that HCFA has yet to release the proposed guidelines; Mr. Nikkel anticipated the release to be forthcoming and opined that the public comment period should begin in early October.

Examination and Enforcement Statistics. The pass rate for the April 11 state exam for nursing home administrators (NHA) was 73%; the national exam pass rate was 74%. On the July 11 NHA exam, the pass rates were 51% for the state test and 61% for the national exam.

From March 15 to July 31, BENHA received four citations from the Department of Health Services (DHS) for "AA" violations, which are violations of standards which lead to a patient's death, and 70 "A" violations, which seriously endanger a patient's safety with a substantial probability of death or serious bodily harm. BENHA conducted nine informal telephone counselling sessions and issued four letters of warning. Finally, BENHA received four accusations from DHS for review and requested seven accusations against NHAs.

In August, BENHA issued its notice of nursing home administrators whose licenses are suspended or revoked or who were placed on probation current through August 6; BENHA is required to publish this information pursuant to AB 1834 (Connelly) (Chapter 816, Statutes of 1987). (See CRLR Vol. 9, No. 3 (Summer 1989) p. 64; Vol. 9, No. 1 (Winter 1989) p. 58; and Vol. 8, No. 3 (Summer 1988) p. 71 for extensive background information.) Currently, 22 NHAs are on probation, nine of whom are presently working as the designated administrator of a nursing home in California.

LEGISLATION:

The following is a status update on bills reported in detail in CRLR Vol. 11, No. 3 (Summer 1991) at page 99:

AB 1615 (Hannigan). Existing law requires an administrator of a residential care facility for the elderly (RCFE), if other than the licensee of the facility, to successfully complete a prescribed certification program. As amended September 9, this bill requires that the certification program contain different requirements for an individual designated as an administrator who holds a valid license as a nursing home administrator, and for an individual who was both the licensee and administrator of the facility on or before July 1, 1991. AB 1615 was signed by the Governor on October 11 (Chapter 848, Statutes of 1991).

SB 679 (Mello), as amended September 10, authorizes courts to award attorneys' fees and costs where it is proven by clear and convincing evidence that a defendant is liable for abuse of an elder or dependent adult, and that the defendant has been guilty of recklessness, oppression, fraud, or malice in the commission of the abuse. SB 679 was signed by the Governor on October 9 (Chapter 774, Statutes of 1991).

AB 1191 (Epple). As amended June 11, this bill would, with specific exceptions, require that a physician, prior to the administration of a physical restraint to a resident of a skilled nursing facility or intermediate care facility, seek consent from the resident (if he/she has the capacity to understand and make health care decisions) or the legal representative of the resident. For a resident who is unable to make health care decisions, as determined by the resident's physician, this bill would require a facility to conduct a physical restraint review process. AB 1191 is a two-year bill pending in the Assembly Ways and Means Committee.

AB 95 (Friedman), as amended May 15, would prohibit (except in an emergency) a long-term health care facility from using a physical restraint on a resident unless the facility has verified that the resident has given his/her informed consent, as specified, to the use of the physical restraint, and the informed consent has been documented by the physician in the resident's medical record. Additionally, this bill would require that skilled nursing and intermediate care facilities' written policies regarding patients' rights ensure that each patient admitted to the facility has the right to be free from any physical restraint which is not required for medical purposes, but is imposed for purposes of discipline or convenience, and is notified of this right. AB 95 is a two-year bill pending in the Assembly Ways and Means Committee.

SB 664 (Calderon), as introduced March 5, would prohibit nursing home administrators, 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 two-year bill is pending in the Senate Business and Professions Committee.

RECENT MEETINGS:

At BENHA's June 5 meeting, Executive Officer Ray Nikkel announced that he anticipates a closer working relationship with DHS' Licensing and Certification district offices. Mr. Nikkel plans to attend a monthly staff meeting of each office so that he may deliver a brief overview of current activity involving the Board, discuss responsibilities within the scope of the Board, review the information available to BENHA and information the Board is interested in receiving, inform the district offices of BENHA's administrator-in-training expectations, and discuss other administrative issues. The meetings will be scheduled throughout the year and Mr. Nikkel will address the Board as they occur.

At its August 14 meeting, BENHA was introduced to Jim Conran, the new Director of the Department of Consumer Affairs. In his remarks to the Board, Conran stated that he is planning a very aggressive agenda toward quality care and consumerism, and that he expects every DCA board and bureau to be responsive to public protection and consumer need.

FUTURE MEETINGS:

To be announced.

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 are licensed optometrists and three are public members. One optometrist position is currently vacant due to the June 3 resignation of Ronald Kosh.

MAJOR PROJECTS:

Disciplinary Guidelines. At its August meeting, the Board adopted Disciplinary Guidelines and Model Disciplinary Orders; at this writing, the Board's guidelines for the imposition and assessment of administrative fines and citations have not been finalized. The purpose of the guidelines is to establish consistency in disciplinary penalties for similar offenses, although mitigating or aggravating circumstances may necessitate variations in individual cases. The guidelines will be used by

the Attorney General's office (which prosecutes disciplinary violations), administrative law judges who preside over disciplinary hearings, optometrists, and the Board itself.

The guidelines include general and specific probationary conditions. The general probationary conditions to be included in all probation cases require disciplined optometrists to obey all federal, state, and local laws, and all rules governing the practice of optometry in California; cooperate with probation surveillance; and successfully complete the probationary period. In addition, the probationary period will be tolled if the respondent moves or practices outside California, and probation will be revoked after proper notice and opportunity to be heard if probation is violated.

The guidelines also enumerate maximum and minimum penalties for specific offenses, as well as suggested conditions that also may be imposed. Specific offenses covered include excessive prescribing; violation of prescription standards; excessive treatment; sexual misconduct; mental or physical illness; gross negligence and inefficiency; failure to refer patient; violation of quality standards for ophthalmic devices; violation of sanitary standards; violations regarding topical pharmaceutical agents; unprofessional conduct, dishonesty, and fraud; practice during suspension; drug abuse; alcohol abuse; aiding and abetting unlicensed practice; acceptance of unlawful employment; unlawful location for practice; deceptive advertising; prohibited arrangements by optometrists; holding oneself out as an optometrist without a certificate; misuse of professional titles or abbreviations; unlawful solicitation; unlawful referrals; employment of cappers or steerers; criminal conviction; procuring a license by fraud; fictitious name violations; violations of probation; and violations by professional corporations.

Refresher Course. The refresher course planned for graduates of foreign optometric schools has turned into a refresher course available to all optometrists. (See CRLR Vol. 11, No. 3 (Summer 1991) p. 99; Vol. 11, No. 2 (Spring 1991) p. 95; and Vol. 11, No. 1 (Winter 1991) p. 81 for extensive background information.) According to Board staff, because public funds are being used to finance the course, it must be open to everyone. The Board has spent $300,000 to implement the eighteen-month course that began on September 9 in Los Angeles through the UCLA Health Sciences Extension Program. The refresher course is being administered by Dr. Martin Schickman and Dr. Feelie Lee of UCLA. The curriculum includes classes in anatomy, neuro-anatomy, histology, physiology, biochemistry, microbiology, and pathology. The cost of the program to students is $3,000.

Random Audit of Optometrists to Ensure Compliance with CE Requirements. The Board has undertaken a random audit of optometrists to ensure that they are complying with mandatory continuing education (CE) requirements and CPR certification. The Board requires that documentation of the required number of CE hours be submitted with an optometrist's license renewal. If the documentation is verified, a renewal is issued; if it cannot be verified, the file is turned over to the enforcement division. By the end of September, approximately 3% of licensed optometrists had been sampled; as a result of those audits, the Board issued 22 notices of violation.

Regulatory Changes. The Board's Legislation and Regulations Committee was scheduled to meet in Sacramento on July 29 to continue its comprehensive review of the Board's regulations; however, this meeting was cancelled. Steve Martini, the Department of Consumer Affairs legal counsel previously assigned to the Board, recently left DCA; a new meeting to review the Board's regulations will not be scheduled until a permanent attorney is appointed to replace him. The Board is presently working with an interim attorney from the Department. (See CRLR Vol. 11, No. 3 (Summer 1991) p. 99; Vol. 11, No. 2 (Spring 1991) p. 96; and Vol. 11, No. 1 (Winter 1991) p. 81 for background information.)

LEGISLATION:

SB 101 (Hart), as amended June 19, establishes statewide guidelines on child support and enacts provisions relating to the enforcement of family support obligations. Among other things, it prohibits various professional licensing agencies, including the Board of Optometry, from issuing or renewing a license to a person listed by the Department of Social Services as being in noncompliance with a support order or judgment issued by a court of this state. Instead, this bill requires the Board to issue a 120-day temporary license to such an applicant or licensee; if, upon the expiration of the temporary license, the applicant is in compliance with all court orders and judgments for support, the Board would be able to issue a regular license. SB 101, which the Board opposed, was signed by the Governor on July 2 (Chapter 110, Statutes of 1991).

The following is a status update on bills reported in detail in CRLR Vol. 11, No. 3 (Summer 1991) at page 100:

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 two-year 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 two-year bill is pending in the Senate Health and Human Services Committee.

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 two-year 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 two-year 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 July 10, this bill would instead require a registered optometrist to furnish to each patient there fitted or supplied with prescription spectacle lenses a specified receipt. This two-year bill is pending in the Assembly Health Committee.

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

RECENT MEETINGS:

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

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

FUTURE MEETINGS:

February 20–21 (location undecided).

May 29–30 (location undecided).

BOARD OF PHARMACY

Executive Officer: Patricia Harris
(916) 445-5014

Pursuant to Business and Professions Code section 4000 *et seq.*, the Board of Pharmacy grants licenses and permits to pharmacists, pharmacies, drug manufacturers, wholesalers and sellers of hypodermic needles. It regulates all sales of dangerous drugs, controlled substances and poisons. The Board is authorized to adopt regulations, which are codified in Division 17, Title 16 of the California Code of Regulations (CCR). To enforce its regulations, the Board employs full-time inspectors who investigate accusations and complaints received by the Board. Investigations may be conducted openly or covertly as the situation demands.

The Board conducts fact-finding and disciplinary hearings and is authorized by law to suspend or revoke licenses or permits for a variety of reasons, including professional misconduct and any acts substantially related to the practice of pharmacy.

The Board consists of ten members, three of whom are public. The remaining members are pharmacists, five of whom must be active practitioners. All are appointed for four-year terms.

MAJOR PROJECTS:

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

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

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

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

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

Compounding for Office Use. At its July 31 meeting, the Board continued the regulatory hearing on proposed sections 1716.1 and 1716.2, regarding the definition of the "reasonable quantity of compounded medication" which a pharmacist may furnish to a prescriber for office use under Business and Professions Code section 4046(c)(1). (See CRLR Vol. 11, No. 3 (Summer 1991) p. 102; Vol. 11, No. 2 (Spring 1991) p. 98; and Vol. 11, No. 1 (Winter 1991) p. 83 for background information.) Proposed new section 1716.1 would clarify the definition of the terms "reasonable quantity," "compounded," and "prescriber office use" as referenced in Business and Professions Code section 4046(c)(1). Proposed new section 1716.2 would specify the minimum types of records that pharmacies must keep when they furnish compounded medication to prescribers in quantities larger than required for the prescriber's immediate office use or when a pharmacy compounds medication for future furnishing.