



REGULATORY AGENCY ACTION

practice" permitted by Business and Professions Code section 3076. Board member Mel Santos suggested that regulations be drafted creating an exception for the treatment of patients who are physically unable to travel to the optometrist's office. Several optometrists in the audience expressed their concern that the current Board position brands as illegal the continuous practice of optometry outside the typical office setting (such as in rest homes or in hospitals). In a telephone interview, Executive Officer Karen Ollinger said that the Board is reluctant to create exceptions which allow the practice of optometry outside the office setting. According to Ms. Ollinger, because of understaffing, the Board is unable to effectively enforce abuses under current law, and could not possibly regulate the activities of optometrists in additional settings. The Board referred the issue to its Regulation Committee to discuss the creation of regulations defining the term "temporary practice."

FUTURE MEETINGS:

May 22-23 in San Diego.

BOARD OF PHARMACY

Executive Officer: Patricia Harris
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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 Revenue Enhancement Programs Between Physicians and Home IV Providers. The Board postponed the November 27 meeting of its special committee investigating options for addressing pharmacist concerns over fee arrangements between physicians and home infusion companies. (See CRLR Vol. 10, No. 4 (Fall 1990) pp. 98-99 for detailed background information.) The committee was scheduled to meet in January to discuss its findings.

In a related issue, Attorney General Opinion No. 90-304, issued in October 1990, concluded that similar financial schemes between radiologists and physicians would violate the "safe harbor" provisions of Business and Professions Code section 650. Specifically, where a group of radiologists contracts with physicians to provide imaging services for the patients of the physicians, and the agreement provides that (1) the group will charge each patient a fee for the services; (2) the fees collected will be transmitted to the physicians; (3) the physicians will pay stipulated amounts to the group for the services; and (4) the total amounts paid by the physicians will be independent of but increase proportionately less than the total fees collected from the patients, performance of the agreement would violate section 650. The Attorney General's opinion may provide some guidance for the Board in determining whether similar financial schemes between physicians and home infusion companies violate section 650.

Pharmacy Shortage. At the request of the California Retailers Association, the Board is studying the feasibility of implementing the National Association of Boards of Pharmacy Licensure Exam (NABPLEX) for licensing California pharmacists. Use of the exam would enable the Board to consider granting license reciprocity to pharmacists licensed in other states. At the Board's October 3 meeting, the Board's consultant estimated that implementation of the new exam would take over two years and would cost between \$17,000 and \$27,000 to implement. At its January meeting, the Board was scheduled to consider whether its staff should proceed further with evaluating the exam for use in California. (See CRLR Vol. 10, No. 4 (Fall 1990) p. 99 for background information.)

Revocation of Licenses for Nonpayment of Renewal Fees. The Board recently announced that, pursuant to Business and Professions Code section 4411, it will revoke the licenses of all pharmacists who have failed to renew their licenses since 1988, unless disci-

plinary charges are pending. Because the procedures for reinstating a license are more stringent when the license has been revoked for disciplinary reasons, in cases where disciplinary charges are outstanding, the Board will pursue administrative proceedings on the charges.

Furnishing of Prescription Drugs by Emergency Room Physicians. In January 1990, in response to an increasing number of inquiries, the Board adopted a policy statement regarding the dispensing of prescription drugs by emergency room physicians. (See CRLR Vol. 10, Nos. 2 & 3 (Spring/Summer 1990) p. 115 for background information.) According to the Board, if medication is needed at a time other than the hospital pharmacy's operating hours, the emergency room physician may write a prescription and dispense up to three doses of the medication from the emergency room's stock, until pharmacy services become available. The Board claims it is authorized to issue such a policy statement under Business and Professions Code section 4050, which gives the Board authority over dispensing drugs, and section 4051, which authorizes the Board to issue statements regarding conduct guidelines to prescribers, including physicians and surgeons.

In response to a request from the California Medical Association, which contends that the Board has no authority to regulate the activities of physicians and that physicians are authorized to personally furnish patients with drugs as are necessary for treatment, the Board revised its policy statement. Conceding that all available pharmacies may be closed during a three-day weekend and acknowledging that the three-dose limit was an arbitrary standard with no specific foundation or necessity, the Board revised its policy to allow an emergency room physician to dispense up to a 72-hour supply from the emergency room's stock.

Proposed Regulatory Change Regarding Continuing Education Advertising. Existing section 1732.3(d), Division 17, Title 16 of the CCR, requires a recognized continuing education provider's advertisements for accredited coursework to indicate the course's number of hours, the provider's number, the name of the accrediting agency, and the date of expiration. The section also directs that this information be provided by a specifically worded statement that must appear in any continuing education course advertisement.

The Board's proposed amendment to section 1732.3(d) would retain the requirement that all continuing education advertisements contain specific



information, but would delete the requirement that the information be included in a specifically worded statement printed in the advertisement. The proposed amendment would also require advertisements to include the continuing education provider's name. The Board was scheduled to hold a public hearing on this proposed change on January 30.

Compounding For Prescribers Office Use. At its January 30 meeting, the Board was tentatively scheduled to hold a discussion of draft regulatory language defining the phrase "reasonable quantity of compounded medication" under Business and Professions Code section 4046(c)(1). The proposed regulation is in response to the Attorney General's Opinion No. 89-1101, which interpreted the terms "reasonable quantity," "compound medication," and "prescriber office use." (See CRLR Vol. 10, No. 4 (Fall 1990) pp. 99-100 and Vol. 10, Nos. 2 & 3 (Spring/Summer 1990) p. 115 for background information.) The Board requested that the Attorney General reconsider or withdraw the opinion. However, the Attorney General's office was unpersuaded by the Board's request and refused to change or withdraw the opinion. The proposed regulation will further clarify what constitutes a reasonable quantity of dangerous drugs and devices for a prescriber's office use. The regulation is intended to address good manufacturing practices and distribution of dangerous drugs and devices to unauthorized persons.

Other Regulatory Changes. The following is a status update on numerous regulatory changes considered and approved by the Board in recent months (see CRLR Vol. 10, No. 4 (Fall 1990) pp. 99-100; Vol. 10, Nos. 2 & 3 (Spring/Summer 1990) pp. 114-115; Vol. 10, No. 1 (Winter 1990) p. 90; and Vol. 9, No. 4 (Fall 1989) p. 75 for background information on these changes):

-Designation of Pharmacist-In-Charge. At its October 3 meeting, the Board held a public hearing on the proposed adoption of new section 1709.1, Division 17, Title 16 of the CCR, regarding designation of a pharmacist-in-charge at each pharmacy. No opposition to the proposed regulation was received, and the Board is preparing the rulemaking file on this regulation for submission to the Office of Administrative Law (OAL) for approval.

-Processing Times for Applications and Registrations. The Board also held a public hearing on October 3 to consider the proposed adoption of section 1706.1, Division 17, Title 16 of the CCR, to implement the Permit Reform Act of 1981, Government Code section 15374

et seq. The Board adopted the rule, which sets forth the processing times for applications for licensure or registration. The Board is required to implement such a regulation before OAL will consider any further regulatory changes concerning licensure or registration. The Board expected to submit the regulation to OAL by early January.

-Ancillary Personnel. On November 19, OAL rejected for a third time the Board's proposed amendment to section 1717, which specifies the tasks which may be performed by an unlicensed person under the supervision of a licensed pharmacist. After the OAL's second rejection of the proposed amended regulation in March, the Board appealed the decision to the Governor's office, which referred the matter back to OAL for reconsideration in light of additional materials submitted by the Board concerning federal regulations permitting unlicensed assistants to perform specified tasks.

On reconsideration, OAL rejected the regulation on grounds it failed to satisfy the consistency standard in Government Code section 11349.1, and determined that the information submitted by the Board was "insufficient to establish that the unlicensed pharmacy assistant envisioned in the proposed regulation would be permitted under Federal law to dispense controlled substances." OAL concluded that even if the proposed regulation were consistent with federal law, "that determination would have no binding effect upon the consistency of the proposed regulation with California law....[T]he actions the non-licensed pharmacy personnel would be allowed by the proposed regulation to perform would be prohibited under State law." The Board may appeal this decision to the Governor's office one final time before considering the introduction of legislation to amend existing provisions of the Business and Professions Code in order to meet OAL's consistency standards.

-Oral Consultation. New sections 1707.1 and 1707.2, which require pharmacists to maintain patient medication profiles for all ongoing patient-consumers, and to provide an oral consultation to each patient or patient's agent, are scheduled to go into effect on March 1, 1991. However, the Board is currently seeking OAL's approval to extend the effective date of these regulations until January 1992.

-English Proficiency Examination. In August 1990, the Board received a 120-day extension from OAL in order to revise its proposed regulatory change to section 1719, which was previously

rejected by OAL on grounds of clarity, necessity, and procedural flaws. The Board revised the regulation to reflect the specific pass score on the Test of Spoken English. The new language was released for the required 15-day notice period and the Board submitted the modified regulation to OAL on December 28.

-Preprinted Prescription Pads. Proposed regulatory section 1717.3 would define a "preprinted, multiple check-off prescription blank" and the permissible ways in which these may be used. The Board submitted this proposal to OAL in December; at this writing, the Board is awaiting OAL's approval.

LEGISLATION:

Anticipated Legislation. The Board is considering the following issues for proposed legislation in 1991:

-Extension of Impaired Pharmacist Program. Pursuant to Business and Professions Code section 4439, the Impaired Pharmacist Program (IPP) is scheduled to sunset on January 1, 1992. The Board may seek to delete the sunset date for the IPP, which has been in operation for five years; 52 individuals have successfully completed treatment programs, and 25 individuals have been terminated prior to completing the program.

-Nonresident Pharmacy Violations. The Board may introduce legislation which would eliminate or extend the January 1, 1992 sunset date for the denial, revocation, or suspension of non-resident pharmacy permits under Business and Professions Code section 4350.6. That section authorizes the Board to revoke, deny, or suspend a non-resident pharmacy registration for conduct which causes serious bodily or psychological injury to a California resident, if the Board has referred the matter to the regulatory or licensing agency in the state where the pharmacy is licensed, and the regulatory or licensing agency fails to initiate an investigation within 45 days of the referral.

-Storage of Legend Devices. The Board may propose legislation which would amend section 4052(b) of the Business and Professions Code, to amend the list of specified legend devices which are exempt from the scope of Chapter 9, Division 2 of the Business and Professions Code, regarding the storage of legend devices in the central storage area of a hospital. The proposed amendments would update the current terminology concerning legend devices and authorize the Board to add or delete dangerous drugs and/or devices from the list of exemptions through



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regulations adopted after good cause shown.

FUTURE MEETINGS:

March 20-21 in Los Angeles.
May 29-30 in Sacramento.
July 30-August 1 in Sacramento.
October 16-17 in Los Angeles.

BOARD OF REGISTRATION FOR PROFESSIONAL ENGINEERS AND LAND SURVEYORS

Executive Officer: Darlene Stroup
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The Board of Registration for Professional Engineers and Land Surveyors (PELS) regulates the practice of engineering and land surveying through its administration of the Professional Engineers Act, sections 6700 through 6799 of the Business and Professions Code, and the Professional Land Surveyors' Act, sections 8700 through 8805 of the Business and Professions Code. The Board's regulations are found in Division 5, Title 16 of the California Code of Regulations (CCR).

The basic functions of the Board are to conduct examinations, issue certificates, registrations, and/or licenses, and appropriately channel complaints against registrants/licensees. The Board is additionally empowered to suspend or revoke registrations/licenses. The Board considers the proposed decisions of administrative law judges who hear appeals of applicants who are denied a registration/license, and those who have had their registration/license suspended or revoked for violations.

The Board consists of thirteen members: seven public members, one licensed land surveyor, four registered Practice Act engineers and one Title Act engineer. Eleven of the members are appointed by the Governor for four-year terms which expire on a staggered basis. One public member is appointed by the Speaker of the Assembly and one by the Senate President pro Tempore.

The Board has established four standing committees and appoints other special committees as needed. The four standing committees are Administration, Enforcement, Examination/Qualifications, and Legislation. The committees function in an advisory capacity unless specifically authorized to make binding decisions by the Board.

Professional engineers are registered through the three Practice Act categories of civil, electrical, and mechanical engineering under section 6730 of the Business and Professions Code. The Title

Act categories of agricultural, chemical, control system, corrosion, fire protection, industrial, manufacturing, metallurgical, nuclear, petroleum, quality, safety, and traffic engineering are registered under section 6732 of the Business and Professions Code.

Structural engineering and geotechnical engineering are authorities linked to the civil Practice Act and require an additional examination after qualification as a civil engineer.

MAJOR PROJECTS:

Regulatory Determination. In September 1989, the law firm of Turner & Sullivan requested a regulatory determination from the Office of Administrative Law (OAL) regarding PELS' policy of requiring registered civil engineers to have one year of responsible field training and one year of responsible office training in order to take the examination for licensure as a land surveyor. (See CRLR Vol. 10, Nos. 2 & 3 (Spring/Summer 1990) p. 117 for background information.) On November 2, OAL issued its determination, finding that the policy is indeed a regulation within the meaning of the Administrative Procedure Act (APA). As a result, PELS' enforcement of the policy violates Government Code section 11347.5(a), which prohibits state agencies from issuing, utilizing, or enforcing agency policies which have not been, but are required to be, adopted under the APA's procedural requirements. Since PELS did not comply with the APA, the regulation is without legal effect.

The Professional Land Surveyors' Act (Act) governs the licensing of land surveyors in California. In order to become licensed, the Act requires applicants to pass two examinations—known as the first division and the second division—unless specifically exempt by statute or regulation. Business and Professions Code section 8741(a) exempts registered civil engineers from taking the first division. Section 8742 requires that all applicants meet certain educational qualifications and experience in land surveying before they may take the second division, and section 8742(a) provides that these requirements may be satisfied by one of the following: (1) graduation from a four-year curriculum with an emphasis in land surveying and two years of actual experience in land surveying, including one year of responsible field training and one year of office training; (2) actual experience in land surveying for at least six years, including one year of responsible field training and one year of responsible office training; or (3) registration as a civil engineer

with two years of actual experience in land surveying. Under PELS' challenged policy, civil engineers applying for land surveyor licensure were required to satisfy the "two years of actual experience in land surveying" applicable to them under section 8742(a)(3) by completing "one year of responsible field training and one year of responsible office training" applicable to non-civil engineer applicants in section 8742(a)(1) and (a)(2).

OAL found that requiring registered civil engineers to obtain "one year of responsible field training and one year of responsible office training in order to take the Professional Land Surveyor examination" implements, interprets, and makes specific Business and Professions Code section 8742(a)(3). Therefore, OAL concluded that PELS' policy is a regulation and subject to the requirements of the APA.

OAL's "underground rulemaking" ruling is the third such determination regarding challenged PELS policies in the past ten months. (See CRLR Vol. 10, Nos. 2 & 3 (Spring/Summer 1990) p. 117 for background information on the other two OAL determinations.)

PELS Rulemaking. On August 31, PELS submitted proposed amendments to section 424, Division 5, Title 16 of the CCR, to OAL. The proposed regulatory action, which was the subject of a November 1989 public hearing, delineates the necessary experience required for registration as a professional engineer based upon completion of various categories of engineering education or work experience. (See CRLR Vol. 10, No. 1 (Winter 1990) p. 92 for background information.)

On October 1, OAL disapproved the proposed regulatory changes, because PELS did not provide the 15-day notice required for substantial sufficiently-related changes as required by the Administrative Procedure Act (APA), and because PELS had not complied with the "reference" standard of the APA.

In response to a public comment received during the initial 45-day notice, PELS added the word "registered" to the existing language of section 424(c), so that qualifying experience could only be gained under a registered professional engineer. Because of this change, PELS reopened the public comment period for fifteen days. During this 15-day period, PELS received a comment urging that the word "registered" be deleted from the text; this comment came from the same person who had originally requested the word's inclusion.