DPA certification. Legislation enacted in 1996 (SB 668, Polanco; Chapter 13, Statutes of 1996) established a certification program within the Board, whereby the Board certifies qualified optometrists who complete additional training to use specific classes of therapeutic pharmaceutical agents (TPA) for a limited number of eye conditions. [16:1 CRLR 69] However, some optometrists who were initially licensed before 1980 have never applied for DPA or TPA certification.

Dr. Anthony stated that the position of the Board has been to continue licensing non-DPA- or TPA-certified optometrists under the assumption that their number would eventually dwindle due to attrition. He expressed concern, however, that current optometric practice is significantly limited and may be inadequate without the use of pharmaceutical agents. Despite a suggestion by Board President Steven Grant, OD, that the Board issue a mandate requiring optometrists to receive DPA training or lose their licenses, the Board agreed to further investigate the status of uncertified practitioners. Dr. Anthony agreed to draft a letter to uncertified optometrists, inquiring as to whether they continue active practice and whether the nature of their practice is limited by their non-certified status. At this writing, Dr. Anthony expects to present a draft of this letter to the Board for approval at its May meeting.

**FUTURE MEETINGS**

- May 16–17, 1999 in San Jose.
- August 20–21, 1999 in Sacramento.

**Board of Pharmacy**

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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**

**Pharmacy Practice on the Internet**

Over the last few months, the Board and the public have witnessed a surge of pharmacy practice activity on the Internet. While the Pharmacy Law requires a pharmacy which offers to compound, dispense, or refill a prescription for a resident of California to be licensed by the Board as a nonresident pharmacy, the Board’s Licensing Committee has requested that the Board sponsor legislation that will require additional disclosure of information on the application form specific to Internet pharmacy practice.

Currently, Deputy Attorney General William Marcus is drafting proposed legislation based on the Licensing Committee's discussions. The legislation would require an Internet pharmacy to disclose specific information on its application for licensure, including its Internet name; its corporate or business name (if different); the names and addresses of its officers, directors, partners, and shareholders; and the location of each pharmacy which will be performing compounding, dispensing, or refilling of prescriptions, maintaining or reviewing patient profiles, or providing patient consultation. Additionally, the applicant must provide proof that it, and any pharmacy or pharmacist it employs or contracts with, is licensed or registered as required by the laws of the host state. Finally, an Internet pharmacy must provide specific descriptive information to consumers on its website.

**CURES Update**

For several years, the Board 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. [16:1 CRLR 69–70; 15:4 CRLR 116; 15:2&3 CRLR 89] 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 (DOJ) Triplicate Prescription Program at the end of the month in which the prescription was filled. 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. 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 DOJ 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. 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 DOJ and the Board 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. The data received from the state’s 5,000 pharmacies are made available online to DOJ, the Board, the Medical Board, the Board of Dental Examiners, and the Osteopathic Medical Board of California.

To facilitate the collection of the required data, the Board adopted section 1715.5, Title 16 of the CCR, in 1998. 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; 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; and sets the compliance date for submission of information. The Board contracted with Atlantic Associates, Inc. in Manchester, New Hampshire to collect all the information, and mailed several notices (with a CURES handbook) to all California pharmacies about the new reporting requirements. The Board warned pharmacies that CURES is operating concurrently with the existing triplicate prescription program; thus, pharmacies are still required to mail original triplicate prescription forms to DOJ at the end of each month.

CURES has arrived at a key point in time, because the Triplicate Prescription Program administered by DOJ’s Bureau of Narcotic Enforcement has been unable to process the vastly increasing number of Schedule II controlled substance prescriptions dispensed in California.

DOJ and the Board submitted a progress report on the data collection project to the legislature on January 1. According to the report, CURES has arrived at a key point in time, because the Triplicate Prescription Program administered by DOJ’s Bureau of Narcotic Enforcement has been unable to process the vastly increasing number of Schedule II controlled substance prescriptions dispensed in California. By the end of 1998, approximately 105,000 California practitioners were eligible to obtain triplicate prescription forms and prescribe Schedule II controlled substances. Also in 1998, those practitioners issued over 2.29 million Schedule II prescriptions. In that same year, however, the Triplicate Prescription Program was able to process only 39,945 such prescriptions into its existing outmoded automated system (down from 256,303 in 1995). During the first seven months in which CURES was operational, it was able to process a total of 892,985 triplicate prescription forms transmitted by pharmacies.

The progress report states that CURES has had a negligible impact on pharmacists. Computer technology and standardization is already an integral part of the pharmacy industry, making pharmacies comfortable with and receptive to the use of automation in performing their daily tasks. Approximately 95% of the 5,000 pharmacies in California are computerized. CURES has had no impact on prescribers, as they continue to write Schedule II prescriptions as they always have.

A second objective of CURES is to provide flexible data analysis to prevent drug diversion according to the specialized information requirements of each governmental user. Through a private contractor, CURES provides the flexibility of using standardized output reports or the option of customizing data output according to the needs of each agency.

The progress report also made several recommendations, including the following: (1) eventually, legislation establishing CURES as a permanent operational program should be pursued; (2) existing Triplicate Prescription Program staff should be reclassified to other positions more suitable to the investigative and analytical duties they will perform for CURES; (3) the program should continue to capture only information on Schedule II controlled substances, but it should begin to evaluate the feasibility of collecting Schedules III-V controlled substances prescription data as well; and (4) the CURES database should eventually be expanded to include information received by the Board pursuant to section 1782, Title 16 of the CCR, regarding excessive sales of drugs that are subject to abuse. The Board has already submitted proposed legislation which will continue to fund CURES and extend it until 2003 (see LEGISLATION).
**Board Proposes Regulations Governing Specialized Refill Pharmacies**

Recently, many new pharmacy operations and concepts have begun to emerge. One such concept is a refill pharmacy, which prepares refill prescriptions for another pharmacy. While the Board has licensed such pharmacies in the past, it has determined that labeling and documentation requirements should be established to assure that patients can readily determine where the prescription was filled. Specifically, pharmacies that receive an original prescription for filling sometimes use another pharmacy for refills. The Board believes that this use of a refill pharmacy may result in confusion to patients who receive medications and who do not know which pharmacy actually provided the medication or whom to contact. This would be especially critical if the medication is dispensed in error or in a form not readily identifiable to the patient. Further, the Board believes that the labeling and recordkeeping practices by both pharmacies should be consistent, to assure that patient safety and confidentiality are maintained.

On February 26, the Board published notice of its intent to adopt section 1707.4, Title 16 of the CCR, to address its concerns about the use of refill pharmacies. The purpose of the Board’s proposal is to (1) allow a pharmacy to utilize the services of another pharmacy to provide refills if it has a contract for these services or has common ownership, (2) specify the labeling requirements for a prescription refilled at a refill pharmacy, including the name of the refill pharmacy and which pharmacy the patient should contact if the patient has questions (this information may be either on the label or in writing accompanying the medication); (3) specify the documentation requirements for the originating pharmacy and the refill pharmacy; and (4) allow a pharmacy to operate as a refill pharmacy as well as fill new prescriptions.

At this writing, the Board is scheduled to hold a public hearing on its proposal to adopt section 1707.4 on May 19.

**Medical Device Retailer Location Restrictions**

One way in which the Board protects consumers is by reviewing the records of medical device retailers. Business and Professions Code section 4132(f) requires medical device retailers to make their records of sale, purchase, and disposition of dangerous devices available, at all times during business hours, to inspection by authorized law enforcement officers. When persons conduct a medical device retail business from their home or the home of someone else, Pharmacy Board inspectors and authorized law enforcement officers have encountered problems gaining access to records because of residential privacy issues.

On March 19, the Board published notice of its intent to adopt section 1748.3, Title 16 of the CCR, to eliminate the possibility that an applicant for a medical device retailer permit would use his/her personal residence or the residence of someone else as a licensed premise. Section 1748.3 would explicitly prohibit a medical device retailer from conducting business from a private residence. In addition, section 1748.3 would prohibit a medical device retailer from locating a warehouse, the primary purpose of which is storage of medical devices, at a private residence.

At this writing, the Board does not intend to hold a public hearing on its proposed adoption of section 1748.3. However, it is accepting written comments until May 3.

**Furnishing of Drugs and Devices by Wholesalers and Manufacturers**

Drug diversion is the illicit distribution, prescribing, dispensing, or use of controlled substances that are manufactured and intended for legitimate purposes. One of the ways in which the Board guards against drug diversion is by reviewing the records of drug wholesalers and manufacturers for compliance with the Pharmacy Law. The records of sale, purchase, and disposition of dangerous drugs and devices are required to be made available, at all times during business hours, for inspection by authorized law enforcement officers. All persons who are involved in drug transactions must be licensees (or their designated agents) of the Board or another governmental agency. When unauthorized persons are involved in drug transactions, the public health, safety, and welfare are put at risk.

The potential for drug diversion arises when drugs are received from manufacturers or wholesalers by non-licensed persons. According to the Board, these non-licensed individuals frequently divert the drugs for illegal use or sale. These drugs may not be maintained according to manufacturers’ specifications, which can result in harm to patients. Further, payment for these drugs may involve non-licensed parties whose interest in the transaction is fraudulent. According to the Board, these individuals use Board-licensed owners of closed-door pharmacies which they set up to operate “straw man” businesses. The drugs purchased at the wholesale discount allowed for this type of pharmacy are then sold on the black market.

On March 19, the Board published notice of its intent to adopt section 1783, Title 16 of the CCR, to eliminate any confusion on the part of drug wholesalers and manufacturers regarding with whom they may make arrangements for the purchase and delivery of drugs, and to ensure that these drugs are maintained at all times by licensees or their designated agents. Section 1783 would define the term “authorized person” to clarify for law enforcement purposes to whom wholesalers may furnish drugs and from whom they may accept payment for drugs. “Authorized person” means a person to whom the Board has issued a permit to purchase dangerous
At its March meeting, the Board approved a report and recommendation of its Licensing Committee that the Board will consider it, along with the Licensing Committee's recommendation that the Board sign it.

Board Reduces Licensing Fees

At its January 20 meeting, the Board adopted section 1749 and amended section 1749.1, Title 16 of the CCR, to reduce most of its licensing fees effective July 1. This action will enable the Board to reduce its reserve fund to approximately one year's expenditures, as required by law. [16:1 CRLR 73]

The Board, however, withdrew its proposed amendment to section 1793.5, which would have reduced initial pharmacy technician registration fees from $50 to $25. The Board based this action on a fee audit report presented at the meeting by Market Value Planners, which was commissioned by the Board to analyze the Board's licensing fee structure to determine whether fees are appropriate for the recovery of the actual cost of conducting its various programs. The report documented that the $50 fee charged for pharmacy technician registration is well below the Board's $143 cost of processing the application; thus, a reduction would be inappropriate.

The Office of Administrative Law approved the Board's amendments on April 20.

Restocking of Ambulances with Supplies and Medications

At its October 1998 meeting, the Board agreed to convene a multi-agency task force to explore legal issues related to the restocking of ambulance supplies (including drugs) by hospitals. An advisory opinion from the Health Care Financing Administration's Office of the Inspector General, which concluded that a hospital's restocking of ambulance supplies likely violates federal anti-kickback law and raises antitrust, tax, pharmacy, contract, and False Claims Act issues, prompted hospitals to discontinue restocking ambulances with supplies and drugs. In turn, some ambulances began to purchase, store, and restock medications and supplies; for controlled narcotics, they were using the license and DEA certificate of their contracted medical director. Because the Board does not believe the Pharmacy Law permits this practice, it decided to convene the task force with representatives from the Department of Health Services (DHS) and the Emergency Medical Services Authority (EMSA). [16:1 CRLR 71]

At its March meeting, the Board approved a report and recommendation of its Licensing Committee that the Board sponsor legislation to authorize the restocking of ambulances by hospital pharmacies and by other providers if certain requirements are met. For example, the purchase of drugs and devices would be under the authority of the local emergency medical services director, and the licensed emergency medical technician and/or paramedic would be responsible for the maintenance and recordkeeping of the dangerous drug and device stock.

At this writing, the Board is still working with DHS and EMSA to draft appropriate language for the legislation.

Implementation of the FDA Modernization Act of 1997

The FDA Modernization Act of 1997, which became effective in November 1998, 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 the related issue of state investigations 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 did not sign an MOU by the law's effective date (November 21, 1998) are 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. [16:1 CRLR 71–72]

At its March meeting, the Licensing Committee advised the Board that NABP circulated a draft MOU for comment in January. Once FDA adopts the final version of the MOU, the Board will consider it, along with the Licensing Committee's recommendation that the Board sign it.

LEGISLATION

SB 1308 (Committee on Business and Professions), as amended April 14, would enact various technical changes affecting licensing boards within DCA. Several of the bill's
provisions would amend the Pharmacy Act in the Business and Professions Code, including the following:

- **SB 1308** would amend section 4008 to require the salary of the Board's inspectors who are pharmacists to be within 5% parity of pharmacists employed by the University of California.

- The bill would amend section 4022 to revise the definition of "dangerous drug or device" to include drugs or devices bearing the statement "Rx only." This change would conform California's definition of "dangerous drug or device" to the federal definition.

- **SB 1308** would add section 4040.5 to the Code to define "reverse distributor" as a person who acts as an agent for pharmacies, drug wholesalers, manufacturers, and other entities by receiving, inventorying, and managing the disposition of outdated or nonsalable controlled substances. The bill would amend section 4043 to expand the definition of "wholesaler" to include a "customs broker" and "reverse distributor," thus requiring customs brokers and reverse distributors to be licensed as drug wholesalers.

- The bill would amend section 4057 to permit the Board to control through regulations (rather than statute) items that may be stored outside a pharmacy's licensed premises.

- **SB 1308** would amend section 4078 to permit a pharmacist to place a false label on a prescription if the labeling is a necessary part of a clinical or investigational drug program approved by the FDA or a legitimate investigational drug project involving a drug previously approved by the FDA. The bill would also permit false labeling in situations where, in the medical judgment of the prescriber, the labeling is necessary for the proper treatment of the patient.

- The bill would amend section 4204 to allow a pharmacist to perform skin-puncture in the performance of routine drug therapy-related patient assessment procedures. Existing law limits a pharmacist's performance of skin puncture to skin puncture for the purposes of training and assisting patients or to monitor medical conditions (including diabetes). SB 1308 would remove these limitations.

- **SB 1308** would also amend section 4202 to require an applicant for registration as a pharmacy technician to be a high school graduate or to possess a general education development equivalent.

- Section 4402 would be amended to provide for the cancellation of licenses which are not renewed within 60 days by the Board, rather than by operation of law.

- Finally, **SB 1308** would amend section 11165 of the Health and Safety Code to expand the purposes of the CURES program to include statistical analysis, education, and research, and extend the program until July 1, 2003 (see MAJOR PROJECTS). The bill would require the Board to submit to the legislature annual reports on the effectiveness of the CURES program on January 1, 2000, 2001, and 2002. [S. Appr]

**AB 141 (Knox),** as introduced on January 11, would require the Board to conduct a study of the incidence of medication errors in pharmacies in California, employing a methodology that uses "test" prescriptions distributed to a statistically significant cross-section of pharmacies in the state. The bill would define a "test" prescription as one that is prepared solely for the purposes of this study and not for the actual medical needs of a patient, and would require all "test" prescription drugs, after examination for purposes of the study, to be forwarded to the Board to remain in its custody until destroyed. The bill would require the Board, in designing the study, to confer with the scientific and academic community to ensure that the study is based on sound scientific and analytic principles. The study is designed to measure the frequency and describe the type of medication errors occurring in California, to improve patient safety, and to identify broader issues that may become the basis for instituting profession-wide standards and changes (see RECENT MEETINGS). AB 141 would also require the Board to issue a report of its findings from the study to the legislature by December 1, 2002.

Last year, Governor Wilson vetoed **AB 1889 (Knox),** a similar bill. In his veto message, the Governor stated that the bill's reference to "placebo" prescriptions was inappropriate, and that any such study should use the term "fictitious" rather than "placebo" to describe prescriptions. AB 141 addresses that concern by using the term "test." Governor Wilson also suggested that a study of this problem could be done by national organizations rather than the Board. [16:1 CRLR 75]

At its March 24 meeting, the Board voted (with pharmacist member Darlene Fujimoto abstaining) to support AB 141 in concept, but to withhold its full support pending appropriate amendments allocating funding for the study and ensuring the confidentiality of those who participate in the study. [A. Appr]

**AB 261 (Lempert),** as introduced on February 3, would permit physicians and pharmacists to enter into protocols under which pharmacists could adjust patients' drug therapy. Under existing law, pharmacists may adjust patients' drug therapy only in specified practice settings and for home health care and patients covered by managed care plans. Under AB 261, protocols for drug therapy would be developed by health professionals, including physicians, pharmacists, and registered nurses. At minimum, the protocol must require that the medical records of the patient be available to both the patient's prescriber and the pharmacist, and that the procedures to be performed by the
pharmacist relate to a condition for which the patient has first seen a physician. AB 261 would permit a pharmacist to order or perform routine drug therapy-related patient assessment procedures (including temperature, pulse, and respiration), order drug therapy-related laboratory tests, administer drugs and biologicals by injection pursuant to a prescriber’s order, and adjust the drug regimen of a patient pursuant to a specific written order or authorization made by the patient’s prescriber for the individual patient and in accordance with the protocol. AB 261 also would allow a patient’s prescriber to prohibit, by written instruction, any adjustment or change in the patient’s drug regimen by the pharmacist. Finally, the bill would require the pharmacist to provide to the supervising physician in writing any change, adjustment, or modification of an approved preexisting treatment or drug therapy within 24 hours.

AB 261 is sponsored by the California Pharmacists Association (CPhA) and is opposed by the California Medical Association. At its March 24 meeting, the Board voted unanimously to support AB 261. [A. Health]

AB 1496 (Olberg), as amended on April 14, would add section 4052.5 to the Business and Professions Code to establish a new “home medical equipment services provider” (HMESP) licensure category under the Board to replace the “medical device retailer” category, and expand the definition of those who must be licensed as home medical equipment services providers. Specifically, AB 1496 would replace references to “medical device retailer” with the term “HMESP” to create a new category of licensure, and define an HMESP as an individual, entity, or corporation engaged in the business of providing home medical equipment services to unrelated sick or disabled individuals where those individuals reside. AB 1496 would define “home medical equipment” as technologically sophisticated medical devices usable in a home care setting, including but not limited to oxygen and oxygen delivery systems, ventilators, continuous positive airway pressure devices, respiratory disease management services, hospital beds and commodes, electronic and computer-driven wheelchairs and seating systems, apnea monitors, dangerous devices, distribution of medical gases to end users for human consumption, and any other similar equipment as defined by regulations adopted by the Board.

AB 1496 would require HMESP licensees to have emergency services available 24 hours per day, 365 days per year, for equipment maintenance if equipment malfunction would threaten a patient’s health. The bill would exempt HMESP licensees that dispense or provide hospital beds or wheelchairs pursuant to a prescription from paying licensing fees as bedding or furniture dealers. Additionally, the bill would exempt from HMESP licensure specified entities and practitioners who already have various licenses, unless the entities or practitioners furnish home medical equipment services through a separate entity. These exemptions include certain home health agencies, hospitals, pharmacies, hospice programs, nursing homes, veterinarians, dentists, and emergency medical services.

The bill’s sponsor, the California Association of Medical Products Suppliers (CAMPS), asserts that consolidating home medical equipment providers’ licensure requirements “under one roof” will increase efficiency and reduce costs. CAMPS further argues that a consolidated form of licensure will improve public safety as there has been significant growth in home health care and increased sophistication in the types of care, equipment, and supplies used in the home. According to CAMPS, current law provides inadequate protection of consumers because it fails to specify what type of equipment or supplies must be regulated but merely refers to the presence of a warning label. Specifically, existing law defines “dangerous device” as any device unsafe for self-use, including any device that bears the statement “Caution: Federal law restricts this device to sale by or on the order of a [blank],” with the blank to be filled in with the designation of the practitioner licensed to use or order use of the device. Finally, CAMPS argues that the expanded licensure scope will curtail Medicare and Medi-Cal fraud in the provision of home medical equipment services.

At its March 24 meeting, the Board took an “oppose unless amended” position on AB 1496. According to the Board, in the eight years it has licensed medical device retailers, it has not received complaints from patients regarding the services and equipment provided by medical device retailers. Instead, its sole enforcement activity has been to investigate complaints of unlicensed activity filed by licensed medical device retailers. The Board contends that if the intent behind AB 1496 is to combat fraud against the Medi-Cal program, the bill should be amended to move the licensing and regulation of the “home medical equipment services providers” listed in the bill to DHS, which is responsible for the Medi-Cal program. [A. Appr]

AB 660 (Cardenas). Existing law generally prohibits a person from dispensing a prescription unless he/she is a pharmacist, in which case a prescription must be given to the pharmacist. However, a pharmacist may refill a prescription without the prescriber’s authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist’s professional judgment, failure to refill the prescription may interrupt the patient’s ongoing care and have a significant adverse effect on the patient’s well-being.

As amended April 28, AB 660 would specify that, during the period commencing November 1, 1999 and ending February 29, 2000, (1) a prescriber is deemed unavailable to authorize a refill if confronted with problems caused by computer failures arising from the inability of computers to properly handle dates; and (2) a pharmacist may refill a prescription, based upon a request made by the patient who is taking the medication, for up to and including 90 days from the date of the request. The purpose of the bill is to ensure that possible delays in the refills of patient prescriptions will not further complicate potential impacts on public safety caused by the Y2K problem. [A. Floor]
AB 724 (Dutra), as amended April 27, would provide that, notwithstanding any other provision of law, during the period commencing December 1, 1999, and ending February 1, 2000, a pharmacist shall refill any refillable prescription with medication sufficient for a period up to and including 60 days, subject to the number and terms of authorized refills, upon request of the person on whose behalf the prescription was written. The bill would authorize a pharmacist, during that same period, to refill any refillable prescription with medication sufficient for a period up to and including 60 days, subject to the number and terms of authorized refills, if the pharmacist determines that it is necessary to fill the prescription for the extended period to prevent possible harm to the person on whose behalf the prescription was written that might result from a Y2K problem complication or failure, or the potential for those events. [A. Apppr]

SB 404 (Alpert), as amended March 18, would authorize a pharmacist to initiate emergency contraception drug therapy in accordance with written guidelines or protocols previously established and approved for his/her practice by a practitioner authorized to prescribe drugs. [S. B&P]

AB 1430 (Bates), as amended April 23, would make a number of changes relating to the prescription and receipt of drugs by Board licensees. Under existing law, dangerous drugs or devices ordered by an entity licensed by the Board must be delivered to the licensed premises and signed for and received by the pharmacist-in-charge or other designated person. A dangerous drug or device transferred, sold, or delivered to any person in the state may only be transferred, sold, or delivered to an entity licensed by the Board, to a manufacturer, or to an ultimate user or the ultimate user’s agent. AB 1430 would provide that, when dangerous drugs or dangerous devices are ordered for an entity licensed by the Board and delivered to the licensed premises, those drugs or devices must be signed for and received by a pharmacist licensed by the Board. The bill would make a similar, related change with respect to the delivery of dangerous drugs or devices to a hospital pharmacy. The bill would also permit a dangerous drug or device to be transferred, sold, or delivered to any entity authorized by law to possess or handle dangerous devices.

Existing law requires that oral and electronic data transmission of prescriptions be reduced to writing. AB 1430 would eliminate that requirement, so long as a hard copy can be produced upon request. The bill would also authorize prescribers and pharmacists to enter prescriptions and orders directly into a pharmacy’s or hospital’s computer from any location, with permission of the pharmacy or hospital. The bill would similarly permit a prescriber to authorize his/her agent to enter a prescription on his/her behalf directly into a dispenser’s computer, with permission of the furnisher. Existing law requires, within 24 hours after any purchaser in this state gives any order for a Schedule II controlled substance to an out-of-state wholesaler or manufacturer for delivery in this state, that the purchaser forward to the Attorney General, by registered mail, a copy of the order. AB 1430 would end that requirement.

This bill is sponsored by Kaiser Permanente and is supported by CPhA. According to Kaiser, this bill would expedite access to prescription medications while decreasing errors and lowering the cost of medical care by allowing physicians and their authorized agents and pharmacists to transmit prescriptions and hospital medication orders directly to a hospital or pharmacy computer from wherever they are. According to Kaiser, it will also allow electronic storage of such orders and prescriptions instead of error-prone and costly paper storage. Kaiser also states that the bill will enable physicians, and other groups of practitioners, to order, receive, and use prescription medication supplies as a group, instead of requiring each individual to pay for and use his/her own supply. Kaiser further argues that this bill will keep pharmacists from being interrupted from patient-care duties just to sign a delivery sheet when another person licensed by the Board could sign for the delivery. Finally, Kaiser states that this bill would repeal an unused and unnecessary requirement for reporting out-of-state controlled substance purchase and shipment transactions to the Attorney General. According to Kaiser, this provision was never enforced, and if it were enforced it would provide no benefit and add substantial cost to the health care system. [A. Apppr]

SB 838 (Figueroa), as amended April 28, would allow the Board to register a nonresident pharmacy that is organized as a limited liability company (LLC) in the state in which it is licensed.

Merck-Medco Managed Care is sponsoring this bill to clarify that the Board may continue its long-standing practice of registering nonresident pharmacies that are organized as LLCs in their home states. An LLC—a hybrid between a partnership and a corporation—is a relatively new form of business organization in California. The Board registered out-of-state LLC pharmacies at least through 1997. At that time, DCA analyzed some uncodified language in the LLC law which prohibits the organization of an LLC for the rendering of professional services. Based on DCA advice, the Board began to reject licensure applications from out-of-state LLC pharmacies. [16:1 CRLR 70-71] The sponsor and its supporters maintain that this bill will clarify ambiguity created by issuance of various legal opinions on the topic, and that certainty in the law is necessary in order to continue to provide low-cost mail order medications. [S. B&P]

SB 188 (Leslie). Existing law generally prohibits any person from selling or dispensing any dangerous drug, or dispensing any prescription, unless he/she is a licensed pharmacist. However, a licensed hospital that contains 100 beds or fewer and does not employ a full-time pharmacist may purchase drugs at wholesale for administration, under the direction of a physician, to patients registered in the...
At the Board’s March meeting, Richard Abood, R.Ph., J.D., Professor of Pharmacy Practice at the University of the Pacific School of Pharmacy, gave a presentation to the Board on the important issue of prescription errors. Dr. Abood reported the results of a recent pharmacist error survey in which 53% of the pharmacists surveyed admitted to committing a drug error within the prior 60 days. According to the survey, wrong drugs and wrong dosages accounted for over 80% of the pharmacists’ errors. Over 85% of chain pharmacists and 66% of independent pharmacists cited workload issues, and 53% of the respondents cited look-alike or sound-alike drug names, as the reason for their errors.

Dr. Abood’s presentation focused on the legal ramifications of prescription errors. He noted that the current trend has been for courts to hold pharmacists to an increasingly higher standard of care regarding pharmacist judgment, and to hold corporations liable under a theory of corporate negligence for the acts of pharmacists employed by them. Dr. Abood spoke briefly about ways to manage the risk of liability to pharmacists and harm to patients. He noted that pharmacists are often discouraged from reporting their errors immediately by the overzealous disciplinary actions taken by state boards of pharmacy and employers. He stressed the need for developing quality assurance plans that provide incentives to pharmacists to report their errors and address the problems of workload which lead to prescription errors.

As noted above, a majority of the Board voted to support AB 141 (Knox), which would require the Board to conduct a study of the incidence of medication errors in pharmacies in California. The Board hopes to identify what types of medication errors are occurring and to develop regulatory standards and changes targeted at such errors to improve patient safety. Further, the Board devoted the April 1999 issue of its Script licensee newsletter to the issue of medication error reporting. Finally, the Legislation and Regulation Committee is currently developing, at the direction of the Board, regulatory changes which would require pharmacies to implement a quality assurance program to address and prevent the recurrence of prescription errors.

FUTURE MEETINGS

- October 20–21, 1999 in Sacramento.