new nurse assistants, a precertification training program, and continuing in-service training, and requires the facility to consider including training regarding the characteristics and method of assessment and treatment of AIDS. As amended May 2, this bill would require, in addition, that each facility consider the unique behavioral and functioning characteristics of individuals with Huntington's disease, Alzheimer's disease, and other dementing disorders so that the highest quality of care may be provided. *[S. Floor]*

LITIGATION

In ***Rains v. Belshe***, 32 Cal. App. 4th 157 (Feb. 8, 1995), the First District Court of Appeal upheld the constitutionality of Health and Safety Code section 1418.8, which provides for the authorization of necessary but non-emergency medical treatment for nursing home patients who lack the mental capacity to consent and have no surrogate decisionmaker. Section 1418.8 authorizes a doctor to determine that a patient is both incompetent and has no surrogate decisionmaker; once the doctor makes these two findings, the patient's decisions are made by an "interdisciplinary team," consisting of the doctor and a nurse, possibly other staff members and, where practicable, a patient representative.

Esther Rains petitioned for a writ of mandate to invalidate section 1418.8 on the grounds that it violates the privacy and due process rights of the nursing home patients it affects. However, the First District Court of Appeal found that a nursing home patient's important interest in obtaining necessary medical treatment even when he/she is unable to provide consent for that treatment outweighs his/her legally protected privacy interest in his/her own personal bodily autonomy. Further, the court held that section 1418.8 does not violate the due process rights of mentally incompetent patients because the statute provides a clear test for the determination of a patient's incapacity to decide on medical care, the opportunity for judicial review of a determination of incapacity, and the participation of a patient representative in the decisionmaking process. Critics of the decision believe the court is improperly giving too much deference to professional medical judgment.

RECENT MEETINGS

At BNHA's February 16 meeting, then-Executive Officer Pamela Ramsey reported that DCA will be adding BNHA to its Applicant Tracking System (ATS); this requires BNHA to allocate one staff person to DCA for six months to assist in the design and implementation of the system. Ramsey also reported that BNHA is the only DCA board that is not on DCA's enforcement tracking system; staff is looking into implementation of this system as well.

At BNHA's May 11 meeting, Interim Executive Officer Curt Augustine reported that some of the Board's planned activities may be delayed due to the change of executive officers. However, Board staff reported that office automation is under way with the purchase of two new computers. BNHA's new Executive Officer Kim Smith assured the Board and the public that the expert witness program is her top priority and she hopes to have the program finalized by early fall. *[15:1 CRLR 81]*

FUTURE MEETINGS

August 17 in San Francisco.
November 9 in San Diego.

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

Branch Office Restrictions As Applied to Independent Practice Associations. In December 1994, the Board consulted Department of Consumer Affairs (DCA) legal counsel Robert Miller about two applications for registration of optometric corporations. While the applications specified only one address, they were apparently intended to be vehicles for the establishment of "independent practice associations" (IPAs) and optometric services would actually be rendered through numerous optometrists practicing at different locations. Because Miller 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 disclaimed having any branch offices, Miller recommended that the applications be denied. However, the Board at its December 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 9–10 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.

Board Publishes Regulatory Proposals. On April 7, the Board published notice of its intent to adopt new sections 1523 and 1524, amend sections 1530, 1531, 1532, 1533, 1535, and 1536, and repeal section 1526, Title 16 of the CCR, regarding the Board's examination process and continuing optometric education requirements. *[15:1 CRLR 82; 14:4 CRLR 89]* Specifically, the Board proposed the following changes:

- New section 1523 would consolidate the Board's examination and application requirements into one reference source for licensure candidates.
- New section 1524 would 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.
- Amendments to section 1530 would repeal the existing language and instead specify that each applicant for licensure must obtain a passing score of at least 75% in each of the required examination sections.
- Amendments to section 1531 would delete antiquated examination composition language and clearly delineate each examination section and its composition.

• Amendments to section 1532 would 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.

• Amendments to section 1533 would 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.

• Amendments to section 1535 would 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.

• Amendments to section 1536 would provide that no more than four hours of continuing education (CE) coursework shall be in the area of practice management; 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; 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, 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. The Board is authorized to require the CPR certification by AB 2943 (Hauser) (Chapter 578, Statutes of 1994). *[14:4 CRLR 89]* The Board also seeks to repeal section 1526, which requires CPR certification as a condition of license renewal, as that requirement will now be contained in section 1536.

Also on April 7, the Board published notice of its intent 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. *[15:1 CRLR 84]*

At this writing, the Board is scheduled to hold a public hearing on all of the above proposed changes on May 23 in South San Francisco.

Board Continues to Oppose MBC Proposal to Permit Medical Assistants to Perform Optometric Tasks. In *Engineers and Scientists of California (ESC), et al. v. Division of Allied Health Professions*, No. 532588 (Apr. 25, 1994), the Sacramento County Superior Court invalidated parts of section 1366, Title 16 of the CCR, the Medical Board of California's (MBC) regulation which sets forth the technical supportive services which may be performed by unlicensed medical assistants (MAs). Due to procedural irregularities in the rulemaking process, the court struck down section 1366(b)(4), which permitted MAs to perform "automated visual field testing, tonometry, or other simple or automated ophthalmic testing" under certain conditions. The regulation was challenged by ESC and COA on both procedural and substantive grounds, but the court did not reach ESC/COA's argument that the regulation impermissibly allows MAs to perform tasks reserved for licensed optometrists. *[14:4 CRLR 89; 14:2&3 CRLR 94; 14:1 CRLR 72]*

In December 1994, MBC's Division of Licensing (DOL) reinstituted the rulemaking process to reinstate the controversial provision. This time, the regulatory language would permit MAs to "perform ophthalmic testing not requiring interpretation in order to obtain test results, including (for example) but not limited to, the operation of automated objective ophthalmic testing equipment, color vision and depth perception." As published, the language precludes MAs from performing "subjective refractions or any other procedure requiring the exercise of any judgement or interpretation of the data obtained on the part of the operator." *[15:1 CRLR 83]*

At the Board's March 9–10 meeting, Executive Officer Karen Ollinger reported that DOL held a public hearing on the proposed regulatory change on February 3; following the hearing, DOL took no action and tabled the issue. Ollinger opined that after DOL reviews the comments and testimony received, it will approve the change and submit the proposal to the Office of Administrative Law (OAL) for review and approval. Ollinger further reported that no action was taken to change the Board's previous decision to oppose the regulatory change, and provided the Board with a copy of her February 2 letter to MBC setting forth the Board's reasons for opposing the proposed change; among other things, Ollinger claimed that MBC lacks statutory authority to authorize the practice of optometry by MAs, and that the proposed regulation lacks clarity as required by the Administrative Procedure Act.

On March 17, DOL released a modified version of its proposed regulatory change for public comment. The modified version retains the changes to section 1366(b)(4) as published and described above; amends section 1366(a)(1) to declare that MAs may not administer local anesthetic agents; and repeals section 1366(d) (which prohibits MAs from practicing optometry) as duplicative of existing law. After another public hearing at its May 11 meeting, DOL adopted the revised language; at this writing, DOL staff is preparing the rulemaking file on these proposed regulatory changes for submission to OAL. (*See* agency report on MBC for related discussion.)

LEGISLATION

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]*

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 April 6, this bill—which is a reintroduction of 1993's AB 1894 (Polanco)—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. *[A. Health]*

SB 640 (Craven). Existing law provides for the examination and licensure of spectacle lens and contact lens dispensers, and prohibits a person from fitting or adjusting contact lenses without being registered or working under the direct responsibility and supervision of a registered contact lens dispenser who is present on the registered premises. As amended May 2, this bill would prohibit, commencing January 1, 1997, any person located outside of California from shipping, mailing, or delivering contact lenses to residents of California unless registered with MBC's Division of Licensing. The bill would require 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 would provide that contact lenses may be dispensed only within one year of the date on the written prescription, and if the written prescription is unavailable to the seller, it would require the seller to directly communicate with the prescriber to confirm the prescription. The bill would also set forth circumstances under which registration may be denied, suspended, or revoked, and establish procedures for renewal of registration. It would authorize the Division of Licensing to adopt regulations necessary to administer these provisions. *[A. Health]*

AB 1107 (Campbell), as amended May 15, would, notwithstanding existing law, permit pharmacists, including nonresident pharmacies, to dispense replacement contact lenses, as defined in accordance with certain requirements. This bill would also add a requirement that nonresident pharmacies maintain records of all replacement contact lenses shipped, mailed, or delivered to California residents. *[A. Appr]*

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. *[15:1 CRLR 83–84]* 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 March 9–10 meeting, the Board decided to pursue legislation authorizing it to convert its annual license renewal system to a biennial license renewal system.

Also at its March meeting, the Board received testimony in support of and opposition to a proposal to allow optometrists to use collagen punctal plugs as a diagnostic tool. Those in support of the proposal testified that it is a quick and progressive procedure; those opposed contended that it is invasive surgery which exceeds an optometrist's scope of practice. Following discussion, the Board agreed to accept collagen punctal plugs as a diagnostic tool for optometrists which falls within the scope of practice of optometry. This policy appears to conflict with the Board's earlier position on this issue; in May 1991, the Board determined that "the use of collagen implants by an optometrist would not be within the current scope of optometric practice." *[11:3 CRLR 99–100]*

FUTURE MEETINGS

May 22–23 in San Francisco.
August 24–25 in Sacramento.
December 1–2 in Orange County.

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.

On January 30, Governor Wilson appointed Caleb Zia to the Board as a public member. Zia is the President and Executive Director of the Minority Business Council of Orange County, as well as the President of Chesterfield Corporation, a business consulting and management firm; he also serves on the board of Allied Biotechnology International, Inc., a research and manufacturing company which produces bio-pharmaceuticals, diagnostic assays, and health care products.

MAJOR PROJECTS

Medical Device Retailer Locked Storage. AB 1807 (Bronshvag) (Chapter 26, Statutes of 1994) authorizes a medical device retailer to establish a locked storage facility for furnishing dangerous devices in emergencies or after working hours; provides that the locked storage may be installed or placed in a service vehicle of the medical device retailer for after-hours or emergency delivery to patients who have prescriptions for dangerous devices; and authorizes the Board to adopt regulations to permit an exempt person to direct a non-licensed employee of a medical device retailer who operates a service vehicle equipped with locked storage to deliver a dangerous device from the locked storage to patients having prescriptions for dangerous devices. *[14:1 CRLR 74]* However, under existing section 1748.1, Title 16 of the CCR, only an exemptee (either a California registered pharmacist or someone who becomes licensed by the Board as an "exemptee" after passing a Board-administered exam) may furnish dangerous devices from a locked storage of a medical device retailer.

On March 17, the Board published notice of its intent to amend section 1748.1 to implement AB 1807 and expand the personnel authorized to provide emergency or after-hours delivery of dangerous devices to patients of a medical device retailer to include an employee who operates a service vehicle. The proposed amendments would require that dangerous devices be furnished from the locked storage only by an exemptee or upon the oral or written direction of an exemptee to an employee of the medical device retailer who operates the service vehicle. The amendments further provide that the exemptee is responsible for checking the contents of the locked storage and for noting on the inventory the dangerous devices furnished within 72 hours of the furnishing of the dangerous device from the locked storage to a patient.

At this writing, the Board is scheduled to hold a public hearing on the proposed amendments to section 1748.1 on May 24 in Sacramento.

Examination Admission Requirements. Also on March 17, the Board published notice of its intent to amend section 1719, Title 16 of the CCR, which specifies