for any disease or pathological condition by an optometrist who meets specified requirements. The bill would establish a seven-member pharmaceutical advisory committee with a prescribed membership to provide advice to the Board as to the use of diagnostic and therapeutic agents. Under this bill, only optometrists who meet several examination and training requirements and agree to accept Medi-Cal patients are permitted to use, dispense, or prescribe therapeutic pharmaceutical agents. AB 2020 would also make it a misdemeanor for any person licensed as an optometrist to refer a patient to a pharmacy that is owned by the licensee or in which the licensee has a proprietary interest. This bill, which sponsored by the California Optometric Association and is opposed by the California Medical Association, was rejected on June 28 but was granted reconsideration. *[S. B&P]*

SB 908 (Calderon), as introduced March 4, would provide that the terms "license" and "certificate of registration" are deemed to be synonymous for the purposes of the provisions of law regarding the licensure and regulation of optometry. *[A. Health]*

SB 921 (Maddy), as introduced March 4, would provide that it is unprofessional conduct for an optometrist to fail to advise a patient in writing of any pathology that requires the attention of a physician when an examination of the eyes indicates a substantial likelihood of any pathology. *[S. B&P]*

LITIGATION

On May 12, in ***California Optometric Association (COA) v. Division of Allied Health Professions, Medical Board of California***, No. 531542, and ***Engineers and Scientists of California (ESC), et al. v. Division of Allied Health Professions, Medical Board of California***, No. 532588, the Sacramento County Superior Court approved the parties' stipulation to consolidate the two cases; *ESC* was designated as the lead case. In this matter, ESC and COA challenge the validity of the medical assistant regulations adopted by the Medical Board's Division of Allied Health Professions, contending that the regulations permit unlicensed medical assistants to perform optometric tasks and functions. At this writing, a trial-setting conference is scheduled for December 6. *[13:2&3 CRLR 100]*

RECENT MEETINGS

At the Board's May 20–21 meeting, DCA legal counsel Robert Miller commented on Business and Professions Code section 651, which authorizes optometrists and other professionals to state in advertisements that they are certified in a particular area of expertise by a private or public board or agency or that they limit their practice to a particular area of expertise. Miller noted that the Board has the authority to allow an optometrist to advertise a certification only after it has approved or recognized the private or public board, agency, or other parent organization that is providing certification. Miller also noted that a recent U.S. Supreme Court ruling provides states with the right to limit such advertising if its use is misleading to the public, but prohibits states from infringing on an individual's right to engage in truthful, non-misleading advertising or to list certifications by bona fide organizations in advertising.

At the Board's August 12–13 meeting, staff announced that the occupational analysis of the practice of optometry is expected to be completed by December. *[13:1 CRLR 59]* Staff also noted that the Board's licensure examination was given July 15–18 at the UC Berkeley School of Optometry; the application fee was $275, which represented a $200 increase over prior years.

FUTURE MEETINGS

December 1–2 in Orange County.

BOARD OF PHARMACY

Executive Officer: Patricia Harris (916) 445-5014

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

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

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

MAJOR PROJECTS

Board Proposes Fee Increases, Citation and Fine System. On August 20, the Board published notice of its intent to amend sections 1749 and 1793.5, Title 16 of the CCR, which specify the schedule of fees and late penalties prescribed by California Pharmacy Law for the licenses, permits, and registrations which the Board issues. The proposed amendments would raise specified fees, including pharmacy and pharmacist biennial renewal fees; according to the Board, the fee increase is necessary to restore the Board's reserve fund and maintain it at a prudent level to enable it to conduct ongoing operations. At this writing, the Board is scheduled to conduct a public hearing on the proposed fee increases at its October 6 meeting in La Jolla.

Also on August 20, the Board published notice of its intent to add new Article 9.5, commencing with section 1775, to Title 16 of the CCR. Specifically, the proposed new article would authorize the Board's Executive Officer to issue citations containing orders of abatement and fines for violations of specified provisions of law; specify the content of a citation and the mode of service upon a licensee; set forth a scheduled of fines ranging from a minimum of $100 to a maximum of $2,500 for violations of specified provisions of the Business and Professions Code; authorize the Executive Officer to issue citations, assess fines, and issue orders of abatement against persons who have performed services for which licensure by the Board is required, but who lack a license; and set forth procedures for contesting or appealing any citation, order of abatement, or fine. At this writing, the Board is scheduled to conduct a public hearing on the proposed citation and fine regulations on October 6 in La Jolla.

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

• On May 28, the Board published notice of its intent to amend section 1732.3, Title 16 of the CCR, regarding the duration of its approval of continuing education (CE) courses. Specifically, the proposed change would provide that a recognized CE provider's coursework shall be valid for three years following the initial Board approval; currently, such coursework is valid for two years following initial Board approval. This change would conform the Board's CE course validity period to that used by the American Coun-

cil on Pharmaceutical Education. *[13:2&3 CRLR 101]* On July 21, the Board conducted a public hearing on the proposed change; following the hearing, the Board unanimously adopted the amendment, which awaits review and approval by the Office of Administrative Law *(OAL)*.

• On May 28, the Board published notice of its intent to amend section 1717(a), Title 16 of the CCR, which provides that—with specified exceptions—no medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia; the Board's proposed amendment would allow pharmacists to refill a prescription for non-liquid oral products in a clean, safe container previously provided for the same patient for the same drug, provided a new label is securely attached to the container. *[13:2&3 CRLR 101]* On July 21, the Board conducted a public hearing on the proposed change; during the hearing, staff noted that a comment submitted by the U.S. Consumer Product Safety Commission stated that federal law does not allow the reuse of child-resistant packaging or containers; the Board discussed whether consumers should have the option of reusing a prescription vial regardless of whether it is child-resistant. Following discussion, the Board agreed to defer the regulation until its October meeting to allow Deputy Attorney General William Marcus time to inquire about the limitation of federal law and regulations. However, the Board modified the proposed language to provide that a pharmacy may, at the request of the patient or his/her agent, reuse prescription containers under the circumstances described above, provided the container is not a child-resistant container; the Board directed staff to release the modified language for an additional fifteen-day public comment period.

Legislature Approves Board's Proposal to Enhance Enforcement Unit. At the Board's July 21 meeting, Executive Officer Patricia Harris reported that the legislature, in the state's 1993–94 budget bill, augmented the Board's budget by $705,000 to enable it to enhance its enforcement unit by hiring five new inspectors, one supervising inspector, one consumer services representative, and one consumer assistance technician. *[13:2&3 CRLR 100; 13:1 CRLR 60]*

Board Holds Enforcement Workshop, Revises Complaint Disclosure Policy. The Board devoted its entire July 22 meeting to an enforcement workshop. Among other things, the Board heard a presentation by Judge Karl Engeman, Director of the Office of Administrative Hearings (OAH), who discussed the disciplinary hearing process and the role of the OAH administrative law judges who preside over those hearings and their use of the Board's disciplinary guidelines. Judge Engeman noted that disciplinary guidelines are recommendations, not mandatory penalties, especially inasmuch as they have not been adopted as regulations pursuant to the Administrative Procedure Act rulemaking process. OAH ALJs use them in proposing disciplinary decisions, but each case is different and the judge must consider aggravating and mitigating circumstances in recommending appropriate penalties.

Also at the enforcement workshop, the Board agreed to revise its existing policy regarding the disclosure of complaint and other enforcement information to inquiring consumers. Under the Board's revised policy, the Board will provide, upon written request, a written summary of the disposition of any complaint it has received which is substantiated and within its jurisdiction. The Board will provide the requesting party with the date the complaint was received, a synopsis of the complaint (*e.g.*, prescription error, label error, unprofessional conduct), and its disposition (*e.g.*, referral for formal disciplinary action, dismissal of minor violations not meriting disciplinary action, and/or technical or practice act violations resolved through non-disciplinary actions). In response to telephone inquiries, the Board will provide an oral summary of the number of substantiated complaints against a licensee. Formal Board disciplinary actions (accusations and decisions) are a matter of public record, as are the names of licensees, license numbers, address of record, date of original license, and current license status.

Finally, the Board decided to proceed with the rulemaking process to adopt regulations to implement its citation and fine authority (*see above*).

LEGISLATION

SB 842 (Presley), as amended July 14, permits the Board to issue interim orders of suspension and other license restrictions, as specified, against its licensees. This bill was signed by the Governor on October 5 (Chapter 840, Statutes of 1993).

AB 2099 (Epple). The Pharmacy Law prohibits a pharmacist from dispensing any prescription except in a container correctly labeled with certain types of information. As amended April 28, this bill additionally requires the container label to identify the condition for which the drug was prescribed if the patient requests it and the prescription identifies the condition. This bill was signed by the Governor on September 8 (Chapter 397, Statutes of 1993).

AB 2155 (Polanco). Existing law requires prescription blanks in triplicate to be issued by the Department of Justice (DOJ) and furnished to any practitioner authorized to write a prescription for Schedule II controlled substances. Existing law prohibits DOJ from issuing more than 100 triplicate prescription blanks to any authorized practitioner. As amended September 7, this bill would have established, until January 1, 1997, the Ad Hoc Committee on Prescription Pain Management to begin a dialogue among the Attorney General, various state boards (including the Board of Pharmacy), and other interested persons focusing on identifying appropriate procedures and techniques for the management of acute, chronic, or intractable pain, and to study various issues involving the treatment of pain and report to the Governor, the Attorney General, various state boards, and the legislature. This bill was vetoed by the Governor on October 8.

SB 432 (Greene). Existing law generally requires every prescription for a Schedule II controlled substance to be in writing. However, when failure to issue a prescription for a Schedule II controlled substance to a patient in a licensed skilled nursing facility, an intermediate care facility, or a licensed home health agency providing hospice care would, in the opinion of the prescriber, present an immediate hazard to the patient's health and welfare or result in intense pain and suffering to the patient, the prescription may be dispensed upon an oral prescription. As amended July 2, this bill instead provides that any order for a Schedule II controlled substance in a licensed skilled nursing facility, intermediate health care facility, or a licensed home health agency providing hospice care may be dispensed upon an oral prescription.

Existing law provides that, upon request, a skilled nursing facility, intermediate care facility, or licensed home health agency providing hospice care shall make available to the dispensing pharmacist copies of signed telephone orders, chart orders, or related documentation substantiating an oral prescription transaction. This bill instead provides that a skilled nursing facility, intermediate care facility, or licensed home health agency providing hospice care shall forward to the dispensing pharmacist a copy of any signed telephone order, chart order, or related documentation substantiating each oral prescription transaction. This bill was signed by the Governor on July 30 (Chapter 245, Statutes of 1993).

SB 1051 (McCorquodale). The Pharmacy Law requires a pharmacist to inform a patient orally or in writing of the harmful effects of a drug dispensed by prescription

if the drug poses a substantial risk to the person consuming the drug when taken in combination with alcohol or if the drug may impair a person's ability to drive a motor vehicle, whichever is applicable, and the Board determines that the drug requires the warning. The Pharmacy Law requires any pharmacy located outside this state that ships, mails, or delivers any controlled substances or dangerous drugs or devices into this state pursuant to a prescription to register with the Board, disclose information regarding the pharmacy to the Board, and meet other conditions. Under the Pharmacy Law, one of those conditions is the requirement that the pharmacy, within a prescribed time period, provide toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. It also requires the toll-free number to be disclosed on a label affixed to each container of drugs dispensed to patients in this state. As amended August 16, this bill requires the Board to adopt specified regulations that apply the same requirements or standards for oral consultation to out-of-state pharmacies that ship, mail, or deliver controlled substances or dangerous drugs or devices to residents of this state, as are applied to in-state pharmacies when the pharmacy ships, mails, or delivers any controlled substances or dangerous drugs or devices to residents of this state. This bill was signed by the Governor on October 2 (Chapter 763, Statutes of 1993).

AB 260 (W. Brown), as amended April 12, and **SB 1048 (Watson)**, as introduced March 5, would establish the Clean Needle and Syringe Exchange Pilot Project, and authorize pharmacists, physicians, and certain other persons to furnish hypodermic needles and syringes without a prescription or permit as prescribed through the pilot project. Governor Wilson vetoed AB 260 on October 8, and SB 1048 is a two-year bill. *[S. Floor]*

AB 667 (Boland). The Pharmacy Law regulates the use, sale, and furnishing of dangerous drugs and devices, as defined; the law prohibits a person from furnishing any dangerous device, except upon the prescription of a physician, dentist, podiatrist, or veterinarian. However, existing law provides that this prohibition does not apply to the furnishing of any dangerous device by a manufacturer, wholesaler, or pharmacy to each other or to a physician, dentist, podiatrist, veterinarian, or physical therapist acting within the scope of his/her license under sales and purchase records that correctly give the date, the names and addresses of the supplier and the buyer, the device, and its quantity. As amended March 29, this bill would provide that the prohibition also does not apply to the furnishing of any dangerous device by a manufacturer, wholesaler, or pharmacy to a chiropractor acting within the scope of his/her license.

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

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

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

Existing law defines the term "prescription" for the purposes of existing law relating to licensure of pharmacists, regulation of pharmacies, and regulation of controlled substances. This bill would revise the definition of the term prescription, for those purposes, to also include electronically transmitted prescriptions, as defined. *[13:2&3 CRLR 100–01]*

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

SB 1153 (Watson), as amended September 3, is no longer relevant to the Board.

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

SB 1136 (Kelley). Existing law sets forth the requirements pursuant to which the Department of Health Services (DHS) may include a new single-source drug on the list of contract drugs purchased under the Medi-Cal program. Among other things, manufacturers are required to request inclusion on the list within 12 months of federal approval for marketing of the drug, and DHS is required to evaluate the request within 90 days of its receipt. In addition, DHS must have concluded contracting for the therapeutic category in which the drug is included prior to federal approval of the drug. Existing law requires recommendations to be made on the inclusion of drugs on the list by the Medi-Cal Contract Drug Advisory Committee. As amended September 7, this bill would instead require manufacturers to request inclusion on the list within 18 months of federal approval, and require DHS to submit the drug to the Medi-Cal Contract Drug Advisory Committee. This bill was signed by the Governor on October 11 (Chapter 1161, Statutes of 1993).

LITIGATION

Huggins v. Longs Drug Stores California, Inc., No. S030711, is still pending before the California Supreme Court; the pharmacy is appealing the Fifth District Court of Appeal's ruling that a pharmacist's provision of incorrect dosage amounts for a prescription which the pharmacist knew or should have known would be administered to an infant by the infant's parents constitutes negligent action by the pharmacist directed at the parent caregivers, which may allow and

gave the parent caregivers to recover damages for negligent infliction of emotional distress. *[13:1 CRLR 63]*

At this writing, oral argument is scheduled for October 14 in ***Californians for Safe Prescriptions v. California State Board of Pharmacy***, No. B073104, pending in the Second District Court of Appeal. The trial court held that the Board followed and complied with the Administrative Procedure Act in promulgating and adopting its pharmacy technician regulations; plaintiffs/appellants are members of a nonprofit organization consisting of approximately 5,000 licensed pharmacists. *[13:1 CRLR 62]*

RECENT MEETINGS

At its July 21 meeting, the Board discussed a proposal for amending section 1751.10, Title 16 of the CCR, to allow licensed pharmacies which are also licensed as home health agencies to dispense emergency kits to home health agency registered nurses who provide care to patients in their homes; staff noted that escalating health care costs have resulted in patients being released earlier from hospitals for convalescence at home. This proposal would allow home health agency registered nurses to carry an emergency kit with stock items upon a written or oral prescription; the provisions would call for a locked, portable unit with only specified drugs and a method for inventory control. Following discussion, the Board directed its Executive Officer to draft appropriate regulatory language; the Board expects to hold a public hearing on the proposal in January or April.

Also in July, Board President Steve Dibble recommended that the Board ask the Drug Enforcement Agency (DEA) for clarification regarding 21 C.F.R. section 1304.04, which requires pharmacists to stamp a red "C" on the hard copy of controlled substance prescriptions; Dibble noted that such a requirement is unnecessary if the pharmacy is computerized. The Board agreed to ask DEA to allow pharmacies to either maintain a separate electronic file of Schedule III-V controlled substances, or maintain a separate physical file of Schedule III-V controlled substances, or mark all Schedule III-V controlled substance prescriptions with a red "C."

Also at its July meeting, the Board unanimously agreed to seek amendments to Business and Professions Code section 4001 to provide that at least one pharmacist position on the Board shall be filled by a pharmacist who actively dispenses prescriptions in the community or outpatient pharmacy setting.

Finally, the Board elected its 1993–94 officers at the July meeting: Raffi Simonian will serve as President, Janeen McBride was elected Vice-President, and M. Standifer Shreve was chosen as Treasurer.

FUTURE MEETINGS

January 26–27 (location to be announced).
April 27–28 (location to be announced).
July 27–28 (location to be announced).

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 8805 of the Business and Professions Code. The Board's regulations are found in Division 5, Title 16 of the California Code of Regulations (CCR).

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.

The Board consists of thirteen members: seven public members, one licensed land surveyor, four registered Practice Act engineers and one Title Act engineer. Eleven of the members are appointed by the Governor for four-year terms which expire on a staggered basis. One public member is appointed by the Speaker of the Assembly and one by the Senate Rules Committee.

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. The committees function in an advisory capacity unless specifically authorized to make binding decisions by the Board.

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. 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 authorities linked to the civil Practice Act and require an additional examination after qualification as a civil engineer.

On June 15, three new Board members were appointed to replace members whose terms had expired. Megan Matthews, the owner of Matthews Land Company in Santa Cruz, replaced George Warriner as a public member; Myrna Powell, the coordinator of the CALL-3 Consumer Action Program at KCRA-TV in Sacramento, replaced Bill Rupp as a public member; and Quang Vu, a mechanical engineer and president of Dahl, Taylor and Associates, Inc., in Newport Beach, replaced Bob Young as a Practice Act engineer member. The terms of the three new members expire on June 1, 1996.

MAJOR PROJECTS

Board Approves New Examination Administration. At the Board's August 27 meeting, the Examination/Qualification Committee presented its findings and recommendations regarding a proposal that PELS develop and administer its own Special Four examinations (corrosion, quality, safety, and traffic) in-house as a cost-saving measure. *[13:2&3 CRLR 104]* Among other things, the Committee noted that the Board currently develops and administers the structural engineering examination using its own resources and expertise; according to the Committee, the Board could use that expertise to develop and administer the Special Four exams and achieve a cost savings of approximately $23,000 per year. The Committee reported that in-house development and administration would allow the Board more control and flexibility over the examinations, and could allow it to explore options such as on-demand testing or computer-generated examinations. The Committee noted that the disadvantage of developing and administering the examinations in-house is that 40% of one staff member's time would be required to coordinate the examinations.