Regulatory Changes. The Board's proposed amendments to section 1502 of its regulations, which would delegate certain Board functions to the executive officer, was not approved by the Department of Consumer Affairs because Board staff failed to file a fiscal impact statement. (See CRLR Vol. 10, Nos. 2 & 3 (Spring/Summer 1990) p. 114 for background information.) Executive Officer Karen Ollinger has withdrawn the proposed rulemaking and expects to resubmit the proposal along with the Board's next rulemaking package.

On January 18, Board legal counsel Steven Martini met with the Board's president and executive officer to sort through current proposals for changes in the Board's regulations. (See CRLR Vol. 11, No. 1 (Winter 1991) p. 81 for background information.) The Board's regulations committee was scheduled to meet on April 10 in Sacramento to continue its comprehensive review of the Board's regulations.

LEGISLATION:

AB 1124 (Frizzelle), as introduced March 5, would establish the right, duty, responsibility, and obligation of a person engaged in the practice of optometry to exercise professional judgment in the performance of his/her duties, including, but not limited to, scheduling, diagnosis, treatment within the scope of practice of optometry, and referral of patients. This bill would also prohibit a health care service plan, and a specialized health care service plan, that provides one or more optometric services, from interfering with the professional judgment of a person engaged in the practice of optometry pursuant to that plan. This bill is pending in the Assembly Health Committee.

AB 1358 (Floyd), as introduced March 7, would specify that a registered optometrist who performs any act constituting the practice of optometry while employed by another optometrist, a physician, or any entity authorized by the laws of this state to employ an optometrist to perform acts constituting the practice of optometry is bound by and subject to the optometry statutes and regulations. This bill would also specify that the Board may suspend or revoke the certificate of registration of, or otherwise discipline, an optometrist who is employed as described above for any of the causes specified in the optometry statutes or regulations. This bill is pending in the Assembly Health Committee.

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 introduced March 4, this bill would instead require a registered optometrist to furnish to each patient there fitted or supplied with prescription lenses a specified receipt. This bill is pending in the Senate Business and Professions Committee.

AB 1046 (Tucker). Existing law requires certain health practitioners, law enforcement officers, and other specified individuals to report any evidence of abuse of an elderly or dependent person. As introduced March 4, this bill would add optometrists to the definition of health practitioner for purposes of the reporting requirements. This bill is pending in the Assembly Human Services Committee.

LITIGATION:

On January 8, the U.S. Court of Appeals for the District of Columbia Circuit denied the Federal Trade Commission's (FTC) petition for rehearing in *California State Board of Optometry v. Federal Trade Commission*, 910 F.2d 976 (D.C. Cir. 1990). This ruling represents a far-reaching victory for the Board; the decision limits the FTC's oversight over anticompetitive activities engaged in or authorized by the Board. (See CRLR Vol. 11, No. 1 (Winter 1991) p. 81; Vol. 10, No. 4 (Fall 1990) pp. 97-98; and Vol. 10, No. 1 (Winter 1990) pp. 88-89 for extensive background information.)

The court let stand its previous decision invalidating the FTC's "Eyeglasses II" rule, which attempted to remove state-imposed restrictions on corporate optometry. The FTC's petition for rehearing argued that the Commission may disallow those regulations issued by state and local governmental entities that lie outside of the "state action" scope of the *Parker v. Brown* exception. However, the court stated that the "Eyeglasses II" rule is "fundamentally flawed" because it is "explicitly directed at state action," in that its "primary focus is on 'state-imposed and state-enforced restrictions.'" The court suggested that the FTC may be able to accomplish some of its purposes without exceeding its rulemaking authority, such as initiating a new proceeding to challenge, within the limits of its proper authority, any practice that it believes to be unfair.

RECENT MEETINGS:

At its February 11 meeting in Sacramento, the Board welcomed two new members, optometrists Gene Calkins and Joe Dobbs, who were appointed by Governor Deukmejian. President Stephen Chun announced the committee assignments for 1991; the Board's four committees are administration/personnel, enforcement, examination/licensing, and regulation/legislation. Legal counsel suggested that the Board limit the committees to two members if it wishes to avoid the public meeting requirement.

FUTURE MEETINGS:

August 22-23 in San Francisco.
November 18-19 in Los Angeles.

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.

At the Board's January 30 meeting, Board President Robert Toomajian introduced three new Board members: pharmacists Janeen McBride of Thousand Oaks and Raffi Simonian of San Diego, and public member Herbert Stoecklein of San Diego.

MAJOR PROJECTS:

Senate Studies Decline of Neighborhood Pharmacies. On January 14, the Senate Select Committee on Small Business Enterprises conducted a hearing entitled "The Decline of the Neighborhood Pharmacies: At What Cost?" The main concern of the Committee is the decline of the neighborhood pharmacy and its impact on the consumer's access to pharmaceutical services.

At the hearing, many reasons were suggested for the decline, including

competition with chain drug stores, mail order pharmacies, and competitive pricing. Board Executive Officer Patricia Harris testified regarding mail order pharmacies, noting that although the Board does not license these pharmacies, they must register with the Board, maintain a toll-free number which is affixed to the prescription container, comply with the Board's triplicate prescription requirements, and be able to readily retrieve their records on California residents.

As a result of the hearing, Board staff expects the Committee to establish a task force to research the relevant issues and possibly propose legislation to address any problem areas.

Nuclear Pharmacy. During its January meeting, at the request of the directors of nuclear medicine and radiopharmacy at UCLA and USC, the Board again considered the potential confusion between the Food and Drug Administration's regulation of the drug aspects of nuclear medicine, the Nuclear Regulatory Commission's jurisdiction over possession and handling of all radioactive materials, and guidelines for medical licensees established by the California Radiologic Health Branch (RHB) of the Department of Health Services. The nuclear medicine practitioners contend that because the radiopharmacist is highly specialized and qualified, the CCR provisions pertinent to pharmacists promulgated by the Board should also apply to radiopharmacists. Currently, radiopharmacists are required to comply with the far more detailed and time-consuming guidelines which RHB prepares. The Board is concerned that new regulatory changes which RHB has proposed may infringe upon the practice of pharmacy. Nonetheless, as conditions currently stand, the Board recognizes that RHB has full authority to propose regulations governing nuclear pharmacy.

Pharmacist Shortage. At its January meeting, the Board rejected implementation of the NABPLEX (National Association of Boards of Pharmacy Licensure Examination), at the recommendation of its Competency Committee. Use of the exam would enable the Board to consider granting reciprocity licensure to out-of-state pharmacists, to resolve an apparent shortage of licensed pharmacists in California. (See CRLR Vol. 11, No. 1 (Winter 1991) p. 82 and Vol. 10, No. 4 (Fall 1990) p. 99 for background information.) The Board felt that the items used in the sample NABPLEX were not as practice-oriented as those in the California exam; also, the exam has potential security problems in that it is not administered under consistent conditions among states. The Board felt these problems would result in incomparable test scores and thus defeat the goal of license reciprocity. Further, California would have to administer its own essay exam, thereby increasing the overall cost to applicants.

Impaired Pharmacist Program. In January, the Board's Impaired Pharmacist Liaison Committee reviewed its structure and goals, and presented recommendations for changes to the Board's Impaired Pharmacist Program for drug- and alcohol-abusing pharmacists. These recommendations, which include extension of the program indefinitely and the renaming of the program to "Pharmacist Recovery Program," have been incorporated into AB 1893 (Lancaster) *(see infra* LEGISLATION).

Since its inception in 1985, 240 pharmacists have participated in the program, with 58 successful completions and one relapse. One-third of the participants withdrew from the program voluntarily prior to completion; program directors attribute this attrition rate to the extensive follow-up and work involved in the program. The Board continues to investigate discipline violations during a pharmacist's participation in the program.

Long-Term Care Facilities. At its January 30 meeting, the Board considered a petition for rulemaking from Amcare, a pharmacy which services long-term and skilled nursing facilities. Amcare requested the adoption of regulations for separate licensure of and special packaging requirements for long-term care pharmacies. Amcare also sought regulations which would modify personnel requirements to allow for use of non-licensed technicians to assist each pharmacist in dispensing and packaging of medications; and allow a long-term care facility pharmacy, when dispensing a prescription in unit dose or modified unit dose form, to use the expiration date on the manufacturer's package unless it can be shown that the unit dose repackaging process harms the effectiveness or potency of the drug. Amcare, on behalf of itself and other long-term care facilities, argued that the distinctions in the type of care provided by long-term care pharmacies justify different regulations; long-term care pharmacies are closed to the public and therefore have no direct contact with consumers.

The Board's counsel determined that the Board lacks authority to create a separate license category. Further, counsel noted that the Board is addressing the issue of pharmacy technicians in pending legislation. Amcare agreed to withdraw its petition, and the Board's president agreed to establish a committee to study the special needs of pharmacies serving long-term care facilities.

Investigation of Revenue Enhancement Programs Between Physicians and Home IV Providers. The Board is continuing to gather information from pharmacists and other sources regarding fee arrangements between physicians and home infusion companies. (See CRLR Vol. 11, No. 1 (Winter 1991) p. 82 and Vol. 10, No. 4 (Fall 1990) pp. 98-99 for background information.) The Board expects to fully discuss this issue at its July 30 meeting.

Board Submits Report on Prescriber Dispensing Complaints. As required by AB 1732 (Isenberg) (Chapter 1600, Statutes of 1988), the Board submitted a report to the legislature in January on complaints involving prescriber dispensing. (See CRLR Vol. 8, No. 4 (Fall 1988) p. 70 for background information.) AB 1732 requires the Board to forward all complaints relating to drugs or dangerous devices dispensed under the provisions of AB 1732 to the Medical Board of California (MBC). In addition, the bill requires that MBC handle those complaints involving serious bodily injury as a case of greatest potential harm to a patient.

The report states that from August 1, 1988, through December 27, 1990, the Board received 31 complaints concerning improper dispensing by licensed physicians. Of the 31 complaints referred to MBC, the Board has received disposition information on 22 of the referrals; however, the report does not note the nature of the dispositions. The Board has not received disposition information on the remaining nine complaints; MBC claims that the complaints are not listed in its complaint tracking system and therefore MBC has no record of their receipt. The Board plans to meet with MBC to discuss a procedure whereby complaints referred from the Board of Pharmacy will be registered in MBC's enforcement complaint tracking system so that they may be accurately tracked and appropriately investigated.

Proposed Regulatory Changes. The following is a status update on numerous regulatory changes considered by the Board in recent months. (See CRLR Vol. 11, No. 1 (Winter 1991) pp. 82-83; Vol. 10, No. 4 (Fall 1990) pp. 99-100; and Vol. 10, Nos. 2 & 3 (Spring/Summer 1990) pp. 114-115 for extensive background information on these changes.)

-Pharmacy Technicians. On January 3, the Governor's Office denied the Board's request to overturn the Office of Administrative Law's (OAL) disapproval

of the pharmacy technician rulemaking file; OAL had rejected for the third time the Board's proposed section 1717, for failure to comply with the consistency standard of Government Code section 11349.1. The Board has proposed legislation which would allow the use of pharmacy technicians *(see infra* LEGISLATION).

-Oral Consultation. On January 11, OAL granted the Board's request to delay implementation of new sections 1707.1 and 1707.2 until January 1, 1992. The Board sought the delay to provide pharmacists with additional time to prepare for and phase in the changes to pharmacy practice mandated by the new oral consultation regulations.

The Board is also concerned about application of these new regulations to out-of-state mail order services; in January, the California Pharmacists Association (CPhA) notified the Board regarding its view that mail order dispensers, as well as traditional community pharmacies, should be required to comply with the regulations. Possible suggestions for application include requiring mandatory 24-hour hotlines for oral consultation; requiring mail order dispensers to provide written information with the prescription; or requiring them to include a written notice informing the patient that consultation is available and is a requirement under California law. CPhA may also seek federal legislation requiring pharmacies providing services to out-of-state patients to meet the requirements set forth by each state.

-Preprinted, Multiple Check-off Prescription Pads. On January 3, OAL approved new section 1717.3, which went into effect in February. The regulation specifies that only one prescription may be prescribed from a single preprinted prescription form, and no controlled substances may be prescribed on a preprinted form.

-English Equivalency Examination. On January 24, OAL approved the Board's amendment to section 1719, which reflects the specific pass score on the Test of Spoken English. The regulation applies to foreign-trained pharmacists and is scheduled to become effective in June.

-Continuing Education Advertising. On January 30, the Board held a regulatory hearing on proposed amendments to section 1732.3(d), pertaining to continuing education advertising. Following the hearing, the Board adopted the proposed amendment subject to a minor technical change in the regulatory proposal (changing "accredited program" to "approved program"), and re-released the regulation for an additional 15-day comment period. The Board expected to submit the rulemaking package to OAL in April.

-Pharmacist-In-Charge. On February 5, OAL approved new section 1709.1, regarding the designation of a pharmacist-in-charge at each pharmacy.

-Processing Times for Applications and Registrations. Proposed new section 1706.1 of the CCR specifies the processing times within which the Board will process applications, pursuant to the Permit Reform Act of 1981, Government Code section 15374 *et seq*. The Board adopted the regulation at an October 1990 public hearing and is preparing to submit the regulation to the Department of Consumer Affairs (DCA) for review. If approved by DCA, the rulemaking file will be submitted with OAL for approval.

-Compounding for Office Use. The Board was scheduled to hold a public hearing at its May meeting concerning proposed modifications to regulatory sections 1716.1 and 1716.2, regarding the definition of the phrase "reasonable quantity of compounded medication" under Business and Professions Code section 4046(c)(1). The proposed regulations would specify the minimum records that must be kept for those pharmacies which compound medication for prescribers' office use.

LEGISLATION:

AB 1226 (Hunter). Existing law, with certain exceptions, authorizes a pharmacist filling a prescription order for a drug product prescribed by its trade or brand name to select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug type. Existing law also requires the Director of the Department of Health Services (DHS) 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. As introduced March 6, this bill would change the standard to be applied by the Director in establishing the formulary to instead apply to those generic drug types and drug products which, if substituted as described above, may pose a threat to the health and safety of patients. This bill would also require the Director to consider all information submitted by any person who requests that the Director make any inclusion, addition, or deletion of a generic drug type or drug product to the formulary. This bill is pending in the Assembly Health Committee.

AB 1253 (Baker). Under existing law, there are various regulations regarding medical devices, including a requirement that no person other than a registered or intern pharmacist or other authorized person may enter an area, place, or premises wherein specified devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged. As introduced March 6, this bill would provide that none of these regulations should be construed to prevent the storage of medical devices in secure central or ward supply areas of clinics, hospitals, institutions, or of the California Rehabilitation Center or certain facilities or institutions for judicial commitments. This bill is pending in the Assembly Health Committee.

AB 1371 (Wright). Existing law prohibits any person from conducting a pharmacy or medical device retailer unless he/she has obtained a certificate, license, permit, or registration from the Board. For those purposes, a medical device retailer does not include any area in a facility licensed by DHS where floor supplies, ward supplies, operating room supplies, or emergency room supplies of dangerous devices are stored or possessed solely for certain treatment purposes. As introduced March 7, this bill would add home care supplies to this exemption list and would add the treatment of patients at home by a licensed home health agency within the permitted treatment purposes. This bill is pending in the Assembly Health Committee.

AB 1893 (Lancaster), as introduced March 8, would revise the applicability of pharmacy laws with respect to certain medical supplies; and retitle the Impaired Pharmacist Program, scheduled for repeal on January 1, 1992, as the Pharmacist Recovery Program and continue its provisions indefinitely. This bill is pending in the Assembly Committee on Consumer Protection, Governmental Efficiency, and Economic Development.

SB 1033 (Marks). Existing law declares the practice of pharmacy to be a profession, and specifies certain activities which a pharmacist is permitted to do, including but not limited to manufacturing, measuring, fitting to the patient, or selling and repairing legend medical devices or furnishing instructions to the patient. As introduced March 8, this bill would modify this authority to permit pharmacists to do manufacturing, measuring, fitting to the patient, or selling

and repairing medical devices without regard to whether they bear a specified legend relating to a federal law prohibition against dispensing without a prescription. This bill is pending in the Senate Business and Professions Committee.

AB 855 (Hunter), as introduced February 27, would provide that notwithstanding any other provision of law, no pharmacist in filling a prescription for a drug product described by its trade or brand name shall select another drug product pursuant to these provisions if the federal Secretary of Health and Human Services or the federal Commissioner of Food and Drugs has proposed to withdraw the generic drug from the market and has issued a notice of opportunity for a hearing because the drug lacks substantial evidence of effectiveness for all labeled indications and for which the Secretary or Commissioner has made no determination that there is compelling justification for its medical need. This bill is pending in the Assembly Health Committee.

AB 1244 (Polanco). Existing law, with specified exceptions, makes it unlawful for any person to manufacture, compound, sell, or dispense any dangerous drug or devices, or to dispense or compound any prescription of a medical practitioner unless he/she is a registered pharmacist. As introduced March 6, this bill would exclude from this registration requirement any nonlicensed pharmacy personnel engaged in performing clerical, inventory, packaging, and dispensing related tasks while assisting, and while under the direct supervision of, a registered pharmacist. The Board previously attempted to accomplish this change by rulemaking; however, the Office of Administrative Law rejected the proposal on three separate occasions, determining that the Board's proposal was inconsistent with federal and state law. (See CRLR Vol. 11, No. 1 (Winter 1991) p. 83 for background information.) This bill is pending in the Assembly Health Committee.

SB 917 (Kopp), as introduced March 8, would require any health care service plan that proposes to offer a pharmacy benefit or proposes to 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 in the Senate Committee on Insurance, Claims and Corporations.

AB 1675 (Margolin), as introduced March 8, would require 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. This bill would require the center to be under the direction of a person, appointed by the Board, who is licensed under the provisions of law relative to the healing arts and who is experienced in providing drug information to the public; that person would be required to comply with requirements and criteria of the Board regarding operation of the center. The bill would require the Board to provide on license renewal forms an opportunity to make voluntary contributions for purposes of the statewide drug information center. This bill is pending in the Assembly Health Committee.

AB 819 (Speier). Existing law provides that, except as otherwise specified, the offer, delivery, receipt, or acceptance by prescribed licensed health professionals of any rebate, refund, commission, preference, patronage dividend, discount, or other consideration, whether in the form of money or otherwise, as compensation or inducement for referring patients, clients, or customers to any person is unlawful, punishable as a misdemeanor or felony. Existing law also provides that it is not unlawful for a person 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, effective July 1, 1992, delete the exception for proprietary or coownership interests, and instead provide that 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 would not exempt the licensee from the prohibition. However, the bill would permit specified licensed health professionals to refer a person to a 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 if the person referred is the licensee's patient of record, there is no alternative provider or facility available, and to delay or forego the needed health care would pose an immediate health risk to the patient. This bill is pending in the Assembly Health Committee.

SB 594 (Roberti), as introduced March 4, would require 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 is pending in the Senate Committee on Health and Human Services.

FUTURE MEETINGS:
July 30-August 1 in Sacramento.
October 16-17 in Los Angeles.

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.