



are deemed to be synonymous for the purposes of the provisions of law regarding the licensure and regulation of optometry. [S. B&P]

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]

SB 842 (Presley), as amended April 13, would authorize the Board to issue interim orders of suspension and other license restrictions, as specified, against its licensees. [A. CPGE&ED]

■ LITIGATION

In *California Optometric Association (COA) v. Division of Allied Health Professions, Medical Board of California*, No. 531542 (filed January 11 in Sacramento County Superior Court), and *Engineers and Scientists of California (ESC), et al. v. Division of Allied Health Professions, Medical Board of California*, No. 706751-0 (filed October 8, 1992 in Alameda County Superior Court), COA and ESC challenge the validity of DAHP's medical assistant regulations.

Following the enactment of SB 645 (Royce) (Chapter 666, Statutes of 1988), it took DAHP over three years to adopt section 1366, Title 16 of the CCR, its regulation defining the technical support services which unlicensed medical assistants (MAs) may perform and establishing standards for appropriate MA training and supervision. During the lengthy rulemaking process, DCA rejected DAHP's proposed regulations twice and the Office of Administrative Law rejected them once before finally approving them in March 1992.

During the rulemaking hearings, COA and the Board of Optometry objected to language in the proposed regulations stating that MAs are permitted to perform "automated visual field testing, tonometry, or other simple or automated ophthalmic testing not requiring interpretation in order to obtain test results, using machines or instruments, but are precluded from the exercise of any judgment or interpretation of the data obtained on the part of the operator." [12:1 CRLR 88-89] However, DAHP overruled the objections and included this language in its final regulations. COA and ESC claim that section 1366 is invalid because the conduct authorized is beyond the scope of DAHP's authority and conflicts with DAHP's enabling statutes; further, it conflicts with Business and Professions Code sections

3040 and 3041 (which define the practice of optometry and prohibit unlicensed persons from engaging in optometry). At this writing, the Attorney General has filed an answer on behalf of DAHP; no court hearing has been set.

■ RECENT MEETINGS

At the February 18 meeting, Executive Officer Karen Ollinger reviewed previously-approved budget changes, and reported that the Board is close to covering its costs. Ollinger also announced that the occupational analysis by Human Resource Strategies is proceeding on schedule. [13:1 CRLR 59] Finally, Board President Thomas Nagy, OD, announced that Board member Stephen R. Chun, OD, was named Optometrist of the Year at the annual California Optometric Association Congress.

■ FUTURE MEETINGS

November 17-18 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 accusations and 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 public. The remaining members are pharmacists, five of whom must be active practitioners. All are appointed for four-year terms.

■ MAJOR PROJECTS

Restructuring the Enforcement Unit. As the Board has not augmented its

enforcement program in at least ten years, it spent considerable time at its October 1992 meeting discussing the need to expand the program in light of the increasing number of pharmacies and licensed pharmacists in California, the establishment of new registration programs such as medical device retailers and pharmacy technicians, and changes in the law governing the practice of pharmacy. [13:1 CRLR 60]

At the Board's April 28-29 meeting, Executive Officer Patricia Harris reported that the Governor and the budget subcommittees in both houses of the legislature have tentatively approved a \$703,000 increase to the Board's 1993-94 budget to establish eight additional enforcement unit positions: five inspectors, one supervising inspector, one consumer services representative, and one office technician. The increase in staff will enable the Board to establish a public assistance unit staffed by complaint handlers to assist consumers who call with questions regarding pharmacy services and pharmacists; complaints would be opened by this unit and referred to the inspection staff for investigation. This process is expected to enable Board inspectors to focus their efforts on inspection, not complaint processing. Harris cautioned that the full legislature has yet to pass the Governor's budget, and that the budget augmentation may be revised or deleted.

Board Discusses Request for Regulatory Change. At its January 20-21 meeting, the Board noted that it had received several requests to revise section 1719(c), Title 16 of the CCR, which provides that, as of April 16, 1992, all candidates for the pharmacist licensure examination who are graduates of a foreign pharmacy school (any school located outside the United States) must demonstrate proficiency in English by achieving a score of at least 220 on the Test of Spoken English administered by the Educational Testing Service. Board member Gilbert Castillo noted that the issue was originally discussed by the Board and referred to its Competency Committee for evaluation; the Committee held preliminary hearings and invited public input. Following discussion, the Board unanimously agreed that it is in the best interest of the consumer to continue to require that foreign pharmacy graduates pass the Test of Spoken English.

Board Considers Electronic Transmission of Prescriptions. At the Board's January 20-21 meeting, the Board's Committee on Electronic Transmission and Faxing of Prescriptions recommended that the Board pursue statutory and regulatory changes to allow for the electronic



transmission of prescriptions. Under the Committee's proposal, the term "electronic transmission prescription" would include both electronic image transmission prescriptions (any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber) and electronic data transmission prescriptions (any prescription order, other than an electronic image transmission prescription, which is electronically transmitted from a licensed prescriber to a pharmacy). Under the proposal, if a prescription is electronically transmitted to a pharmacy, the pharmacy must maintain a hard copy. Following discussion, the Board unanimously agreed to pursue statutory and regulatory changes to allow for the electronic transmission of prescriptions; the proposal was subsequently included in the Department of Consumer Affairs' omnibus bill, AB 1807 (Bronshvag) (see LEGISLATION).

Board Considers New Rulemaking Proposals. At its January 20-21 and April 28-29 meetings, the Board discussed a proposal to amend section 1732.3, Title 16 of the CCR, regarding continuing education (CE) courses. Among other things, section 1732.3 currently provides that a recognized CE provider's coursework shall be valid for two years following the initial Board approval; the Board is considering amending this section to provide that such coursework would be valid for up to three years following Board approval. This modification was suggested by the Board's Continuing Education Committee in recognition of the American Council on Pharmaceutical Education's policy allowing its approved CE providers to use an expiration date of three years for some courses. The Board is expected to pursue this regulatory change; at this writing, however, the Board has not published notice of its intent to do so in the *California Regulatory Notice Register*.

At its April 28-29 meeting, the Board discussed the possibility of amending section 1717(a), Title 16 of the CCR, which specifies that no medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia; section 1717(a) provides for an exception to the rule and designates one type of prescription container which may be reused under specific conditions, including the condition that the container be used for the same drug for the same patient. The Board is expected to pursue an amendment to section 1717(a) to include an additional type of prescription container which may be reused under specific circumstances; at this writing, however, the Board has not published notice of its

intent to do so in the *California Regulatory Notice Register*.

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

• **Compounding for Prescriber Office Use.** The Board's adoption of new sections 1716.1 and 1716.2, Title 16 of the CCR, defines the quantity of compounded medication which a pharmacist may provide to a prescriber for office use, and specifies the minimum types of records that pharmacies must keep when they furnish compounded medication to prescribers in quantities larger than required for the prescriber's immediate office use or when a pharmacy compounds medication for future furnishing. [13:1 CRLR 61]

The Office of Administrative Law (OAL) originally disapproved this regulatory action in June 1992 on the basis that it failed to meet the clarity and necessity standards of the Administrative Procedure Act. The Board amended its proposal at its October 1992 meeting to resolve OAL's concerns, and released the modified language for a fifteen-day public comment period in December. The Board then resubmitted the proposal to OAL, which approved the action on April 7.

• **Medical Device Retailers' Locked Storage Requirements.** On January 19, OAL approved the Board's adoption of new section 1748.2, Title 16 of the CCR, which provides that a medical device retailer (MDR) may leave a dangerous device in a retail area of the MDR premises during an absence of an exemptee if the item is of sufficient size and weight that removal from the premises would be difficult. Any dangerous devices designated for display under section 1748.2 shall be specifically listed in the written policies and procedures of the MDR. [13:1 CRLR 62]

However, OAL disapproved the Board's proposed adoption of section 1748.1, Title 16 of the CCR, also regarding MDR locked storage; among other things, the original version of section 1748.1 would have provided that dangerous devices shall be furnished from locked storage only upon the oral or written authorization of an exemptee to an employee of the MDR who operates the service vehicle. OAL found that the Board lacked statutory authority to allow a non-licensed person to dispense dangerous devices at the direction of an exemptee in this manner. The Board subsequently modified the language, released it for a fifteen-day public comment period, and resubmitted it to OAL; among other things, the modified version provides that dangerous devices

shall be furnished from locked storage only by an exemptee. OAL approved the Board's adoption of section 1748.1 on May 12.

• **Patient Consultation Regulations.** On March 3, OAL approved the Board's amendments to sections 1707.1 and 1707.2, and its adoption of new section 1707.3, Title 16 of the CCR, which revise the Board's patient consultation requirements to comply with federal Omnibus Budget Reconciliation Act of 1990 (OBRA 90) standards. [13:1 CRLR 61]

However, at its April meeting, the Board discussed further amendments to section 1707.2. Subsection (a) of section 1707.2 requires a pharmacist to provide oral consultation to a patient or his/her agent, upon request or whenever the pharmacist deems it warranted. Under subsection (b), a pharmacist must provide oral consultation whenever the prescription drug has not previously been dispensed to a patient, and whenever a prescription drug not previously dispensed to a patient in the same dosage, form, strength, or with the same written directions is dispensed by the pharmacy. Subsection (e) states that, notwithstanding the requirements in (a) and (b), that a pharmacist is not required to provide oral consultation when a patient or the patient's agent refuses such consultation. According to the Department of Health Services (DHS), the Board's current regulations may not be in compliance with OBRA 90, which apparently requires pharmacists to offer an oral consultation—an element which the Board's regulations lack. Following discussion, the Board unanimously agreed to leave its consultation regulations as they are, and to seek clarification from DHS and the Health Care Finance Administration (HCFA) on this issue.

LEGISLATION

AB 260 (W. Brown), as amended April 12, and **SB 1048 (Watson)**, as introduced March 5, would each establish the Clean Needle and Syringe Exchange Pilot Project, and would authorize pharmacists, physicians, and certain other persons to furnish hypodermic needles and syringes without a prescription or permit as prescribed through the pilot project. [A. Floor; S. H&HS]

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 and 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. As amended April 26, this bill would instead define a "hospital pharmacy" to mean a pharmacy licensed by the Board and located within a general acute care hospital, as defined, acute psychiatric hospital, as defined, or a special hospital, as defined in accordance with certain requirements. *[S. B&P]*

SB 842 (Presley), as amended April 13, would permit the Board to issue interim orders of suspension and other license restrictions, as specified, against its licensees. *[A. CPGE&ED]*

AB 1807 (Bronshvag), as amended May 3, would require a pharmacy, except a nonresident pharmacy, that ships or mails prescriptions to residents of California to provide certain toll-free telephone service, and written notification of the availability of that service 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, for these purposes, to include electronically transmitted prescriptions, as defined.

Under existing law, it is a misdemeanor for any person to falsely represent himself/herself to be a person who can

lawfully prescribe a drug, or to falsely represent that he/she is acting on behalf of a person who can lawfully prescribe a drug, in a telephone communication with a registered pharmacist. This bill would also make it a misdemeanor to make these false representations by electronic communication. *[A. W&M]*

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 would additionally require the container label to identify the condition for which the drug was prescribed if the patient requests it and the prescription identifies the condition. *[A. W&M]*

AB 2155 (Polanco). Existing law requires prescription blanks in triplicate to be issued by the Department of Justice and furnished to any practitioner authorized to write a prescription for Schedule II controlled substances. Existing law prohibits the Department of Justice from issuing more than 100 triplicate prescription blanks to any authorized practitioner. As introduced March 5, this bill would establish the Medical and Pharmacy Ad Hoc Committee within the Department of Consumer Affairs, and require it to study all matters regarding the Department of Justice's ongoing monitoring and oversight activities of prescriptions for Schedule II controlled substances and advise the Attorney General on these matters. It would require the Committee membership to consist of a pharmacist and various persons who are engaged in prescribed specialties of medical practice. *[A. W&M]*

SB 432 (Greene). Existing law generally requires every prescription for a controlled substance classified in Schedule II to be in writing. One exception to this general requirement is when failure to issue a prescription for a controlled substance classified in Schedule II 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; under the circumstances, the prescription may be dispensed upon an oral prescription. As amended May 19, this bill would instead 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 prescription. *[S. Jud]*

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 California 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 California 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 April 21, this bill would require the Board to adopt regulations that apply the same requirements or standards for oral consultation between the pharmacy and the patient, under certain circumstances, to a nonresident pharmacy as are applicable to a pharmacy that has been issued a permit by the Board. *[S. Appr]*

SB 1153 (Watson). Existing law provides for the Medi-Cal program administered by DHS, pursuant to which medical benefits, including certain prescription drugs, are provided to public assistance recipients and certain other low-income persons. As amended April 28, this bill would establish the Drug Utilization Review Board to review, evaluate, and make recommendations to DHS on retrospective drug utilization reviews, standards applications, educational interventions, and drug utilization program profile development. This bill would also require the Board of Pharmacy, with the advice of the Drug Utilization Review Board, to adopt and publish guidelines and standards to be used by pharmacists in their counseling of Medi-Cal recipients. *[S. Appr]*

AB 2020 (Isenberg), as amended May 18, would, among other things, authorize optometrists to use, prescribe, and dispense specified pharmaceutical compounds to a patient. This bill would also 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. *[A. Floor]*

SB 1136 (Kelley). Under the Medi-Cal program administered by DHS, pharma-



cists are reimbursed for covered drugs based on prices determined by the Department; existing law authorizes pharmacists to select a generic drug type, as defined, over a name brand drug product when filling a prescription, unless the prescriber specifies otherwise. As amended May 5, this bill would require that a generically substitutable product shall not be reimbursable if the DHS Director determines that a product from a company subject to rebates as an innovator company under federal law is lower in net cost to the state than a generically substitutable product not subject to the rebates; it would require the Director to notify pharmacists of these determinations. [S. Appr]

■ LITIGATION

Plaintiffs are appealing the trial court's ruling in *Californians for Safe Prescriptions v. California State Board of Pharmacy*, No. BS019433 (Dec. 15, 1992), which held that the Board followed and complied with the Administrative Procedure Act in promulgating and adopting its pharmacy technician regulations. [13:1 CRLR 62] Plaintiffs, members of a non-profit organization consisting of approximately 5,000 licensed pharmacists, filed a notice of appeal on January 5; at this writing, no date for oral argument has been set.

On February 18, the California Supreme Court granted the pharmacy's petition for review of the Fifth District Court of Appeal's decision in *Huggins v. Longs Drug Stores California, Inc.*, No. F016033 (Dec. 4, 1992). The appellate court held 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 directed at the parent caregivers, which may allow the caregivers to recover damages for negligent infliction of emotional distress. [13:1 CRLR 63]

■ RECENT MEETINGS

At the Board's January 20-21 meeting, the Board considered its Long-Term Care Committee's recommendation that it adopt proposed standards for pharmacies servicing long-term care facilities. Among other things, the standards state the obligations of pharmacies servicing such facilities, which include establishing procedures for obtaining and providing necessary drugs on a timely manner, including on a 24-hour basis, and for the availability of emergency drug supplies, in conformity with federal and state laws and regulations, and maintaining drug information services available to facility nursing staff, prescribers, other physi-

cians, and the facility's consultant pharmacist. Following discussion, the Board unanimously adopted the standards.

■ FUTURE MEETINGS

October 6-7 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 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.

At its January 29 meeting, PELS selected Harold L. Turner as its new Executive Officer; Turner, formerly California's Deputy Auditor General, was hired to replace Darlene Stroup, who resigned in August 1992. [13:1 CRLR 64] In February, Governor Wilson announced the appointment of Stephen H. Lazarian as PELS' new public member; Lazarian is a self-employed attorney from Pasadena who formerly served on the Contractors State License Board from 1985-92 and was its chair from 1988-89.

■ MAJOR PROJECTS

Proposed Elimination of Title Act Protection for Traffic Engineers. At its March 12 meeting, PELS discussed the possible elimination of Title Act coverage for traffic engineering. The proposed action is opposed by S.E. Rowe, General Manager of the City of Los Angeles' Department of Transportation, who contends that title protection for traffic engineering is necessary primarily because of its "extreme implications in saving lives and reducing injuries and property damage to the public." If protection is eliminated, Rowe contends that a registered civil engineer with little or no experience in traffic engineering could make traffic recommendations on behalf of his/her clients. Department of Consumer Affairs (DCA) legal counsel Don Chang noted that preparation of certain traffic mitigation or worksite traffic control plans does not constitute the practice of civil engineering. Board President Larry Dolson referred the matter to a special committee to further consider the scope of Title Act coverage.

At PELS' April 23 meeting, Board member Ted Fairfield reported that, based on a review of current National Council of Examiners for Engineering and Surveying (NCEES) test questions and most college curricula, there appear to be inconsistencies between the definition and educa-