prescription, and information identifying both the patient and the prescribing optometrist or physician; and prohibits the filling of expired prescriptions except when the patient's spectacles are damaged, broken, or lost. Under section 2559.6, it is unprofessional conduct to dispense spectacle lenses on or after January 1, 1999 for prescriptions that fail to meet the requirements of section 2541.1. This bill was signed by the Governor on March 16 (Chapter 8, Statutes of 1998).

AB 2721 (Miller), as amended August 10, establishes a four-year term of office, expiring on June 1, for members of the Board of Optometry. This bill also provides that any Board licensee who engages in, or aids and abets, prostitution-related offenses in the workplace is guilty of unprofessional conduct and subject to disciplinary action and fines up to $5,000. This bill was approved by the Governor on September 29 (Chapter 971, Statutes of 1998).

Recent Meetings

At its November 14 meeting, the Board reelected Steven S. Grant, OD, as President and Gerald J. Easton, OD, as Vice President. Dr. John Anthony was elected Secretary, replacing Patricia L. Gee, EdD, in this position. Reappointed Board members Dr. Sheilah Titus and Dr. Patricia Gee were also sworn in.

Also at the November meeting, Dr. Grant reported on the progress of the 1998 occupational analysis study. An occupational analysis is designed to capture information with respect to the major tasks optometrists perform in their professional work. *[14:1 CRLR 71]* Information on the knowledge, skills, and abilities required of licensed optometrists in order to perform these tasks competently will be collected and used to evaluate the Board's current licensing examination for appropriateness of test parameters and criteria. Of 2,000 surveys mailed to selected optometrists in September 1998, 578 have been returned and submitted to R & D Data Corporation for tabulation and interpretation. DCA's Office of Examination Resources is satisfied with both the numbers and demographic distribution of the surveys returned. The final report should be completed by early 1999. The results will not be ready by the next scheduled licensure exam (January 11, 1999 in Sacramento) but will be reflected in questions on the June 29, 1999 examination.

SB 668 (Polanco) (Chapter 13, Statutes of 1996) authorizes the Board to certify optometrists who are qualified to use specific classes of therapeutic pharmaceutical agents (TPA) for a limited number of eye conditions, upon completion of specified education, training, and examination. Section 1568 of the CCR, adopted by the Board in 1997 to implement SB 668, requires that applicants for TPA certification complete a Board-approved, 80-hour didactic course and specifies the University of California at Berkeley (UCB) and the University of Southern California (USC) as institutions where such a course will be offered. The Board has been working with UCB and USC to develop the TPA course.

In November, the Board voted to approve a proposed TPA course which will be offered by UCB. The course will combine 60–65 hours of Internet and distance learning with 15–20 hours of onsite, hands-on training at Berkeley. The course is being subsidized by Vision Service Plan (VSP), a national managed care provider of vision services, in a joint effort with UCB to reduce the financial hardships and accessibility problems that have made it difficult for optometrists to obtain TPA certification. Terry Dougherty of VSP commented that such a course will help VSP reach its goal of requiring that all VSP providers are TPA-certified.

Future Meetings

- March 14–15, 1999 in Fullerton.
- May 16–17, 1999 in San Jose.
- August 20–21, 1999 in Sacramento.
- November 14–15, 1999 in San Diego.

Board of Pharmacy

Executive Officer: Patricia Harris ♦ (916) 445-5014 ♦ Internet: www.dca.ca.gov/pharmacy/

Pursuant to Business and Professions Code section 4000 *et seq.*, the Board of Pharmacy grants licenses and permits to pharmacists, pharmacy interns, pharmacy technicians, pharmacies, pharmacy corporations, nonresident pharmacies, wholesale drug facilities, medical device retailers, veterinary food-animal drug retailers, out-of-state distributors, clinics, and hypodermic needle and syringe distributors. 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 the Pharmacy Law and its regulations, the Board employs full-time inspectors who investigate 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 misconduct substantially related to the practice of pharmacy.

The Board of Pharmacy is a consumer protection agency located within the Department of Consumer Affairs (DCA). The Board, which meets five times per year, consists of eleven members, four of whom are nonlicensees. The remaining members are pharmacists, five of whom must be active practitioners. All Board members are appointed for four-year terms.

Major Projects

Data Collection Portion of CURES Pilot Project Commences

For many years, the Board of Pharmacy has been involved

in a multi-agency project to automate the current paper-based "triplicate system" used when a physician or other authorized prescriber prescribes, and a pharmacist dispenses, Schedule II controlled substances. *[15:4 CRLR 116; 15:2&3 CRLR 89; 15:1 CRLR 86]* Under the triplicate system, prescribers must prescribe Schedule II narcotics on a state-issued triplicate form. The prescriber retains one copy and gives the remaining two copies to the patient. To have the prescription filled, the patient takes the remaining two parts of the form to a pharmacy. The pharmacy endorses the prescription, retains a duplicate, and checks the form for compliance with Health and Safety Code section 11206. Section 11164 of the Health and Safety Code requires the pharmacy to transmit the original of the triplicate form to the Department of Justice's Triplicate Prescription Program at the end of the month in which the prescription was filled.

For many years, the Board of Pharmacy has been involved in a multi-agency project to automate the current paper-based "triplicate system" used when a physician or other authorized prescriber prescribes, and a pharmacist dispenses, Schedule II controlled substances.

The purpose of the triplicate system is to monitor closely the prescribing and dispensing of Schedule II controlled substances to control effectively the abuse and diversion of these narcotics while allowing patient access to appropriate medications. Prescription drug diversion is the illicit distribution, prescribing, dispensing, or use of controlled substances that are manufactured and intended for legitimate purposes. Drug diversion can occur at many points in the drug distribution chain, beginning with the manufacturer and ending with the patient or consumer. Much prescription drug diversion occurs at the prescribing, dispensing, or patient level, which is predominantly the focus of the triplicate system. However, prescribers and dispensers complain that the paper-intensive triplicate system is burdensome in light of modern electronic recordkeeping methods.

AB 3042 (Takasugi) (Chapter 738, Statutes of 1996) added section 11165 to the Health and Safety Code, which requires the Board of Pharmacy and the Department of Justice to establish the Controlled Substance Utilization Review and Evaluation System (CURES) to electronically monitor the prescribing and dispensing of Schedule II controlled substances by all practitioners authorized to prescribe or dispense them, "contingent upon the availability of adequate funds." In the meantime, AB 3042 requires that CURES be implemented as a three-year pilot project commencing on July 1, 1997, to be administered concurrently with the existing triplicate system, to examine the comparative efficiencies between the two systems. Thus, the statute requires the Department of Justice and Board of Pharmacy to engage in a major data collection process to determine the relative efficiencies of the existing triplicate system and the electronic maintenance of Schedule II narcotics data.

To facilitate the collection of the required data, the Board adopted section 1715.5, Title 16 of the CCR, on April 10, 1998 as an emergency regulation. Thereafter, it published notice of its intent to permanently adopt the section on April 24; the Office of Administrative Law (OAL) approved the regulation on August 27. Section 1715.5 requires a dispensing pharmacy to provide specified information on the patient, prescriber, and pharmacy for each prescription of a Schedule II controlled substance; specifies the format in which the information is to be provided; designates the Board of Pharmacy to select the location for submission of the information; establishes the timeframe for submitting information; provides an alternate method of submission and threshold reporting requirements for pharmacies without electronic reporting capability; specifies the reporting requirements for partially filled or dispensed prescriptions; sets the compliance date for submission of information; and provides for a one-time $75 reduction in the next license renewal fee for pharmacies that comply with section 1715.5 by September 8, 1998.

The Board has contracted with Atlantic Associates, Inc. in Manchester, New Hampshire to collect all the information, and has sent several notices (with a CURES handbook) to all California pharmacies about the new reporting requirements. The Board warned pharmacies that the CURES project is operating concurrently with the existing triplicate prescription program; thus, pharmacies are still required to mail original triplicate prescription forms to the Department of Justice at the end of each month.

The Board and the Department must submit a progress report on the data collection project to the legislature by January 1, 1999. When the pilot project is completed in June 2000, the legislature will determine the need for continuation of the current triplicate program.

Licensing Limited Liability Companies

At its October meeting, the Board's Licensing Committee discussed an emerging legal issue concerning the licensure of a limited liability company (LLC) as a pharmacy. An LLC is a form of business enterprise established in 1994 by the Beverly-Killea Limited Liability Company Act, Corporations Code section 17000 *et seq. [14:4 CRLR 120]* The LLC structure offers business owners the limited liability of a corporation and the pass-through tax advantages of a partnership. An uncodified provision of the Beverly- Killea Act prohibits an LLC from rendering "professional services." According to a March 1998 legal opinion by DCA attorney Christopher Grossgart, it is generally accepted that the uncodified language prevents DCA and its constituent licensing agencies from issuing "professional" licenses to an LLC; for example, an LLC is precluded from holding a license to practice as a pharmacist, a dentist, or a physician.

A more controversial question has been whether the uncodified language also prevents a DCA agency from issuing a permit to an LLC to operate a business in which professional services are rendered, and in fact dozens of LLCs have submitted applications to the Board for pharmacy, medical device

retailer, and wholesaler licenses. Based on DCA advice, the Board has interpreted the uncodified language narrowly and has denied the issuance of these licenses to LLCs. Applicants have countered that these permits are merely "business" licenses and, as such, are not encompassed within the prohibition against an LLC rendering "professional" services. Whether a distinction can be made between "professional" and "business" licenses has been the subject of great dispute. The Department of Health Services (DHS) for example, has rejected DCA's narrow construction of the uncodified language.

In a subsequent October 8 memo, Grossgart recommended that the Board consider sponsoring legislation adding section 4208 to the Business and Professions Code, which would authorize it to issue "site" permits to an LLC to operate as a pharmacy, medical device retailer, wholesaler, or veterinary medical drug retailer. As the law currently authorizes the Board to issue "site" permits to corporations which have the same liability shield as an LLC, this proposed legislation—in Grossgart's view—would not adversely affect consumer protection.

At the full Board's October 28 meeting, member Darlene Fujimoto expressed concern that licensure of LLCs might be unrelated to the Board's overall strategic plan and asked how such licensure would benefit the practice of pharmacy. Deputy Attorney General Bill Marcus responded that allowing licensure to LLCs would decrease the Board's exposure to litigation. He reiterated that a considerable number of LLCs have applied for licensure to establish pharmacies and are likely to challenge the Board when their applications are denied. Because some LLCs were granted licenses before DCA's position on LLCs was clear, some applicants have suggested that the Board has acted arbitrarily.

At its October 28 meeting, the Board voted unanimously to refer the issue whether to seek the addition of Business and Professions Code section 4208 to its Legislation and Regulation Committee for study and recommendation to the Board.

Restocking of Ambulances with Supplies and Medications

The Board has recently been asked to tackle a thorny problem regarding the restocking of ambulance supplies (including drugs) by hospitals. The Health Care Financing Administration's Office of the Inspector General (OIG) has released an advisory opinion which concludes that a hospital's restocking of ambulance supplies likely violates federal anti-kickback law and raises several other legal problems, including antitrust, tax, pharmacy, and contract law issues, and possible violation of the federal False Claims Act. Relying on OIG's opinion, the California Healthcare Association (CHA) has adopted a policy of discouraging the common practice of hospitals restocking ambulance supplies (including drugs).

Federal anti-kickback law, 42 U.S.C. section 1320a–7b(b), sets forth penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration (*e.g.*, anything of value, including supplies and drugs) in order to induce business reimbursed by a federally funded program such as Medicare, Medicaid, or CHAMPUS. California also has an anti-kickback statute at Welfare and Institutions Code section 14107.2(a). In its advisory opinion, OIG described a particular case in which a hospital provided supplies without charge to municipal ambulance companies. Because the ambulance company could influence a patient's choice of hospital, and because of the risk that an ambulance company would use its influence to direct a patient to a hospital that provides the ambulance company with free goods, OIG concluded that the arrangement would likely constitute prohibited remuneration under the federal anti-kickback statute. In OIG's view, state law giving patients the right to determine their destination is insufficient to deter abuse where the hospital provides remuneration, including the provision of free goods, to the ambulance service.

Adopting the position of CHA, many hospitals have discontinued the practice of restocking ambulances. This is not a problem for general supplies, but concerns have arisen about the issue of restocking of controlled substances. Some ambulances are purchasing, storing, and restocking medications and supplies. For controlled substances, they are using the license and DEA certificate of their contracted medical director. According to Pharmacy Board Executive Officer Patricia Harris, the Pharmacy Law does not specifically authorize clinics or hospital medical directors (or other physicians) to supply emergency vehicles with dangerous drugs, dangerous devices, or controlled substances. Any specific authority must be found elsewhere, such as federal or state law and regulations governing emergency vehicles.

The Board has recently been asked to tackle a thorny problem regarding the restocking of ambulance supplies (including drugs) by hospitals.

On October 28, the Board voted unanimously to form a task force with representatives from the California Society of Health Systems Pharmacists, the Department of Health Services, and possibly the Office of Emergency Services to draft legislation that would authorize the storage, dispensing, and purchasing of dangerous drugs and devices for use by emergency personnel.

Implementation of the FDA Modernization Act of 1997

On November 9, 1997, Congress passed the Food and Drug Administration Modernization Act of 1997. The law was signed by President Clinton on November 21, 1997 and became effective on November 21, 1998. The FDA Modernization Act of 1997 requires FDA and the fifty states to enter into a memorandum of understanding (MOU) regarding the compounding of drugs. Compounding is the process by which a pharmacist combines, mixes, or alters ingredients to specialize a medication for a patient, at the direction of a physician. Section 503A of the Act recognizes compounding as an element of the practice of pharmacy that is to be regulated by the states, and distinguishes it from "manufacturing" which falls within the jurisdiction of the FDA. The purpose of the

section is "to ensure continued availability of compounded drug products as a component of individualized therapy, while limiting the scope of compounding so as to prevent manufacturing under the guise of compounding." The purpose of the MOU is to address the interstate distribution of "inordinate amounts" of compounded drug products and a state's investigation of complaints regarding this distribution.

The law instructs the FDA and the National Association of Boards of Pharmacy (NABP) to develop a standard MOU for state boards. The goal of the MOU is to obtain state agreement on two issues: (1) protocols for the appropriate investigation of complaints relating to compounded drug products shipped out-of-state; and (2) establishment of appropriate restrictions on the amount of compounded drugs shipped in interstate commerce, including "safe harbors" for pharmacists who distribute compounded products in interstate commerce. Pharmacies located in a state that does not sign a MOU by the law's effective date (November 21) will be subject to FDA's "safe harbor" provision, whereby compounded products may not exceed 5% of the total prescription orders dispensed or distributed by that pharmacy. The MOU's "safe harbor" language is intended to address circumstances in which interstate distribution of compounded medications can exceed 5% of the total quantity of dispensed medication.

At its October 28 meeting, the Board decided it would take no action at the time; the Board directed the Licensing Committee to monitor the progress of the MOU being developed by the FDA and NABP.

Recycling of Nursing Home Drugs

The American Medical Association recently adopted a policy reflecting recommendations made by its Council on Scientific Affairs in a written report entitled *Recycling of Nursing Home Drugs.* The report makes recommendations on ways to reduce medication waste in long-term care facilities (LTCFs). The report defines "medication waste" as any medication that has been dispensed and paid for but not consumed by a particular LTCF patient. Based on limited studies, the report stated that the cost associated with unused medication in LTCFs is 4–10% of the total costs of medications dispensed. More than 90% of the wasted medication is due to discontinuation or change in medication or the death, transfer, or hospitalization of the resident.

Based on the report, the AMA has adopted a policy consistent with the American Society of Consultant Pharmacists (ASCP) to support the return and reuse of medications to the dispensing pharmacy to reduce waste associated with unused medications in LTCFs and to offer substantial savings to the health care system. AMA and ASCP recommend that medications be returned and reused only if (1) they are not controlled substances, (2) they are dispensed in tamper-evident packaging and returned with packing intact, (3) in the professional judgment of the pharmacist, the medications meet all federal and state standards for product integrity, (4) policies and procedures are followed for the appropriate storage and handling of medications at the LTCF and for the transfer, receipt, and security of medications returned to the dispensing pharmacy, (5) a system is in place to track restocking and reuse to allow medications to be recalled if required, and (6) a mechanism (reasonable for both the payer and the dispensing LTCF pharmacy) is in place for billing only the number of doses used or crediting the number of doses returned, regardless of payer source.

On October 28, the Board unanimously voted to adopt the Licensing Committee's recommendation that the Board participate as a member of a task force with interested parties to address the issue of recycling nursing home drugs.

Acceptable Remedial Pharmacy Coursework

SB 1349 (Committee on Business and Professions) (Chapter 549, Statutes of 1997) added section 4200.1 to the Business and Professions Code; effective July 1, 1998, this provision requires candidates who have failed the Board's licensure examination after four attempts to complete 16 semester units or the equivalent of pharmacy coursework approved by the Board as a condition of eligibility for reexamination.

In April 1998, the Board published notice of its intent to adopt section 1725, Title 16 of the CCR, to specify the criteria for acceptable remedial pharmacy coursework. Under section 1725, coursework that meets the requirements of section 4200.1 of the Business and Professions Code is any pharmacy coursework offered by a pharmacy school approved by the American Council on Pharmaceutical Education or recognized by the Board. A final examination must be part of the course of study. When a candidate applies for reexamination after four failed attempts, he/she must furnish evidence of successful completion of at least 16 semester units or the equivalent of remedial pharmacy coursework; evidence of successful completion must be posted on a transcript from the pharmacy school sent directly to the Board. Following a 45-day public comment period, the Board adopted section 1725; OAL approved the regulation on October 5, and it became effective on November 4.

Practical Training for Pharmacy Technician Trainees

Business and Professions Code section 4115 establishes the pharmacy technician category, and directs the Board to adopt regulations specifying that tasks which may be performed by a pharmacy technician under the direct supervision of a licensed pharmacist; section 1793.2, Title 16 of the CCR, specifies those tasks. Business and Professions Code section 4202 requires the Board to adopt regulations setting forth the qualifications for registration as a pharmacy technician, and the required contents of acceptable pharmacy technician training courses. Section 1793.4, Title 16 of the CCR, sets forth the qualifications for pharmacy technician registration; under section 1793.4(d), one method of qualification is to work for at least one year performing the tasks specified in section 1793.2 while employed or utilized as a pharmacy technician, assisting in the preparation of prescriptions for an inpatient of a hospital or for an inmate of a correctional facility. Section 1793.6, Title 16 of the CCR, specifies a three different methods of qualifying for pharmacy technician registration, and the types of knowledge which an acceptable training program should impart to a registration

candidate. One of the approved types of training programs places a pharmacy technician trainee in a pharmacy to perform the functions of a pharmacy technician under the direct supervision and control of a licensed pharmacist.

Effective July 1, 1997, SB 1553 (Kelley) (Chapter 798, Statutes of 1996) removed an exemption from the pharmacy technician registration requirement for persons employed or utilized as a pharmacy technician to assist in the filling of prescriptions for an inpatient of a hospital or for an inmate of a correctional facility. This amendment created "catch-22" problems for the Board and for individuals then enrolled in pharmacy technician training programs, because it could be interpreted to preclude persons serving an externship in a pharmacy, and attempting to qualify for pharmacy technician registration under section 1793.4(d), from obtaining the required training.

In early 1998, the Board drafted legislation to fix the problem created by SB 1553; the language was ultimately amended into SB 2239 (Committee on Business and Professions), which was passed by the legislature and becomes effective on January 1, 1999 (see LEGISLATION). In the meantime, the Board amended section 1793.6, Title 16 of the CCR, on an emergency basis in August 1997, and then readopted the emergency amendments on several occasions throughout 1998. Under the amendments, a current enrollee of a pharmacy technician training course that meets the requirements of section 1793.6 may obtain all or part of his/her practical instruction as an enrollee of that course in a pharmacy; such an enrollee must wear a badge that clearly identifies him/her as a "pharmacy technician trainee." The amendments further state that the tasks performed by the trainee must be limited to the tasks described in section 1793.2, and require that the tasks be performed in compliance with state and federal laws and with verification and documentation by a licensed pharmacist as required by subsections 1793.7(a) and (b).

SB 2239 has now fixed this problem by adding section 4115.5 to the Business and Professions Code, which clarifies that, notwithstanding any other provision of law, a pharmacy technician student may be placed in a pharmacy as a pharmacy technician trainee to complete an externship for the purpose of obtaining practical training that is required by the Board as a condition of becoming registered as a pharmacy technician. The new statute also sets forth standards for the supervision of pharmacy technician trainees serving in externships in pharmacies.

Board Proposes to Reduce License Renewal Fees

Sections 1749.1 and 1793.5, Title 16 of the CCR, set forth various fees and penalties charged by the Board for licenses, permits, registrations, and other services. Business and Professions Code section 4400(s) directs the Board to maintain a reserve fund equal to approximately one year's expenditures.

In the early 1990s, to help offset a large budget deficit in the state's general fund, the state's Budget Act permitted the director of the Department of Finance to remove any surplus exceeding three months of operating expenses from any special fund agency. *[12:4 CRLR 1]* In the case of the Board of Pharmacy, $5.4 million was transferred from the Board's reserve fund to the general fund. This transfer made it difficult for the Board to meet operational expenses with respect to its enforcement and consumer awareness programs. To help meet its expenses, the Board sought a fee increase, which was granted and became effective on July 1, 1995. *[15:2&3 CRLR 90]*

On behalf of the licensees of a number of occupational agencies whose reserve funds were raided by the state, Los Angeles attorney Richard Fine sued the state to compel reimbursement of the removed funds. *[15:4 CRLR 39–40]* The state recently settled the lead case, *Malibu Video Systems, et al. v. Kathleen Brown, et al.*, No. BC082830 (Los Angeles County Superior Court), and agreed to refund the monies to the agencies over a multi-year period. In fiscal year 1998–99, the Board of Pharmacy was reimbursed $3,798,197 of the $5.4 million transferred to the general fund in fiscal year 1991–92. The Board anticipates the return of an additional $1,138,990 during fiscal year 1999–2000. Based upon projected revenues and expenditures, the Board will end fiscal year 1999–2000 with a reserve of 19.6 months' worth of operational expenditures; it will have 18.9 months by fiscal year 2000–2001, and 17.9 months by fiscal year 2001–2002.

In light of this recovery, the Board published notice on November 27 of its intent to reduce its pharmacist and pharmacy renewal fees in order to slow the accrual of funds and achieve a fund level consistent with approximately one year's operating expenses. The Board has determined that the proposed regulatory action would reduce its reserve fund to a level of 16.6 months by fiscal year 1999–2000, 13.0 months by fiscal year 2000–2001, and 9.2 months by 2001–2002. The fund level achieved by 2001–2002 would be consistent with the provisions of Business and Professions Code section 4400(s), and would be considered prudent by DCA and the Department of Finance.

Under the Board's proposed amendments, its pharmacist biennial renewal fee would be $115, and its annual pharmacy renewal fee would be $175, effective July 1, 1999. At this writing, the Board does not plan to hold a public hearing on the proposed amendments, but is accepting written comments until January 11, 1999.

Legislation

SB 2239 (Committee on Business and Professions), as amended August 24, enacts various technical changes affecting licensing boards within DCA; several of the bill's provisions affect the Board of Pharmacy.

As noted above, SB 2239 adds section 4115.5 to the Business and Professions Code, concerning pharmacy technician trainee externships (see MAJOR PROJECTS). This provision expressly authorizes any pharmacy technician student (defined as a person enrolled in a pharmacy technician training program operated by a California public postsecondary education institution or by a private postsecondary vocational institution approved by the Bureau for Private Postsecondary and Vocational Education) to be placed in a pharmacy as a pharmacy technician trainee to complete an externship for the purpose of obtaining practical training that is required by the Board as a condition of becoming registered as a pharmacy techni-

cian. The new provision also states that a pharmacy technician trainee participating in such an externship may perform pharmacy technician duties only under the immediate and personal supervision and control of a pharmacist who is on the premises and has the trainee within his/her view at any time the trainee performs such duties. The pharmacist is directly responsible for the conduct of the trainee, and must verify any prescription prepared by the trainee by initialing the prescription label before the medication is disbursed to a patient. No more than one pharmacy technician trainee per pharmacist may participate in an externship. An externship may last up to 120 hours; however, if the externship involves a rotation between a community and hospital pharmacy for the purpose of training the student in distinct practice settings, it may last for 320 hours. At all times while on the job, the trainee must wear identification that indicates his/her student status.

SB 2239 also amends section 4301 of the Business and Professions Code to restore cash compromise as unprofessional conduct and grounds for disciplinary action. Last year's SB 1349 repealed this subsection since the Board's prosecutors had not used it in years. However, as SB 1349 was nearing enrollment, a cash compromise case appeared. SB 2239 restores section 4301(m) to define the cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances as unprofessional conduct; the record of the compromise is conclusive evidence of unprofessional conduct.

SB 2239 adds section 4301.5 to the Business and Professions Code to provide that if a California-licensed pharmacist is also licensed in another state or jurisdiction, and that other state or jurisdiction suspends or revokes that license, the pharmacist's California license shall be suspended automatically for the duration of the other state's suspension or revocation. The Board must notify the pharmacist regarding the status of his/her California license and of his/her right to have the issue of penalty heard under a new expedited procedure established in this section.

SB 2239 also amends section 4322 of the Business and Professions Code to impose substantially higher civil penalties and fines on a person who attempts to secure or secures licensure for him/herself or another person by making false representations, or who fraudulently represents him/herself to be licensed. This offense is punishable as a misdemeanor; upon conviction, a fine of $5,000 (increased from $400) and imprisonment of 50 days could be imposed.

The bill also amends Health and Safety Code section 11166 to permit pharmacists to fill prescriptions for Schedule II drugs within 14 days after the triplicate was written; existing law prohibits dispensing if the prescription is "tendered" to the pharmacist seven days after it is issued.

Finally, SB 2239 repeals and reenacts Health and Safety Code section 11167 to extend from 72 hours to seven days the period within which a prescriber's emergency oral order for a Schedule II drug must be followed by the triplicate prescription. This bill was signed by the Governor on September 26 (Chapter 878, Statutes of 1998).

SB 440 (Maddy). Under existing law, a pharmacist may perform certain procedures or functions as part of the care provided by a health care facility, a licensed clinic, or a provider under contract with a health plan, in accordance with policies, procedures, or protocols of that facility, licensed clinic, or health plan. As amended June 25, SB 440 permits a pharmacist to also perform procedures and functions as part of the care provided by a home health agency licensed by the state Department of Health Services. A pharmacist performing any of these procedures for a licensed home health agency must perform the procedures in accordance with a written, patient-specific protocol approved by the treating or supervising physician; any change, adjustment, or modification of an approved preexisting treatment or drug therapy must be provided in writing to the treating or supervising physician within 24 hours. This bill was signed by the Governor on August 21 (Chapter 347, Statutes of 1998).

SB 625 (Rosenthal), as amended April 23, requires health plans that provide prescription drug benefits and maintain one or more drug formularies to provide to members of the public, upon request, a copy of the current list of prescription drugs on the formulary by major therapeutic category; and to maintain an expeditious process by which prescribing providers may obtain authorization for a medically necessary nonformulary prescription drug. This bill was signed by the Governor on June 19 (Chapter 69, Statutes of 1998).

AB 974 (Gallegos), as amended June 3, prohibits health plan contracts covering prescription drug benefits that are issued, amended, or renewed on or after July 1, 1999 from limiting or excluding coverage for a drug for an enrollee if the drug previously had been approved for coverage by the plan for a medical condition of the enrollee and the plan's prescribing provider continues to prescribe the drug for the medical condition, provided that it is appropriately prescribed and is considered safe and effective for treatment. This bill does not preclude the prescribing provider from prescribing another drug that is covered by the plan and is medically appropriate, nor does it prohibit generic drug substitutions pursuant to specified existing law. AB 974 also requires every health plan that covers prescription drug benefits to comply with certain notice requirements with respect to whether the plan uses a formulary and to provide certain information about drugs on the formulary to the public, upon request. Under AB 974, plans that use a formulary must provide an enrollee or member of the public, upon request, with a list of all of the drugs contained in the plan's formulary, and provide information, by telephone, about whether specific drugs are on the plan's formulary. This bill was signed by the Governor on June 19 (Chapter 68, Statutes of 1998).

SB 1606 (Lewis), as amended August 24, provides that, commencing July 1, 1999, limitations imposed on the number or quantity of oral or suppository form drugs provided by a pharmacy to a skilled nursing or intermediate care facility shall not apply to an automated drug delivery system, when a pharmacist controls access to the drugs. *[15:4 CRLR 117–18]* The bill also provides that, commencing July 1, 1999, access to an automated drug delivery system shall be limited to personnel authorized by law to administer drugs and who

have an access code to the system; sets forth requirements of a health facility and pharmacy with regard to the installation, operation, and review of an automated drug delivery system; and exempts an automated drug delivery system from certain labeling requirements. This bill was signed by the Governor on September 22 (Chapter 778, Statutes of 1998).

AB 1889 (Knox), as amended August 25, would have required the Board of Pharmacy to conduct a study of medication error rates and negative drug interaction, using $300,000 from the Board's Contingent Fund. The Governor vetoed the bill on September 27. In his veto message, the Governor stated that the methodology of the study was wrongly conceived and that the study was potentially unnecessary because current pending studies could provide the same information sought by the proposed study.

AB 2687 (Gallegos), as amended August 28, authorizes a local health officer who determines that a person within his/her jurisdiction is unlawfully dispensing or furnishing dangerous drugs or devices to take action to stop such sales, including receiving and investigating complaints from the public, other licensees, or health care facilities; issuing an order to the person to immediately cease and desist from the unlawful activity; and ordering the closure of the business operated, managed, or owned by that person. The bill also authorizes a local health officer to order the immediate closure of a business upon reasonable suspicion that the business poses an immediate threat to public health, welfare, or safety. The bill requires that any person whose business is closed as a result of local health officer action be given notice and a hearing to show cause why the closure is unwarranted. This bill makes it a misdemeanor for any unlicensed person to knowingly dispense or furnish a dangerous drug or dangerous device, or to knowingly own, manage, or operate a business that dispenses or furnishes a dangerous drug or dangerous device, when that business is not licensed to dispense or furnish such products. Upon conviction, each violation is punishable by imprisonment in a county jail not to exceed one year, or by a fine not to exceed $5,000, or by both that fine and imprisonment. Upon a second or subsequent conviction, each violation is punishable by imprisonment in a county jail or by fine. This bill was signed by the Governor on September 22 (Chapter 750 of the Statutes of 1998).

Effective January 1, 1999, section 1715 requires the pharmacist-in-charge of each pharmacy to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy laws.

AB 2693 (Migden), as amended August 18, provides that a prescription for a Schedule II controlled substance for use by a patient who has a terminal illness is exempt from the triplicate requirement; however it must comply with requirements set forth in the bill. AB 2693 requires such a prescription to be signed and dated by the prescriber and to contain the name of the person for whom the controlled substance is prescribed, the name and quantity of the controlled substance prescribed and directions for use, the address of the person for whom the controlled substance is prescribed, and specific information about the prescriber such as telephone number and federal controlled substance registration number. The prescription must also indicate that the prescriber has certified that the patient is terminally ill by the words "11159.2 exemption." The bill further authorizes a pharmacist to fill such a prescription when there is a technical error in the certification, provided that he/she has personal knowledge of the patient's terminal illness, and subsequently returns the prescription to the prescriber for correction within 72 hours.

The bill defines "terminally ill" as a patient who, in the reasonable medical judgment of the prescribing physician, has been determined to be suffering from an illness that is incurable and irreversible; whose illness, in the reasonable medical judgment of the prescribing physician, will, if the illness takes its normal course, bring about the death of the patient within a period of one year; and whose treatment by the physician prescribing a Schedule II controlled substance is primarily for the control of pain, symptom management, or both, rather than for cure of the illness.

The Board opposed AB 2693 for several reasons. First, the Board asserted that some patients would learn that the term "11159.2 exemption" means they have a terminal illness, which would undermine attempts to keep terminal diagnoses from patients. Second, the bill obligates the pharmacist to assure the patient is terminally ill to be exempt from the triplicate prescription, requiring the pharmacist to contact the prescriber for verification. Third, the Board fears that the bill will facilitate drug diversion of Schedule II drugs by creating another way to prescribe, dispense, and account for the dispensing of Schedule II drugs without compliance with the triplicate system. Finally, the Board argued that because the CURES report is due by January 1, 1999, this bill is premature in its piecemeal elimination of the triplicate requirement for this category of prescription. However, this bill was signed by the Governor on September 23 (Chapter 789, Statutes of 1998).

AB 2721 (Miller), as amended August 10, clarifies that Pharmacy Board members serve a term of four years, expiring on June 1. The bill also provides that any Board licensee who engages in, or aids and abets, prostitution in the workplace is guilty of unprofessional conduct and is subject to disciplinary action against his/her license; the bill also provides for the imposition of a civil penalty in such cases. This bill was signed by the Governor on September 29 (Chapter 971, Statutes of 1998).

SB 2238 (Committee on Business and Professions), as amended August 26, requires the Board of Pharmacy to initiate the rulemaking process on or before June 30, 1999, to adopt regulations requiring its licentiates to provide notice to clients and customers that they are licensed by the state of California. SB 2238 also requires the Board to submit to the DCA Director, on or before December 31, 1999, its method for ensuring periodic evaluation of every licensing examination that it administers. This bill was signed by the Governor on September 28 (Chapter 879, Statutes of 1998).

Recent Meetings

At its October meeting, Board staff gave a presentation to the Board on its new "self-assessment" program under section 1715, Title 16 of the CCR. Effective January 1, 1999, section 1715 requires the pharmacist-in-charge of each pharmacy to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy laws. The assessment must be performed before March 31 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever (1) a new pharmacy permit has been issued, or (2) there is a change in the pharmacist-in-charge.

The primary purpose of the self-assessment is to promote compliance with the law through self-examination and education. The Board has developed two forms to guide a pharmacist's self-assessment: Form 17I-29 is for community pharmacies, and Form 17I-30 is for hospital inpatient pharmacies. The forms require the pharmacist-in-charge to evaluate the pharmacy's compliance with federal and state laws and regulations regarding facility condition and security, drug stock, posting of certificates and notices, pharmacist-in-charge obligations, intern pharmacist activities, pharmacy technician activities, general pharmacy practice, corresponding responsibility for filling controlled substances prescriptions, prescription requirements, prescription labeling and dispensing, refill authorization, prescription transfers, confidentiality of prescriptions, recordkeeping requirements for all dangerous drugs, recordkeeping requirements for controlled substances, automated dispensing devices, repackaging for use by the pharmacy, compounding unapproved drugs for future use or prescriber use, and electronic transmission of prescriptions. Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Future Meetings

- January 20–21, 1999 in Orange County.
- March 24–25, 1999 in Sacramento.
- May 12–13, 1999 in San Diego.
- July 28–29, 1999 in San Francisco.
- October 20–21, 1999 in Sacramento.

Board of Podiatric Medicine

Executive Officer: James H. Rathlesberger ♦ (916) 263-2647 ♦ Internet: www.dca.ca.gov/bpm/

The Board of Podiatric Medicine (BPM) regulates the practice of podiatry in California pursuant to Business and Professions Code section 2460 *et seq.* and Article 12 of the Medical Practice Act (Business and Professions Code section 2220 *et seq.*). BPM's regulations appear in Division 13.9, Title 16 of the California Code of Regulations (CCR).

The mission of the Board of Podiatric Medicine is to ensure the protection of consumers through proper use of the licensing and enforcement authorities delegated to it by the legislature. BPM is a consumer protection agency within the Department of Consumer Affairs (DCA) and its Medical Board of California (MBC).

The Board licenses doctors of podiatric medicine (DPMs), administers two licensing tests per year, approves colleges of podiatric medicine, and enforces professional standards by initiating investigations and taking disciplinary action where appropriate. The Board consists of four licensed podiatrists and three public members.

Major Projects

BPM Undergoes the Sunset Review Process

During the fall of 1997, the necessity and performance of BPM were reviewed by the Joint Legislative Sunset Review Committee (JLSRC) and DCA under the "sunset review" process set forth in SB 2036 (McCorquodale) (Chapter 908, Statutes of 1994). Under the sunset process, the legislature inserts an expiration date into the enabling act of each DCA regulatory board; prior to that date, the JLSRC must review the need for and performance of the board, and the legislature must pass a bill extending the life of the agency or it ceases to exist. *[15:4 CRLR 32]* As required under the statute, BPM submitted a lengthy report describing its mission, functions, and activities on October 1, and answered questions from JLSRC members at a hearing on November 17, 1997.

BPM's sunset report contained some interesting and somewhat controversial recommendations. First, BPM recommended that its composition be converted from a professional member majority to a public member majority. At the time, the Board was composed of four podiatrists and two public members. Although most non-health care occupational licensing boards (with the exception of the Board of Accountancy) are dominated by public members, only one California health care licensing board—the Board of Vocational Nurses and Psychiatric Technicians—consists of a public member majority, and it only recently achieved that status during its 1996–97 sunset review process. BPM proposed to become the second, with a nine-member board consisting of five public members and four DPMs.

BPM first voted to seek a public member majority in November 1995. *[15:4 CRLR 104]* Throughout 1996 and 1997, BPM held public hearings on its proposal to convert to a public member majority. Strenuously opposing the proposal at every hearing was the California Podiatric Medical Association (CPMA). At BPM's sunset hearing, CPMA testified that "the Board of Podiatric Medicine is fulfilling its public protection role in an exemplary fashion with its current professional member majority." CPMA stated that it is unaware