and falls within the scope of the practice of optometry. However, on May 1, Board staff responded to these inquiries, stating that the "use of collagen implants by an optometrist would not be within the current scope of optometric practice."

Board Relocates Office. Effective June 10, the Board moved its office to a new location at 400 R Street, Suite 3130, Sacramento, CA 95814.

LEGISLATION:

SB 664 (Calderon), as introduced March 5, would prohibit optometrists, 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 1479 (Burton). The Robert W. Crown California Children's Services Act requires the Department of Health Services (DHS) to establish and administer a program of services for physically defective or handicapped persons under the age of 21 years; the Act requires the DHS Director to establish those conditions coming within the definition of "handicapped child." As amended May 29, this bill would require any condition established by the Director which is treatable by an ophthalmologist to be deemed treatable by an optometrist if the condition is within the scope of practice of optometry. This bill is pending in the Assembly Ways and Means Committee.

The following is a status update on bills reported in detail in CRLR Vol. 11, No. 2 (Spring 1991) at page 96:

AB 1124 (Frizzelle), as introduced March 5, would, among other things, 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 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 amended April 15, 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 bill passed the Senate on May 2 and is pending in the Assembly Health Committee.

AB 1046 (Tucker), as introduced March 4, would add optometrists to the list of individuals required to report any evidence of abuse of an elderly or dependent person. This bill was passed by the Assembly on May 30 and is pending in the Senate Judiciary Committee.

LITIGATION:

April 8 was the Federal Trade Commission's (FTC) deadline for seeking U.S. Supreme Court review of the D.C. Circuit's decision in *California State Board of Optometry v. Federal Trade Commission*, 910 F.2d 976 (D.C. Cir. 1990). The FTC failed to file a petition for *certiorari;* thus, the Board has prevailed in its challenge to the FTC's jurisdiction to adopt rules prohibiting state boards of optometry from engaging in anticompetitive conduct. (See CRLR Vol. 11, No. 2 (Spring 1991) p. 96; Vol. 11, No. 1 (Winter 1991) p. 81; and Vol. 10, No. 4 (Fall 1990) pp. 97-98 for background information on this case.)

RECENT MEETINGS:

At its May 23 meeting, the Board reviewed a draft of its Consumer Education Pamphlet, which is expected to be released in late 1991. The pamphlet contains information about the Board; defines the differences between an optometrist, an ophthalmologist, and an optician; describes common eye and refractive conditions; discusses environmental considerations relevant to eye safety; describes the contents of an adequate eye examination; provides information about contact lenses; informs consumers about steps to take if they are dissatisfied with the services received; and discusses the confidentiality of a patient's records and the patient's right to obtain copies of his/her records.

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.

MAJOR PROJECTS:

Pharmacy Shortage. On April 23, the Board submitted written testimony to the Office of Statewide Health Planning and Development regarding the shortage of pharmacists in California. The Office had solicited testimony in conjunction with two statewide hearings it conducted during April and May, the results of which will be compiled in a report to the legislature with findings and recommendations relative to the need for allied health professionals in California.

In its testimony, the Board noted that there is a general consensus among interested parties that the pharmacy shortage is due in part to outside influences on the profession (such as insurance companies) which are dictating practice decisions; practicing pharmacists discouraging students from entering into the profession; job dissatisfaction due to stress and long hours; difficulty with the California examination; and significant changes in the pharmacist population.

According to the Board, there are a number of possible responses to the

shortage, including the legalized use of pharmacy technicians (*see infra* LEGISLATION); addressing quality of life issues (better salaries and working conditions); partial licensure reciprocity between states; having the profession take a firm, unified position on issues regarding contracts and reimbursements; and focusing recruiting efforts at an early point in a student's education.

The Board concluded its testimony by noting that resolution of the pharmacist shortage will probably be based on several factors, but stated that one of the key elements will be the use of pharmacy technicians for all those functions that pharmacists do not need to perform, but which require pharmacist supervision.

Investigation of Revenue Enhancement Programs Between Physician and Home IV Providers. The Board's subcommittee investigating concerns over fee arrangements between physicians and home infusion companies has turned over the information it has compiled from pharmacists and other sources to the Attorney General's office; the AG's office hopes to prepare a recommendation for the Board to consider at its July meeting. (See CRLR Vol. 11, No. 2 (Spring 1991) p. 97; Vol. 11, No. 1 (Winter 1991) p. 82; and Vol. 10, No. 4 (Fall 1990) pp. 98-99 for background information.)

In a related issue, AB 819 (Speier) would amend Business and Professions Code section 650 to provide that, subject to specified exceptions, it is unlawful for 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. (*See infra* LEGISLATION.)

Attorney General Opinion No. 91-305. At its March 20 meeting, the Board discussed a request by Assemblymember Tricia Hunter for an Attorney General's opinion concerning the following questions:

-Do the laws affecting pharmacies dispensing drugs in California also apply to out-of-state mail order pharmacies filling prescriptions for people living or at least using an address in California?

-Would state regulation of out-of-state mail order pharmacies be forbidden by federal regulation of interstate commerce?

-Would a drug listed on California's negative drug formulary, making it illegal to dispense in California, also be illegal for out-of-state pharmacies to dispense via mail in California?

At the meeting, Deputy Attorney General William Marcus opined that the Board is authorized to regulate mail order pharmacies, and may have the authority to require prescriptions to comply with certain provisions of the Health and Safety Code. Mr. Marcus added that a formal Attorney General's Opinion on the matter is forthcoming.

In a related issue, the Board recently considered the Mail Order Pharmacy Survey Report prepared by the U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, and concluded that, at this time, there is no indication of abuse in the mail order pharmacy industry (*see infra*).

Nonresidential Pharmacy Complaint Information. At its May 29 meeting, the Board reviewed a report it submitted to the legislature on March 29 regarding complaints involving nonresidential pharmacies. The report was prepared pursuant to SB 2213 (Craven) (Chapter 1424, Statutes of 1988), which requires the Board to maintain a record of all nonresidential pharmacy complaint referrals involving serious bodily or psychological injury to a resident of this state and any action taken against a licensee as a result of a referral, and to report its findings to the legislature. (See CRLR Vol. 8, No. 4 (Fall 1988) p. 70 for background information.)

The report noted that during the reporting period of October 1, 1988 through March 22, 1991, the Board received twelve complaints concerning alleged nonresidential pharmacy violations. Of the twelve complaints, nine were referred for review and appropriate action to the regulatory/licensing agency in the state in which the pharmacy was located; the remaining three complaints were investigated by the Board but not referred to another state agency. The major category of complaint was prescription error, including cases where the container was properly labeled but contained the wrong medication. Two complaints involved patient harm; those complaints are presently under investigation by other state agencies.

According to the report, it is the Board's policy to investigate and track all complaints concerning nonresidential pharmacies, and such investigations are handled no differently than an investigation of a California pharmacy.

Nuclear Pharmacy. At its March 20 meeting, the Board continued its discussion regarding the potential confusion between the Nuclear Regulatory Commission's (NRC) jurisdiction over possession and handling of all radioactive materials and the guidelines for medical licensees (including radiopharmacists) established by the Radiologic Health Branch (RHB) of the state Department of Health Services (DHS). (See CRLR Vol. 11, No. 2 (Spring 1991) p. 97 for background information.)

At the meeting, former Board member Glenn Yokoyama reported that he and Board Supervising Inspector Ken Sain attended an NRC Agreement State Meeting regarding NRC's proposal to adopt a Quality Assurance Rule. California is an agreement state, which means that NRC delegated its authority to regulate nuclear medicine to RHB. However, it appears to some parties that NRC's proposed rule would preempt that delegation and negatively impact the practice of nuclear medicine and pharmacy in California. Because of this, the Board opposes NRC's proposed rule.

Mr. Yokoyama reported that it appears that the NRC will adopt the rule despite the comments made by the agreement states. The Board unanimously voted to contact NRC officials and reaffirm its opposition to the Quality Assurance Rule.

Licensure of Drug Wholesalers. On April 12, the Board published notice of its intent to amend section 1780, Title 16 of the CCR, regarding minimum standards for drug wholesalers. In 1987, the federal Prescription Drug Marketing Act directed the FDA to adopt national standards for the state licensure of drug wholesalers. In September 1990, the FDA adopted these standards and published them in the *Federal Register.* The standards require all states to license drug wholesalers by September 15, 1992, in compliance with FDA's minimum requirements.

According to the Board, California must add several provisions to its existing requirements in order to achieve compliance with the federal standards. These new provisions, which would be added to section 1780, deal with security systems to protect drugs stored or handled by a wholesaler; inspection requirements for incoming or outgoing shipments; procedures for handling returned, damaged, or outdated drugs; and requirements concerning written procedures, policies, and staffing.

Under the proposed changes, wholesalers would be required to have an alarm system, exterior lighting, and a security system protecting against internal thefts. Incoming shipments must be examined for container damage. Outgoing shipments must be inspected to ensure product identity and integrity. Drugs which are returned, damaged, or outdated, or whose outer or inner container seals have been broken must be physically separated from other drugs. Wholesalers must establish and maintain written policies and procedures for the

receipt, security, storage, inventory, and distribution of drugs. Wholesalers would also be required to maintain records in accordance with federal provisions for at least three years, including the names of officers, directors, and managers, as well as their duties and qualifications.

After a May 29 public hearing on the proposed revisions, the Board adopted the amendments subject to minor modifications. The Board was expected to release the modified text for a 15-day public comment period during late June or early July.

Compounding for Office Use. Also on May 29, the Board held a regulatory hearing concerning its proposal to adopt new 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. 2 (Spring 1991) p. 98; Vol. 11, No. 1 (Winter 1991) p. 83; and Vol. 10, Nos. 2 & 3 (Spring/Summer 1990) p. 115 for background information on the Attorney General's Opinion which prompted these regulatory changes.)

Proposed new section 1716.1 would clarify the definition of the terms "reasonable quantity," "compounded," and "prescriber office use," as referenced in section 4046(c)(1). The term "reasonable quantity" would be defined as a quantity not to exceed that which is sufficient for a prescriber's office use for 180 days; that which is reasonable based upon its intended use, the nature of the prescriber's practice, and the stability of the compounded medication; and that which the pharmacy can safely compound and supply. The term "prescriber office use" would be defined as application or administration in the office or distribution to patients of not more than a 72-hour supply.

Proposed new section 1716.2 would specify the minimum types of records that pharmacies must keep when they furnish compounded medications to prescribers in quantities larger than required for the prescriber's immediate office use or when a pharmacy compounds medication for future furnishing. Those records would include the date of preparation, lot number, expiration date (in no event to exceed six months), signature or initial of the compounding pharmacist, and a description of the product, including its formula, manufacturer of raw materials, quantity, package size, and number of units prepared.

Following the May 29 hearing, the Board decided that technical refinements to the language may be necessary; the Board was scheduled to review a modified version of the text at its July 31 meeting in San Diego.

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. 2 (Spring 1991) p. 98; Vol. 11, No. 1 (Winter 1991) p. 83; and Vol. 10, No. 4 (Fall 1990) pp. 99-100 for background information on these changes):

-Continuing Education Advertising. The Board's proposed revision to section 1732.3(d), pertaining to continuing education advertising, was recently approved by the Director of the Department of Consumer Affairs (DCA) and was scheduled for submission to the Office of Administrative Law (OAL) for review in mid-June.

-Processing Times for Applications and Registrations. Proposed 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*. The DCA Director approved the new section in May; the Board expected to submit the rulemaking package to OAL for review in mid-June.

LEGISLATION:

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.

The following is a status update on bills reported in detail in CRLR Vol. 11, No. 2 (Spring 1991) at pages 98-99:

AB 1226 (Hunter), as introduced March 6, would change the standard to be applied by the Director of the Department of Health Services (DHS) 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 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). Existing law permits the Board to waive specified licensure requirements for pharmacies, hospital pharmacies, and medical device retailers, as defined, if, in the opinion of the Board, a high standard of patient safety can be provided. As amended April 29, this bill would permit the Board to waive any requirement of licensure for pharmacies, hospital pharmacies, and medical device retailers if those conditions are met. This bill would also provide that existing regulations do not prohibit the storage of medical devices in secure central or ward supply areas of specified establishments. This bill is pending in the Assembly Ways and Means Committee.

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 May 23, this bill would extend 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 would require 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 passed the Assembly on May 29 and is pending in the Senate Business and Professions Committee.

AB 1893 (Lancaster), as amended May 24, would revise the applicability of pharmacy laws with respect to certain medical supplies; retitle the Impaired Pharmacist Program, scheduled for repeal on January 1, 1992, as the "Pharmacist Recovery Program" and continue its provisions indefinitely; and extend 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 is pending in the Assembly Ways and Means 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 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 U.S. Secretary of Health and Human Services or the U.S. 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 passed the Assembly on May 30 and is pending in the Senate Business and Professions Committee.

AB 1244 (Polanco), as amended May 6, would permit 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. This bill is pending in the Assembly Health Committee.

SB 917 (Kopp), as amended May 2, 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 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. The bill would require the Board to provide on license renewal forms an opportunity to make voluntary contributions to the statewide drug information center. This bill passed the Assembly on May 30 and is pending in the Senate Business and Professions Committee.

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 would not exempt the licensee from the prohibition. This bill is pending in the Assembly Health Committee.

SB 594 (Roberti), as amended May 8, 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 on the Senate floor.

RECENT MEETINGS:

At the Board's March 20 meeting, Executive Officer Patricia Harris announced that the Board's budget is in good shape and that there should be adequate funding to sustain all Board operations through the end of the fiscal year.

Also in March, the Board announced that Board member and actress Cindy Williams recently filmed a 30-second public service announcement (PSA) on the Board's new mandatory oral consultation regulation. (See CRLR Vol. 11, No. 2 (Spring 1991) p. 98; Vol. 10, Nos. 2 & 3 (Spring/Summer 1990) p. 115; and Vol. 10, No. 1 (Winter 1990) p. 90 for background information.) The PSA stresses to consumers the importance of asking their pharmacist when they have questions regarding their medications. The PSA will be distributed to television stations throughout the state.

At the Board's May 29 meeting, staff reported that it is processing a budget change proposal (BCP) seeking budget authorization for the 1992-93 fiscal year to install a toll-free telephone line for consumers to use to contact the Board; the Board is seeking three staff positions to handle these calls, and would redirect certain portions of its enforcement workload to these staff positions. This BCP was to be submitted to the Department of Consumer Affairs for review in June.

Also at the May meeting, the Board announced that it is relocating its offices to 400 R Street, Sacramento, California 95814; the move was expected to take place in early June.

FUTURE MEETINGS:

October 16-17 in Los Angeles.
January 22-23 in Sacramento.
March 18-19 in San Diego.

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