administration and may consist of a national exam, a state exam, or both. *[15:2&3 CRLR 84; 15:1 CRLR 82]*

As proposed in December 1994, BNHA's proposed changes to sections 3116, 3151, 3152, 3160, and 3162, Title 16 of the CCR, would, among other things, provide that two hours of CE credit shall be given for attending a public meeting of BNHA, and eight hours of CE credit will be given for participating in a Board-sponsored state licensing examination item writing session; BNHA may, in lieu of conducting its own investigation, accept the findings of the National Association of Boards of Nursing Home Administrators regarding CE courses and providers, and adopt those findings as its own; any licensed NHA may be approved to serve as a preceptor if the individual, among other things, has an active NHA license and is not on probation by the Board; and sixty hours is the maximum number of hours an administrator-in-training may work and train each week. *[15:2&3 CRLR 84; 15:1 CRLR 81–82]* At its August 17 meeting, BNHA modified its proposed changes to section 3116 (regarding applicant qualifications) and deleted all proposed amendments to section 3160 (regarding preceptor qualifications). On August 23, BNHA released the modified text of section 3116 for an additional 15-day public comment period; at this writing, the proposed changes to sections 3116, 3151, 3152, and 3162 are being reviewed by OAL.

LEGISLATION

SB 472 (Petris). Existing law expresses legislative findings regarding Alzheimer's disease and states that existing diagnostic and treatment centers have improved the quality of care of patients with this disease. Existing law provides that the functions of these centers shall be designed to serve certain prescribed purposes, including to increase the training of health care professionals with respect to Alzheimer's disease. As amended July 19, this bill amends existing law to provide that the purpose is to increase the training of health care professionals with respect to Huntington's disease also. It authorizes these centers to develop and approve curricula regarding certain aspects of other acquired brain impairments. The bill provides that health care facilities, adult day health care centers, residential care facilities for the elderly, and other providers of health care or personal care services to children with disabilities, adults, or older adults may offer the curricula to employees and it may satisfy up to four hours annually of any in-service training requirement.

Existing law requires the Director of Mental Health to contract with a nonprofit agency meeting prescribed criteria to act as the Statewide Resources Consultant and prescribes the duties of the consultant to include, but not be limited to, serving as an information and technical assistance clearinghouse for brain-impaired adults, as defined, and their families, and caregivers, and to develop and conduct related training. This bill specifies that the duties of the consultant may include reviewing proposed training curricula regarding individuals with brain damage, as defined, assisting organizations that serve families with adults with Huntington's disease and Alzheimer's disease in reviewing data, and forwarding this information to the appropriate state departments for consideration. This bill was signed by the Governor on October 4 (Chapter 551, Statutes of 1995).

Future Legislation. At its August 17 and November 30 meetings, BNHA agreed to pursue several legislative changes. In addition to a bill increasing the statutory cap on BNHA licensing fees (*see* MAJOR PROJECTS), the Board also intends to pursue legislation amending Business and Professions Code section 3905 to clarify its position regarding the absence of NHAs for more than thirty consecutive days, the appointment of acting NHAs, and the deadlines for Board notification; proposed changes to Business and Professions Code sections 3924.7 and 3924.8 regarding criminal background checks for applicants and licensees; and several technical or cleanup changes.

RECENT MEETINGS

At BNHA's August meeting, Executive Officer Kim Smith reported that she and Board member Dr. Orrin Cook are continuing to meet with various officials from the Department of Social Services (DSS) to discuss the future of the residential care facilities for the elderly (RCFE) administrator certification program; for many years, BNHA has been considering assuming RCFE certification responsibilities, which are currently carried out by DSS' Community Care Licensing Division. *[13:2&3 CRLR 98; 13:1 CRLR 58; 12:4 CRLR 111–12]* Smith also noted that the Community Residential Care Association of California has already stated its opposition to BNHA's efforts to take over the certification of RCFE administrators.

Also at BNHA's August meeting, Executive Officer Smith reported that DCA's Office of Examination Resources had agreed to conduct an occupational analysis of the NHA profession. Smith expects that the survey will be completed in August 1996; the $10,000 cost for the analysis will be divided between fiscal years 1995–96 and 1996–97.

Also in August, BNHA discussed staff's proposal to implement Business and Professions Code section 125.9 by creating a citation and fine system; such a system would give staff a means to deal with minor administrative violations, and would have the potential to raise additional funding for the Board's operations. Following discussion, the Board directed staff to further develop the proposal and present its findings and recommendations to the Board. However, at its November meeting, BNHA tabled the citation and fine proposal, and directed the Disciplinary Committee to readdress the issue prior to the Board's next meeting.

At its November 30 meeting, the Board discussed the upcoming sunset review process. *[14:4 CRLR 20, 87]* Executive Officer Smith urged the Board to immediately begin preparing for the review process; she requested that the Board appoint a two-member sunset review subcommittee to work with staff in preparing BNHA's report to the legislature, which is due in October. Board members Dr. Orrin Cook and Marilyn Jesswein volunteered to serve on the subcommittee; Gloria Johnson will serve as an alternate.

FUTURE MEETINGS

February 15 in Sacramento.
August 15 in Sacramento.

BOARD OF OPTOMETRY

Executive Officer: Karen Ollinger (916) 323-8720

Pursuant to Business and Professions Code section 3000 *et seq.*, the Board of Optometry is responsible for licensing qualified optometrists and disciplining malfeasant practitioners. The Board establishes and enforces regulations pertaining to the practice of optometry, which are codified in Division 15, Title 16 of the California Code of Regulations (CCR). The Board's goal is to protect the consumer patient who might be subjected to injury resulting from unsatisfactory eye care by inept or untrustworthy practitioners. The Board consists of nine members—six licensed optometrists and three public members.

MAJOR PROJECTS

Board and COA At Stalemate Over Independent Practice Association Issue. For over one year, the Board has been considering two applications for reg-

istration of optometric corporations; while the applications specify only one address, they are apparently intended to be vehicles for the establishment of "independent practice associations" (IPAs) whereby optometric services would actually be rendered through numerous optometrists practicing at different locations. Because Department of Consumer Affairs (DCA) legal counsel Robert Miller has interpreted these offices to be "branch offices" subject to the restrictions and registration requirement of Business and Professions Code section 3077, and because both applicants expressly disclaim having any branch offices, Miller recommended that the applications be denied. However, the Board at its December 1994 meeting decided to revisit the section 3077 branch office restrictions, and scheduled a discussion of this issue for its March meeting. *[15:1 CRLR 83]*

At the Board's March 1995 meeting, Miller reported that he had several conversations with California Optometric Association (COA) legal counsel Mark Andrews regarding this matter. Miller still contended that by arranging for optometric services to be provided by professional practitioners, IPAs are effectively practicing optometry at multiple locations in violation of the branch office limitations. However, Andrews argued that IPAs do not practice optometry but merely act as entities which market optometric services, and thus are not in violation of the branch office limitations. Miller conceded that COA's argument may have merit, and informed the Board that there may be alternative interpretations of the law in this regard. The Board generally agreed that further research should be conducted to assist it in determining whether IPAs are in fact practicing optometry. Accordingly, the Board unanimously agreed to appoint a committee, including representatives of the Board and COA, to study issues concerning IPAs and report its findings and recommendations to the Board at a future meeting. *[15:2&3 CRLR 85]*

Following a further tangle between COA and Miller at the Board's August meeting, the Board decided to convene a special meeting on the IPA issue on September 22. Miller reiterated his position that the Board is not authorized to license an IPA as a professional optometric association as the IPA inherently violates the branch office restriction in Business and Professions Code section 3077. Following extensive discussion, a motion to seek repeal of section 3077 died for lack of a second, leaving the Board and COA at a stalemate.

At the Board's December meeting, Miller reported that COA would be seeking an author for legislation which would exempt IPAs from section 3077's coverage; accordingly, the Board is not expected to take further action on this matter at this writing.

Rulemaking Update. On May 23, the Board held a public hearing on the proposed adoption of new sections 1523 and 1524, amendments to sections 1530, 1531, 1532, 1533, 1535, and 1536, and repeal of section 1526, Title 16 of the CCR, regarding the Board's examination process and continuing optometric education requirements.

Among other things, these changes would consolidate the Board's examination and application requirements into one reference source for licensure candidates; provide for the approval of the applications for examination for those applicants who have paid the necessary fees and whose credentials have been approved by the Board's Executive Officer; specify that each applicant for licensure must obtain a passing score of at least 75% in each of the required examination sections; delete antiquated examination composition language and clearly delineate each examination section and its composition; clarify that an applicant who has failed to pass either the Clinical and Demonstration or Laws and Regulations examination sections after a period of five consecutive calendar years from the date of the first examination must retake both examination sections; provide that an inspection by an examinee of the papers he/she wrote while taking the Board examination must be made by that person before the expiration of 90 days after the examination results are mailed; specify that the Board requires successful completion of the National Board of Examiners in Optometry's (NBEO) Basic and Clinical Science examination sections as a condition of eligibility to take the Board's Clinical Demonstration and Laws and Regulations examination sections, and delete language authorizing an applicant to otherwise furnish satisfactory evidence of his/her eligibility pursuant to the provisions of Chapter 7 of Division 2 of the Business and Professions Code; provide that no more than four hours of continuing education (CE) coursework shall be in the area of practice management; provide that CE offerings approved by the International Association of Boards of Examiners in Optometry, known as the Council on Optometric Practitioner Education, are approved as meeting the required standards of the Board; specify that a licensee is exempt from CE requirements if he/she was first licensed by examination within the twelve months immediately preceding the annual license renewal date; and provide that, as a condition of license renewal, all licensees are required to maintain current certification in cardiopulmonary resuscitation (CPR), and the training required for the CPR certificate may not be credited toward the required CE hours. *[15:2&3 CRLR 85; 15:1 CRLR 82; 14:4 CRLR 89]*

Also on May 23, the Board held a public hearing on its proposal to amend section 1560, Title 16 of the CCR, to add the drug tetracaine hydrochloride, a topical anesthetic with a maximum usage concentration of 0.5%, to the list of topical pharmaceutical agents which may be used by California optometrists in their examination of patients. *[15:2&3 CRLR 86; 15:1 CRLR 84]*

Following the hearing, the Board adopted the changes, which await review and approval by the Office of Administrative Law (OAL).

Performance of Ophthalmic Tasks by Medical Assistants. Over the Board of Optometry's objections, the Medical Board's Division of Licensing (DOL) adopted, at its May 1995 meeting, amendments to section 1366, Title 16 of the CCR, which defines the technical supportive services which may be performed by unlicensed medical assistants (MAs). The amendments would permit MAs to perform ophthalmic testing which does not require interpretation in order to obtain test results; delete existing subsection 1366(d) (which prohibits MAs from practicing optometry) as duplicative of existing law; and add a specific reference to Business and Professions Code section 2069 (which prohibits MAs from administering any local anesthetic agents). *[15:2&3 CRLR 65, 86; 15:1 CRLR 65-66, 83]* At this writing, the rulemaking file on DOL's amendments is pending review by the DCA Director, after which it will be submitted to OAL.

LEGISLATION

AB 1107 (Campbell). Under existing law, the right to sell or furnish prescription lenses is limited exclusively to licensed physicians, optometrists, and registered dispensing opticians. As amended August 28, this bill authorizes, notwithstanding that limitation, a pharmacist to dispense replacement contact lenses in accordance with certain requirements; these requirements are also made applicable to nonresident pharmacists.

Existing law requires nonresident pharmacies, as defined, to register with the Board of Pharmacy and to disclose certain information to that Board and provides for the denial, revocation, and suspension of nonresident pharmacy registration for

failure to comply with certain requirements. This bill adds the requirements for dispensing replacement contact lenses to the requirements for which nonresident pharmacy registration may be denied, revoked, or suspended. The bill requires that nonresident pharmacies comply with certain requirements, maintain certain records, and disclose certain information to the Pharmacy Board; adds the requirement that those pharmacies maintain records of all replacement contact lenses shipped, mailed, or delivered to California residents; and requires that these records be available for inspection upon request by the Pharmacy Board or the Medical Board's Division of Licensing. This bill also requires any pharmacy, including nonresident pharmacies, dispensing replacement contact lenses to comply with certain laws governing advertising of contact lenses, and to register with DOL at the time of initial licensure or registration or upon renewal of the license or registration. This bill was signed by the Governor on October 9 (Chapter 719, Statutes of 1995).

SB 640 (Craven), as amended August 29, prohibits, commencing January 1, 1997, any person located outside of California from shipping, mailing, or delivering contact lenses to residents of California unless registered with the Medical Board's Division of Licensing, and provides that only replacement lenses may be shipped, mailed, or delivered to a patient. This bill requires the nonresident contact lens seller to complete an application, pay prescribed licensure and renewal fees, and satisfy various conditions in order to obtain and maintain registration. The bill provides that contact lenses may be sold only within one year of the date on the written prescription, and if the written prescription is unavailable to the seller, it requires the seller to directly communicate with the prescriber or his/her authorized agent to confirm the prescription. The bill also sets forth circumstances under which registration may be denied, suspended, or revoked, and establishes procedures for renewal of registration. It authorizes DOL to adopt regulations necessary to administer these provisions. This bill was signed by the Governor on October 12 (Chapter 853, Statutes of 1995).

SB 668 (Polanco). Existing law provides that it is unlawful for a person to engage in the practice of optometry without first obtaining a certificate of registration from the Board. As amended September 14, this bill—which is a reintroduction of 1993's AB 1894 (Polanco) *[14:4 CRLR 89; 13:4 CRLR 78]*—would authorize ancillary personnel who work under the supervision of an optometrist to assist in the preparation of the patient and the preliminary collection of data. It would prohibit an optometrist from permitting ancillary personnel to collect data requiring the exercise of professional judgment or skill of an optometrist that includes performing any subjective refraction procedures, contact tonometry, data analysis, or diagnosis, or prescribing and determining any treatment plan. *[S. Conference Committee]*

SB 510 (Maddy). Under existing law, the practice of optometry includes, among other things, the examination of the human eye or eyes, or its or their appendages; the analysis of the human vision system, either subjectively or objectively; and the use of pharmaceutical agents for the sole purpose of the examination of the human eye or eyes for any disease or pathological condition. Existing law authorizes the Board of Optometry, with the advice and consent of the Medical Board of California, to designate the specific topical pharmaceutical agents to be used for these purposes. As amended May 2, this bill would state the intent of the legislature that the scope of optometric practice be as set forth in this bill, and that optometrists be prohibited from performing acts outside the scope of practice as set forth in the bill.

In a modified reintroduction of 1994's AB 2020 (Isenberg) *[14:2&3 CRLR 94]*, SB 510 would provide that the practice of optometry includes, among other things, the examination of the human eye, or its appendages, and the analysis and diagnosis of conditions of the human vision system, either subjectively or objectively. The bill would delete the requirement that the Board designate the pharmaceutical agents to be used, and authorize the use of specified diagnostic pharmaceutical agents for purposes of examining the human eye or eyes or its or their appendages for any disease or pathological condition. The bill would also authorize the use, prescribing, and dispensing of specified therapeutic pharmaceutical agents (TPAs) to a patient by an optometrist for the purposes of treating the human eye or eyes, or its or their appendages, for any disease or pathological condition by an optometrist who meets specified requirements. It would exclude from these TPAs controlled substances specified in state and federal law, and prohibit the administration by an optometrist of drugs administered by injection or intravenously. This bill would specify additional practices that are included and excluded from the practice of optometry.

SB 510 would also provide that any use, prescribing, or dispensing of a pharmaceutical agent to a patient by an optometrist pursuant to these provisions is limited to that which is incidental to the practice of optometry, and would specify that dispensing by the optometrist to a patient be without charge. This bill would make it a misdemeanor for any person licensed as an optometrist to refer a patient to a pharmacy that is owned by that licensee or in which the licensee has proprietary interest.

Existing law authorizes only a physician, dentist, podiatrist, or veterinarian to prescribe or write a prescription and to dispense drugs and devices to patients in his/her office, under prescribed conditions. Existing law authorizes the Board to determine educational and examination requirements, with the advice and consent of MBC, of optometrists to be permitted to use diagnostic pharmaceutical agents. SB 510 would instead authorize the Board to determine educational and examination requirements, with the advice and consent of MBC, of optometrists who are issued an original certificate of registration before January 1, 1996, to be permitted to use diagnostic pharmaceutical agents. This bill would establish a seven-member pharmaceutical advisory committee with a prescribed membership to provide advice to the Board as to the use of diagnostic and therapeutic agents.

This bill would also authorize the Board to determine educational and examination requirements, with the advice and consent of the pharmaceutical advisory committee established by the bill, for licensure of optometrists who are issued an original certificate of registration on or after January 1, 1996, to be permitted to use diagnostic pharmaceutical agents and use, dispense, or prescribe TPAs. It would authorize only optometrists who successfully complete several examination and training requirements to be permitted to use, dispense, or prescribe TPAs.

Existing law requires the Board to require, by regulation, that optometrists, as a condition of licensure renewal, submit proof of having obtained certain continuing education. This bill would require licensees to complete, at a minimum, 25 hours of continuing education per year, and would require that one-third of those hours relate to the diagnosis, treatment, and management of ocular disease.

This bill would state the intent of the legislature that to the extent an optometrist's scope of practice is equivalent to that of a physician, and optometrist shall be subject to the same criminal penalties as could be applied to a physician. *[S. B&P]*

AB 1969 (Isenberg), as amended April 5, is very similar to SB 510 but would include within the expanded scope of practice of optometrists the examination of the adnexa for any disease or pathological

condition; and would authorize the use, prescribing, and dispensing of specified TPAs to a patient by an optometrist for the purposes of treating the human eye or eyes, or its or their appendages and adnexa. Also, instead of providing that any use, prescribing, or dispensing of a pharmaceutical agent to a patient by an optometrist is limited to that which is incidental to the practice of optometry, AB 1969 would require that such use, prescribing, or dispensing of a pharmaceutical agent be limited only to the practice of optometry. *[A. Health]*

Future Legislation. At its August 24–25 meeting, the Board discussed concerns about SB 510 (*see above*), and announced that it would seek an author for a Board-sponsored scope of practice/TPA bill. On October 10, however, Senator Polanco proposed a new COA-sponsored measure—Preprint SB 9—which was apparently drafted without input from the Board. The measure would create a new certification program within the Board of Optometry to certify California optometrists to diagnose and treat certain diseases and pathological conditions of the eye(s), impose educational and training requirements on those seeking certification, increase the continuing education requirements and time within which these requirements must be met for license renewal of optometrists certified to treat and diagnose certain ocular conditions, establish a TPA advisory committee within the Board, eliminate the advice and consent authority of DOL concerning the use of topical pharmaceutical agents, prohibit optometrists from holding themselves out to the public as being "specialist(s) in eye disease," and authorize the Board to impose a new fee relative to the issuing of TPA certificates. This bill would also make it unprofessional conduct for an optometrist not to refer a patient to an appropriate physician when response to treatment does not occur within a reasonable time, and revise the Pharmacy Law in order to authorize prescriptions by TPA-certified optometrists.

According to the Board, there are several similarities and differences between SB 510 and Preprint SB 9. For example, both bills would delete the DOL advice and consent authority, and both bills would hold TPA-certified optometrists to the same standard of care as physicians. However, Preprint SB 9 would state that TPA-certified optometrists may use only topical (no oral) TPAs for treating eyes and the appendages and adnexa for any anterior segment disease or pathological condition. Under SB 510, TPA-certified optometrists must agree to accept Medi-Cal patients and would not be able to administer drugs by injection or intravenously.

At its December meeting, the Board voted to take an oppose position on Preprint SB 9, and unanimously agreed to seek an author to carry its own TPA legislation.

LITIGATION

In ***United States v. Vision Service Plan***, No. 94CV02693, filed by the U.S. Department of Justice (DOJ) in U.S. District Court for the District of Columbia in December 1994, the federal government alleged that California-based Vision Service Plan (VSP), the country's largest vision care insurance plan, violated section 1 of the Sherman Act by illegally requiring so-called "most favored nation" (MFN) clauses in its contracts with optometrists. According to DOJ, the MFN clause prohibits each VSP optometrist from charging VSP patients higher fees than those charged non-VSP patients; requires VSP optometrists to notify VSP if a published VSP fee schedule exceeds their usual and customary fee, and requires them to accept the lower fee; and requires participating optometrists to accept reduced fees if VSP determines the optometrist has charged it higher fees than those charged non-VSP patients. According to Anne Bingaman, assistant attorney general in charge of DOJ's Antitrust Division, the MFN clause discourages optometrists from offering discounts to non-VSP patients from competing plans, and vision care insurance plans that had previously contracted with optometrists at discounts between 20–40% were no longer able to obtain those discounts.

On the same day it filed the lawsuit, however, DOJ also filed a proposed consent decree which—if approved by the court—would settle the matter. Under the proposed consent decree, VSP will discontinue its practice of using the challenged MFN clause and will adopt a new fee system based on a range of fees accepted by optometrists. Also pursuant to the proposed consent decree, VSP would be prohibited from maintaining, adopting, or enforcing any policy or practice of linking payments made by VSP to any VSP panel optometrist to fees charged by the optometrist to any non-VSP patient or any non-VSP plan; differentiating its payments to, or other treatment of, any VSP panel optometrist because the optometrist charges any fee lower than that charged by the optometrist to the VSP, to any non-VSP patient, or to any non-VSP plan; taking any action to discourage any VSP panel optometrist from participating in any non-VSP plan or from offering or charging any fee lower than that paid to the optometrist by VSP to any non-VSP patient or to any non-VSP plan; monitoring or auditing the fees that any VSP panel optometrist charges any non-VSP patient or non-VSP plan; and communicating in any fashion with any VSP panel optometrist regarding the his/her participation in any non-VSP plan or regarding the his/her fees charged to any non-VSP patient or to any non-VSP plan. *[15:2&3 CRLR 87; 15:1 CRLR 83–84]*

On November 13, DOJ agreed to revise its final judgment and competitive impact statement in response to VSP's request to change the settlement because it found it difficult to comply with operating agreements with states for which it acts as agent for Medicaid or Medicare programs under the agreement, and because it encountered difficulties in trying to calculate fees for panel optometrists under the terms of the original proposal. Among other things, the revised agreement:

–permits VSP to implement the reimbursement methodologies of any Medicare program or any state Medicaid program it may administer, including collecting fee information, while precluding VSP from using that fee information in setting the fees that VSP pays its panel optometrists for providing services to VSP patients not covered by Medicare or Medicaid;

–eliminates VSP's ability to collect information and calculate payments to panel optometrists based on modal or median fees; and

–allows VSP to retain the option of calculating the fees that it pays panels optometrists based on their usual and customary fees, and permits VSP to ask each panel optometrist to report annually only the optometrist's usual and customary fees before any discounts are applied and to verify, if warranted, only the fee information.

At this writing, the court has not yet approved the proposed consent decree.

In ***State of Florida v. Johnson & Johnson, et al.***, No. 94-619-CIV-J-20, the Florida Attorney General filed a nationwide class action in U.S. District Court for the Middle District of Florida against Bausch & Lomb Inc., Johnson & Johnson Vision Products Inc., the American Optometric Association, the Contact Lens and Anterior Segment Society, and nine optometrists; the Attorney General contends that the defendants engaged in a conspiracy to restrict the sale of soft contact lenses. According to the action, the defendants made soft contact lenses available

only to optometrists, ophthalmologists, and opticians—who often mark up the lens prices significantly—and not to alternative channels of distribution such as pharmacies, mail-order firms, and similar entities which may offer discounted prices on the lenses. The action further claims that the named optometrists and the Society tried to persuade lens manufacturers not to distribute soft lenses to alternative chains of distribution, and that the Society threatened not to prescribe the lenses of any manufacturer which sold its product to pharmacies or mail-order channels of distribution. At this writing, the matter is not expected to be heard until at least late 1996 or early 1997.

RECENT MEETINGS

At its December 1–2 meeting, in response to questions regarding the amount of time necessary to complete the rulemaking process, the Board reviewed the procedural requirements which must be met in order to adopt, amend, or repeal a regulation; staff will also prepare and distribute a flowchart explaining the rulemaking process as set forth in the Administrative Procedure Act.

Also at its December meeting, the Board reelected John Anthony, OD, to serve as President; Robert Dager, OD, to serve as Vice-President; and Mona Tawatao to serve as Secretary.

FUTURE MEETINGS

March 15–16 in Anaheim.
May 13–14 in San Jose.
August 22–23 in Sacramento.
November 18–19 in San Diego.

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, medical device retailers, 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 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 nonlicensees. The remaining members are pharmacists, five of whom must be active practitioners. All are appointed for four-year terms.

In May 1995, Board member Kent Wilcox resigned, but will continue to serve until Governor Wilson appoints his replacement.

MAJOR PROJECTS

Distribution of Drug Samples. On May 24, the Board held an informational hearing on the distribution of drug samples in California. Under the current system of distribution, sales representatives of drug manufacturers supply physicians with drug samples to be dispensed directly to patients. The Board held the hearing to receive comments on whether this system provides the best approach to a patient's drug therapy, and to explore alternative approaches to the current system of drug sample distribution.

An issue paper which accompanied the Board's hearing notice identified the positive outcomes of drug sample therapy; specifically, the Board stated that drug sample distribution allows patients to begin drug therapy immediately, reduces patient costs, and allows physicians to readily test a patient's reaction to the drug. However, the Board expressed concerns that drug samples are not monitored and accounted for during their handling, transportation, and distribution to physicians. Other unresolved issues arising out of the distribution and dispensing of drug samples include the fact that no record of use or monitoring of the drug therapy can be maintained by a pharmacist; without record of use, the pharmacist is unable to evaluate a drug's interaction with the patient's entire medication regimen to prevent adverse reactions; the patient will not receive counseling on the use of the drug from a pharmacist; the potential for diversion of drug samples for unintended use by patients; the unauthorized sale of samples by pharmacies; the fact that unlicensed sales representatives of drug manufacturers have access to drugs with no state oversight of storage conditions or means of accounting for quantities dispensed; and the lack of a means to track a drug sample if it is recalled.

The Board is considering an alternative to the current system of sample distribution through the use of a voucher/coupon method of distribution. Under this proposal, a physician could issue a voucher or coupon to a patient, allowing the patient to receive a free sample quantity of a drug from a pharmacy; the free amount that is dispensed would then be billed to the manufacturer.

During the informational hearing, the Board considered comments from manufacturers, practitioners, and representatives of professional associations in support of and in opposition to modifying the existing system of drug sample distribution. In support of the status quo, Dr. Ben Shwachman of the California Medical Association (CMA) stated that the Board has not identified and proven that a problem exists under the current system. Furthermore, CMA contends that current law adequately regulates manufacturers and physicians in the distribution and dispensing of drug samples. Others in favor of the current system noted that the alternative voucher system would only add more recordkeeping requirements and increase costs; issues of distribution accountability and control should not impair the availability of samples to the medically indigent; pharmacists' inability to update patient drug records is not a realistic justification to discredit the dispensing of drug samples by physicians in light of the numerous prescriptions filled by out-of-state pharmacies; physicians maintain documentation of sample drugs dispensed in the patient's records along with results of the medical examination for which the drug therapy was recommended; and diversion is not a serious health concern since samples do not include Schedule II drugs.

In opposition to the current method of dispensing drug samples, Robert Marshall of the California Pharmacists Association (CPhA) expressed support for the alternative voucher method of dispensing samples through a pharmacy. CPhA contends that the proposed method would allow entry of relevant data in the patient profile, eliminate the waste of different packaging used on sample sizes, afford patients adequate labeling not found on samples, and provide the opportunity for oral consultation with a pharmacist. Those also opposed to the existing system of drug sample distribution emphasized that patients to whom samples are dispensed are not receiving drugs judged on their pharmacological merits but as a result of marketing strategies. Other advocates of the proposed voucher system contend that the alternative method of sample distribution would better protect the public through the services offered by a pharmacist and the safeguards of drug accountability.

Following public comments, the Board clarified that physicians are held to the same standards required of pharmacists