1479 (Burton), which would have specified that, for purposes of the Robert W. Crown California Children's Services Act, any condition designated by the Director of Health Services as treatable by an ophthalmologist is deemed treatable by an optometrist if the condition is within the scope of practice of optometry.

RECENT MEETINGS

At its August 24 meeting, the Board reported on a discussion with the Medical Board of California's (MBC) Division of Allied Health Professions regarding existing law as it relates to the relationship between optometrists and opticians sharing office space. Business and Professions Code section 655 prohibits optometrists and opticians from entering into any "membership, proprietary interest, co-ownership, landlord-tenant relationship, or any profit-sharing arrangement in any form, directly or indirectly...." The Board of Optometry interprets section 655 as prohibiting an optician from sharing office space with an optometrist. However, the Medical Board's Registered Dispensing Optician Program (RDO) contends that, so long as there is no violation of section 655, an optician may share office space with an optometrist.

RDO further contends that no consumer harm can result from an optician sharing an office with an optometrist, and that it is to consumers' benefit to have an optometrist in the same office. According to Attorney General's Opinion No. 80-417 (March 4, 1981), the legislature intended to prohibit landlord-tenant business relationships between optometrists and opticians "in order to eliminate the potential conflicts of interest inherent in them." All of the agencies involved are expected to further investigate the issues involved; MBC is considering whether to request a second legal opinion in light of repeated inquiries regarding the propriety of office-sharing relationships.

FUTURE MEETINGS

To be announced.

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

"Operation Goldpill" Targets Pharmacy Fraud. On June 30, U.S. Attorney General William Barr and FBI Director William Sessions announced that more than 1,000 FBI agents and 120 other federal law enforcement officers were making arrests, conducting searches, and seizing assets in over 50 cities nationwide, including San Francisco, as part of "Operation Goldpill," the most widespread criminal fraud investigation of the health care industry ever carried out by the FBI. At this writing, federal authorities have seized 56 pharmacies and arrested 82 pharmacists, including one San Francisco-based pharmacist.

Operation Goldpill consisted of a two-year FBI investigation which uncovered illegal diverting, repackaging, and distribution of medications and intentional excessive or false billing by pharmacists which defrauded federally-funded programs and private insurance companies. Among other things, the FBI found evidence that numerous pharmacists were filling prescriptions with generic drugs and charging consumers for more expensive brand name drugs, billing Medicaid and insurance carriers multiple times, and billing for prescriptions never written or filled. The federal government is charging such individuals with fraud and conspiracy offenses which carry prison terms of five to fifteen years and fines up to $250,000.

OAL Approves Pharmacy Technician Regulations. On August 12, the Office of Administrative Law (OAL) approved the Board's amendment to section 1717(c) and adoption of new sections 1793–1793.7, Title 16 of the CCR. This regulatory action establishes qualifications and registration procedures for pharmacy technicians who may assist registered pharmacists with specified tasks, pursuant to AB 1244 (Chapter 841, Statutes of 1991), and should pave the way for implementation of the Board's new oral consultation requirement (*see infra*). *[12:2&3 CRLR 135]*

Patient Consultation Regulations. On May 28, OAL approved the Board's amendments to sections 1707.1 and 1707.2, Title 16 of the CCR, delaying until November 1 the effective date of the Board's patient consultation regulations, which require pharmacists to maintain patient medication profiles for all ongoing patient-consumers and to provide an oral consultation to each patient or patient's agent whenever a new prescription is dispensed, with specified exceptions. *[12:2&3 CRLR 135]*

On August 28, the Board published notice of its intent to further amend sections 1707.1 and 1707.2, and to adopt section 1707.3, regarding the patient consultation requirements. According to the Board, these proposed changes would align existing California pharmacy regulations with provisions of the federal Omnibus Budget Reconciliation Act of 1990 (OBRA 90) which establish patient consultation by pharmacies as a requirement for Medicaid-covered patients and specifies required and permissive duties for pharmacists in this regard.

As of November 1, section 1707.1 requires a pharmacy to maintain a patient medication profile for each patient it serves and specifies certain elements this profile shall contain for each patient and each prescription. Section 1707.1 also specifies the retention period for the patient's medication profile. The Board's proposed amendments to section 1707.1 would add several express identifiers required by OBRA 90, such as the patient's telephone number, date of birth or age, and gender. Also, section 1707.1(a)(1)(C) would be amended to require that the patient medication record include any of the following which may relate to drug therapy: patient allergies, idiosyncracies, all prior and current medications including non-prescription medications and relevant devices, or medical conditions which are communicated by the patient or the patient's agent.

As of November 1, section 1707.2 clarifies the duty to consult and the notice to consumers regarding the consultation, which must be conspicuously posted in each pharmacy subject to Business and Professions Code section 4333. The

Board's proposed amendments to section 1707.2 would do the following:

–require, in situations where the patient or the patient's agent is not present to receive consultation from a pharmacist, that the patient or agent receives written notice of his/her right to request consultation and a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record;

–require an amplification of the precautions and relevant warnings that must be given during consultation (*i.e.*, that the pharmacist must advise the patient of common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered); and

–incorporate optional elements of a consultation which OBRA 90 mandates if warranted in the professional judgment of the pharmacist, such as the name and description of the medication, the route of administration, dosage form, dosage, and duration of drug therapy, any special directions for use and storage, precautions for preparation and administration by the patient, prescription refill information, appropriate actions required if common severe side or adverse effects occur, and action to be taken in the event of a missed dose.

The Board's proposed new section 1707.3 would make the current regulations consistent with the prospective drug utilization review requirements of OBRA 90, by requiring that a pharmacist perform a review of drug therapy and the patient medication record before each prescription is filled or delivered to the patient or the patient's agent. This review must include screening for severe potential drug therapy problems.

The Board was scheduled to hold a public hearing on these proposed regulatory actions on October 14 in Los Angeles.

In a related matter, at its July 28 meeting, the Board discussed its concern over the delivery of medications to patients through the mail, and how consumers receiving such medication would receive the mandated patient consultation. To address these concerns, the Board has drafted proposed amendments to Business and Professions Code section 4050.2 and to section 1707.2, Title 16 of the CCR. The regulatory changes to section 1707.2 would provide that when a patient or agent is not present to receive the required oral consultation, including but not limited to a prescription that is shipped by mail, the pharmacist shall ensure that the patient receives written notice of his/her right to request consultation and a telephone number by which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record. At this writing, the Board has not yet published notice regarding this regulatory revision in the *California Regulatory Notice Register*.

The proposed legislative change to Business and Professions Code section 4050.2 would require any pharmacy which ships or mails prescriptions to a patient in California to provide a toll-free service for a patient to contact a pharmacist who has access to that patient's records; this telephone service would be required to be available during specific periods of the day and a minimum number of hours during the week. The Board may seek to have this change included in the Department of Consumer Affairs' omnibus bill during the 1993–94 legislative session.

Board Exempts Kaiser From Patient Consultation Requirement. On June 26, Kaiser Permanente and the University of Southern California's School of Pharmacy submitted a joint proposal to the Board which would exempt Kaiser from implementing the Board's patient consultation requirement in all its facilities, and instead allow it to implement a research model. Kaiser's proposal outlined two complementary controlled trials designed to compare the effects of three different consultation and pharmacy practice models on patient health outcomes, medication compliance, and resource utilization. The three models Kaiser proposed to test are the "status quo" prior to November 1 (pharmacist consultation only when deemed necessary by a pharmacist or upon a patient's request), mandatory pharmacist consultation for new or changed prescriptions, and an alternative model which provides pharmaceutical care to patients at high risk for drug-related problems. Section 1731, Title 16 of the CCR, authorizes the Board to waive any of its regulations as to an accredited school of pharmacy recognized by the Board if the dean of the school of pharmacy submits—and the Board approves—an experimental plan or program regarding new and innovative methods for drug handling, teaching, research, or to develop new and better methods or concepts involving the ethical practice of medicine. Any such plan or program approved by the Board shall have definite time limitations; progress reports must be filed as required by the Board. At its July 28–29 meeting, the Board approved the USC/Kaiser proposal, thus granting Kaiser an exemption from the Board's new patient consultation regulations.

OAL Disapproves Compounding for Office Use Regulations. On June 22, OAL disapproved the Board's proposal to adopt new section 1716.1 and 1716.2, Title 16 of the CCR. Section 1716.1 would define the quantity of compounded medication which a pharmacist may furnish to a prescriber for office use under Business and Professions Code section 4046(c)(1), and section 1716.2 would specify 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. *[12:2&3 CRLR 136]*

OAL disapproved the proposed sections on the basis that they failed to meet the clarity and necessity standards of the Administrative Procedure Act (APA); OAL also found that the Board failed to respond adequately to comments, as is required by the APA. Specifically, OAL determined that the regulations use undefined, ambiguous, and confusing terms; fail to specify the standards which will apply; and differ from the Board's stated explanation of intent. Also, OAL found that the Board did not provide the factual basis for limiting supplies of compounded medications to 180 days, in packaging for 72 hours or less, or for limiting prescribers to furnishing no more than 72-hour supplies to their patients.

The Board has 120 days from the date of OAL's disapproval to amend and resubmit the rulemaking file to OAL for review.

Pharmacist-in-Charge Regulations. On May 27, the Board held a public hearing on its proposal to amend section 1709.1, Title 16 of the CCR, which would allow a pharmacist to be the pharmacist-in-charge at two pharmacies if only one of these pharmacies is open at any given time and if that pharmacist is the only pharmacist at each pharmacy. The Board received no written or oral comments regarding this proposed amendment, and unanimously adopted it. This proposal awaits review and approval by OAL. *[12:2&3 CRLR 136]*

Other Regulatory Action. The following is an update on other regulatory changes recently pursued by the Board *[12:2&3 CRLR 136]*:

• ***Licensure of Drug Wholesalers.*** On June 22, OAL approved the Board's regulatory amendments to section 1780, Title 16 of the CCR, which change California's requirements for drug wholesalers so that they meet or exceed the standards of the federal government under the Prescription Drug Marketing Act of 1987.

• ***Medical Device Retailers Locked Storage***. The rulemaking file regarding the Board's proposed adoption of new sections 1748.1 and 1748.2, Title 16 of the CCR, regarding the proper storage of dangerous devices at medical device retailer (MDR) retail sites, and the delivery of devices by MDRs to patients after hours or in emergency situations, awaits review and approval by OAL.

• ***Partial Filling of Schedule II Prescriptions***. On September 3, OAL approved the Board's adoption of new section 1745, Title 16 of the CCR, which permits the partial filling of Schedule II controlled substance prescriptions for inpatients of skilled nursing facilities or for terminally ill patients.

LEGISLATION

The following is a status update on bills reported in detail in CRLR Vol. 12, Nos. 2 & 3 (Spring/Summer 1992) at pages 136–37:

SB 2044 (Boatwright) declares legislative findings regarding unlicensed activity and authorizes all Department of Consumer Affairs boards, bureaus, and commissions, including the Board of Pharmacy, to establish by regulation a system for the issuance of an administrative citation to an unlicensed person who is acting in the capacity of a licensee or registrant under the jurisdiction of that board, bureau, or commission. This bill was signed by the Governor on September 28 (Chapter 1135, Statutes of 1992).

AB 3415 (Tucker) excludes from the definition of "dangerous devices" any prosthetic or orthopedic devices that do not require a prescription. This bill also deletes an existing provision of law which requires that any retailer who sells prosthetic or orthotic dangerous devices on the premises have a prescribed fitting room under certain circumstances. This bill was signed by the Governor on July 6 (Chapter 121, Statutes of 1992).

AB 3286 (Tucker) permits a medical device retailer to dispense, furnish, transfer, or sell a dangerous device to a licensed physical therapist. This bill was signed by the Governor on July 18 (Chapter 271, Statutes of 1992).

AB 2638 (Boland) would have provided that a medical device retailer may dispense, furnish, transfer, or sell a dangerous device to a licensed chiropractor. This bill was vetoed by the Governor on September 26.

AB 2525 (Brown) and **SB 1418 (Moore)** each would have established the Clean Needle and Syringe Exchange Pilot Project, and would have authorized pharmacists, physicians, and certain persons authorized under the pilot project to furnish hypodermic needles and syringes without a prescription or permit as prescribed through the pilot project. These bills were vetoed by the Governor on September 30.

AJR 63 (Bronzan) urges the President and Congress to authorize the FDA to investigate a new transitional nonprescription drug category available only through licensed pharmacists, with the goal of decreasing the time needed for the FDA to approve a drug for over-the-counter status. This resolution was chaptered on July 23 (Chapter 83, Resolutions of 1992).

AB 3133 (Hunter), among other things, specifies that no provision of law prohibits the sale of dangerous devices to licensed home health agencies and licensed hospices, as defined. This bill was signed by the Governor on September 28 (Chapter 1104, Statutes of 1992).

AB 2743 (Frazee) amends Business and Professions Code section 4038 to delete the exemption of pharmacies and licensed manufacturers from the definition of the term wholesaler, and deletes specific provisions providing for payment of costs of investigations and disciplinary proceedings with respect to pharmacists. This bill was signed by the Governor on September 30 (Chapter 1289, Statutes of 1992).

SB 664 (Calderon). Existing law prohibits pharmacists, among others, from charging, billing, or otherwise soliciting payment from any patient, client, customer, or third-party payor for any clinical laboratory test or service if the test or service was not actually rendered by that person or under his/her direct supervision, unless the patient is apprised at the first solicitation for payment of the name, address, and charges of the clinical laboratory performing the service. This bill also makes this prohibition applicable to any subsequent charge, bill, or solicitation. This bill was signed by the Governor on June 4 (Chapter 85, Statutes of 1992).

AB 1226 (Hunter) repeals Business and Professions Code section 4047.7, which requires the Director of the Department of Health Services to establish a formulary of generic drug types and drug products which the Director determines demonstrate clinically significant biological or therapeutic inequivalence and which, if substituted, would pose a threat to the health and safety of patients receiving medication if that medication is substituted by a pharmacist in lieu of a brand name drug prescribed by a prescriber. This bill was signed by the Governor on August 16 (Chapter 485, Statutes of 1992).

AB 855 (Hunter) requires that a general acute care hospital and acute psychiatric hospital establish and implement a written policy to ensure that each of its patients receives prescribed information from a pharmacist or registered nurse unless already provided by a physician regarding medications received at the time of discharge. This bill was signed by the Governor on September 26 (Chapter 985, Statutes of 1992).

SB 917 (Kopp) would have required certain health care service plans that propose to offer a pharmacy benefit or change their relationship with pharmacy providers to give written or published notice to pharmacy service providers of the plan's proposal, and give those providers an opportunity to submit a bid to participate in the plan's panel of providers on the terms proposed. This bill was vetoed by the Governor on July 29.

AB 819 (Speier) was substantially amended and is no longer relevant to the Board.

The following bills died in committee: **SB 1986 (Marks)**, which would have prohibited disability insurers that provide coverage for pharmaceutical services from requiring their insureds or persons covered by the policy to obtain pharmaceutical services exclusively from nonresident pharmacies, and would have provided that insurers may not impose any limitations on coverage of pharmaceutical services provided by in-state pharmacies that are not also imposed on nonresident pharmacies; and **AB 2070 (Isenberg)**, which would have generally made it unlawful for specified healing arts licensees to refer a person to any laboratory, pharmacy, clinic, or health care facility solely because the licensee has an ownership interest in the facility.

LITIGATION

On June 24, the California Supreme court denied review of the Second District Court of Appeal's opinion in ***People v. Doss***, No. B046265 (Apr. 1, 1992), in which the appellate court ruled that Business and Professions Code section 4230 does not confer blanket immunity on a pharmacist to possess controlled substances for any purpose on pharmacy premises. *[12:2&3 CRLR 137]*

RECENT MEETINGS

At its May 27–28 meeting, the Board elected Stephen E. Dibble and Gilbert Castillo to be Board president and vice-president, respectively. These officers will each serve one-year terms.

Also at its May 28–29 meeting, the Board agreed to pursue a budget change

proposal (BCP) for the 1993–94 fiscal year to redesign and augment the Board's enforcement unit. Specifically, the Board's BCP would request $333,000 in order to add three pharmacy inspectors and one consumer services representative, and to make permanent a limited-term office technician position established on July 1.

FUTURE MEETINGS

January 20–21 in Sacramento.
April 28–29 in Sacramento.
July 28–29 in Sacramento.

BOARD OF REGISTRATION FOR PROFESSIONAL ENGINEERS AND LAND SURVEYORS

Interim Executive Officer: Curt Augustine
(916) 920-7466

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.

MAJOR PROJECTS

PELS Searches for New Executive Officer. In late August, PELS Executive Officer Darlene Stroup announced her decision to step down as EO but to continue working for the Board on a "special assignment" until October 31. Following that announcement, PELS President Larry Dolson appointed Curt Augustine to serve as PELS' Interim EO until the Board can find a permanent replacement for Stroup. At PELS' September 25 meeting, Dolson departed from the meeting agenda and failed to introduce Augustine until well into the meeting; furthermore, Dolson did not discuss the details of Stroup's "special assignment" nor how the Board intends to pay for the services of two executive officers until Stroup's resignation becomes effective.

At its September 25 meeting, the Board devoted substantial time to discussing the preferred qualifications for its new executive officer. Many Board members expressed interest in hiring a registered engineer; others focused on the need to hire an individual with substantial administrative experience. The Board decided to solicit applicants who demonstrate ability in either area.

Board Awards Professional Land Surveyor Consultant Contract. At PELS' June 5 meeting, Board members continued to debate whether PELS should use the bidding procedures specified in the "Little Brooks Act," Government Code section 4525 *et seq.*, in soliciting applicants for its professional land surveyor consultant position. The Little Brooks Act provides a procedure for selecting private architectural, landscape architectural, engineering, environmental, land surveying, and construction project management services for public projects on the basis of demonstrated competence and professional qualifications necessary for satisfactory performance of the job, as opposed to selection on the basis of minimum competence and competitive bidding. Although the Act does not indicate those situations when its bidding procedures must be used, Government Code section 4529 does provide that the Act "shall not apply where the state or local agency head determines that the services needed are more of a technical nature and involve little professional judgment and that requiring bids would be in the public interest." The alternative procedure for awarding contracts involves the release of a request for proposals (RFP). Under the RFP process, bids are evaluated to determine if they meet the minimum qualifications; thereafter, the contract is awarded to the lowest bidder who possesses the minimum qualifications.

PELS determined that its land surveyor consultant would—among other things—review complaints to determine whether a violation of the Professional Land Surveyors' Act has occurred; serve as a witness for the Board in disciplinary hearings against land surveyors; respond to requests for information and interpretation of the Act; review and coordinate land surveyor examination appeals; act as in-house consultant for the Board staff relative to land surveying questions; and develop and monitor regulatory packages relating to land surveying. The job description prepared by the Board established as 50% of the evaluation criteria "land surveying experience and knowledge of professional methods, procedures, requirements, and standards." However, Department of Consumer Affairs (DCA) legal counsel Don Chang advised the Board that the services called for in the job description would be of a technical nature rather than the professional practice of land surveying, and that compliance with the RFP procedure, as opposed to the Little Brooks Act, was appropriate. Thus, PELS issued an RFP; however, the Board received only two proposals, only one of which scored above the minimum qualifying score. At its December 1991 meeting, PELS decided to reject the bids received pursuant to the RFP process and directed staff to rewrite the proposal to include consideration of the Little Brooks Act criteria. The Board took this action despite that fact that it has