SB 613 (Calderon). Existing law requires a registered optometrist who temporarily practices optometry outside or away from his/her regular place of practice to deliver to each patient there fitted or supplied with glasses a specified receipt. As amended July 10, this bill would instead require a registered optometrist to furnish to each patient there fitted or supplied with prescription spectacle lenses a specified receipt. This two-year bill is pending in the Assembly Health Committee.

AB 1046 (Tucker), as introduced March 4, adds optometrists to the list of individuals required to report any evidence of abuse of an elderly or dependent person. This bill was signed by the Governor on July 27 (Chapter 197, Statutes of 1991).

RECENT MEETINGS:

At its August meeting, the Board discussed the status of its consumer education pamphlet, which was turned over to the Administration Committee for revision because it fails to address consumer concerns and questions that are received at the Board's office. Executive Officer Karen Ollinger will draft recommendations for language that adequately addresses consumer needs.

Also in August, Karen Ollinger announced that the Board would be hiring an additional staff member to assist in processing the backlog of discipline cases pending at the Board.

FUTURE MEETINGS:

February 20–21 (location undecided).

May 29–30 (location undecided).

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:

Investigation of Fee Agreements Between Physicians and Home Health Agencies. For several months, a Board subcommittee has been investigating concerns over fee arrangements between physicians and home health agencies; last spring, the subcommittee submitted the evidence it had compiled and its findings to the Attorney General's office. (See CRLR Vol. 11, No. 3 (Summer 1991) p. 101; Vol. 11, No. 2 (Spring 1991) p. 97; and Vol. 11, No. 1 (Winter 1991) p. 82 for background information.)

On July 22, Deputy Attorney General William Marcus replied with a preliminary opinion that such arrangements ("kickbacks") probably violate Business and Professions Code section 650. In reaching his conclusion, Marcus evaluated various sample contracts between physicians and home health agencies which call for payment from the home health agency to the physician/prescriber. Marcus noted that the obligations of the prescriber under most of the contracts were "simply those which the primary physician would ordinarily be expected to provide his or her patient. . . ." In other words, "the physician is being paid by the home health agency for what he or she is already, as the patient's physician, obligated to provide." If this is the case, then the physician is probably being paid for the referral, and that is illegal under section 650.

Marcus recommended that the Board identify and discipline violators as appropriate, and work with other licensing boards to enforce the law against their licensees. In response, the Board is considering drafting regulatory proposals which would require the disclosure of contracts between home health care companies and health care consultants.

In a related issue, AB 819 (Speier) and AB 2070 (Isenberg) would amend section 650 to generally make it unlawful for licensed health professionals to refer a person to any laboratory, pharmacy, clinic, or health care facility in which the referring party has an ownership interest. (*See infra* LEGISLATION.)

Federal Policy Guide Regarding New Drug Repacking. In its Compliance Policy Guide 7132c.06, the federal Food and Drug Administration (FDA) states that "each step in the manufacture and processing of a new drug or antibiotic, from handling of raw ingredients to final packaging, must be approved by FDA, whether carried out by the original manufacturer or by some subsequent handler or repacker of the product. Pharmacists are not exempt from these statutory requirements; however, the agency regards mixing, packaging, and other manipulations of approved drug [sic] by licensed pharmacists, consistent with the approved labeling of the product, as an approved use of the product if conducted within the practice of pharmacy, *i.e.*, filling prescriptions for identified patients." In a July 16 letter from the Board to the FDA, the Board sought clarification as to whether manipulation by a pharmacy of an FDA-approved drug constitutes manufacturing (which requires registration as a manufacturer) when "(1) it is contrary to the manufacturer's package insert, or (2) it is prepared for a specific patient in advance, but in anticipation of, a prescription, or (3) it is prepared in anticipation of receiving one or more prescriptions for the product, as manipulated, but for a specific patient." At this writing, the Board has not yet received a response from FDA.

Compounding for Office Use. At its July 31 meeting, the Board continued the regulatory hearing on proposed sections 1716.1 and 1716.2, regarding the definition of the "reasonable quantity of compounded medication" which a pharmacist may furnish to a prescriber for office use under Business and Professions Code section 4046(c)(1). (See CRLR Vol. 11, No. 3 (Summer 1991) p. 102; Vol. 11, No. 2 (Spring 1991) p. 98; and Vol. 11, No. 1 (Winter 1991) p. 83 for background information.) Proposed new section 1716.1 would clarify the definition of the terms "reasonable quantity," "compounded," and "prescriber office use" as referenced in Business and Professions Code section 4046(c)(1). Proposed new 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.

At the July meeting, the Board made minor changes to the proposed language which, among other things, allows consideration of stability studies when preparing quantities for use over more than six months, and includes repackaging in the definition of compounding. The Board subsequently released the new language for a 15-day comment period; comments received were scheduled to be reviewed at the Board's October meeting. At that meeting, the Board planned to finalize the proposed language and adopt the regulatory changes, subject to approval by the Department of Consumer Affairs and the Office of Administrative Law (OAL).

Partial Filling of Schedule II Prescriptions for the Terminally Ill. In September, the Board published notice of its proposal to adopt section 1745, Title 16 of the CCR. The proposed regulation would permit partial filling of Schedule II controlled substance prescriptions when (1) the prescription is at least partially filled within seven days of the date of issue; (2) the prescription is for a terminally ill patient; (3) the patient is in chronic pain; (4) the pharmacist records the date and amount of each partial filling in a readily retrievable form and on the original triplicate prescription, and his/her initials; (5) no portion of the prescription is dispensed more than 30 days from the date of issuance of the prescription; and (6) the original triplicate prescription is forwarded to the Department of Justice at the end of the month in which it has been completely filled or the month in which the prescription has been cancelled or discontinued by the death of the patient.

According to the Board, this proposed regulation is consistent with a new federal rule, specifically C.F.R. section 1306.13(b), which took effect July 3, and would clarify when and how a pharmacist may partially fill a prescription for Schedule II drugs. The Board was scheduled to hold a public hearing on proposed section 1745 on October 16.

Part-Time Pharmacists-in-Charge. At its July 31 meeting, the Board discussed the possibility of amending section 1709.1, Title 16 of the CCR, which governs the designation of the pharmacist-in-charge at each pharmacy and prohibits a pharmacist from acting as pharmacist-in-charge at more than one pharmacy. The Board has received inquiries as to whether this rule prevents a pharmacist from being the pharmacist-in-charge at two or more pharmacies when those pharmacies are open only part-time and are not open during the same hours. The Board was scheduled to resume this discussion at its October meeting, in anticipation of a formal amendment proposal.

Regulatory Update. The following is a status update on regulatory changes considered and approved by the Board in recent months (see CRLR Vol. 11, No. 3 (Summer 1991) pp. 101–02; Vol. 11, No. 2 (Spring 1991) p. 98; and Vol. 11, No. 1 (Winter 1991) p. 83 for detailed background information on these changes):

-Continuing Education Advertising. The Board's revision to section 1732.3(d), pertaining to continuing education advertising, was approved by OAL on July 9.

-Processing Times for Application and Registrations. New section 1706.1 specifies the time periods within which the Board will process applications pursuant to the Permit Reform Act of 1981, Government Code section 15374 *et seq.* Section 1706.1 was approved by OAL on July 22.

-Minimum Standards for Drug Wholesalers. At its May meeting, the Board adopted proposed amendments to section 1780, regarding minimum standards for drug wholesalers, subject to minor modifications. The modified language was released for a 15-day comment period commencing on June 18; no comments were received. At this writing, the proposed amendments await review and approval by OAL.

LEGISLATION:

AB 1188 (Speier), as amended May 13, subjects Schedule IV drugs to the California Uniform Controlled Substances Act, thus requiring that prescriptions for these drugs have the signature, date, and other specified information wholly written in ink or indelible pencil in the handwriting of the prescriber. This bill also prohibits a person from refilling a Schedule III or IV prescription in an amount which exceeds a 120-day supply. This bill was signed by the Governor on October 5 (Chapter 592, Statutes of 1991).

AB 2070 (Isenberg), as amended August 19, would generally make 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. However, a licensee could make those referrals if the person referred is the licensee's patient of record, there is no alternative provider or facility available, and the licensee certifies that to delay or forego the referral would cause an unneeded health risk to the patient. This two-year bill is pending in the Senate Rules Committee.

The following is a status update on bills reported in detail in CRLR Vol. 11, No. 3 (Summer 1991) at pages 102–03:

AB 1371 (Wright). Existing law contains a variety of provisions regulating medical device retailers, with which each retailer must comply on or before July 1, 1991. As amended June 13, this bill extends the date for compliance until July 1, 1992 for home health agencies and hospices licensed under specified provisions. During the one-year period of exemption, this bill requires the Board, licensed home health agencies, and licensed hospices to work together to develop language for legislation regarding the handling of dangerous devices by home health agencies and hospices that proposes safeguards necessary to protect the public health and that is least restrictive on the functioning of home health agencies and hospices. This bill was signed by the Governor on July 29 (Chapter 253, Statutes of 1991).

AB 1253 (Baker), as amended April 29, permits the Board to waive any requirement of licensure for pharmacies, hospital pharmacies, and medical device retailers if specified conditions are met. This bill also provides that existing regulations do not prohibit the storage of medical devices in secure central or ward supply areas of specified establishments. This bill was signed by the Governor on October 5 (Chapter 594, Statutes of 1991).

AB 1893 (Lancaster), as amended August 19, revises the applicability of pharmacy laws with respect to certain medical supplies; retitles the Impaired Pharmacist Program, scheduled for repeal on January 1, 1992, as the "Pharmacist Recovery Program" and continues its provisions indefinitely; and extends indefinitely provisions of existing law which authorize the Board, until January 1, 1992, to deny, revoke, or suspend a nonresident pharmacy registration for conduct which causes serious bodily or psychological injury to a resident of this state, subject to specified conditions. This bill was signed by the Governor on October 7 (Chapter 654, Statutes of 1991).

AB 1244 (Polanco) permits a pharmacy technician, as defined, to perform packaging, manipulative, repetitive, or other nondiscretionary tasks while assisting, and while under the direct supervision of, a registered pharmacist. As amended August 19, this bill requires such technicians to be registered with and certified by the Board, with

specified exceptions. This bill was signed by the Governor on October 11 (Chapter 841, Statutes of 1991).

AB 1675 (Margolin), as introduced July 18, would have required the Board to designate a statewide drug information center for the purpose of offering direct telephone assistance or referral to health care providers for any person desiring information relating to prescription drugs. The bill would have required the Board to provide on license renewal forms an opportunity to make voluntary contributions to the statewide drug information center. This bill was vetoed by the Governor on October 13.

SB 594 (Roberti), as amended July 18, would have required the State Department of Alcohol and Drug Programs and the Department of Aging to jointly administer a statewide roundtable to develop a consistent, long-term medication education program model for elderly consumers. This bill was vetoed by the Governor on October 9.

SB 664 (Calderon), as introduced March 5, would prohibit 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, except as specified. This bill is pending in the Senate Business and Professions Committee.

AB 1226 (Hunter), as introduced March 6, would change the standard to be applied by the Director of the Department of Health Services in establishing a formulary of generic drug types and drug products, to require him/her to identify those generic drug types and drug products which, if substituted by a pharmacist for a drug product described by the prescriber by its trade or brand name, may pose a threat to the health and safety of patients. This bill is pending in the Assembly Health Committee.

SB 1033 (Marks), as introduced March 8, would permit pharmacists to manufacture, measure, fit to the patient, sell, and repair medical devices without regard to whether they bear a specified legend relating to a federal prohibition against dispensing without a prescription. This bill is pending in the Senate Business and Professions Committee.

AB 855 (Hunter), as amended July 16, would require a pharmacist to obtain a patient's consent prior to filling a prescription order for a drug product prescribed by its trade or brand name with a substitute drug product. This two-year bill is pending in the Senate Business and Professions Committee.

SB 917 (Kopp), as amended June 11, would require certain health care service plans that propose to offer a pharmacy benefit or change its 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 is pending at the Assembly desk.

AB 819 (Speier). Existing law provides that it is not unlawful for prescribed licensed health professionals to refer a person to a laboratory, pharmacy, clinic, or health care facility solely because the licensee has a proprietary interest or coownership in the facility. As introduced February 27, this bill would instead provide that, subject to specified exceptions, it is unlawful for these licensed health professionals to refer a person to any laboratory, pharmacy, clinic, or health care facility which is owned in whole or in part by the licensee or in which the licensee has a proprietary interest; the bill would also provide that disclosure of the ownership or proprietary interest does not exempt the licensee from the prohibition. This bill is pending in the Assembly Health Committee.

RECENT MEETINGS:

At the Board's July 31 meeting, staff reported that a budget change proposal to create a toll-free telephone number for consumer inquiries has been postponed until the 1993–94 fiscal year. (See CRLR Vol. 11, No. 3 (Summer 1991) p. 103 for background information.) The postponement was attributed to the need to concentrate funding on the Board's enforcement backlog.

FUTURE MEETINGS:

January 22–23 in Sacramento.
March 18–19 in San Diego.
May 27–28 in Sacramento.

BOARD OF REGISTRATION FOR PROFESSIONAL ENGINEERS AND LAND SURVEYORS

Executive Officer: Darlene Stroup (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 President pro Tempore.

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:

Rulemaking Update. At its August 2 meeting, the Board discussed proposed changes to section 472, Division 5, Title 16 of the CCR (fines for citations against a professional engineer or land surveyor). (See CRLR Vol. 11, No. 3 (Summer 1991) p. 104 and Vol. 11, No. 2 (Spring 1991) pp. 100–01 for background information.) The proposed section would authorize the Board to impose fines up to $2,500 and lists seven factors the Executive Officer should