enhances the practice of optometry than 60 units covering management. Conran also called the Board's treatment of foreign-trained graduates a disgrace, alluding to the Board's past refusal to accept foreign optometric training, and its foot-dragging in creating a remedial training course for foreign graduates after being directed to do so by the legislature. (See CRLR Vol. 10, Nos. 2 & 3 (Spring/Summer 1990) p. 113; Vol. 9, No. 4 (Fall 1989) p. 73; and Vol. 9, No. 3 (Summer 1989) pp. 64–65 for extensive background information.)

Conran concluded his remarks by offering his assistance and encouraging the Board to make constructive changes before DCA or the legislature imposes changes on the Board without regard to its input. "You'd better get with it quickly," observed Conran. Board members had no questions for Conran.

At its November meeting, the Board elected the following officers for 1992: Thomas R. Nagy, president; Pamela J. Miller, vice president; and Julia Preisig, secretary. Nagy and Miller are optometrists and Preisig is a public member of the Board. Also, Bob Miller has been reassigned to the Board to replace Steve Martini as the Board's DCA legal advisor.

FUTURE MEETINGS:

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:

Pharmacy Technician Regulations. AB 1244 (Polanco) (Chapter 841, Statutes of 1991), which was signed into law on October 11, permits a pharmacy technician, as defined, to perform packaging, manipulative, repetitive, or other nondiscretionary tasks while assisting, and while under the direct supervision of, a registered pharmacist. (See CRLR Vol. 11, No. 4 (Fall 1991) pp. 105–06 for background information.) The Board of Pharmacy is authorized to adopt regulations defining the functions which may be performed by a pharmacy technician. In December, the Board published notice of its intent to amend section 1717(c) and adopt new sections 1793–1793.7, Division 17, Title 16 of the CCR, to define the qualifications and permissible duties of pharmacy technicians.

Existing section 1717(c) lists certain duties which must be performed by a pharmacist and those duties which may be performed by non-licensed personnel, such as typing prescription labels and requesting and receiving refill authorization subject to prior review by a pharmacist. The Board proposes to incorporate portions of this section into new sections 1793.1 and 1793.3. Specifically, proposed section 1793.1 would list functions which only a pharmacist may perform and which may not be delegated to a pharmacy technician; section 1793.2 would identify the tasks which a pharmacy technician may perform under the direct supervision and control of a licensed pharmacist, including removing drugs from stock, counting, pouring, or mixing pharmaceuticals, placing the products into a container, affixing labels to containers, packaging and repackaging; and proposed section 1793.3 would describe and update tasks which may be performed by non-licensed personnel who are not pharmacy technicians, to include the entry of prescriptions into a computer record system.

Proposed section 1793.4 would establish registration requirements for pharmacy technicians, and authorize the Board to issue a certificate to an applicant who has met any of the following requirements: has obtained at least an associate of arts degree in a field of study directly related to the duties performed by a pharmacy technician; has completed a training course specified by the Board; is eligible to take the Board's pharmacist licensure exam; or has one year's experience (a minimum of 1,500 hours) performing the tasks of a pharmacy technician while assisting a pharmacist in the preparation of prescriptions in specified facilities. Section 1793.5 would specify the training courses which are acceptable to the Board in satisfaction of the requirement in section 1793.4. Section 1793.6 would establish requirements for pharmacies employing technicians; in particular, it clarifies that nonpharmacist personnel must work under the direct supervision of a registered pharmacist, the supervising pharmacist must be on the premises at all times, and the pharmacist must indicate that all prescriptions prepared by a technician have been checked by initialing the prescription label before the medication is given to the patient. The subsection also requires a technician to wear identification clearly identifying him/her as a technician.

The Board held an informational public hearing on the proposed pharmacy technician regulations on November 12; it was scheduled to hold a formal regulatory hearing on these regulations on January 21.

Locked Storage and Emergency Delivery Requirements for Medical Device Retailers. Since July 1991, the Board of Pharmacy has licensed medical device retailers (MDRs) as a separate class. MDRs are non-pharmacy firms that may dispense, upon prescription, "dangerous devices" such as hypodermic syringes and other items that are marked by the manufacturer as available upon prescription only. Each retail site of an MDR must have a Board-licensed individual designated as "in charge." This individual may be a pharmacist or an "exemptee," a separately-licensed individual authorized to dispense dangerous devices. The Board recently proposed the adoption of new sections 1748.1 and 1748.2, Title 16 of the CCR, regarding the proper storage of dangerous devices at MDR retail sites and the delivery of devices to patients after hours or in emergency situations.

Proposed section 1748.1 would provide that an MDR may use locked storage (a lock box or locked area) for the emergency dispensing of dangerous devices. Locked storage may be installed or placed in a service vehicle of the MDR for purposes of delivery, set-up, or after-hours emergency service of dangerous devices to patients having prescriptions on file for the dangerous device. No hypodermic needles or syringes may be stored in this locked storage. Section 1748.1 would also provide that dangerous devices shall be furnished from the locked storage only upon the oral or written authorization of an

exemptee to an employee of the MDR who operates the service vehicle; the service vehicle and the locked storage contained therein shall be locked at all times; a current inventory and record of all dangerous devices placed into and furnished from the locked storage shall be maintained by the MDR for three years; within 72 hours of furnishing a dangerous device from the emergency storage, the exemptee shall be responsible for checking the contents of the locked storage and noting the dangerous devices furnished on the inventory; and the exemptee shall be responsible for checking the contents of the locked storage on a weekly basis.

Proposed section 1748.2 would permit an MDR to keep a dangerous device in a retail area of the premises during the absence of an exemptee, if the device is of sufficient size and weight as to make removal "difficult." The Board was scheduled to conduct a public hearing on this proposal on January 22.

Board Delays Patient Consultation Regulations Again. In August 1990, the Office of Administrative Law (OAL) approved the Board's adoption of new sections 1707.1 and 1707.2, Title 16 of the CCR, which require pharmacists to maintain patient medication profiles for all ongoing patient-consumers and provide an oral consultation to each patient or patient's agent, with specified exceptions. The oral consultation requirement was originally scheduled to take effect on March 1, 1991. However, on January 11, 1991, OAL approved the Board's request to delay the effective date until January 1, 1992. (See CRLR Vol. 11, No. 2 (Spring 1991) p. 98 for background information.) The Board delayed the implementation to (1) provide pharmacists with additional time to prepare for and phase in the changes to pharmacy practice mandated by sections 1707.1 and 1707.2; (2) permit a more assistive resolution to the pharmacy technician issue; and (3) amend Board regulations to foster spatial arrangements in pharmacies that are conducive to privacy for performing patient consultation. However, at this writing, the Board has not yet proposed regulations concerning spatial arrangements, and only recently initiated its proceeding to adopt technician regulations (*see supra*).

At its October 16 meeting, the Board heard a report from its Patient Consultation Implementation Committee, which was formed to hear concerns from and provide feedback to interested parties regarding the new regulations. Committee Chair Gilbert Castillo informed the Board that the Committee had received several requests for delays or waivers of the oral consultation requirement from affected pharmacies. He stated that the Committee's recommendation was to proceed with implementation as scheduled.

The Board then entertained testimony from representatives of several large pharmacy chains, HMOs, and trade associations, including Longs Drugs, Kaiser Permanente, and the California Retailers Association. These companies complained that the imposition of such broad new duties on the entire industry may lead to selective compliance (depending on the adequacy of the pharmacy's staffing), inconsistency, and potential liability problems. Further, and after eighteen months' lead time, these companies argued that they were unprepared to comply on January 1 without the use of pharmacy technicians, and this new category of pharmacy employee is not expected to be authorized by regulations until at least April. The representatives also implied that if the regulations went into effect as scheduled, they may initiate litigation to challenge them.

Board members pointed out that the effective date had already been delayed once in response to these concerns, and that it had been apparent for some time that the regulations providing for technicians would not be in place before the consultation requirement became effective. The Board voted 3–2 to proceed with implementation on January 1.

Notwithstanding that action, the Board continued to receive requests to once again delay implementation of the oral consultation requirement. Board President William Tan called a special meeting on December 4 to reconsider the Board's previous vote. At that meeting, industry representatives again claimed to be unprepared to comply with the regulations without additional staff and expressed concern that delivery of medications might be delayed if the Board required them to comply with the oral consultation rule on January 1. Finally, the Board voted to delay the effective date until November 1, 1992.

Upon consultation with OAL, the Board will adopt a two-part procedure to accomplish the delay: (1) it will suspend the regulations as an emergency action for the 120 days allowed for such actions under the Administrative Procedure Act (Government Code section 11346.1(e)); and (2) it will proceed with an ordinary rulemaking action to change the effective date to November 1. The Board was scheduled to hold public hearings on the formal regulatory action at its March 18 meeting; at this writing, the emergency suspension awaits OAL approval.

Partial Filling of Schedule II Prescriptions. At its October 16 meeting, the Board held a public hearing on its proposed adoption of section 1745, Title 16 of the CCR. As originally proposed, section 1745 would allow partial filling of Schedule II controlled substance prescriptions for terminally ill patients who are in chronic pain, under certain circumstances. (See CRLR Vol. 11, No. 4 (Fall 1991) p. 105 for background information.) During the hearing, the Board amended the text to add new language which would also allow partial filling when the prescription is for an inpatient of a skilled nursing facility. The Board released the modified language for a 15-day comment period ending on December 24, and was expected to adopt the new language at its January meeting.

Federal Policy Guide Regarding New Drug Repacking. In a July 16 letter to the federal Food and Drug Administration (FDA), the Board sought clarification of FDA's Compliance Policy Guide 7132c.06. (See CRLR Vol. 11, No. 4 (Fall 1991) p. 104 for background information.) The guide defines FDA policy regarding drug manipulations which are approved if conducted within the practice of pharmacy, and those manipulations which constitute "manufacturing" and require separate FDA approval. Although FDA has not formally replied to the Board, its district supervisor for southern California forwarded a number of documents to the Board on this subject. The documents indicate that FDA is working on the issue with the National Association of Boards of Pharmacy (NABP). It is NABP's position that compounding and manufacturing are distinct activities, and that compounding is a proper part of the practice of pharmacy. Further, NABP opined that it is beyond the scope of FDA's authority for it to intrude "upon the state regulation of pharmacy practice." At its October meeting, the Board essentially agreed with NABP's position, and noted that clarification is still needed as to whether the "breaking down of bulk drugs for prescription or known need" constitutes manufacturing. The Board voted to send another letter to FDA expressing its concern and seeking such clarification.

Part-Time Pharmacists-in-Charge. At its October meeting, the Board continued its discussion of possible amendments to section 1709.1, Title 16 of the CCR, which governs the designation of the pharmacist-in-charge at each pharmacy and prohibits a pharmacist from

acting as pharmacist-in-charge at more than one pharmacy. (See CRLR Vol. 11, No. 4 (Fall 1991) p. 105 for background information.) In response to inquiries, the Board decided to clarify one narrow exception to that prohibition. At the meeting, the Board agreed on a proposed amendment that would allow a pharmacist to be pharmacist-in-charge at two pharmacies when each such pharmacy employs only that pharmacist and is not open at any time when the other pharmacy for which that pharmacist is the pharmacist-in-charge is open. The Board anticipated publishing notice of this amendment in January and holding a public hearing at its March meeting.

Regulatory Update. The following is a status update on regulatory changes considered and approved by the Board in recent months (see CRLR Vol. 11, No. 4 (Fall 1991) p. 105; Vol. 11, No. 3 (Summer 1991) p. 102; and Vol. 11, No. 2 (Spring 1991) p. 98 for background information):

-Compounding for Office Use. The Board has adopted proposed new section 1716.1, which defines the quantity of compounded medication which a pharmacist may furnish to a prescriber for office use under Business and Professions Code section 4046(c)(1), and proposed new section 1716.2, which specifies 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. At this writing, the proposed sections await review and approval by OAL.

-Minimum Standards for Drug Wholesalers. At its May meeting, the Board adopted proposed amendments to section 1780, regarding minimum standards for drug wholesalers. At this writing, the proposed amendments await review and approval by OAL.

LEGISLATION:

AB 2070 (Isenberg), as amended August 19, would generally make it unlawful for specified healing arts licensees to refer a person to any laboratory, pharmacy, clinic, or health care facility solely because the licensee has an ownership interest in the facility. However, a licensee could make those referrals if the person referred is the licensee's patient of record, there is no alternative provider or facility available, and the licensee certifies that to delay or forego the referral would cause an unneeded health risk to the patient. This two-year bill is pending in the Senate Rules Committee.

SB 664 (Calderon) would prohibit pharmacists, 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 bill is pending in the Senate Business and Professions Committee.

AB 1226 (Hunter) would change the standard to be applied by the Director of the Department of Health Services in establishing a formulary of generic drug types and drug products, to require him/her to identify those generic drug types and drug products which, if substituted by a pharmacist for a drug product described by the prescriber by its trade or brand name, may pose a threat to the health and safety of patients. This bill is pending in the Assembly Health Committee.

SB 1033 (Marks) would permit pharmacists to manufacture, measure, fit to the patient, sell, and repair medical devices without regard to whether they bear a specified legend relating to a federal prohibition against dispensing without a prescription. This bill is pending in the Senate Business and Professions Committee.

AB 855 (Hunter), as amended July 16, would require a pharmacist to obtain a patient's consent prior to filling a prescription order for a drug product prescribed by its trade or brand name with a substitute drug product. This two-year bill is pending in the Senate Business and Professions Committee.

SB 917 (Kopp), as amended June 11, would require certain health care service plans that propose to offer a pharmacy benefit or change its relationship with pharmacy providers to give written or published notice to pharmacy service providers of the plan's proposal, and give those providers an opportunity to submit a bid to participate in the plan's panel of providers on the terms proposed. This bill is pending at the Assembly desk.

AB 819 (Speier). Existing law provides that it is not unlawful for prescribed licensed health professionals to refer a person to a laboratory, pharmacy, clinic, or health care facility solely because the licensee has a proprietary interest or co-ownership in the facility. This bill would instead provide that, subject to specified exceptions, it is unlawful for these licensed health professionals to refer a person to any laboratory, pharmacy, clinic, or health care facility which is owned in whole or in part by the licensee or in which the licensee has a proprietary interest; the bill would also provide that disclosure of the ownership or proprietary interest does not exempt the licensee from the prohibition. This bill is pending in the Assembly Health Committee.

Future Legislation. At this writing, the Board is drafting three legislative proposals for the 1992 session. First, the Board may seek to repeal a portion of Business and Professions Code section 4038 which exempts pharmacies and state-licensed drug manufacturers from licensure requirements as wholesalers. The federal Prescription Drug Marketing Act requires state licensure of any firm that wholesales prescription drugs; thus, California's exemption is in conflict with the federal law.

Second, the Board may seek to correct an erroneous reference in Business and Professions Code section 4033, which occurred as a result of sections being renumbered in 1980.

Third, the Board may propose an amendment to Business and Professions Code section 4366 to allow the Board to recover its investigative and other enforcement costs from a disciplined licensee in cases other than drug diversion, as is currently permitted. The Board wants broad discretion to recover its costs in other cases—*e.g.*, filling unauthorized prescriptions or professional misconduct.

The California Pharmacists' Association (CPA) has announced its four-part legislative program for 1992. First, CPA will seek legislation aimed at out-of-state mail order pharmacies. According to CPA, certain health care insurers and other plans currently encourage the use of out-of-state pharmacies by offering different co-payments or deductibles for drugs ordered from those pharmacies. CPA believes this system discriminates against California pharmacies and sends California dollars out-of-state, instead of supporting the local economy. CPA may seek legislation that would prohibit indemnity health care plans from providing unequal co-payment and deductible plans for out-of-state mail order pharmacy benefits.

Second, CPA supports a pending congressional resolution which would ask FDA to establish a transitional class of drugs between the existing prescription and over-the-counter classes. Included in this transitional category would be drugs that had been prescription-only, but are destined for reclassification by FDA as over-the-counter. Pharmacists would be allowed to dispense these drugs without a physician's authorization, but would be required to consult with the patient on the use of the drug.

Third, CPA supports SB 917 (Kopp), a two-year bill which would require certain health care service plans, when offering new pharmacy benefits in an area, to notify all pharmacies in the area and take bids from all such pharmacies (*see supra*).

Finally, CPA may seek legislation to provide that it is a felony offense for any person who, in order to obtain any drug, falsely represents him/herself to be a physician or other person who may lawfully prescribe the drug, or falsely represents that he/she is acting on behalf of a person who may lawfully prescribe the drug, in a telephone communication with a registered pharmacist; currently, such an act constitutes a misdemeanor.

RECENT MEETINGS:

At its October 16 meeting, the Board once again discussed the possibility of adopting regulations to better control fee arrangements between physicians and home health agencies. (See CRLR Vol. 11, No. 4 (Fall 1991) p. 104; Vol. 11, No. 3 (Summer 1991) p. 101; and Vol. 11, No. 2 (Spring 1991) p. 97 for background information.) Specifically, the Board has been considering regulations that would require the disclosure of contracts between home health care companies and health care consultants and which would provide the Board with authority to access the financial records of pharmacies. Department of Consumer Affairs (DCA) legal counsel Robert Miller suggested that the Board work with the DCA Director, who has broad investigory powers to obtain such records; the Board took no formal action at the October meeting.

Also at its October meeting, the Board discussed the final rule adopted by the federal Nuclear Regulatory Commission (NRC) which requires medical licensees to establish quality management programs in an effort to reduce misadministrations of radiopharmaceuticals. (See CRLR Vol. 11, No. 3 (Summer 1991) p. 101 for background information.) The Board had previously opposed such a requirement as unnecessary in light of existing state regulations, and not warranted by the data compiled by the NRC. Despite this and other opposition, the NRC adopted the rule. The Board heard testimony from radiopharmacists who believe the rule places an enormous burden on small businesses without adding any safety or other benefit to the public beyond what is already in place. The Board agreed to send another letter to the NRC requesting that the Commission reconsider the rule.

The Board also discussed a letter from Deputy Attorney General Edward G. Weil advising the Board that the state Department of Justice has received numerous complaints that pharmacists are not providing the FDA-required patient package insert (PPI) when dispensing conjugated estrogens. Mr. Weil recommended that the Board notify its licensees of their potential liability not only under federal law, but for civil penalties under Proposition 65 when the PPI is not provided. Proposition 65, the Safe Drinking Water and Toxics Enforcement Act of 1986, provides that "no person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the State of California to cause cancer, birth defects or reproductive harm," without providing a "clear and reasonable warning." Proposition 65 applies to consumer products in general, and to prescription drugs; in 1987, the state determined that conjugated estrogens are a chemical known to cause cancer under Proposition 65. The Board agreed to publish a warning to licensees in its next newsletter. Board member Robert Toomajian noted that in light of the upcoming oral consultation requirement (*see supra* MAJOR PROJECTS), pharmacists should be notified of other prescription drugs that are known to cause cancer. Deputy Attorney General Bill Marcus opined that, to his knowledge, conjugated estrogens are the only drug identified by the state as cancer-causing thus far in its Proposition 65 implementation process.

FUTURE MEETINGS:

May 27–28 in Sacramento.
July 29–30 in San Francisco

BOARD OF REGISTRATION FOR PROFESSIONAL ENGINEERS AND LAND SURVEYORS

Executive Officer: Darlene Stroup
(916) 920-7466

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 Rules Committee.

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.

Board members and industry representatives expressed sorrow at the October 12 death of Board member Clarence E. (Bill) Mackey. In December, Governor Wilson appointed David J. Slawson as the Board's land surveyor member. Slawson, the president of a civil engineering firm, replaces former Board member James Dorsey. The Governor also appointed Mim Scott to the Board as a public member. Scott, a senior vice-president of a master-planned community developer, fills the seat of former Board member Robert Thornberg. Finally, the Senate Rules Committee reappointed public member Sharon Reid to the Board for her final four-year term.