



REGULATORY AGENCY ACTION

Following Palmer's presentation, BENHA formed a subcommittee consisting of Nancy Campbell and John Colen to analyze all aspects of the program and report its findings and recommendations at the Board's next meeting.

Examination and Enforcement Statistics. The pass rate for the January 9 state exam for nursing home administrators (NHA) was 60%; the national exam pass rate was 54%.

In February, BENHA issued its notice of nursing home administrators whose licenses are suspended or revoked or who were placed on probation through January 30; BENHA is required to publish this information pursuant to AB 1834 (Connelly) (Chapter 816, Statutes of 1987). As part of its implementation of AB 1834, BENHA provides the Department of Health Services (DHS) with a monthly list of all changes of facility administrators reported to the Board, as well as a list of all nursing home administrators who have had their licenses revoked, suspended, or have been placed on probation during the last three years. In return, DHS provides BENHA with copies of enforcement actions initiated against facilities including facility license revocation actions, final involuntary decertifications from the Medicare/Medi-Cal programs, and all class "AA" and "A" citations issued after July 1, 1988. The February report reveals that twelve NHAs are on probation, five of whom are presently working as the designated administrator of nursing homes in California.

From December 1, 1991 through March 31, 1992, BENHA received three citations from DHS for "AA" violations, which are violations of standards which lead to a patient's death, and 69 "A" violations, which seriously endanger a patient's safety with a substantial probability of death or serious bodily harm. BENHA conducted six informal telephone counselling sessions, issued two letters of warning, and requested three accusations against NHAs.

BENHA Releases Newsletter. In its February newsletter, the Board reminded NHAs that at least ten hours, or 25%, of each NHA's continuing education requirement must be in the area of aging or patient care. Courses relating to patient care may include any elements of the physical, psychological, or sociological aspects of care. Courses concerning aging should relate to the processes and facets of aging, and may relate to any of its biological, mental, or sociological implications.

LEGISLATION:

SB 2044 (Boatwright), as amended

April 2, would declare legislative findings regarding unlicensed activity and authorize all Department of Consumer Affairs boards, bureaus, and commissions, including BENHA, to establish by regulation a system for the issuance of an administrative citation to an unlicensed person who is acting in the capacity of a licensee or registrant under the jurisdiction of that board, bureau, or commission. [A. CPGE&ED]

SB 664 (Calderon). Existing law prohibits 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, unless the patient is apprised at the first solicitation for payment of the name, address, and charges of the clinical laboratory performing the service. As amended March 12, this bill would also make this prohibition applicable to any subsequent charge, bill, or solicitation. This bill passed both the Senate and Assembly, and is currently awaiting Senate concurrence in Assembly amendments.

The following bills died in committee: **AB 1191 (Epple)**, which would have, with specific exceptions, required 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; and **AB 95 (Friedman)**, which would have prohibited (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 to the use of the physical restraint, and the informed consent has been documented by the physician in the resident's medical record. AB 95 died in committee.

RECENT MEETINGS:

At its February 5 meeting, BENHA reviewed and approved a notice which will be sent to all licensees informing them of BENHA's plan to raise its biennial license renewal fee from \$190 to approximately \$225. At this writing, however, no legislation has been introduced to accomplish this fee increase.

At its April 7 meeting, BENHA reviewed its 1992 goals and objectives. BENHA's goals include establishing a 1993-94 budget based upon available resources that assures the continuance of

essential operations necessary to accomplish the Board's mission; obtaining legislative authorization to increase fees charged by the Board to ensure that adequate funds are available for the Board to carry out its functions; seeking legislation to move the RCFE administrator certification program from DSS to BENHA; providing input, reviewing, and implementing the new federal nursing home administrator standards; and taking appropriate remedial and formal disciplinary actions against licensees who violate the laws and regulations governing the management and operation of long-term care facilities.

Also at its April meeting, BENHA held its annual election of officers and unanimously elected James Wark to serve as chair, Nancy Campbell as vice-chair, and Stroube Richardson as secretary.

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 1991 resignation of Ronald Kosh. At the end of June 1992, two more positions will become vacant upon expiration of the terms of optometrist Gene D. Calkins and public member Joseph D. Abella.

MAJOR PROJECTS:

Board Votes to Repeal Examination Appeal Process. On February 20, the Board held a public hearing regarding its proposal to amend section 1533 and repeal section 1533.1, Division 15, Title 16 of the CCR, which would effectively abolish examination appeals. [12:1 CRLR 89] Currently, licensure candidates may appeal their exam score if they fail to receive a passing grade, cite the specific items in



question, and adhere to specified time limits.

According to the Board, the amendment to section 1533, which would permit a candidate for licensure to inspect only his/her answer sheets instead of his/her examination papers, is based on exam security. The Board contends that it is not able to develop a large enough pool of test questions to allow for such free access to prior examination questions without compromising the security of its examination. The proposed amendments would also eliminate the current two-hour time limitation for review of one's examination papers, as such a restriction would no longer be appropriate.

Eyexam2000 of California, Inc., opposed the Board's proposed amendments to section 1533, stating that without access to the examination questions, a licensure candidate would be effectively precluded from making any determination as to whether either a scoring error or a subjective scoring decision, which may otherwise be appealable, might have occurred. Eyexam2000 noted that other professions have similar concerns regarding examination security and have addressed them in some manner other than completely eliminating any opportunity for a candidate to review his/her exam and confirm that it was appropriately scored. Additionally, Eyexam2000 contended that, without the opportunity to review the exam itself, candidates are forced to trust that all exams were reviewed without human or mechanical error and that no questions are open to dual interpretation.

The repeal of section 1533.1 would effectively abolish the existing process of appealing examination results. According to the Board's initial statement of reasons, the appeal process requires a considerable amount of staff time to administer—time that could be devoted to other programs—and the possibility that an applicant will be successful on appeal does not outweigh the burden placed on the Board; thus, the Board contends that the appeal process should be eliminated.

The Board's proposed elimination of the appeal process was opposed by both the California Optometric Association (COA) and Eyexam2000 at the February 20 hearing. COA characterized the elimination of the appeal provision as "inappropriate" and suggested streamlining current procedures rather than repealing them; COA urged the Board to retain some type of examination appeal procedure.

Eyexam2000 also urged the Board to reject the proposed repeal of section 1533.1, contending that the Board's own Initial Statement of Reasons acknow-

ledges the possibility that an applicant may be successful on appeal; thus, Eyexam2000 argued that such a process is worthwhile. Also, without an appeal procedure, there is no adequate method by which either the examiners and scorers or the applicants may monitor the reliability of the Board's examination. Finally, Eyexam2000 contended that there is an inherent unfairness in requiring an applicant to undertake the burden and expense of retaking an examination when he/she may otherwise be able to successfully appeal the results of the first exam.

Bob Miller, the Department of Consumer Affairs (DCA) legal counsel who advises the Board, responded to these concerns by contending that actual problems with the Board's examination are rare. Miller informed the Board that no formal appeal process would exist if section 1533.1 is repealed and no formal response to candidates' questions would be required; however, applicants who do not pass the exam could still address the Board. After further discussion, the Board voted 4-2 to amend section 1533 and repeal section 1533.1. At this writing, the Board is preparing the rulemaking file for submission to DCA for review and approval; if approved, the rulemaking file will be submitted to the Office of Administrative Law (OAL) for review and approval.

Regulations Committee Meets. After nine months of rescheduling meetings, the Board's Legislation and Regulations Committee finally met in Sacramento in a January 10 closed session to review a number of the Board's regulations; Board members Joseph Dobbs and Mel Santos, Executive Officer Karen Ollinger, and legal counsel Bob Miller were present. The Committee reviewed sections 1502, 1510, 1518, 1526, 1535, and 1536, Division 15, Title 16 of the CCR, and discussed potential regulations relating to the accreditation of optometry schools by the Board, mobile practice, and optometric technicians/assistants. At the Board's February 20 meeting, the Committee's recommendations were discussed and the Board voted to commence the rulemaking process to pursue the following three proposals:

—First, section 1502 currently delegates certain responsibilities to the Board's secretary or, in the secretary's absence, to the Executive Officer. These duties include receiving and filing accusations; issuing notices of hearing and statements of issues; receiving and filing notices of defense; determining the time and place of disciplinary hearings under Government Code section 11508; issuing

subpoenas; and setting dates for hearings. The Board voted to seek an amendment to section 1502 to instead delegate these responsibilities solely to the Executive Officer.

—Second, section 1510 describes conduct which constitutes "professional inefficiency" by an optometrist. The Board will pursue an amendment to section 1510 to add the failure to inform any patient for whom treatment is prescribed, in terms understandable to that patient (or legal guardian, if appropriate), of the risks and benefits of the treatment as constituting professional inefficiency.

—Third, the Board will seek amendments to section 1535, which describes examination requirements. The Board's proposed amendments would require the successful completion of the National Board Examination in Optometry, in addition to the successful completion of the Board examination described in section 1531, Title 16 of the CCR. This change would allow an applicant for licensure to take these exams in any sequence.

At this writing, these proposed actions have not been published in the *California Regulatory Notice Register*.

The Board agreed not to amend section 1518, regarding the criteria necessary for the issuance of a fictitious name permit; section 1526, requiring proof of CPR certification for license renewal; and section 1536, which describes the Board's continuing education requirements. Also, the Board determined that there is no need to change or expand its current practice of accepting the accreditation of optometry schools from the Council on Optometric Education. The Board will hold fact-gathering hearings on mobile practice and optometric technician/assistant issues prior to determining whether regulatory action is necessary. These informal hearings are scheduled for September 15 and 22; the locations have yet to be determined.

Optometry Refresher Course Seeks Instructors. Under section 1530.1 of the Board's regulations, all graduates of foreign schools must furnish satisfactory evidence of their completion of a curriculum which is "reasonably equivalent" to that required by California law. If the foreign curriculum is deficient, the applicant is permitted to remedy deficiencies and qualify for admission to the Board's examination upon furnishing satisfactory evidence of adequate remedial education. While this section establishes the possibility of remedial education, no such remedial education program has ever been available to foreign graduates, such that their only option is to retake and complete



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an entire course of study at a Board-approved optometry school. During the summer of 1990, after years of debate, controversy, and intervention by Senate President pro Tempore David Roberti, the Board was required by the legislature to spend \$300,000 of its reserve fund to establish an approved refresher course for all optometrists, especially graduates of foreign and out-of-state optometric schools. [10:4 CRLR 113; 10:2/3 CRLR 87-88]

The course was designed by the Board and the University of California, and commenced in September 1991 in Los Angeles through the UCLA Health Sciences Extension Program. It includes classes in anatomy, neuro-anatomy, histology, physiology, biochemistry, microbiology, and pathology; the cost of the program to students is \$3,000.

However, the program is experiencing difficulty in acquiring instructors to teach clinical optometrics. The administrator of the refresher course, Dr. Feelie Lee of UCLA, has approached both the Southern California College of Optometry (SCCO) and the University of California School of Optometry at Berkeley, but has been unable to obtain a commitment from instructors to teach. Lee is exploring other options such as hiring instructors from out of state, although this probably will not be a viable option due to budget constraints.

The Board itself has not taken an active role to ensure the success of the program; although it spent over \$300,000 to implement the eighteen-month course, the Board now contends that it lacks jurisdiction to actively support the course. At its February 20 meeting, the Board discussed its alleged lack of jurisdiction to assist UCLA. The Board attributed the difficulties of finding instructors to the degree of specialization required and reluctance on the part of the two optometry schools in California to have their faculty participate. According to Board members, SCCO—which, because of its close proximity to UCLA, is the most feasible choice for obtaining instructors—is hesitant to have its faculty teach the refresher course because it fears competition from the UCLA program and does not want the use of its faculty to be construed as an endorsement of the program. The Board determined that it has no control over the process of selecting instructors and that there is little it can do to facilitate the process. Board member Pamela Miller stated that, legally and ethically, assisting UCLA is out of the Board's jurisdiction.

Karen McGagin, Special Assistant to DCA Director Jim Conran, denounced the Board's position, stating that DCA

believes that the Board, having expended over \$300,000 on the course, must take an active role to ensure the course is a success instead of sitting back and watching it fail. DCA contends that the Board must exhaust all opportunities to assist UCLA and explore avenues other than the two optometry schools in California. McGagin noted that without assistance from the Board, the course could fail; she said that DCA is willing to help the Board resolve existing problems.

The Board responded to DCA's concerns by placing ads in its newsletter and having Board members meet with SCCO representatives to further the process of finding instructors. The notice placed in the Board's newsletter garnered some response from California optometrists. However, at its May meeting, the Board again insisted that it is not a sponsor of the program.

Board Commences Occupational Analysis. The Board recently awarded a contract to Human Resources Strategies to undertake an occupational analysis of practicing optometrists to test their level of knowledge and to determine the scope of their practice. By examining the profession, the Board hopes to determine whether its current licensure examination tests appropriate areas of knowledge. The analysis was scheduled to begin in June and is expected to take one year to complete; a mid-year report is tentatively scheduled to be presented at the Board's November meeting.

Board Responds to DCA Request for Information. The Department of Consumer Affairs recently required the Board to provide DCA with current information regarding the Board's role and functions. For example, DCA asked the Board to discuss the need for regulation in the field of optometry. The Board responded by stating that it receives over 400 complaints per year against optometrists practicing in the state; many of these complaints allege serious violations of the law and often indicate a substantial risk to the public. According to the Board, "the basis for regulating optometrists is the tremendous harm which can be caused to the consumer of optometric services. In the past year, the board has taken formal disciplinary action against ten licensed optometrist [sic] for violations of the law...." According to the Board's 1991 newsletter, only one of these disciplinary actions resulted in actual time off practice (see *infra* "Board Publishes Newsletter").

The Board explained that a doctor of optometry is a primary health care provider who can diagnose, manage, and treat conditions (and, in many states, dis-

eases) of the human eye and visual system. An incompetent practitioner can inflict serious damage to the structures of the eye which could cause problems ranging from mild discomfort to blindness; in addition, an incompetent optometrist could delay treatment of very serious disease conditions such as brain tumors, glaucoma, diabetic retinopathy, and hypertensive retinopathy.

According to the Board, its regulation of optometry "does not restrict the supply of practitioners. The State Board Examination is available to all who have graduated from an accredited college or school of optometry. All candidates who pass the National Board Examination and the California State Board Examination are allowed to practice in the state of California. The supply of practitioners is limited only by the number of candidates that pass (or do not pass) the state board examination."

Although acknowledging that the "closest root profession to optometry is ophthalmology," the Board stated that "the ophthalmologist receives little or no training in the areas that are specifically unique to optometry." Further, the Board opined that optometry cannot be compared to any other vision care profession and that, if the Board's functions were taken over by some other entity, "consumers of optometric services and the optometrists themselves would not receive the same level of service they now receive...."

Board Publishes Newsletter. In April, the Board released its newsletter entitled *News and Annual Report 1991*. This newsletter, which is directed at practicing optometrists and others interested in optometry, includes a list of the Board's members, committees, and staff; provides information on the 1992 licensure examination; describes the optometry refresher course; discusses changes in the mandatory continuing education (CE) program and the CE audit; and provides updates on the Board's enforcement activities, regulations, and legislation. The newsletter also includes the names of nine persons against whom the Board took disciplinary action between January 1991 and February 1992; six of these cases were stipulations which resulted in no time off practice, and only one case resulted in revocation.

LEGISLATION:

SB 2044 (Boatwright), as amended April 2, would declare legislative findings regarding unlicensed activity and authorize all DCA boards, bureaus, and commissions, including the Board of Op-



tometry, to establish by regulation a system for the issuance of an administrative citation to an unlicensed person who is acting in the capacity of a licensee or registrant under the jurisdiction of that board, bureau, or commission. [A. CPGE&ED]

AB 2566 (O'Connell). Existing law limits the amount the Board of Optometry may charge for its license application and renewal fees. Currently, the Board's application fee may not exceed \$75; if an applicant is found ineligible to take the exam, the applicant is entitled to a refund of no more than \$50. The current renewal fee is limited to \$85. As introduced February 10, this Board-sponsored bill would raise the application fee ceiling to \$275; the refund ceiling to \$175; and the renewal ceiling to \$150. [S. B&P]

AB 3242 (Isenberg). Under existing law, the practice of optometry includes, among other things, the examination of the human eye or its appendages; the analysis of the human vision system, either subjectively or objectively; and the determination of the powers or range of human vision and refractive states of the human eye, including the scope of its general condition. As amended April 21, this bill would provide that the practice of optometry includes examination of the adnexa of the human eye and the analysis and diagnosis of conditions of the human vision system, either subjectively or objectively. [A. Health]

SB 664 (Calderon). Existing law prohibits 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, unless the patient is apprised at the first solicitation for payment of the name, address, and charges of the clinical laboratory performing the service. As amended March 12, this bill would also make this prohibition applicable to any subsequent charge, bill, or solicitation. This bill would also make it unlawful for any optometrist to assess additional charges for any clinical laboratory service that is not actually rendered by the optometrist to the patient and itemized in the charge, bill, or other solicitation of payment. This bill passed both the Senate and the Assembly and is currently awaiting Senate concurrence in Assembly amendments.

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 defec-

tive 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. [S. H&HS]

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. [A. Health]

The following bills died in committee: **AB 1124 (Frizzelle)**, which would have established 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; and **AB 1358 (Floyd)**, which would have specified 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.

LITIGATION:

In an unpublished February 4 decision, the Second District Court of Appeal ruled that section 1526, Title 16 of the CCR, a 1988 regulation which requires optometrists to obtain certification to administer cardiopulmonary resuscitation (CPR) as a condition of licensure or license renewal, is invalid as it exceeds the scope of authority granted to the Board.

In *Halverson v. State Board of Optometry*, No. B055937, the plaintiff filed a complaint pursuant to Government Code section 11350, seeking a declaration that the CPR requirement is invalid and an injunction enjoining its enforcement. Under section 11350, a regulation may be declared invalid if the agency's determination that the regulation is reasonably necessary to effectuate the purpose of the statute is not supported by substantial evidence. At the time it adopted the rule,

the Board argued it was necessary because, by 2000, half of those people seeking optometric services will be age 45 or older and at risk of having a sudden cardiac arrest. Because the legislature mandated the Board to protect the "health and safety of those members of the public availing themselves of services offered and performed in optometric offices," the Board contended that its CPR regulation is necessary to provide that protection. The trial court upheld the rule.

The Second District reversed and rejected the Board's justification, finding that the Board is authorized to establish minimum qualifications and levels of competency to practice optometry; according to the court, nothing in the practice of optometry has any relationship to the need to administer CPR. The court found no evidence that any procedure in the practice of optometry increases the risk of cardiac arrest or that one is more likely to suffer cardiac arrest at an optometric office than at any other place. The court noted that while CPR certification for all optometrists may be desirable, it should not be a prerequisite for an optometry license.

Following the Second District's ruling, the Board began informing optometrists, through its newsletter and license renewal notices, that CPR is no longer a requirement for licensure.

RECENT MEETINGS:

At its February 20 meeting, the Board unanimously voted to delegate the review of requests for extensions to complete continuing education (CE) requirements to the Executive Officer and/or the President of the Board.

Also in February, the Board noted that it is randomly auditing optometrists to ensure compliance with CE requirements; the random audits began in August 1991. With each license renewal notification, the Board instructs the optometrist to return documentation of completion of required CE hours. If the documentation is verified, a renewal is issued; if it cannot be verified, the file is turned over to the Board's enforcement division. As of February 19, 270 of 300 optometrists audited have submitted appropriate documentation of required hours of CE.

At its May 13 meeting, the Board briefly discussed the possibility of accepting the National Board Examination in Optometry as California's licensing examination. Some Board members believe that California should adopt that exam because other states are changing to it and it would be less expensive to administer; other members expressed concern about



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losing control over the examination. The Board plans to address this issue at a future meeting.

FUTURE MEETINGS:

August 21-22 in Sacramento.
November 20-21 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:

Attorney General Issues Opinion Regarding Out-of-State Pharmacies. On March 3, the Attorney General's Office filed Opinion No. 91-305, responding to the following three questions submitted by Assemblymember Tricia Hunter: (1) whether California laws governing pharmacies apply to out-of-state mail order pharmacies which fill prescriptions and mail them to people in California; (2) whether California's current regulation of out-of-state mail order pharmacies is consistent with the commerce clause of the U.S. Constitution; and (3) under California law, whether a generic type drug listed on the negative drug formulary established by the Director of Health Services may be substituted for a brand name drug by an out-of-state pharmacy when filling prescriptions and mailing them to people in California. [11:3 CRLR 101]

The opinion answered all three questions affirmatively, under specified conditions. Regarding the first question, the Attorney General noted that Business and Professions Code section 4084.6 prohibits an out-of-state pharmacy from doing business in California unless it obtains an out-of-state distributor's license from the Board of Pharmacy, or is registered with the Board as a nonresident pharmacy. Out-of-state drug distributors are required by law to comply with Chapter 9 of the Business and Professions Code, which contains most of the statutes that govern pharmacies in California, and Division 21 of the Health and Safety Code. Nonresident pharmacies must comply with Business and Professions Code sections 4050.1 and 4383, and Health and Safety Code section 11164. Thus, the opinion concluded that California laws do apply in limited circumstances to out-of-state pharmacies which fill prescriptions and mail them to people in California; the extent of their applicability depends on how the particular pharmacy is licensed.

Regarding California's regulation of out-of-state pharmacies, the Attorney General noted that in determining whether a state-created impact on interstate commerce falls within permissible bounds, the U.S. Supreme Court established a "balancing test" in *Pike v. Bruce Church Inc.*, 397 U.S. 137, 142 (1970). Under that test, where the statute regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits. According to the opinion, a local purpose which has traditionally been favored by the Court is one promoting the health and safety of a state's inhabitants. Based on its findings that the state will be given considerable latitude given the subject matter of the regulation, the laws are applied indiscriminately to in- and out-of-state pharmacies, and the burden on interstate commerce is "clearly minimal in relation to the legitimate state purpose of protecting the health and welfare of California residents," the Attorney General's Office concluded that California's regulation of out-of-state pharmacies does not offend the Commerce Clause.

Regarding the third question, the Attorney General noted that, with certain exceptions and qualifications, Business and Professions Code section 4047.6 allows a pharmacist to substitute a generic drug for a brand name drug when filling a prescription. Business and Professions Code section 4047.7 provides that one

such exception applies when the generic drug type or drug product has been listed on the "negative drug formulary" by the Director of the Department of Health Services (DHS); if a drug is listed by the DHS Director on the negative drug formulary, a pharmacist may not substitute it for a brand name drug. The Attorney General found that compliance with section 4047.7 is required of all pharmacies in California and any pharmacy licensed as an out-of-state drug distributor pursuant to Business and Professions Code section 4084.6. However, because pharmacies registered as nonresident pharmacies need comply only with Business and Professions Code sections 4050.1 and 4383 and Health and Safety Code section 11164 in order to maintain their registration and do business in California, pharmacies registered as nonresident pharmacies may substitute a generic type drug listed on the negative drug formulary established by the DHS Director for a brand name drug when filling prescriptions and mailing them to people in California. According to the opinion, however, no drug is currently listed on the negative drug formulary.

FDA Clarifies Policy Regarding New Drug Repackaging. Last July, the Board sought clarification of the U.S. Food and Drug Administration's (FDA) Compliance Policy Guide (CPG) 7132c.06, which 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." The Board asked FDA to clarify whether "the breaking down of bulk drugs for prescription or known need" constitutes manufacturing. Specifically, the Board asked whether manipulation by a pharmacist 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." [12:1 CRLR 91; 11:4 CRLR 104]