the direct, immediate, and personal supervision and control of a pharmacist. Any pharmacist responsible for a pharmacy technician must be on the premises at all times and the pharmacy technician must be within the pharmacist's view, except when the pharmacy technician is employed to assist in the filling of prescriptions for an inpatient of a hospital or for an inmate of a correctional facility. As amended September 7, SB 188 requires the Board—notwithstanding the above limitations—to adopt regulations to accommodate the temporary absence of a pharmacist for breaks and lunch periods pursuant to Labor Code section 512 and the orders of the Industrial Welfare Commission without closing the pharmacy. This change was prompted by SB 651 (Burton), which mandates breaks and lunch periods for most pharmacists (see above). During temporary pharmacist absence, a pharmacy technician may remain in the pharmacy but may only perform nondiscretionary tasks; the pharmacist remains responsible for the pharmacy technician and must review any task performed during the pharmacist's temporary absence. The Board recently adopted emergency regulations to implement this provision of SB 188 (see MAJOR PROJECTS).

Existing law generally prohibits any person from selling or dispensing any dangerous drug, or dispensing any prescription, unless he/she is a licensed pharmacist. However, a licensed hospital that contains 100 beds or fewer and does not employ a full-time pharmacist may purchase drugs at wholesale for administration, under the direction of a physician, to patients registered in the hospital or to emergency cases under treatment in the hospital. These hospital drug dispensing activities operate under a so-called "limited drug room license." SB 188 authorizes hospitals that have a limited drug room license and that meet the statutory definition of a "small and rural hospital" to dispense drugs to outpatients under limited circumstances, and defines those circumstances. The bill is designed to assure patients in rural areas that their needs for medication can be met in a reasonable manner. SB 188, an urgency bill, was signed by the Governor on October 9 (Chapter 900, Statutes of 1999) and took effect on that date.

**AB 724 (Dutra)**, as amended September 7, is the "Year 2000 Problem Good Government Omnibus Act of 1999," and is intended to address problems that may arise from Y2K computer failures. Among other things, AB 724 provides that, notwithstanding any other provision of law, during the period commencing December 1, 1999, and ending February 1, 2000, a pharmacist may refill any refillable prescription subject to the number and terms of authorized refills, upon request of the person on whose behalf the prescription was written, provided (1) the prescriber is unavailable to authorize the early dispensing of the medication refill, and (2) the refill medication dispensed does not exceed the dosage prescribed to sustain the patient with uninterrupted therapy during this period. The Governor signed AB 724 on October 7 (Chapter 784, Statutes of 1999).

**SB 816 (Escutia)**. Existing law permits a nurse practitioner (NP) to "furnish" prescription drugs and devices, in accordance with standardized procedures developed by the NP and his/her supervising physician, under specified circumstances; the term "furnish" is defined as the ordering of a drug or device in accordance with the standardized procedure, and transmitting an order of a supervising physician. Existing law also permits a physician assistant (PA), under specified circumstances and while under the supervision of a physician, to administer or provide prescription drugs to a patient, or transmit orally or in writing on a patient's record or transmittal order, a prescription to a person who may lawfully furnish the medication. SB 816 adds "ordering" prescription drugs and devices to existing provisions of law permitting NPs and PAs to "furnish" or "transmit" drugs and devices in accordance with procedures developed by the NP or PA and his/her supervising physician. SB 816 also requires all NPs and PAs who are authorized to furnish or issue drug orders for controlled substances to register with the DEA.

This bill also defines the term "drug order" as an order for medication which is dispensed to or for a patient, issued by a NP or PA as an individual practitioner, within the meaning of the Code of Federal Regulations; and specifies that a drug order issued by a NP or PA shall be treated in the same manner as a prescription of the supervising physician. Finally, the bill provides that all references to the term "prescription" in the Business and Professions Code and the Health and Safety Code shall include drug orders issued by NPs or PAs, and deems the signature of a NP or PA on a drug order to be the signature of a prescriber for purposes of the Business and Professions Code and the Health and Safety Code (thus authorizing pharmacists to fill them). This bill was signed by the Governor on October 7 (Chapter 749, Statutes of 1999).

**AB 1545 (Correa)**, as amended September 3, expands and clarifies existing law that permits NPs and PAs to furnish prescriptions for medicine that are within standardized procedures, as long as certain conditions are met. Specifically, AB 1545 permits a NP who is functioning pursuant to a standardized procedure or protocol, or a PA functioning under the supervision of a physician, to hand to a patient of the supervising physician a prescription drug prepackaged by a physician, a manufacturer, or a pharmacist; and requires, if applicable, that the name of the NP or PA appear on the container label of any such prescription. The bill also permits a NP or PA to sign for the delivery of a complimentary sample of a dangerous drug or device, and adds the Board of Registered Nursing and the Physician Assistant Committee to the list of regulatory bodies to which the Board of Pharmacy is required to forward all complaints related to the dispensing of dangerous drugs or devices. This bill was signed by the Governor on October 9 (Chapter 914, Statutes of 1999).

**SB 838 (Figueroa)**, as amended April 28, allows the Board to register a nonresident pharmacy that is organized as a limited liability company (LLC) in the state in which it is licensed. Merck-Medco Managed Care sponsored this bill to

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clarify that the Board may continue its longstanding practice of registering nonresident pharmacies that are organized as LLCs in their home states. An LLC—a hybrid between a partnership and a corporation—is a relatively new form of business organization in California. The Board registered out-of-state LLC pharmacies at least through 1997. At that time, DCA analyzed some uncodified language in the LLC law which prohibits the organization of an LLC for the rendering of professional services. Based on DCA advice, the Board began to reject licensure applications from out-of-state LLC pharmacies. [16:1 CRLR 70-71] The sponsor and its supporters maintain that this bill clarifies ambiguity created by issuance of various legal opinions on the topic, and that certainty in the law is necessary in order to continue to provide low-cost mail order medications. Governor Davis signed SB 838 on July 6 (Chapter 73, Statutes of 1999).

**AB 1430 (Bates)**, as amended September 9, would have made a number of changes relating to the prescription and receipt of drugs by Board licensees. First, it would have eliminated an existing prohibition and provided that dangerous drugs or devices may be furnished without a prescription to a professional corporation, partnership, or other entity comprised of licensed health care professionals who are lawfully able to receive these drugs, provided that specified criteria and procedures are met. Further, the bill would have eliminated an existing requirement that electronic data transmission prescriptions, as defined, be reduced to writing by the pharmacist.

The Board worked with the bill's author and sponsor, Kaiser Permanente, to resolve many concerns about AB 1430, and all of the Board's requested changes were amended into the bill. However, an eleventh-hour amendment to the bill would have restricted the Board's authority to regulate drug wholesalers by precluding it from enforcing new section 1783, Title 16 of the CCR, for at least one year (see MAJOR PROJECTS); thus, the Board opposed the bill. The Attorney General's Office also opposed AB 1430, arguing that it would (1) inappropriately broaden the authority of manufacturers and wholesalers to provide dangerous drugs and devices, (2) diminish the authority of the Board of Pharmacy to closely monitor the acquisition and maintenance of such drugs by providers, and (3) fail to provide strict policies and procedures for identification of those authorized to obtain dangerous drugs. On October 10, Governor Davis agreed with the Board and the AG and vetoed AB 1430, expressing concern that "this bill could create avenues for the illicit diversion of controlled substances" and urging the author to work with the Attorney General on crafting a product that eliminates this potential. Because the Governor vetoed AB 1430, regulatory section 1783 is now in effect.

**AB 141 (Knox)**, as amended August 16, would require the Board to conduct a study of the incidence of medication errors in pharmacies in California, and report its findings to the legislature by December 1, 2004. [S. Appr]

**AB 1496 (Olberg)**, as amended September 10, is no longer relevant to the Board of Pharmacy. Prior versions of

the bill would have added section 4052.5 to the Business and Professions Code to establish a new "home medical equipment services provider" licensure category under the Board to replace the "medical device retailer" category, and expanded the definition of those who must be licensed as home medical equipment services providers.

**AB 660 (Cardenas)**, as amended April 28, is also a Y2K bill authorizing pharmacists to refill prescriptions between November 1, 1999 and February 29, 2000 under certain circumstances (see above). [S. B&P]

**SB 404 (Alpert)**, as amended in March 1999, would authorize a pharmacist to initiate emergency contraception drug therapy in accordance with written guidelines or protocols previously established and approved for his/her practice by a practitioner authorized to prescribe drugs. [S. B&P]

### RECENT MEETINGS

At its May 20 meeting in San Diego, the Board elected pharmacist Richard Mazzoni as its president, public member Robert Elner as vice-president, and public member Caleb Zia as treasurer.

At its May and July meetings, the Board discussed its ongoing difficulty in retaining experienced and qualified inspectors, pharmacists who are employed by the Board to investigate consumer and other complaints made to the Board about licensees. At the May meeting, Executive Officer Patty Harris reported that eight of the Board's 19 inspector positions were vacant; by the July meeting, 10 of the 19 inspector positions were vacant. The high attrition rate in Board inspector positions has been a serious problem since 1994, and is due in large part to the low salary paid to Board inspectors. According to Harris, the gap between Board inspector salaries and private sector pharmacist positions is about \$20,000; there is even a substantial gap between the salary of Board inspectors and similar positions at other state agencies, which makes it very difficult for the Board to recruit and retain inspectors. Unfortunately for the Board, a provision in early versions of SB 1308 (Committee on Business and Professions) (Chapter 655, Statutes of 1999) requiring the salary of the Board's pharmacist inspectors to be within 5% parity of pharmacists employed by the University of California [16:2 CRLR 52] was deleted on August 30 due to opposition by the Davis administration's Department of Personnel Administration (DPA). However, according to a Board memorandum distributed on October 12, DPA has agreed to provide Board inspectors with a 10% augmentation in addition to the 4% increase for state employees. Hopefully, this increase will stem the tide of vacancies and permit the Board to shore up its staff of inspectors.

### FUTURE MEETINGS

- January 25-27, 2000 in Riverside.
- April 12-13, 2000 in Sacramento.
- July 25-26, 2000 in San Diego.
- October 18-19, 2000 in San Francisco.