Orr presented the Bureau's Quarterly Report, which reviewed the appointment of Michael A. Kelley as Director of the Department of Consumer Affairs, and the Department's task force recommendations for the Bureau. Chief Orr also reported that the Bureau stayed under its budget again this year, which was originally $659,000 but was reduced to $554,843. The proposed 1988-89 budget is considerably less than that amount.

Patricia Bustos will continue as Chair of the Advisory Board until the next meeting. Elections could not be held due to lack of a quorum.

FUTURE MEETINGS:

To be announced.

BOARD OF PHARMACY

Executive Officer: Lorie G. Rice
(916) 445-5014

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. 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:

OAL Disapproves Proposed Regulation. On December 17, 1987, the Board resubmitted proposed regulatory section 1781.5 for the third time to the Office of Administrative Law (OAL) for approval. (See CRLR Vol. 8, No. 1 (Winter 1988) p. 69 and Vol. 7, No. 2 (Spring 1987) p. 64 for background information.) The proposed regulation would provide an exemption for certain manufacturers and wholesalers of drugs from the general requirement that a California licensed pharmacist be present and in control of the manufacturing or wholesaling premises. On January 14, OAL once again disapproved the proposed regulation, on grounds that it still does not satisfy the clarity standard.

Public Hearing. On January 20, the Board held a public hearing on two proposed regulatory changes: an amendment to section 1717(a), chapter 17, Title 16 of the California Code of Regulations, concerning reuse of clean containers in a licensed health facility for non-liquid oral products; and section 1718.1, regarding the distribution of drugs not bearing a manufacturer's expiration date. (See CRLR Vol. 8, No. 1 (Winter 1988) p. 69 for details on these proposed regulations.)

The Board adopted both changes, and has submitted the rulemaking file to the OAL.

Proposed Continuing Education Regulations. In the last two years, the OAL has twice disapproved the Board's proposed changes to its complex continuing education (CE) regulations. (See CRLR Vol. 8, No. 1 (Winter 1988) pp. 68-69 for background information.) According to the Board's Initial Statement of Reasons accompanying its most recent proposed version, OAL's second disapproval prompted the Board to "evaluate its program and its effectiveness." In its statement, the Board reviewed its bifurcated and rather confusing CE regulations, and stated that it is "concerned not only with the bureaucratic nature of its CE program, but also believes that pharmacists as professionals should have more flexibility in determining what program best meets his/her needs, and that it should be the responsibility of the profession to monitor the quality of CE."

The statement explained that the Board's CE regulations presently contain two kinds of course designations: "accredited" and "acceptable." A pharmacist must obtain thirty hours of CE every two years, of which fifteen must be "accredited." Currently, there are three systems for reviewing CE: (1) the provider is accredited through the American College of Pharmaceutical Education (ACPE); (2) the coursework is reviewed by the Board through its CE Committee; or (3) there is no review at all, as with "acceptable" courses.

In its evaluation, the Board determined that CE should be more accessible to pharmacists; more emphasis should be placed on the provider application process; there should be only one category of CE; and the standards of ACPE should be incorporated as part of the accreditation process.

Thus, the Board has proposed a new set of CE regulations in chapter 17, Title 16 of the California Code of Regulations. Section 1732 is a definitional section; the proposed amendments would define the new terms that will be used in the CE article, and delete those terms no longer applicable. Section 1732.05 would designate the ACPE and the Accreditation Evaluation Service of the California Pharmacists Association as accreditation agencies; establish criteria for the designation of other organizations as accreditation agencies; and impose certain requirements on the agencies with respect to the CE providers they recognize and accredit. Section 1732.05 also sets forth grounds upon which the Board may revoke accreditation agency designation.

Section 1732.1 lists requirements for recognized CE providers, including registration with the Board and approval by a Board-designated accreditation agency. The section also describes the content and quality of acceptable CE courses; and requires providers to furnish certificates of completion to all enrollees with specified information thereon, and maintain CE course attendance records.

Section 1732.2 would allow pharmacists to petition the Board for credit if a CE course was taken from a non-recognized provider, and would also provide a mechanism for Board licensees to obtain CE credit for courses approved by the Board of Medical Quality Assurance, the Board of Registered Nursing, the Board of Podiatric Medicine, and the Board of Dental Examiners.

Section 1732.3 would deem all coursework offered by recognized providers (who have been approved by an accreditation agency) as approved for California pharmacists, unless the accreditation agency has denied the course as a result of an audit. This section would also require the accreditation agencies to review selected coursework offered by its providers, and specifies the requirements and the factors to be considered when auditing courses.

Section 1732.4 would require upon written request that each recognized provider submit materials to the accreditation agency for review. Finally, section 1732.7 would allow providers to file complaints with the Board against accreditation agencies; this section is deemed necessary because the Board is proposing that the accreditation agency both approve the provider and audit the coursework.

The Board was scheduled to conduct a public hearing on its proposed CE regulations on April 6 in Los Angeles.

Proposed Fee Increases. The Board has also proposed to amend section 1749 of its regulations to increase its licensure fees, as authorized by SB 79 (Chapter 657, Statutes of 1987), which became effective on January 1, 1988. The proposed regulations include (among others) a fee increase for filing an application for the pharmacist's examination ($155); the pharmacist's licensure examination ($75); original certification of registration ($115); biennial renewal of a pharmacist's license ($115); pharmacy permit ($340); renewal pharmacy permit ($175); issuance and renewal of a wholesaler's permit ($550); and issuance and renewal of a hypodermic license ($90).

The Board was scheduled to hold a public hearing on its proposed fee increases on April 6 in Los Angeles.

LEGISLATION:

SB 2213 (Craven), introduced February 17, would require any pharmacy located outside California which ships, mails, or delivers any controlled substances or dangerous drugs or devices into California to register with the Board, disclose specified information to the Board, and meet certain other conditions. SB 2213 is pending in the Senate Business and Professions Committee; at this writing, the bill is scheduled for hearing on April 11.

SB 2731 (Campbell), introduced February 19, would exempt from the definition of "manufacturer" a pharmacy which compounds a drug for parenteral therapy, pursuant to a prescription, for delivery to another person licensed to possess that drug. This bill would also require a pharmacy which compounds a drug for another pursuant to the above provision to report that information to the Board within thirty days of commencing that compounding. SB 2731 is also scheduled for an April 11 hearing before the Senate Business and Professions Committee.

AB 513 (Hill), formerly *AB 513 (Tucker),* was amended on March 9, and would also exempt from the definition of a "manufacturer" a pharmacy compounding a drug for parenteral therapy, pursuant to a prescription, for delivery to another person licensed to possess that drug. AB 513 was approved by the Senate Business and Professions Committee on March 15, and is pending on the Senate floor at this writing.

AB 3578 (Moore), introduced February 17, would allow licensed drug wholesalers to sell hypodermic syringes and needles without a permit. The bill would also add licensee incompetence, fraud, and deceit as grounds for discipline by the Board, and would allow the Board to recover its investigative and prosecutorial costs from the licensee in certain disciplinary cases, including attorneys' fees and costs attributable to obtaining injunctive relief.

AB 3578 would also prohibit owners, managers and administrators of a disciplined Pharmacy Board licensee from holding certain ownership or management positions with any licensee of the Board; further, pharmacists put on probation by the Board would be prohibited from serving as the pharmacist-in-charge of a pharmacy. This bill is pending in the Assembly Health Committee.

AB 4499 (Felando), introduced February 19, would authorize a pharmacist to substitute a generically equivalent drug for a prescribed drug only if it is listed as having a "Code A" by the federal Food and Drug Administration; if it has a "Code B," the pharmacist must obtain authorization from the prescriber prior to substitution. AB 4499 is pending in the Assembly Health Committee.

AB 2683 (Hughes), as introduced in August 1987, would have required any person who sells, furnishes, or distributes prophylactics in California to be licensed by the Board. As amended on January 21, the bill would prohibit the manufacture, packaging, sale, furnishing, or distribution of prophylactics which fail to conform to standards adopted by the Department of Health Services, and would require the Department to adopt those standards. AB 2683 passed the Assembly on January 27, and is pending in the Senate Health and Human Services Committee at this writing.

AB 44 (Calderon), AB 1953 (Filante), AB 1238 (Moore), AB 1732 (Isenberg), and *SB 1534 (Keene)* have all died in committee. (See CRLR Vol. 7, No. 4 (Fall 1987) pp. 63-64 for details on these bills.)

FUTURE MEETINGS:

May 24-25 in Sacramento.

POLYGRAPH EXAMINERS BOARD

Executive Officer: Dia Goode
(916) 739-3855

The Polygraph Examiners Board operates within the Department of Consumer Affairs. The Board has authority to issue new licenses and to regulate the activities of an estimated 655 examiners currently licensed in California under Business and Professions Code section 9300 *et seq.* The Board has no jurisdiction over federally-employed polygraph examiners.

The Polygraph Examiners Board consists of two industry representatives and three public members, all appointed to four-year terms. The Board has a sunset date of January 1, 1990.

MAJOR PROJECTS:

Regulatory Changes. In January, the Office of Administrative Law approved the Board's adoption of sections 3472 and 3410 of chapter 34, Title 16 of the California Code of Regulations. Section 3472 allows federal, state, and local government agencies to provide continuing education with Board approval. Section 3410 (previously numbered as proposed section 3842) defines certain "polygraph records" which examiners are required to retain for two years. (See CRLR Vol. 7, No. 4 (Fall 1987) p. 64 for background information.)

Pre-Employment Inquiry Seminar. The Board had scheduled a seminar on pre-employment inquiries for January. (See CRLR Vol. 7, No. 4 (Fall 1987) p. 64.) Due to a shortage of funds, the Board postponed the seminar. It is now scheduled to take place in conjunction with the Board's next meeting; the date is undecided.

Budget. Business and Professions Code section 9321(b) appropriated $50,000 in the form of a loan from the General Fund to the Board. The statute provides that the Board was to pay $10,000 interest in 1986, and that the balance was to be repaid in increments of not less than $10,000 each fiscal year. The appropriation also states that the Board shall pay back the entire loan by January 1, 1990, which is its sunset date. Executive Officer Dia Goode recently reported that the Board paid the 1986 $10,000 interest payment, but has not been able to make any payments on the balance.

The recent fee increase, effective January 1, 1988, will not be enough to remedy the Board's fiscal crisis. The Board anticipates only 90 new licensees and 400 renewals this year. However, the Board's budget problems may be resolved through SB 2220 (*see infra* LEGISLATION).

LEGISLATION:

SB 2219 (Dills), introduced February 17, would provide that if a polygraph license is renewed more than thirty days after its expiration, the licenseholder, as a condition precedent