only to optometrists, ophthalmologists, and opticians—who often mark up the lens prices significantly—and not to alternative channels of distribution such as pharmacies, mail-order firms, and similar entities which may offer discounted prices on the lenses. The action further claims that the named optometrists and the Society tried to persuade lens manufacturers not to distribute soft lenses to alternative chains of distribution, and that the Society threatened not to prescribe the lenses of any manufacturer which sold its product to pharmacies or mail-order channels of distribution. At this writing, the matter is not expected to be heard until at least late 1996 or early 1997.

■ RECENT MEETINGS
At its December 1–2 meeting, in response to questions regarding the amount of time necessary to complete the rulemaking process, the Board reviewed the procedural requirements which must be met in order to adopt, amend, or repeal a regulation; staff will also prepare and distribute a flowchart explaining the rulemaking process as set forth in the Administrative Procedure Act.

Also at its December meeting, the Board reelected John Anthony, OD, to serve as President; Robert Dager, OD, to serve as Vice-President; and Mona Tawatao to serve as Secretary.

■ FUTURE MEETINGS
March 15–16 in Anaheim.
May 13–14 in San Jose.
August 22–23 in Sacramento.
November 18–19 in San Diego.

BOARD OF PHARMACY
Executive Officer: Patricia Harris
(916) 445-5014

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

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

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

In May 1995, Board member Kent Wilcox resigned, but will continue to serve until Governor Wilson appoints his replacement.

■ MAJOR PROJECTS
Distribution of Drug Samples. On May 24, the Board held an informational hearing on the distribution of drug samples in California. Under the current system of distribution, sales representatives of drug manufacturers supply physicians with drug samples to be dispensed directly to patients. The Board held the hearing to receive comments on whether this system provides the best approach to a patient’s drug therapy, and to explore alternative approaches to the current system of drug sample distribution.

An issue paper which accompanied the Board’s hearing notice identified the positive outcomes of drug sample therapy; specifically, the Board stated that drug sample distribution allows patients to begin drug therapy immediately, reduces patient costs, and allows physicians to readily test a patient’s reaction to the drug. However, the Board expressed concerns that drug samples are not monitored and accounted for during their handling, transportation, and distribution to physicians. Other unresolved issues arising out of the distribution and dispensing of drug samples include the fact that no record of use or monitoring of the drug therapy can be maintained by a pharmacist; without record of use, the pharmacist is unable to evaluate a drug’s interaction with the patient’s entire medication regimen to prevent adverse reactions; the patient will not receive counseling on the use of the drug from a pharmacist; the potential for diversion of drug samples for unintended use by patients; the unauthorized sale of samples by pharmacies; the fact that unlicensed sales representatives of drug manufacturers have access to drugs with no state oversight of storage conditions or means of accounting for quantities dispensed; and the lack of a means to track a drug sample if it is recalled.

The Board is considering an alternative to the current system of sample distribution through the use of a voucher/coupon method of distribution. Under this proposal, a physician could issue a voucher or coupon to a patient, allowing the patient to receive a free sample quantity of a drug from a pharmacy; the free amount that is dispensed would then be billed to the manufacturer.

During the informational hearing, the Board considered comments from manufacturers, practitioners, and representatives of professional associations in support of and in opposition to modifying the existing system of drug sample distribution. In support of the status quo, Dr. Ben Shwachman of the California Medical Association (CMA) stated that the Board has not identified and proven that a problem exists under the current system. Furthermore, CMA contends that current law adequately regulates manufacturers and physicians in the distribution and dispensing of drug samples. Others in favor of the current system noted that the alternative voucher system would only add more recordkeeping requirements and increase costs; issues of distribution accountability and control should not impair the availability of samples to the medically indigent; pharmacists’ inability to update patient drug records is not a realistic justification to discredit the dispensing of drug samples by physicians in light of the numerous prescriptions filled by out-of-state pharmacies; physicians maintain documentation of sample drugs dispensed in the patient’s records along with results of the medical examination for which the drug therapy was recommended; and diversion is not a serious health concern since samples do not include Schedule II drugs.

In opposition to the current method of dispensing drug samples, Robert Marshall of the California Pharmacists Association (CPHA) expressed support for the alternative voucher method of dispensing samples through a pharmacy. CPHA contends that the proposed method would allow entry of relevant data in the patient profile, eliminate the waste of different packaging used on sample sizes, afford patients adequate labeling not found on samples, and provide the opportunity for oral consultation with a pharmacist. Those also opposed to the existing system of drug sample distribution emphasized that patients to whom samples are dispensed are not receiving drugs judged on their pharmacological merits but as a result of marketing strategies. Other advocates of the proposed voucher system contend that the alternative method of sample distribution would better protect the public through the services offered by a pharmacist and the safeguards of drug accountability.

Following public comments, the Board clarified that physicians are held to the same standards required of pharmacists.
with respect to the labeling of drug medications dispensed to a patient, including samples. Furthermore, medical offices are subject to the same recordkeeping and storage requirements as are pharmacies.

At its July 26 meeting, the Board continued to review comments presented at the informational hearing in May, as well as written comments submitted thereafter. The Board discussed its concern that a non-licensed sales representative of a drug manufacturer may handle and transport legend items (i.e., those drugs not available over the counter). Deputy Attorney General William Marcus informed the Board that sales representatives are authorized under federal and/or state law to handle and transport drugs as agents of businesses appropriately licensed or registered by the Department of Health Services or by the Board; the storage of drugs in a sales representative’s car is permitted as an extension of a manufacturer’s licensed premises.

Following discussion, the Board decided by a vote of 7-1 to table the issue and appoint a study group to conduct further research and review relevant documents on the current system of drug sample distribution and viable alternatives. In the interim, the Board will send notices to the Medical Board of California, the Osteopathic Medical Board of California, the Board of Dental Examiners, the Board of Podiatric Medicine, and the Veterinary Medical Board reiterating the legal requirements as are pharmacies.

Supporters of draft section 1793.8, Title 16 of the CCR, which would permit pharmacy technicians in general acute care hospitals who meet certain requirements to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose cassettes for patients whose orders have previously been reviewed by a pharmacist.

On May 24, the Board held an informational hearing to evaluate the pharmacy technician program. The Board solicited comments on the program’s effectiveness, recommended changes for improvement, and comments on the draft version of section 1793.8. The Board received comments in support of and opposition to the proposal to implement a program allowing hospital pharmacy technicians to check the work of other technicians.

Supporters of draft section 1793.8, such as California Society of Health-System Pharmacists (CSHP) and Kaiser Permanente (Kaiser), urged the adoption of the section to establish requirements for TCT programs in acute care hospitals. Representing CSHP, Teresa Miller explained that technicians have been checking technicians in California hospitals for years; although the Board’s official position is that such practice contravenes current regulations, Board inspectors have ineffectively dealt with such ongoing violations in hospital pharmacies. Albert Carver of Kaiser suggested that section 1793.8 is long overdue as Board regulations have not kept pace with developments in the profession over the years.

In agreement with CSHP and Kaiser, the University of California School of Pharmacy reported that the changing role of hospital pharmacists requires their availability to participate in patient pharmaceutical care as part of a clinical team of doctors, nurses, and pharmacists. The California Association of Hospital and Health Systems and the Golden Gate Society of Health-System Pharmacists joined in support of expanding the technician program; both suggested that the less stringent statutory requirements for hospital pharmacy technicians are due to the quality assurance process which already exists in hospitals in the form of hospital rules, regulations, and accreditation standards.

However, those in opposition to the TCT proposal asserted their unified position that patient harm will result from allowing unsupervised pharmacy technicians to check the work of other pharmacy technicians. Phillip Grauss, President of the Marin County Pharmaceutical Association and appearing on behalf of twenty local California pharmacy associations, emphasized that part of the “pharmaceutical care” expected of a pharmacist is checking and correcting the potentially lethal mistakes made by pharmacy technicians; while acknowledging that everyone—including pharmacists—makes mistakes, Grauss recognized that a pharmacist is more likely to perform his/her duties conscientiously to protect his/her license and to uphold a professional duty to provide quality patient care. In contrast, Grauss contended that pharmacy technicians do their tasks mechanically; he opined that their tendency to glance over filled prescriptions without scrutinizing for accuracy makes them inappropriate to be responsible for the final check in the process of dispensing drugs.

Robert Marshall of CPhA challenged the results of research projects presented at the hearing which indicated that pharmacy technicians are at least as proficient as pharmacists at the task of checking completed prescription orders in the inpatient environment; CPhA further offered to conduct a survey of all California pharmacists to determine their experience with the use of pharmacy technicians.

Marshall also spoke on behalf of six professional organizations in presenting a joint Statement on Pharmacy Technicians in which several concerns and suggestions for improving the program were discussed. The Joint Statement opposed allowing pharmacy technicians to check the prescription preparation of other technicians under any circumstances, regardless of the practice setting. The Joint Statement further addressed pharmacist liability; while these six organizations insisted that the supervising pharmacist must assume legal responsibility for all pharmacy ser-
VICES PERFORMED BY A TECHNICIAN, THEY REASONED THAT A SUPERVISING PHARMACIST CANNOT AND SHOULD NOT BE LIABLE FOR THE WORK OF A TECHNICIAN WHOSE THE PHARMACIST DOES NOT PERSONALLY INSPECT. THE JOINT STATEMENT ALSO STIPULATED THE EXEMPTION OF INPATIENT HOSPITAL PHARMACY TECHNICIANS FROM THE REQUIREMENT OF BOARD REGISTRATION; IN EFFECT, THOSE PHARMACY TECHNICIANS ARE NOT SUBJECT TO A CRIMINAL BACKGROUND CHECK COMPLETED DURING THE PROCESS OF REGISTRATION, DEFEATING A SAFETY MECHANISM AGAINST POTENTIAL DRUG DIVERSION.

Despite their differences on the TCT issue, both proponents and opponents of the TCT proposal agreed that the Board must adopt additional regulations to improve the pharmacy technician program. There appeared to be a general consensus that registration and certification should be required of all pharmacy technicians, including technicians at inpatient facility pharmacies who are currently exempt; further, many opined that continuing education should be required of all technicians as a prerequisite to registration renewal.

In its May 24 discussion, the Board grappled with the currently illegal practice of techs checking techs in California's hospitals. The Board noted that an illegal procedure which becomes a standard practice is still illegal; however, a practice so pervasive in California's hospitals makes enforcement of current regulations problematic. The Board noted that an alternative to enforcement is the revision of current laws and regulations to reflect professional practices that get ahead of the law.

At its July 26 meeting, the Board resumed its discussion of the TCT issue. After reviewing the comments received at the May 24 informational hearing and the numerous comments submitted thereafter, the Board also considered the fact that similar TCT programs are permitted in the states of Washington and Minnesota. The Board decided by a vote of 6-1, with one abstention, to move forward with a regulation hearing to take action on the adoption of proposed section 1793.8.

On September 1, the Board published notice of its intent to adopt section 1793.8 and amend section 1793.7. Following an October 25 public hearing, the Board voted 6-3 to reject the proposed changes; however, the Board further decided to form and refer the issue to a pharmacy technician committee to conduct a general review of the technician program and explore the issue of registration of hospital pharmacy technicians.

AUTOMATION OF THE TRIPlicate PROGRAM. On July 18, the Board's Oversight Committee on the Automation of the Triplicate Program (Oversight Committee) approved the final version of the Feasibility Study Report (FSR) prepared by the Hawkins Data Center; the goal of the study was to research and develop an automated information system to process Schedule II drugs, which are currently processed manually through a paper-based triplicate system. This triplicate system monitoring program is administered by the Bureau of Narcotics Enforcement (BNE) under the California Department of Justice (DOJ). The FSR proposed the creation of an electronic system called the Controlled Substance Utilization Review and Evaluation System (CURES), which would electronically monitor and track controlled substance prescriptions dispensed statewide. [15:2 & 3 CRLR 89: 15:1 CRLR 86]

Also at its July 18 meeting, the Oversight Committee discussed seeking funding in order to implement the CURES project; according to the CURES Funding Subcommittee, about $500,000 is needed to implement CURES. According to the FSR timeline, if funding is granted in July 1996, the earliest implementation of CURES would be January 1998. To avoid further postponement in implementing CURES, the Oversight Committee is seeking federal and state funding while encouraging agencies responsible for regulating healing arts professions to contact Attorney General Dan Lungren and ask him to find funding for the CURES program during this fiscal year.

Also on July 18, the Oversight Committee discussed the parallel issue of seeking legislation authorizing the Board to implement the electronic tracking system for Schedule II drugs. While the authority to maintain a controlled substance tracking system currently rests with BNE, the Board is concerned that if funding is not granted, the automation project will not go forth. Should efforts to seek funding for the program in fiscal year 1996-1997 fail, the Committee intends to seek DOJ's support of legislation in 1996 to transfer the controlled substance monitoring program to the Board.

At its July meeting, the Board decided by a vote of 7-1 to seek legislation to place with the Board the monitoring program for controlled substances, including any paper-based or electronic monitoring system, but only in the event BNE's appeal for federal and state funding is denied. At its October 26 meeting, the Board considered for the first time the possibility of becoming a co-applicant with the Department of Justice in seeking federal funding of the CURES project.

"THIRD CLASS" OF DRUGS. Under current law as established by the federal Food and Drug Administration (FDA), two classes of drugs exist: prescription drugs and nonprescription or over-the-counter (OTC) drugs. While prescription drugs are dispensed only under the order of a licensed prescriber and used under the prescriber's direct supervision, OTC drugs may be purchased without a prescription and are to be used according to the required label directions and warnings. Nonprescription drugs must satisfy the FDA's safety standards and labeling requirements to become available over the counter.

As more drugs transition from prescription-only status to OTC availability, the Board is concerned about the effects on patient care. When prescription drugs become available for public sale and use, the issue of concern is the patient's appropriate use of the drug without the oversight of a health care professional. At its July 26 meeting, the Board discussed a proposal to seek the establishment of a third class of drugs which could only be sold by a health professional authorized by law to prescribe or dispense such drugs.

In 1992, CPhA sponsored AJR 63, which stated California's support for a proposal authorizing the FDA to establish a transitional nonprescription category of drugs available only through a licensed pharmacist. [12:4 CRLR 117] However, a "transitional" class of drugs is distinct from the Board's proposed "third class" of drugs. The "third class" concept represents a permanent and fixed new category of drugs, neither prescription nor OTC, and available only through a pharmacist; a "transitional" class is intended to facilitate a drug's transition to OTC status for general sales, and therefore would only temporarily restrict access by requiring purchase through a pharmacist for a limited time during which drug use consultation could be given.

Although support for an intermediate class of drugs exists among pharmacists' professional organizations, a recent report from the U.S. General Accounting Office (GAO) questioned the benefits of creating such a class. In August 1993, GAO issued a report entitled Nonprescription Drugs: Value of a Pharmacist-Controlled Class Has Yet To Be Demonstrated, which summarizes a study of the drug distribution system of ten countries and the state of Florida, all of which have some form of an intermediate class of drugs. GAO's report concludes that there is a lack of evidence extant to support a fundamental change to the existing two-class drug distribution system. The report adds that the benefits of an intermediate class, fixed or transitional, are unclear and no evidence exists to show the overall superiority or inferiority of a system that restricts the
sale of at least some nonprescription drugs to pharmacies.

On October 25, the Board held an informational hearing on the establishment of a third class of drugs. The Board solicited comments and suggestions from pharmacy manufacturers of over-the-counter and prescription drugs, consumer groups, health care professionals, and pharmacy organizations. At the hearing, the Nonprescription Drug Manufacturers Association (NDMA) opposed the creation of a third class of drugs in California. NDMA contended that FDA's detailed procedure for approving a drug’s switch to nonprescription status assures that OTC drugs are safe and effective for use, and that the procedure requires manufacturers to research each drug's safety and efficacy and follow up on adverse events pre- and post-marketing. NDMA further informed the Board that drug manufacturers have developed consumer education programs to promote the safe use of OTC drugs; NDMA itself has undertaken a joint promotion with Reader’s Digest to inform the public about reading labels, the proper use of medication, and the dangers of mixing drugs. Finally, NDMA contended that although expanding the role of pharmacists in a new intermediate drug class to improve drug use is justified, GAO's report suggests that the benefits are uncertain. The California Retailers Association (CRA) also opposed the creation of a third class of drugs. CRA argued that in matters of self-health care, the current system effectively empowers consumers with a widening selection of medicines for self-care deemed safe and effective by FDA, keeps health care costs low due to competitive prices, and makes nonprescription medicines more widely accessible at convenient times and varied locations. CRA contended that a new intermediate class of drugs would increase health care costs and diminish access, resulting in a disproportionate impact on the traditionally underserved populations in urban and rural areas of the state.

The National Association of Boards of Pharmacy (NABP) has had a longstanding policy in support of a nonprescription, third class of drugs. According to NABP, the limitation on who can dispense the drug would further the goal of providing patients with the opportunity to consult with a health care professional on the proper use of drug medication. NABP has expressed a general concern that more consumers will start to diagnose their own illnesses and misuse a drug. In addition, several pharmacists' professional organizations and individual community pharmacists testified at the Board's informational hearing in support of creating an intermediate class of drugs.

The American Pharmaceutical Association (APhA) testified that APhA has publicly supported the availability of medication without prescription for self-care since 1964, while urging development of adequate safeguards to assure safe and effective drug use. APhA believes these goals can be achieved through the development of a transitional class of drugs. APhA expressed concern that while an OTC drug is safe for use if a patient follows the directions and heeds the warning, consumers have and will continue to impulsively mix and match medications. APhA believes that a transitional class of drugs would benefit consumers through education by requiring consumers to receive advice from a professional health care provider on the proper use of a medication before it later becomes an OTC drug.

CPhA similarly expressed its longstanding policy of supporting a transitional class of drugs. CPhA suggested that the Board consider creating a transitional class of drugs rather than a fixed, third class of drugs in the effort to employ a pharmacist as an active safeguard against improper drug use. CPhA opined that it is not the role of the pharmacist to make a drug safer; rather, it is the role of the pharmacist to make the use of the drug more appropriate.

The California Society of Hospital Pharmacists (CSHP) also supported further pursuit of a transitional class of drugs as an opportunity to facilitate the transfer of a drug from prescription to OTC status. CSHP suggested that the Board consider model programs where a third class of drugs exist, as in Florida. CSHP further expressed its support of the Board’s efforts to promote the pharmacist’s involvement in the provision of pharmaceutical care.

While the supporters above advocated creation of an intermediate class of drugs to serve as a transitional phase, some parties favored a permanent third class of drugs. The Pharmacist Planning Services, Inc. (PPSI) supports the creation of a third class of drugs where pharmacist consultation is mandatory and transition to OTC status is not automatic, but subject to evaluation of reports of the drug’s adverse reactions, side effects, and other problems. PPSI suggested allowing a two-year trial period to lapse before making the decision to advance a drug to OTC status, return it to prescription-only, or keep the drug in the third class. PPSI also claims that OTC drug manufacturers have done little to improve labels on OTC drugs, despite PPSI's petition to the FDA and CPhA's introduction of a legislative resolution to increase print size.
Once restocking is completed, the information is sent back online to the pharmacy to be checked to ensure accountability.

PCP's pilot study demonstrated that the accuracy and accessibility of the first dose of medication was improved through the use of an onsite automatic medication dispensing machine. The study was conducted at a long-term care facility, on a thirty-bed subacute care nursing station. A control group of 54 random new orders, accounting for approximately 33% of total new orders, was studied during a three-month period prior to implementation of the automated system. This control group was used to illustrate the three stages of the current distribution system: the care facility nurse telephones or faxes the prescription order to the pharmacy; the pharmacist screens the order by accessing the pharmacy database to review the patient's profile; and once approved and filled by the pharmacist, the prescription is delivered to the nursing station at the care facility to be administered to the patient. An obvious disadvantage of the current system is the delay in receiving the medication which the patient may need immediately; depending on the location of the nursing facility and traffic, delivery may take several hours.

A considerable time saving occurred in administering medications to patients with the automated system. At the same thirty-bed subacute long-term care nursing station, a different 54 random new orders (accounting for approximately 33% of total new orders) were studied during a second three-month period of implementing the automated system. While the initial two steps of sending the order to the pharmacy and allowing the pharmacist the opportunity to screen the order are identical to that in the current system described above, the last step of delivering the medication is more efficiently accomplished. Under the automated system, when the pharmacist has reviewed the order, the nurse then electronically transmits the approval for the medication dose to the online medication located at the facility which placed the order. This allows a nurse at the care facility to access the medication only to remove the first dose of a specific type of medication as dispensed by the pharmacist's electronic approval. Because travel time is eliminated, patients at a care facility which is remote from a pharmacy can receive their medication as soon as their prescription is approved and transmitted by the pharmacist.

Another issue the Board discussed is legal limitations on the continued use of the Pyxis automated medication in any expanded pilot project. Under current law, no provision allows for the storage of dangerous drugs, including controlled substances, in facilities other than pharmacies, hospital pharmacies, community, free or surgical clinics, manufacturers or wholesaler premises, and physician offices. Further, Deputy Attorney General Bill Marcus explained that under existing law, the authority to dispense Schedule II controlled substance medications, in other than an emergency, is limited; no Schedule II drugs may be dispensed without a triplicate form prescription or for an amount that would exceed a 72-hour supply. While the pilot study limited the administration of a controlled substance medication to the first dose only, which is clearly within the allowable dosage supply limit, the Board will need to address the issue of administering Schedule II drugs, if any, to comply with dispensing requirements established by the Bureau of Narcotic Enforcement.

Following discussion, the Board decided by a vote of 7-1, with one abstention, to support further study of this program in conjunction with a school of pharmacy; the Board also voted to work with Patient Care Pharmacy and other organizations to censure legislation to provide for the authorized use of the automated dispensing machines in long-term care facilities.

**Minimum Standards for Wholesalers.** On November 11, the Board published notice of its intent to amend section 1780, Title 16 of the CCR, which describes the minimum standards for all wholesale establishments for which the Board issues permits. The Board's proposed changes would remove from the section an existing requirement that floor plans and elevations of the storage area of a pharmacy wholesaler be approved by the Board as a condition for the issuance of a wholesaler permit; the applicant for a wholesaler license would be required to certify that it meets the requirements of section 1780 at the time of licensing or renewal. Additionally, the changes would update the references to the United States Pharmacopeia Standards to reflect the twenty-third revision now in use.

At this writing, the Board is scheduled to hold a public hearing on these proposed changes on January 24 in El Segundo.

**Graduates of Foreign Pharmacy Schools.** Also on November 17, the Board published notice of its intent to amend section 1720.1, Title 16 of the CCR, which describes the requirements for pharmacist licensure for foreign pharmacy school graduates, including evaluation of their pharmacy school coursework. Among other things, the Board's proposed changes would remove an existing reference to coursework evaluation by the Credentials Evaluation Service of the International Education Research Foundation. Also, the educational eligibility component required for admission to the pharmacist licensure examination would be limited to receipt of a satisfactory grade on the Foreign Pharmacy Equivalency Examination; a combination of foreign and domestic coursework would no longer establish eligibility.

At this writing, the Board is scheduled to hold a public hearing on these proposed changes on January 24 in El Segundo.

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

- **Medical Device Retailer Locked Storage.** On August 1, the Office of Administrative Law (OAL) approved the Board's amendments to section 1748.1, Title 16 of the CCR, which expand the personnel authority to provide emergency or after-hours delivery of dangerous devices to patients of a medical device retailer to include an employee who operates a service vehicle. [15:2&3 CCR 88; 14:1 CCR 741]

- **Examination Admission Requirements.** On August 4, OAL approved the Board's amendments to section 1719, Title 16 of the CCR, which specify that candidates taking the Test of Spoken English (TSE) after June 30, 1995 must achieve a score of at least 50, while candidates taking the TSE before June 30, 1995 are subject to the previous minimum score of 220. [15:2&3 CCR 88]

- **Revisions to Building and Security Standards.** At its July 26 meeting, the Board held a public hearing on its proposal to repeal sections 1711, 1712, 1713, and adopt new section 1714, Title 16 of the CCR. Proposed section 1714 would streamline the pharmacy licensure application for pharmacies licensed after July 1, 1996, and would apply to all licensed pharmacies after January 1, 1998. The proposed section would eliminate the existing floor plan review and approval process and replace it with simplified general building standards defined with less restrictive physical criteria. [15:2&3 CCR 89]

After the public hearing, the Board made two modifications to the text of proposed section 1714. The first modification clarifies that subsection (a) will apply to all pharmacies; the second modification requires "new" pharmacies governed under section 1714 to have a "readily accessible restroom" which must contain a toilet and washbasin with running water. The Board adopted the proposed section 1714 subject to these modifications; on July 31, the
Board released the modified version of proposed section 1714 for a 15-day public comment period which expired on August 21.

At its October 26 meeting, the Board proceeded to further modify section 1714; among other things, the Board made additional textual modifications to clarify its intent to require all pharmacies (not just newly-licensed pharmacies) to have a private consultation area. The Board again adopted section 1714 with these added modifications and released the revised text for another 15-day public comment period in November.

Following the second 15-day public comment period, the Board submitted the rulemaking file to the Department of Consumer Affairs (DCA) on November 22; DCA approved the proposal on December 28. At this writing, the rulemaking file awaits review and approval by OAL.

* Citation and Fine Program. On May 31, OAL approved the Board’s addition of new Article 9.5, commencing with section 1775, Title 16 of the CCR, establishing a citation and fine program. The provisions authorize a Board inspector or committee to issue citations containing orders of abatement and/or fines for the unlicensed practice of pharmacy and for violation of the pharmacist’s duty to provide oral consultation before dispensing medication. [15:2&3 CRLR 90; 15:1 CRLR 84; 14:4 CRLR 91–92]

### LEGISLATION

**Future Legislation.** At its July meeting, the Board agreed to pursue legislation to place the administration of the triplicate monitoring program for controlled substances with the Board (see MAJOR PROJECTS).

**AB 611 (Aguilar),** as amended July 3, creates a new licensure program to be administered by the Board—the veterinary food-animal drug retailer, defined as a place (other than a pharmacy) that holds a valid wholesaler certificate, license, permit, or registration, from which veterinary drugs for food-producing animals are dispensed to a prescription from a veterinarian, and which is issued a permit for that location by the Board. The bill defines the term “veterinary food-animal drugs” to include any drug intended for use in food-producing animals that, by federal or state law, may be dispensed only by the prescription of a licensed veterinarian.

Under AB 611, a veterinary food-animal drug retailer must be placed under the charge of a responsible person exempt from the pharmacist registration requirement, who has completed a training program approved by the Board and passed an examination administered by the Board; may dispense veterinary food-animal drugs for food-producing animals under specified conditions; and may dispense veterinary food-animal drugs only to another veterinary food-animal drug retailer, a pharmacy, a veterinarian, or to a veterinarian’s client pursuant to a veterinarian’s prescription.

**AB 611 also establishes minimum standards for veterinary food-animal drug retailers, and requires them to establish written policies and procedures regarding certain information. The bill also requires a consulting pharmacist to be retained to review these policies and procedures, and to certify at least twice a year whether the retailer is in compliance with the requirements of the Pharmacy Law. The bill also establishes the initial fee for a veterinary food-animal drug retailer certificate, license, permit, or registration at $400, and establishes the renewal fee at $250. This bill was signed by the Governor on August 3 (Chapter 350, Statutes of 1995).

**AB 1107 (Campbell).** Under existing law, the right to sell or furnish prescription lenses is limited exclusively to licensed physicians, optometrists, and registered dispensing opticians. As amended August 28, this bill authorizes, notwithstanding that limitation, a pharmacist to dispense replacement contact lenses, as defined, in accordance with certain requirements. These requirements are also made applicable to nonresident pharmacists.

Existing law requires nonresident pharmacies, as defined, to register with the Board and to disclose certain information to the Board; and provides for the denial, revocation, and suspension of nonresident pharmacy registration for failure to comply with certain requirements. This bill adds the requirements for dispensing replacement contact lenses to the requirements for which nonresident pharmacy registration may be denied, revoked, or suspended. The bill requires that nonresident pharmacies comply with certain requirements, maintain certain records, and disclose certain information to the Board. This bill also adds the requirement that those pharmacies maintain records of all replacement contact lenses shipped, mailed, or delivered to California residents; and requires that these records be available for inspection upon request by the Board or the Division of Licensing of the Medical Board of California (MBC). This bill also requires any pharmacy, including nonresident pharmacies, dispensing replacement contact lenses to comply with certain laws governing advertising of contact lenses, and to register with MBC at the time of initial licensure or registration or upon renewal of the license or registration. This bill was signed by the Governor on October 9 (Chapter 719, Statutes of 1995).

**AB 1529 (Vasconello).** Existing law generally prohibits the possession of marijuana or concentrated cannabis and prohibits the planting, cultivating, harvesting, drying, or processing of marijuana. As amended September 5, this bill would have provided that these prohibitions do not apply to any person who possesses, plants, cultivates, harvests, dries, or processes marijuana for his/her own personal medicinal use or for the personal medicinal use of another of whom the person is an immediate family member or for whom the person is the legal guardian or primary caretaker, as defined, where the medicinal use has been approved in writing by a licensed physician for the treatment of AIDS, cancer, glaucoma, or multiple sclerosis. This bill was vetoed by the Governor on October 15.

**SB 988 (Polanco).** Existing law provides for the licensure, regulation, and discipline of pharmacists and pharmacies by the Board; existing law exempts certain activities, drugs and devices, and facilities from the application of this law. As amended April 25, this bill also exempts the furnishing of dangerous drugs and devices, as defined, to recognized schools of nursing, in certain circumstances. This bill also authorizes a wholesaler or pharmacy to furnish dangerous drugs to certain officers of an ocean vessel in accordance with certain procedures and federal regulations. [15:1 CRLR 87]

Existing law also sets forth the requirements for licensure as a pharmacist for applicants who graduate from a foreign pharmacy school. This bill revises those requirements. [15:1 CRLR 86]

**SB 988 also revises requirements relating to the filing of petitions for reinstatement of a revoked or suspended certificate, or any other license, registration, permit, or exemption issued by the Board, and requires the automatic suspension of a pharmacist’s certificate if the pharmacist or other licensee, certificant, permittee, registrant, or exemptee is incarcerated after conviction of a felony in accordance with specified procedures. This bill was signed by the Governor on September 2 (Chapter 442, Statutes of 1995).

**AB 1136 (V. Brown).** Existing law provides for the licensure and regulation of health care service plans (HCSP) by the Department of Corporations. Existing law defines a specialized HCSP contract as a contract for health care services in a single specialized area of health care, including dental care. As amended September 12,
this bill would revise this definition to clarify that the contract may be for pharmaceutical benefits. It would also require, commencing January 1, 1998, the Commissioner of Corporations to ensure that when formularies are created for pharmaceutical benefits, the formularies are subject to review by the plan’s quality assurance program.

The Pharmacy Law provides for the licensure and regulation of pharmacists, to be administered by the Board. Existing law imposes various requirements on HCSPs and insurers, and permits those plans and insurers to enter into various contracts with health care providers. Existing law requires each HCSP to disclose certain information regarding the benefits, services, and terms of the plan contract in order to provide the public, subscribers, and enrollees with a full and fair disclosure of the terms of the plan. This bill would require a HCSP to disclose the extent that the plan pays or offers to pay financial remuneration to a dispenser for substituting a prescribed drug for another drug.

Existing law states the intent of the legislature regarding HCSPs. This bill would also state the intent relating to the dispensing of pharmaceutical drug benefits by those plans. [A. Conference Committee]

**AB 1113 (Rogan).** Existing law categorizes controlled substances into five schedules; only controlled substances in Schedules II to V, inclusive, may be prescribed, and only as specified. Existing law categorizes levoalphacetylmethadol (LAAM) as a Schedule I controlled substance; as amended July 15, this bill transfers LAAM from Schedule I to Schedule II, thus allowing it to be prescribed. This bill was signed by the Governor on September 2 (Chapter 455, Statutes of 1995).

**AB 322 (Alpert), as introduced February 9, would transfer the controlled substance methylphenidate from Schedule II to Schedule III. [A. PubS]**

**AB 1163 (V. Brown).** Existing law provides for the licensure and regulation of pharmacists and provides that a violation of the provisions regulating the practice of pharmacy is subject to criminal sanction. Existing law also provides that a registered nurse who is authorized by administrative regulations and is employed by or serves as a consultant for a licensed skilled nursing, intermediate care or other health care facility, may orally or electronically transmit to the dispenser a prescription lawfully ordered by a person authorized to prescribe drugs or devices, and requires the dispenser to record the name of the person who transmits the order. As introduced February 23, this bill would similarly permit a registered nurse who is employed by a home health agency to orally transmit a prescription, and require the furnisher to record the name of the person who transmits the order. [A. PubS]

**SB 641 (Cronen).** Existing law authorizes a licensed pharmacist to dispense drugs upon a transmittal order of a physician assistant (PA) who has been delegated that authority by a physician. As introduced February 22, this bill would state the intent of the Legislature to enact guidelines for pharmacists who accept Schedule II prescriptions from PAs in accordance with those provisions. [S. B&P]

**SB 922 (Mello).** Existing law requires the Board to adopt regulations that apply the same requirements or standards for oral consultation to certain out-of-state pharmacies that are applied to certain in-state pharmacies, and provides that the regulations shall not result in any unnecessary delay in patients receiving their medication. As introduced February 23, this bill would additionally provide that the regulations shall not result in any unnecessary expense to patients receiving their medication. [S. B&P]

**SB 959 (Mello), as introduced February 23, would state the intent of the Legislature that pharmacists be prohibited from receiving compensation for the dispensing of prescription drugs beyond a predetermined dispensing fee established by the patient’s insurance carrier. [S. Rls]**

**SB 777 (Polanco).** Existing law excludes from the practice of psychology the prescribing of drugs. As amended May 2, this bill would require the Board of Psychology to establish and administer a certification program to grant licensed psychologists prescriptive authority, as defined, and to develop procedures for that certification with the advice of the state Department of Health Services and the Board of Pharmacy. The bill would require each applicant for certification to satisfy certain educational and training requirements. This bill would also delete the exclusion of the prescribing of drugs by certified psychologists from the practice of psychology. [S. B&P]

**SB 510 (Maddy), as amended May 2, would authorize optometrists to use specified diagnostic drugs and to prescribe specified therapeutic pharmaceutical agents (TPAs) incidental to their practice of optometry (excluding controlled substances).** Currently, California optometrists have no prescriptive authority. This bill would make it a misdemeanor for any optometrist to refer a patient to a pharmacy that is owned by the optometrist or in which the optometrist has a proprietary interest (see agency report on BOARD OF OPTOMETRY for a detailed discussion of this bill). [S. B&P]

**AB 1969 (Isenberg), as amended April 5, is substantially similar to SB 510 above; however, instead of providing that any use, prescribing, or dispensing of TPAs to a patient by an optometrist is limited to that which is incidental to the practice of optometry, AB 1969 would require that such use, prescribing, or dispensing of a pharmaceutical agent be limited only to the practice of optometry. [A. Health]

**AB 1572 (Allen), as amended May 2, would, among other things, repeal the existing Pharmacy Law and reenact it as revised as reorganized. The purpose of the bill is not to change any substantive provision of existing pharmacy law, but to recast it into a more organized format and to eliminate duplication and archaic language. This bill is sponsored by the Board of Pharmacy and is the product of several years of work by the Pharmacy Law Committee. [A. Health]**

### LITIGATION

In Smith v. California State Board of Pharmacy, 37 Cal. App. 4th 229 (July 31, 1995), the Fourth District Court of Appeal reversed the San Diego County Superior Court’s judgment denying Thomas Smith’s petition for a writ of administrative mandamus; Smith sought the writ in order to set aside the decision of the Board, which adopted the ruling of an administrative law judge (ALJ) and revoked Smith’s license to practice pharmacy. The ALJ’s decision was based in part on a negligence theory which was not alleged in the accusation filed against Smith. In reversing the superior court’s ruling which denied the petition for writ of mandate, the Fourth District held that the failure of the accusation to give Smith adequate notice that the Board was going to rely upon a theory of negligence constituted a procedural due process violation.

### RECENT MEETINGS

At its May 24 meeting, the Board met with Senior Assistant Attorney General Ron Russo to discuss the disciplinary process, particularly the Board’s concern about the length of time required by the Attorney General’s Office to file a case and then prosecute it before an administrative law judge (ALJ) from the Office of Administrative Hearings (OAH). Russo explained that in the past, some cases have been backlogged for several years due to staffing constraints at the AG’s Office and calendar overload at OAH. However, he reported that additional deputies have been hired and statistics show that the
timeframe for processing cases has improved. The Board and Russo agreed that in those cases when settlement terms are requested, Board staff will prepare these terms in a boilerplate format to be modified as needed by the deputy attorney general assigned to the case.

Also on May 24, member Marilyn Shreve requested that the Board institute a reporting system requiring employers of licensees to report to the Board when they seek termination of a licensee for drug-related reasons. Employment laws and liabilities have discouraged employers from reporting the fraudulent activities of their employees. Several issues concerned the Board, including whether employers should also report pharmacists who make significant or multiple errors, and whether the employer would be exempt from liability should the Board use reported information to take disciplinary actions against the pharmacist. The Board's Recovery Program, which began in 1985, provides a less threatening mechanism whereby management can report impaired pharmacists, as pharmacists enter the program by employer referral or voluntarily for treatment without the Board's knowledge. However, when theft of drugs is involved and loss of a controlled substance is not accounted for as required by law, then the Board must take appropriate disciplinary action or impose mandatory program treatment in lieu of discipline. The Board resolved to discuss this matter in its next newsletter.

On May 25, Shreve reported on the progress of the consumer education plan directed toward educating the public about the new pharmacist consulting law. (15:2 & 3 CRLR 93; 15:1 CRLR 87; 14:4 CRLR 94) Board staff has incorporated the new logo adopted by the Board with the slogan "Be Aware and Take Care: Talk to Your Pharmacist" on the Board's printed materials. At its July meeting, the Board resumed discussion of this matter, noting that National Pharmacy Week had been scheduled for October 22-28, with the theme of "Communicate Before YouMedicate." Various other Board efforts to promote consumer education are also under way, including development of a media package with educational videotapes, and press conferences to be held in conjunction with schools of pharmacy and professional associations in California's major cities.

Also on May 25, the Board elected Marilyn Standifer Shreve as its new president, Darlene Fujimoto as vice-president, and Caleb Zia as treasurer. At its July 26 meeting, the Board resumed discussion of its concern that OAH ALJs have not consistently adhered to the Board's disciplinary guidelines in enforcement proceedings, especially in serious drug diversion cases. Senior Assistant Attorney General Ron Russo reported that OAH is drafting "Rules of Court" which will formalize procedures for more consistent adjudication. The Board also considered various options to improve the efficiency of processing disciplinary matters, including seeking limited peace officer status for some Board inspectors and incorporating new methods of undercover operations and surveillance. The Board further requested Deputy Attorney General Bill Marcus to draft amendments to Business and Professions Code section 4232 to modify the current treatment of unaccounted-for controlled substances in drug diversion cases. Under existing law, this is only considered a recordkeeping violation; the Board would like the legislature to amend section 4232 to enable it to treat such violations as justification for charges of diversion with the penalty of license revocation.

At its July 26 meeting, the Board discussed the procedure for setting appropriate levels of supervision for licensees on probation. The Northern Interim Committee (NIC) and the Southern Interim Committee (SIC), each consisting of three Board members and Board inspectors, were created to oversee this process. The NIC and SIC hold meetings at which a pharmacist on probation submits a letter from his/her employer verifying the current level of supervision. The NIC or SIC reviews the information and the circumstances of the case and then requires a specified level of supervision during the probation period. There are four general levels of supervision: continuous (75% to 100% of a shift), substantial (at least 50% of a shift), partial (at least 25% of a shift), and daily review (supervisor's review of probationer's daily activities within a 24-hour period). A probationer may appeal a required level of supervision and request modification. To avoid excessive restraints on the licensee's practice that would prevent gainful employment during the probation period, the Board may reduce the supervision level and increase the frequency of monitoring by an inspector. The Board delegated to the supervising inspectors the authority to set the level of supervision for the probationer at an earlier stage. The level would be set at a probation office conference with the licensee; no appeal process would follow (the supervision level for all probationers is reviewed annually, however, by the supervising inspector); the supervision level must be written clearly, signed by the probationer, and kept on file. In delegating this authority, the Board intends to provide its supervising inspectors with specific guidelines for establishing an appropriate level of supervision. At its October 26 meeting, the Board adopted a set of proposed guidelines for setting supervision level for probationers. While in general cases, these guidelines do not provide for an appeal once a supervision level is set, appeals will be considered by the Executive Officer and supervising inspector after 90 days in extreme circumstances where the probationer can document a hardship. DCA legal counsel Chris Grossgart clarified that the guidelines are not binding regulations on inspectors, but serve as a guide for them to use in their discretion. The Board further explained that the guidelines are intended for use in those cases where only general supervision exists and no specific conditions of probation have been set by the Board.

Also at its October meeting, the Board discussed FDA's proposed adoption of 21 C.F.R. Parts 201, 208, 314, and 601, which would establish the requirements for prescription drug product labeling and written medication guides. FDA has determined that statistics show patient compliance with the proper use of a drug is best achieved when a patient receives both oral consultation and useful written information when the prescription is dispensed. FDA's "Healthy People 2000" goal proposes that by 2000, 75% of Americans will receive written information with each new prescription, increasing to 95% by 2006. FDA is considering the "Med Guide" program, much like the successful food labeling programs, which is aimed at providing useful written drug information in a consistent format. The Board noted that while many Californians currently receive written information about their prescriptions on the drug dispensing receipt, the printed format and content of drug information vary from pharmacy to pharmacy. The Board acknowledged that it would be difficult to provide written information for diverse medication situations. However, the Board suggested that this could be addressed when FDA implements a standard format for printed drug information by providing a computerized format with a comment area for pharmacists to customize the information to address the patient's entire drug therapy. The Board noted that because patients do not always read written information, it is imperative that the pharmacist discusses and explains the written information. While improved drug labeling and a standard format of drug information is essential, the Board agreed that the role of a pharmacist to
provide oral consultation to ensure patient compliance in the proper use of drugs is equally indispensable.

**FUTURE MEETINGS**

January 24–25 in Los Angeles.
March 27–28 in Sacramento.
May 29–30 in San Diego.
July 24–25 in San Francisco.
October 23–24 in Sacramento.

**BOARD OF REGISTRATION FOR PROFESSIONAL ENGINEERS AND LAND SURVEYORS**

**Executive Officer:**

Harold L. Turner
(916) 263-2222

The Board of Registration for Professional Engineers and Land Surveyors (PELS) regulates the practice of engineering and land surveying through its administration of the Professional Engineers Act, sections 6700 through 6799 of the Business and Professions Code, and the Professional Land Surveyors Act, sections 8700 through 8806 of the Business and Professions Code. The Board’s regulations are found in Division 5, Title 16 of the California Code of Regulations (CCR), sections 400 through 471.

The basic functions of the Board are to conduct examinations, issue certificates, registrations, and/or licenses, and appropriately channel complaints against registrants/licensees. The Board is additionally empowered to suspend or revoke registrations/licenses. The Board considers the proposed decisions of administrative law judges who hear appeals of applicants who are denied a registration/license, and those who have had their registration/license suspended or revoked for violations.

Professional engineers are registered through the three Practice Act categories of civil, electrical, and mechanical engineering under section 6730 of the Business and Professions Code. Land surveyors, another Practice Act category, are registered through section 8725 of the Business and Professions Code. The Title Act categories of agricultural, chemical, control system, corrosion, fire protection, industrial, manufacturing, metallurgical, nuclear, petroleum, quality, safety, and traffic engineering are registered under section 6732 of the Business and Professions Code. Structural engineering and geotechnical engineering are “title authorities” linked to the civil Practice Act and require an additional examination after qualification as a civil engineer.

The Board consists of thirteen members: seven public members, one licensed land surveyor, four registered Practice Act engineers and one Title Act engineer. The Governor appoints eleven of the members for four-year terms that expire on a staggered basis. Additionally, both the Assembly Speaker and the Senate Rules Committee appoint one public member each.

The Board has established four standing committees and appoints other special committees as needed. The four standing committees are Administration, Enforcement, Examination/Qualifications, and Legislation. Committees function in an advisory capacity unless specifically authorized by the Board to make binding decisions.

PELS is subject to a “sunset” provision. Section 8710 of the Business and Professions Code, which vests power in the Board, will “become operative on January 1, 1999, and, as of January 1, 1999, is repealed, unless a later enacted statute, which becomes effective on or before January 1, 1999 deletes or extends the dates on which it becomes inoperative and is repealed.”

At its July 14 meeting, PELS welcomed new public member Millicent Safraan. In November, public member Megan Matthews resigned from the Board.

**MAJOR PROJECTS**

**Executive Officer Resigns.** At a special December 15 PELS meeting, Executive Officer (EO) Harold Turner tendered his resignation; Turner, who served as the Board’s EO for three years, has taken a position with the Bureau of State Audits. Following a closed session, the Board announced the appointment of Cindi Christenson as Interim EO; Christenson is a registered mechanical engineer who has worked at PELS since 1989. PELS also established a Special Committee for the Recruitment of an Executive Officer, comprised of the Board president, vice-president, and chair of the Administrative Committee, appointed the Board president to serve as the Committee chair, and authorized the Committee chair to undertake any actions on behalf of the Board which are necessary to recruit highly qualified candidates for the EO position, and to report to the Board at each meeting on the processes that have been implemented and the progress of the recruitment process.

PELS also decided that the Board itself should interview highly qualified candidates and make the final hiring decision by vote, as required by statute.

**Professional Engineers Act Rewrite Goes to Public Forum.** PELS is currently in the midst of a comprehensive review and rewrite of the Professional Engineers (PE) Act, its regulations, and the way the state of California licenses and classifies various engineering disciplines; this effort has resulted largely from November 1993 criticism by the Center for Public Interest Law (CPIL) that PELS’ engineering statutes and regulations are extremely vague and in need of major restructuring and modernization, and former Board President Rich Johnson’s “white paper” entitled Confronting the Issues of Engineering Discipline Definitions, in which Johnson agreed with CPIL that the Board’s statutes are internally inconsistent and lack clarity. [14:4 CRLR 95; 14:2&3 CRLR 99; 14:1 CRLR 77]

Significantly, the Board wants to implement “generic registration,” under which it would grant only one generic PE license instead of the three Practice Act registrations, thirteen Title Act registrations, and two “title authority” registrations currently offered. Generic registration would conform California’s licensing system with those in most other states. The Board feels the current system’s complexity serves no purpose and only confuses the consumer. The highlights of PELS’ draft PE rewrite are as follows:

- All registrants would be registered generically as PE’s, with designations as to areas of practice in which they have been deemed qualified by testing, rather than being registered in specific branches of engineering. All registrants would be required to provide engineering services in a competent manner, and their registration would be at risk if they fail to do so.

- Traditional Title Act categories would be eliminated and essentially converted to practice acts because generic PE registration would be required in order to perform prior Title Act work. In other words, all engineering practice would be regulated by the Board.

- The rewrite of the PE Act would allow applicants to test in any of seventeen areas in which the National Council of Examiners for Engineering and Surveying (NCEES) offers an exam. It would eliminate PELS’ current registrations in quality, safety, traffic, and corrosion engineering, because NCEES does not offer exams in these disciplines; and add aeronautical, ceramic, environmental, mining/materials, and structural engineering exams (as NCEES has developed exams in those areas). When an applicant passes any exam, he/she would receive a professional engineering license and would be deemed qualified in the area tested, but could practice in any area of engineering. For example, a PE who has tested in agricul-