



**BE AWARE & TAKE CARE:**  
Talk to your pharmacist!

# The Script

CALIFORNIA BOARD OF PHARMACY JANUARY 2002

## Quality Assurance Regulation Approved

In October 2000, Governor Davis signed legislation requiring all pharmacies to develop quality assurance programs to study and evaluate prescription errors to prevent recurrence of such errors. In 2001, the Board developed a regulation with provisions to implement the new legislation and establish parameters for the quality assurance programs. This regulation has been approved and became effective January 1, 2002. The final text of this regulation (Section 1711 of the California Code of Regulations) can be found under Law Update on page 32.

The Board's goal for quality assurance programs is to reduce the

frequency of medication errors through the systematic study of those errors. Such study will provide pharmacists with the knowledge to improve pharmacy processes and enhance existing procedures to reduce the incidence of medication errors.

The Board is a staunch advocate of quality assurance programs because its concern with the growing body of evidence documenting the threat of medication errors to patient health. Medication errors are the most frequent consumer complaint received by the Board, and the Board believes that systems and process analysis is the most effective means to reduce the frequency and severity of medication errors.

## Summary of Quality Assurance Program Requirements

- Every pharmacy must develop a quality assurance program to study medication errors and take steps to prevent recurrence of the error.
- A "medication error" is defined as any variation from a prescription or drug order not corrected prior to furnishing the drug to the patient (generic and dosage form substitutions are not errors).
- The quality assurance program must be documented in written policies and procedures and readily retrievable in the pharmacy.
- The pharmacist must notify the patient and the prescriber that a medication error has occurred and the steps required to avoid injury or mitigate the error.

See *Quality Assurance*, Page 36

## California budget woes severely impact Board of Pharmacy service

Many of you may have heard that California is facing its steepest revenue decline since World War II and a \$12.4 billion deficit this year and next. To deal with the fiscal crisis, Governor Davis ordered a 20% cut for all general funded agencies (these are state agencies that receive their funding from state income and general taxes) and a state hiring freeze.

The Board of Pharmacy is a special funded agency whose revenue comes from the application and renewal fees paid by its licensees. Fortunately, because the Board is special funded, it is exempt from the 20% cut to its operating budget; however, it is still subject to the statewide hiring freeze.

Currently, the Board has seven vacancies, which is one-third of its office staff in Sacramento. These staff are responsible for the many administrative activities such as: processing applications, issuing permits, cashiering, answering the

See *Budget Woes*, Page 35

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## President's Message

By Steve Litsey, Pharm.D., FCSHP  
President, Board of Pharmacy

This message of *"The Script"* will focus on the results of the 2001 legislative session, which ended in September.

Five Board of Pharmacy-sponsored legislative bills passed this year, representing a sizeable and extraordinary level of legislation activity. The Board wishes to recognize the efforts of the Board of Pharmacy staff, the support of the pharmacy professional associations, trade associations, and public interest groups.

The following Board-sponsored bills were signed by the Governor and became law on January 1, 2002:

- AB 809 (Salinas)—Permits nonprofit and government clinics to use automated dispensing devices controlled by a pharmacist.
- AB 826 (Cohn)—Permits pharmacists to provide consulting services in unlicensed care settings and permits pharmacists to initiate prescriptions under protocol in outpatient settings.
- SB 293 (Torklakson)—Requires pharmacies engaging in injectable sterile compounding to obtain an additional license from the Board, and also requires that such sterile compounding be performed in a manner consistent with guidelines adopted by the Board. This bill exempts pharmacies licensed either by the Board or by the Department of Health Services and accredited by

the Joint Commission on the Accreditation of Health Care Organizations from the new compounding licensing requirement in this bill.

- SB 340 (Speier)—Permits nonprofit clinics to contract with pharmacies to distribute drugs purchased in the 340B drug discount program. This bill also permits pharmacists, under limited circumstances, to make dosage form changes without consulting the prescriber.

Related to this bill, the Board would like to recognize Thomas S. Nelson, RPh., past president of the Board of Pharmacy for his vision and persistence in pursuing passage of a law permitting pharmacists to make dosage form

changes. Our gratitude also to the California Pharmacists Association and public groups for their support of this bill.

- SB 724 (Business & Professions Committee)—Omnibus Bill—Makes various technical changes to pharmacy law such as: allowing a pharmacy at a patient's request to repackage a drug previously dispensed to a patient and revising the licensure requirements for becoming an exemptee of a wholesale facility. This bill also makes the record of a cash compromise for a violation related to the Medi-Cal program conclusive evidence of unprofessional conduct.

Other legislation containing important changes to pharmacy law is highlighted elsewhere in this issue—"Changes in Pharmacy Law for 2002" on page 3.

See *President's Message, Back Cover*

## Pharmacy Manpower Task Force Report Completed

The Pharmacy Manpower Task Force presented its final report on the pharmacist shortage in California at the January 2002 Board meeting. The task force was established by the Board and charged with proposing solutions to address the pharmacist shortage in California so that patients have continued access to pharmacist's care and prescription services. This report, reflecting the task force's serious approach to their charge and collective consensus, required five public meetings held over a 10-month period and much thoughtful and comprehensive deliberation. The complete report is available on the Board's website: [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov).

The Board will consider the report's recommendations during its 2003 strategic planning session on April 26, 2002, in Sacramento at 400 R Street, 1st Floor Hearing Room. The Board will decide whether to incorporate some or all of the proposed solutions as objectives in the 2003 strategic plan.

This meeting is open to the public and public participation is always welcomed and encouraged. Additionally, those wishing to submit comments on the report for the strategic planning session must submit them by letter or fax (916) 327-6308 to the Board by April 1, 2002.

[www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)

## Changes in Pharmacy Law for 2002

Unless otherwise specified all the following bills take effect on January 1, 2002. The exact language of the new and amended statutes noted below can be found in “Law Update,” beginning on page 16.

**AB 207 (Matthews)  
Chapter 622, Statutes  
of 2001**

### Standard Drug Benefit Card

**H&SC 1363.03** and Insurance Code **10123.194**—requires health plans to include standard drug benefit information on identification cards issued to consumers. The information required includes the:

- Name or logo of the benefit administrator or health care service plan issuing the card,
- Consumer’s identification number, and
- Telephone number that pharmacy providers may call for assistance.

**AB 536 (Bates)  
Chapter 352, Statutes  
of 2001**

### Pharmacy Technician Ratio

**B&PC 4115**—changes the ratio of pharmacy technicians to pharmacists in community pharmacy settings. The new ratios are as follows:

- The first pharmacist on duty may supervise one pharmacy technician.
- Each additional pharmacist on duty may supervise two pharmacy technicians.

For example, a pharmacy with two pharmacists on duty may have three pharmacy technicians. A pharmacy with three pharmacists on duty may have five pharmacy technicians. The bill also specifies that pharmacists may, with certain restrictions, refuse to supervise more than one pharmacy technician.

**AB 559 (Wiggins)  
Chapter 458, Statutes  
of 2001**

### Epinephrine Auto-Injectors

**B&PC 4119.2**—permits pharmacies to furnish epinephrine auto-injectors to school districts and county offices of education if:

- The epinephrine auto-injectors are furnished exclusively for use at a school district site or county office of education; and
- A physician and surgeon provides a written order that specifies the quantity of epinephrine auto-injectors to be furnished.

**AB 586 (Nation)  
Chapter 501, Statutes  
of 2001**

### Clinical Laboratory Testing

**B&PC 1206.5, 4052.1** and **4102** repealed—clarifies existing law relating to pharmacists performing clinical laboratory tests.

**AB 809 (Salinas)  
Chapter 310, Statutes  
of 2001**

### Automated Dispensing Devices

**B&PC 4186**—allows nonprofit and certain government clinics that are licensed by the Board to dispense drugs to their patients to employ an automated dispensing device operated remotely by a pharmacist.

**AB 826 (Cohn)  
Chapter 262, Statutes  
of 2001**

### Pharmacists’ Care Enhanced

**B&PC 4050, 4051, 4052**—allows pharmacists to perform clinical functions outside of a pharmacy or other licensed health facility. Please see page 1 of the October 2001 issue of *The Script* for more detail.

**SB 293 (Torlakson)  
Chapter 827, Statutes  
of 2001**

### Sterile Compounding

**B&PC 4127, 4127.1, 4127.2, 4127.3, 4127.4, 4127.5** and **4127.6**—requires that pharmacies who compound injectable sterile drug products obtain a separate license from the Board of Pharmacy. That license will require annual inspection by the Board and that the pharmacy complies with guidelines on sterile compounding adopted by the Board. The bill also permits the Board to immediately close any sterile compounding operation if an investigation indicates an immediate threat to the public health or safety. The licensure requirement takes effect when the Board adopts regulations specifying guidelines for sterile injectable compounding.

## Changes in Pharmacy Law

*Continued from Page 3*

**SB 298 (Figueroa)**  
**Chapter , Statutes of**  
**2001**

### Nurse Midwives

**B&PC 2725.1, 2746.51, 4040, 4060, 4061, 4076, 4170, 4175,**and **H&SC 11026** and **11150**—permits certified nurse midwives to issue drug orders in a manner similar to that of nurse practitioners and physician assistants. These drug orders are treated as prescriptions are in every respect.

**SB 340 (Speier)**  
**Chapter 631, Statutes**  
**of 2001**

### Dosage Form and Contract Pharmacy

**B&PC 4052.5** and **4126**—permits pharmacists to change the form of a medication (e.g., pill to liquid) without obtaining the prescriber's authorization if the change will improve the patient's ability to comply with the prescribed drug therapy.

The bill also permits clinics, and other eligible entities, to contract with a pharmacy to have the pharmacy dispense drugs purchased in the 340B discount drug program to the clinic's patients.

**SB 633 (Sher)**  
**Chapter 656, Statutes**  
**of 2001**

### Mercury Fever Thermometers

**Public Resources Code 15025** and **15026**—requires that mercury fever thermometers may only be furnished pursuant to a prescription and requires all entities (including pharmacies) furnishing mercury fever thermometers to obtain a hypodermic needle and syringe permit from the Board of Pharmacy. This requirement takes effect July 1, 2002.

**SB 724 (Business**  
**and Professions**  
**Committee) Chapter**  
**728, Statutes of 2001,**  
**Omnibus Measure**

### Repackaging Drugs

**B&PC 4033** and **4052.7**—permits pharmacies to repackage previously dispensed medications upon consumer request.

### Exemptees

**B&PC 4053, 4160** and **4196**—changes the qualifications required to become an exemptee. Exemptees must now have:

- At least a high school education,
- One year's paid work experience related to the distribution of dangerous drugs and dangerous devices, and
- Completed a training course approved by the Board of Pharmacy.

In addition, exemptees will no longer be restricted to working at a particular site. Exemptees may move from facility to facility obtaining a change of permit from the Board.

Lastly, each wholesale facility (including veterinary food-animal drug retailers) must designate an exemptee-in-charge who is responsible for the operation of the facility in compliance with applicable state and federal law. An exemptee-in-charge functions in much the same manner as a pharmacist-in-charge does in a pharmacy.

### Temporary Pharmacy Licenses

**B&PC 4110**—permits the Board to issue a temporary pharmacy license at its discretion. Existing authority only permits the issuance of a temporary license for a transfer of ownership.

### Out-of-State Distributor: When License Required; Application

**B&PC 4161**—recasts the wording (requirements remain the same) to clarify this statute.

### Retired Licensee

**B&PC 4200.5**—expands circumstances under which the Board can issue a retired license.

### Unprofessional Conduct

**B&PC 4301**—establishes the cash compromise of any Medi-Cal violation as unprofessional conduct. ("Cash compromise" refers to any money paid as a consequence of a disciplinary action.)

### Fees

**B&PC 4400**—eliminates the pharmacy remodeling application fee, and the exemptee examination fee becomes the exemptee application fee, as the Board will no longer administer exemptee exams.

# Pharmacists as part of a Disaster Medical Assistance Team (DMAT)

In the event of major medical disasters, DMATs, which are comprised of medical and support personnel (pharmacists and pharmacy interns and technicians, doctors, nurses, PAs, NPs, paramedics, EMTs, respiratory technicians, lab technicians, etc.) are activated. DMATs are designed to be a rapid-response element to supplement local medical care when needed during a disaster or other unusual event.

The Emergency Medical Services Authority (EMSA), pursuant to sections 1797.150 and 151 of the California Health & Safety Code is responsible to:

- Prepare for and respond to any medical disaster by mobilizing and coordinating emergency medical services to mitigate health problem emergencies.
- Provide personnel and medical supplies and materials from unaffected regions of the state.
- Provide prompt delivery of disaster medical resources to local governments in support of their existing disaster medical response.
- Arrange for evacuation of injured disaster victims to hospitals in areas/ regions not impacted by a disaster.

To help meet these responsibilities, DMATs are utilized.

## What do DMATs do?

Standard DMATs provide medical care either in hospital or clinical settings (augmenting local resources that have been overtaxed) or in austere conditions such as field treatment sites established for a specific disaster response. Teams are also deployed as “standby resources” at special events such as political conventions, presidential inaugurations, Olympics, Special Olympics, etc. Specialty DMATs provide mortuary

assistance, veterinary assistance, burn treatment care, surgical assistance, and mental health care.

## Why pharmacists on DMATs?

A critical member of the DMAT, the pharmacist is responsible for the preparation or compounding of prescriptions of physicians and other licensed practitioners at the site of a disaster or major emergency. The pharmacist:

- Carries out clinical pharmacy functions of drug selection, compounding, and dispensing of a varied range of therapeutic agents.
- Develops special formulas, extemporaneous compounding and special preparations.
- Resolves problems in the area of biopharmaceutical effectiveness, including problems concerning solubility, stability, incompatibility, etc.
- Provides authoritative advice to the National Disaster Medical System (NDMS) disaster teams concerning contra-indications and side effects of drugs.
- Provides information based on experience in dealing with a medical staff regarding questions concerning concentration, number of dosages in a solution, etc. and suggests alternative medications to avoid incompatibilities, alleviate side effects, overcome potential drug combinations and prevent antagonistic reactions.
- Supervises performance of the pharmacy interns and technicians and carries out a full range of administrative duties in the performance of supervisory responsibilities.

## What are pharmacists' qualifications for a DMAT?

To be a member of a DMAT, pharmacists must be licensed to practice pharmacy in a state or territory of the United States, or the District of Columbia and have one year of professional experience related to the duties of a pharmacist.

## Are team members paid for their service?

Teams train and organize as volunteers, but when federally activated and deployed to a disaster or special event, they are paid as employees of the federal government.

## What would my commitment be if I joined a DMAT?

Each team has specific requirements, typically participation once a month at either a team meeting or a training event. When the team is deployed, members have the option of making themselves available.

## Where are California teams located?

California teams are located in San Diego, Los Angeles, Orange County, San Bernardino, San Francisco Bay Area, and the Sacramento Region.

## How to get more information or join a California DMAT

The California Emergency Medical Services Authority (EMSA) has extensive information and membership applications on its website: [www.emsa.ca.gov](http://www.emsa.ca.gov) or you may call (916) 322-4336.



## KEY FACTS ABOUT

# Emergency Contraception

## Emergency Contraception is a safe and effective way to prevent pregnancy after sex.

Consider using emergency contraception if:

- ▶ You didn't use a contraceptive during sex, or
- ▶ You think your contraceptive didn't work.

## What are Emergency Contraceptive Pills?

Emergency contraceptive pills contain the same medication as regular birth control pills and help to prevent pregnancy. There are three basic types of emergency contraceptive pills:

- ▶ Plan B™ progestin-only pills
- ▶ Preven™ estrogen/progestin pills
- ▶ High doses of regular oral contraceptive pills.

## Pills should be started within 72 hours (three days) after unprotected sex.

Emergency contraceptive pills require two doses:

- ▶ First dose within 72 hours of unprotected intercourse
- ▶ Second dose 12 hours after the first dose

Emergency contraceptive pills are more effective the sooner they are taken.

## Safe and effective.

- ▶ Progestin-only pills reduce the risk of pregnancy by 89%.\*
- ▶ Combined estrogen/progestin pills reduce the risk of pregnancy by 75%.\*
- ▶ For regular, long-term use, other contraceptive methods are more effective.
- ▶ Emergency contraceptive pills do not protect against sexually transmitted infections, including HIV/AIDS.

\* Pregnancy risk reduction based on one-time use.

## Won't cause an abortion.

- ▶ Emergency contraceptive pills are NOT the same as RU-486 (the abortion pill).
- ▶ Emergency contraceptive pills are not effective after implantation; they cannot interrupt an established pregnancy.

## Won't harm a developing fetus.

- ▶ If emergency contraceptive pills are mistakenly taken during pregnancy, they will not harm the developing fetus.
- ▶ Using emergency contraceptive pills will not affect a woman's ability to become pregnant in the future.

## Women can keep pills at home in case of emergency.

- ▶ Many women find it convenient to have emergency contraceptive pills on hand in case of an emergency.
- ▶ Medical providers or your pharmacist can provide emergency contraceptive pills before they are needed.

## Medical follow up after taking Emergency Contraceptive Pills.

- ▶ If you don't get a normal period within 3 weeks, you can use an at home pregnancy test to find out if you are pregnant. You may also visit your healthcare provider to check to see if you are pregnant.
- ▶ It is important to visit your doctor or clinic if you need a regular birth control method or services to prevent sexually transmitted infections or AIDS.

In California all income-eligible women and men may receive no-cost family planning services through the Family PACT program. If you don't have a doctor or clinic, call **1-800-942-1054** to find a Family PACT provider near you.

*Prepared by the Pharmacy Access Partnership in consultation with the American College of Obstetricians and Gynecologists District IX, the California Pharmacists Association and the California State Department of Health Services. Part of this material adapted from PATH. Reviewed by the California State Board of Pharmacy.*

# Emergency Contraception Implementation of SB 1169



On October 14, 2001 Governor Gray Davis signed SB 1169, which authorizes a pharmacist to initiate emergency contraception (EC) drug therapy in accordance with standardized protocols developed by the pharmacist and an authorized prescriber acting within his or her scope of practice. The law takes effect January 1, 2002. The following are responses to frequently asked questions regarding implementation of this law.

## **Do I have to participate in an emergency contraception program?**

No. Like all other direct-patient care activities (such as pharmacist-provided immunizations), providing EC under protocol is entirely optional for pharmacists. Pharmacists who choose not to initiate EC under protocol may still receive prescriptions from prescribers for EC drug therapy. Such prescriptions should be filled and counseled just like any other prescription with counseling conducted per OBRA requirements and state law.

## **If I choose to initiate EC under protocol, what is required?**

Prior to initiating EC, a pharmacist must have completed a training program on EC, delivered by an ACPE provider or another training program approved by the Board of Pharmacy.

A pharmacist must also develop a protocol in collaboration with an authorized prescriber acting within his or her scope of practice. The protocol must be signed by both the pharmacist and prescriber. A copy does not need to be submitted to the Board, but a copy should be kept by both the pharmacist and the prescriber.

Each patient receiving EC initiated by a pharmacist must be provided with a

standardized fact sheet. This fact sheet is to be developed by the Board, in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The standardized fact sheet shall include, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical follow-up and other appropriate information. Until the Board's fact sheet is developed, it is agreed that the fact sheet provided by the Pharmacy Access Partnership (see opposite page) is acceptable during the interim. This fact sheet can also be found on the Board's website: [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov).

Due to the sensitive nature of this service, patients must be counseled in the pharmacy areas designated for patient consultation. Also due to the sensitive nature of this service, all pharmacy staff, including clerks and technicians, should be provided information about the program and reminded of confidentiality requirements, which apply to not only this service, but all pharmacy services.

## **What must be included in the training program?**

Training programs will vary in duration and content depending on the provider. The law stipulates, however, that training programs must include, but is not limited to, conduct of sensitive communications, quality assurance, referral to additional services and documentation. A typical program may also include a review of the physiology of the menstrual cycle and pregnancy, pharmacology of the drug therapy, indications for use, safety and efficacy of EC products, and pharmacy readiness.

## **Where can I obtain EC training?**

The California Pharmacists Association Educational Foundation has been offering an 18-hour training to pharmacists since early 2001 and approximately 100 pharmacists have been trained to date. Shorter training programs (3-5 hours) are under development and will likely be offered in the first quarter of 2002 by the CPhA, the University of Southern California School of Pharmacy and the Southern California Society of Health-System Pharmacists. It is expected that other providers also have programs under development.

## **What must be included in the protocol signed by an authorized provider?**

The protocol should be developed collaboratively between the pharmacist and authorized provider. The protocol should address which drug therapy or therapies may be provided, and the procedure to follow when patients come to the pharmacy (e.g. obtaining the date of the patient's last menstrual period and the patient's date of birth, circumstances which require referral).

## **Is there a time limit for which the protocol is valid?**

While no "expiration date" has been applied to protocols, it is highly recommended that the pharmacist and prescriber review the protocol for currency and appropriateness at least annually.

## **What sort of documentation is required?**

If a prescription is dispensed, the prescription record must be kept for a minimum of three years, just as any other prescription record (Section 4333 of the Business & Professions Code).

The patient intake form and any notes made by the pharmacist, along with documentation that the standardized fact sheet has been provided, should be considered medical records. Pharmacists should keep these records in a filing system separate from their pharmacy records. Such records must be kept for a minimum of three years after the last date the patient has been seen. However, it is usually recommended that medical records be retained for a much longer period of time and, if possible, indefinitely. If keeping the records indefinitely is not possible, it is recommended that they be kept at least 10 years. Under no circumstances should records of treatment of minors be kept less than 3 years after the minor reaches the age of 18. If and when the records are destroyed, steps must be taken to protect the confidentiality of the information.

#### What else should I know about confidentiality?

As mentioned above, consideration to implementing EC services is a good time to be reminded of and remind staff of the confidential nature of all pharmacy transactions and the necessity to keep all patient information secure and private.

Pharmacists are also reminded that in California parental/guardian consent is not required for birth control, pregnancy testing or prenatal care (among other health care services beyond the scope of

this article) and, as such, parental/guardian notification is not allowed without the consent of the minor. Thus, pharmacists and their staff should be cognizant of the type of information they are sharing with parents and guardians of minors who obtain pharmacy services.

#### What if a woman comes in seeking EC and no one in the pharmacy is trained to provide it?

The patient should be referred to a pharmacy which has personnel that is trained to provide EC, a family planning clinic or the woman's regular primary care provider, with emphasis on getting the woman seen within 72 hours of unprotected intercourse and the earlier the better. The Pharmacy Access Partnership is maintaining a consumer-friendly toll free number to (800/323-1336) and website (<http://www.EC-help.com>) which include a listing of all pharmacies in California providing EC to the general community. In addition, the Pharmacy Access Partnership's website is a "professional resource" which pharmacists can access at [www.pharmacyaccess.org](http://www.pharmacyaccess.org).

The following are some additional general facts about EC drug therapy:

- EC pills contain the same medication as regular birth control pills and work in the same way to prevent pregnancy (primarily through the prevention of ovulation)

- EC drug therapy requires two doses. One within 72 hours of unprotected intercourse and the second 12 hours later

- EC drug therapy is NOT RU-486 (mifepristone) and will NOT cause an abortion

- EC drug therapy will NOT interrupt an established pregnancy or harm a developing fetus

Written by Elizabeth Johnson, Pharm.D., consultant to the California Pharmacists Association

## Beware of Look/Sound-Alike Drugs

To reduce the potential for medication errors related to drug names that sound or look alike, the United States Pharmacopeia publishes a list of such drugs in poster form. Copies of the poster are available from:

Gail Bormel

USP

12601 Twinbrook Parkway

Rockville, MD 20852

Or you may log on to [www.usp.org](http://www.usp.org).

## PUBLIC DISCLOSURE POLICY

### Inspections/Complaints/Investigations/Disciplinary Actions

In response to telephone inquiries, the California State Board of Pharmacy will provide an oral summary of the number of substantiated complaints against a licensee received within the last five years. A substantiated complaint is a complaint or investigation that has been mediated or investigated by the board and a violation of pharmacy law has been determined. Unsubstantiated complaints will not be disclosed.

Upon written request, the Board will provide a written summary of the dispositions of any substantiated complaint. The Board will provide the requesting party with the date the complaint was received, the name and title of the licensees

See *Public Disclosure*, Page 13

## Board is seeking

Presently, the Board is seeking to enlarge its base of practicing pharmacists on the Board's Competency Committee. The Competency Committee develops and scores the Board's pharmacist licensing examination and is comprised of representatives from a cross section of professional practice and each of California's schools of pharmacy.



## Drug Expiration Guidelines Inquiry

There are still inquiries regarding the drug expiration date to be entered on prescription container labels. One inquiry referred to the following statement published in the July 2001 issue of *The Script*:

*The expiration date placed on the prescription label should be that of the effectiveness of the drug (Business & Professions Code section 4076[a][9]). That date, in most circumstances, is the date printed on the manufacturer's container #.*

The writer goes on to say: "Five paragraphs later, this statement is made:"

*...Beyond-use dates for multiple-unit containers, such as a typical prescription vial, remain as follows: "not later than (a) the expiration date on the manufacturer's container or (b) one year from the date the drug is dispensed, whichever is earlier."*

The writer continues, "Since the great majority of medications have an expiration date in excess of one year, the beyond-use date applied by pharmacists on the prescription label would, in most instances, have to be one year from the date of dispensing. This is in direct conflict with the first statement.

What is the correct thing to do when applying an expiration date to the normal prescription vial of medication? Use 1) The expiration date on the manufacturer's container, or 2) One year from date of dispensing unless the manufacturer's date is earlier?"

The answer is that both the above options are correct. The "guidelines" published in both the July and October issues of *The Script* are that-guidelines. There is no hard, fast rule for use on every prescription. Some drugs, upon being opened, become subject to easy contamination and might require a shorter expiration date. Along with the guidelines, and most importantly, the pharmacist must use his or her professional judgement to assure that expired drugs are not dispensed.

The Board's primary concern is that pharmacies do not dispense expired drugs—drugs with expiration dates beyond that on the manufacturer's container.

### Dichloralphenazone (Midrin®) is now Schedule IV

*Please note that the Drug Enforcement Administration has designated dichloralphenazone, its salts, isomers, and salts of isomers as a Schedule IV controlled substance. The most widely known product impacted by this change is Midrin®, but this change also impacts any generic or other brand name drugs that contain dichloralphenazone. The final rule notice on this subject was issued on August 16, 2001.*

## Competency Committee membership applications

Practicing pharmacists who have been licensed within the last five years are especially encouraged to apply. Applications must include your curriculum vitae, a cover letter describing your area of pharmacy experience or practice, and three letters of reference from pharmacists who are familiar with your work. Please submit applications to:

Competency Committee  
Appointments

Board of Pharmacy

400 R Street, Suite 4070

Sacramento CA 95814

Those who are interested should be aware that membership in this committee is professionally challenging, as well as time-

consuming. The committee meets six times annually in two-day meetings. There is also a two-day annual goal-setting session and occasional (one to two days) subcommittee work. Attendance is a critical component of committee membership.

The Board president appoints members, and membership is for a maximum of eight years.

## Changes in the Board

*The Board wishes to welcome David (Dave) J. Fong, Pharm.D. and extend its best wishes and appreciation to departing professional member, Holly Strom, R.Ph.*

### New Member

Dave Fong, born and raised in California, graduated from the University of California, Berkeley, with a B.A. in economics. He then obtained his Doctor of Pharmacy from the University of California, San Francisco. Subsequently, Dr. Fong began his career with Longs as a staff pharmacist in 1975. In 1977, he was promoted to Assistant Director of Professional Affairs and moved to the corporate office. In 1983, Dr. Fong was named in-store computer project manager, and in 1988, was promoted to Vice President of Pharmacy. He has served as Longs' Senior Vice President of Pharmacy since 1995 and is a member of the Board of Directors for the operating company.

Dr. Fong is also a registered pharmacist in Colorado. He sits on the Pharmacy Manpower Task Force for California's Board of Pharmacy and is a former chairman of the Pharmacy Affairs Committee for the National Association of Chain Drug Stores (NACDS). He is also a member of pharmacy advisory committees for Amgen, Warner-Chilcott, Upjohn Company, Schering and Roche Laboratories. Dr. Fong is also active in the pharmacy education process, serving on the Board of Overseers for the University of California at San Francisco's School of Pharmacy and the Curriculum Committee for the University of the Pacific School of Pharmacy.

### Departing Member

The Board wishes to convey its gratitude to Holly Strom for her commitment and many contributions to Board policy. She was appointed to the Board in 1993 by Governor Pete Wilson and re-appointed in 1997 to a four-year term. During her tenure on the Board, Ms. Strom served as president, chair of the Pharmacy Manpower Task Force and of the Licensing Committee. She also has been a member of the Competency Committee and participated in the NAPLEX audit. Her dedication to strengthening pharmacists' care and enhancing patient outcomes will be remembered by all those who worked with her.

Ms. Strom notes, "I am so proud of the achievements attained by this board over the last eight years. I feel that our activities have contributed to the health of Californians and substantially improved the level of pharmacists' care provided to patients. I am honored to have been a part of the Board's many activities to guide pharmacy into the 21st century."

## Pharmacy Self-Assessment forms can be faxed to you

The Pharmacy Self-Assessment forms have been mailed to all pharmacies, but if your pharmacy did not receive one, you may have one faxed to you by calling the Board of Pharmacy's Fax on Demand service.

To obtain the self-assessment form for **community pharmacy and hospital pharmacy that dispenses prescriptions**: telephone the Board of Pharmacy at (916) 445-5014, option 9 (Fax on Demand), option 1 (forms), option 6.

To obtain the self-assessment form for **hospital inpatient pharmacy**: telephone (916) 445-5014, option 9 (Fax on Demand), option 1 (forms), option 7.

You will hear a recording telling you that there is one fax in that mailbox, and it will ask you to enter your fax number. If you are calling from outside the 916 area, remember to include a 1 and your area code before your fax number.

The forms can also be downloaded from the Board's website: [www.pharmacy.ca.gov/forms\\_pubs.htm](http://www.pharmacy.ca.gov/forms_pubs.htm).

**Important Note: Please do NOT mail the completed forms to the Board**-unless you are specifically asked to do so. The completed forms are to be retained at the pharmacy.

# Understanding Federal and State Laws Related to Pain Management Prescriptions for the Terminally Ill

Pain and symptom management are essential in allowing a terminally ill patient the comfort of being able to prepare for death without the debilitating and depressing effects of severe pain. In attempts to control their patients' suffering and ensure that terminally ill patients have the best quality of life for as long as possible, hospices, physicians, nurses, and pharmacists have asked questions and raised issues about the application and interpretation of those federal and California laws that involve pain medication prescriptions for Schedule II controlled substances (CII). The purpose of this article is to clarify these laws so that healthcare providers can effectively work together to manage pain for terminally ill patients.

To fully understand the pharmacist's and hospice's roles in pain management, it is perhaps necessary here to first define "hospice." The concept of hospice began in Europe during the Middle Ages. The word hospice originally meant a place of shelter where travelers, on their way to or from the Holy Land, could find rest.

In the 1800s, modern day hospice developed and came to be associated with care for the terminally ill. In 1971, America's first hospice opened, and in 1998, more than 45,000 terminally ill patients in California chose hospice as a specialized form of "interdisciplinary health care which is designed to alleviate the physical, emotional, social, and spiritual discomforts of an individual who is experiencing the last phases of a terminal disease and to provide supportive care for the primary care person and the family of the patient under hospice care." (California Health & Safety Code [H&SC] 11167.5).

The following information is offered to answer pharmacists' questions related to pain management for the terminally ill and the laws involved:

## **Q1. Why are community pharmacists becoming increasingly more involved in the care of hospice patients?**

**A1.** In order to provide quality pain management and palliative care for terminally ill patients, timely and sometimes rapid interventions are required. Drug therapy is an integral component of palliative care, and with the large majority of hospice patients being cared for in their homes, hospices and caregivers rely on the availability and ease-of-access of local community pharmacies for their patients' drug therapy needs.

## **Q2. Are all hospice patients terminally ill?**

**A2.** Yes, all patients receiving hospice care are terminally ill. Although an agency's name may include the word "hospice," it may be a dually licensed facility that provides home health care and hospice services. However, some home health care patients may not be terminally ill.

## **Q3. Are the California and federal definitions for "terminal illness" the same?**

**A3.** No. California law defines terminal illness as a "medical condition resulting in a prognosis of life of one year or less, if the disease follows its natural course" (H&SC 1746[I]). For purposes of the prescribing laws, the California definition of a terminal illness is a life expectancy of one year or less. Federal law requires that patients electing to receive the Medicare or Medi-Cal Hospice Benefit must be determined by two physicians to have a "medical prognosis that his or her life expectancy is six months or less, if the illness runs its normal course" (Title 42 Code of Federal Regulations Section 418.3).

## **Q4. What sections of the federal and California law must a pharmacist be familiar with when filling and dispensing CII prescriptions for hospice patients?**

**A4.** Pain is one of the most prevalent symptoms experienced by the terminally ill. The CII opiate analgesics (e.g. morphine, oxycodone, fentanyl,

hydromorphone, etc.) are considered to be the most effective drugs in managing moderate to severe pain in hospice patients. Pharmacists need to, therefore, be familiar with both the federal and state laws that deal with prescribing and dispensing controlled substances for hospice patients. Applicable sections of the federal and state provisions are outlined in the table on pages 14 & 15.

## **Q5. What are the differences between the federal and California laws regarding CII prescriptions for hospice patients and how are these differences reconciled when there are conflicts or inconsistencies between them?**

**A5.** In general, most of the differences between the federal and state laws are due to two major factors: 1) how a CII prescription is transmitted and; 2) how a routine and an emergency CII prescription are processed for a hospice patient.

When a federal law conflicts with a state law governing CII prescriptions, the more stringent of the two provisions takes precedence. This means that if federal law prohibits something and California law does not, it is prohibited. Similarly, if federal law permits something and California prohibits it, it is prohibited. In the same way, if federal does not require that something be done and California law requires that it be done, it must be done.

## **Q6. Are written triplicate CII prescriptions for hospice patients always required? If not, when and how can a written non-triplicate CII be used for a hospice patient?**

**A6.** No. A triplicate is not required for a CII prescription. H&SC section 11159.2 provides an exemption from the use of California triplicates for CII prescriptions that are issued for terminally ill patients and permits the use of ordinary written prescription blanks. H&SC 11159.2 requires the prescriber to certify that the patient is terminally ill by writing or typing the words, "11159.2 exemption"

on the non-triplicate prescription form and requires that it be filled within 14 days from the date issued.

H&SC 11159.2 also requires that the original non-triplicate CII prescription must be in the pharmacist's possession before the drug can be dispensed and includes the following information in the prescriber's own handwriting (note this is more stringent than the new triplicate requirements in H&SC 11161) in order for the non-triplicate to be filled:

- the issue date,
- the prescriber's signature,
- the patient's name,
- the name of the drug, quantity to be dispensed and directions for use.

There is no requirement that the rest of the information needed for the prescription be in the prescriber's own handwriting, but the non-triplicate prescription cannot be filled if the "11159.2 exemption" notation is missing. The patient's address, the name of the prescriber, address, phone number, category of prescriber licensure, and federal controlled substance registration number are also required but may be completed by the prescriber or someone else.

If the notation is there but is technically incorrect (e.g. wrong section number listed, '11159.2', 'terminally ill' or 'non-triplicate' is written instead of the required certification), the prescription may be filled if: 1) the pharmacist has personal knowledge of the patient's terminal illness; and 2) returns the prescription to the prescriber for correction of the notation within 72 hours.

**Q7. Can a routine CII prescription be ordered verbally for a hospice patient?**

**A7.** No. The federal and state laws are in conflict with respect to verbally (or orally) transmitted CII prescriptions. California H&SC 11167.5 permits pharmacists to fill routine CII prescriptions that have been transmitted verbally for patients of a licensed home health agency providing hospice (and also allows for the filling of verbal CII prescriptions in an emergency [H&SC

11167]). The federal law however, permits pharmacists to fill verbally transmitted CII prescriptions only in an emergency (21 CFR Section 1306.11(d)). The stricter federal law for CII prescriptions therefore prevails; emergency CII prescriptions are the only prescriptions that can be ordered verbally, and must be transmitted by the prescriber (see Question 8).

**Q8. What are the circumstances for a hospice patient to require an emergency CII prescription, and how would it be ordered and filled?**

**A8.** Terminally ill patients can often suffer rapidly escalating pain with acutely painful episodes superimposed on already present chronic pain. Such circumstances are defined to be emergencies "where failure to issue a prescription may result in loss of life or intense suffering" (H&SC 11167-definition of an emergency). These emergency circumstances may occur however, when it is not reasonably possible for the prescriber to provide the original written CII triplicate prescription to the pharmacy prior to dispensing without causing further undue suffering. H&SC 11167 though, also provides that in an emergency "an order for a CII substance may be dispensed on an oral, written, or electronic transmission order."

Terminally ill patients are often admitted to hospice in severe and out-of-control pain and may require emergency CII analgesics. These emergency prescriptions are most quickly ordered and transmitted as verbal prescriptions (and though they may also be faxed, this question and answer assumes emergency circumstances would dictate that verbal CII prescriptions be used). Both the federal (21 CFR 1306.11[d]) and California law (H&SC 11167) require that the pharmacist must reduce the verbal prescription to writing before dispensing only that quantity necessary to meet the emergency. The prescriber must then supply a written CII triplicate prescription (a non-triplicate "11159.2 exemption" prescription cannot be the basis for a verbal order and cannot be used) for the emergency quantity prescribed within seven days (or postmarked by the seventh day)

following transmission of the original order.

Federal law requires that the original written prescription must show the words "Authorization for Emergency Dispensing" and the date of the original verbal order. If the prescriber fails to comply, the pharmacist must promptly notify both the Bureau of Narcotic Enforcement (BNE) within 144 hours and the DEA of the prescriber's failure to supply the written triplicate, and make a record of having notified the BNE.

**Q9. How must a CII prescriber-issued triplicate prescription for a hospice patient be filled and processed if it is faxed?**

**A9.** This question assumes the faxed CII prescriptions to be routine orders. Federal law (21 CFR 1306.11(g) permits a pharmacy to fill a CII prescription for a patient enrolled in a hospice certified by Medicare or licensed by the state by noting on the faxed prescription that the patient is a hospice patient and allows the faxed prescription copy to serve as the original. H&SC 11167.5 allows a pharmacist to accept a routine faxed CII prescription for a patient in a licensed skilled nursing facility, an intermediate care facility, or a licensed home health agency providing hospice care. The pharmacist is required to reduce the faxed prescriptions to writing on a pharmacy-generated triplicate form (which is issued by the California Department of Justice's BNE and who allows the pharmacy-triplicate form to serve as the original, federal law notwithstanding).

In addition to the information required for all CII prescriptions, the pharmacy-generated triplicate must note:

- the date the prescription was electronically transmitted by the prescriber, and
- the name and address of the licensed facility, home health agency providing hospice care, or licensed hospice that is serving the patient.

The original pharmacy-generated triplicate prescription sheet shall be properly endorsed by the pharmacist with the:

- pharmacy’s state license number,
- signature of the pharmacist, and
- name and address of the pharmacy.

The signature of the patient (or the caregiver) or the person who received the controlled substance for the hospice must be entered on the triplicate and then the completed prescription should be forwarded to the Department of Justice at the end of the month in which the prescription was filled. The duplicate is retained by the pharmacist and the triplicate forwarded to the prescriber at the end of the month in which the prescription was written.

**Q10. How must a CII “11159.2 exemption” prescription for a hospice patient be filled and processed if it is faxed?**

**A10.** Non-triplicate ‘11159.2’ CII prescriptions written for terminally ill hospice patients may be faxed and filled for routine orders as well, if they have been issued under and meet the requirements of H&SC 11159.2 (see Question #6). A faxed non-triplicate prescription does not need to generate a pharmacy-triplicate but the controlled substance cannot be dispensed until after the pharmacist obtains the original prescription from the prescriber.

**Q11. Can a written CII prescription for a hospice patient be partially filled?**

**A11.** Yes. Federal law (21 CFR 1306.13(a) allows for a written CII prescription (triplicate in California) to be partially filled for any patient if the pharmacist is unable to supply the full quantity noted on the prescription. The pharmacist must make a notation of the quantity supplied on the face of the triplicate and the remaining **portion must be filled within 72 hours of the first partial filling.**

**In the instance of a terminally ill patient, both federal law (21 CFR 1306.13(b)) and California law (California Code of Regulations section 1745) permit the written triplicate CII prescription for a terminally ill patient to be partially filled.** The prescription must be tendered and at least partially filled within fourteen days following the date of issue. The date and quantity dispensed and the initials of the dispensing pharmacist must be recorded on the prescription with no portion being dispensed more than 30 days from the prescription’s date of issuance. Regardless of how many times the prescription is partially filled, the total amount of all the partial-fills shall not exceed the quantity written on the face of the prescription. Partial-fills for pharmacy-generated triplicates are also permitted and, in addition to the partial-fill dates, quantities and RPh initials, the original pharmacy-generated triplicate must also be signed by the person

*From Public Disclosure, Page 8*

involved, a summary of the complaint (prescription error, label error, unprofessional conduct, etc.) and the disposition of the complaint, including:

- the non-disciplinary action taken (i.e., correction ordered, notice of violation, office conference, compliance committee review, citation with or without fines)

OR

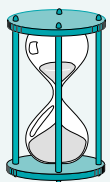
- referral for formal disciplinary action (Attorney General’s Office) - if available, a copy of the accusation (alleged violations of pharmacy law) and the decision, if final

The Board will also provide a written summary of any routine compliance inspections completed within the last five years. This includes a summary of any corrections ordered. (These are minor violations of pharmacy law that are noted on the inspection report and the focus of compliance is through education).

**Licensee Information**

The following licensee information is a matter of public record and is provided upon request:

- Licensee name
- License number
- Name of licensed facility owner (including the corporation name and corporate officers) and the pharmacist-in-charge
- Address of record
- Date original license issued
- Current license status



**I had a wonderful time!**

By  
**Hope Tamraz**  
Editor, *The Script*

By the time everyone reads this newsletter, I will have retired from the Board of Pharmacy. After more than 17 years of scheduling exam applicants, issuing intern permits, processing and evaluating foreign graduate applications, approving and auditing continuing education, and producing the newsletter, I felt it was time to go. And I used the editor’s prerogative of allowing myself some space within which to say goodbye.

During my stay with the Board, it was great to share in the pharmacy profession from the sidelines. It was a great ride, I met some great people, made some wonderful friends, and I know I will miss it all!

Federal	State
<b>Faxing a prescription for a Schedule II (C II) controlled substance</b>	
<p><b>21 CFR 1306.11(a)</b> Except as indicated below, a C II prescription may be faxed from the prescriber to the pharmacy, but the controlled substance may not be dispensed until after the pharmacist obtains the original written, signed prescription.</p>	<p>There is no similar provision in state law. Note that in California, a C II prescription must be written on a triplicate prescription form.</p>
<b>Emergencies</b>	
<p><b>21 CFR 1306.11(d)</b> In an emergency, a pharmacist may dispense up to a 72-hour supply of a Schedule II controlled substance, based on an oral prescription. The pharmacist must reduce the prescription to writing. The prescriber must provide a written prescription to the pharmacy for the controlled substance within seven days; the pharmacy must notify the DEA if the prescriber fails to do so. The written prescription must show the words "Authorization for Emergency Dispensing" and the date of the original oral order.</p>	<p><b>H&amp;SC 11167</b> In an emergency, a pharmacist may dispense a C II controlled substance on a prescription transmitted orally or electronically by the prescriber. The pharmacist must reduce the prescription to writing. The prescriber must supply a written triplicate prescription for the controlled substance within seven days (or postmarked by the seventh day) following the transmission of the original order. The pharmacy must notify the BNE within 144 hours of the prescriber's failure to supply the written triplicate and make a record of having done so.</p>
<b>Patients of long term care facilities (LTC)</b>	
<p><b>21 CFR 1306.11(f)</b> For a resident of an LTC, a pharmacist may dispense a C II controlled substance, based on a faxed prescription from the prescriber. The faxed copy of the prescription may serve as the original written prescription.</p>	<p><b>H&amp;SC 11167.5</b> For a resident of a skilled nursing facility (SNF) or intermediate care facility (ICF), a pharmacist may dispense a C II controlled substance, based on a prescription transmitted orally or electronically from the prescriber. The pharmacist must reduce the prescription to writing on a pharmacy-generated triplicate prescription form. The person receiving the controlled substance at the SNF or ICF must sign the pharmacy-generated triplicate prescription. The pharmacy must obtain a copy of any original signed order from the facility.</p>
<b>For home infusion pharmacies-injectable C II narcotics</b>	
<p><b>21 CFR 1306.11(e)</b> A home infusion pharmacy may dispense a C II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion, based on a faxed prescription from the prescriber. The fax will serve as the original written prescription.</p>	<p>There is no parallel provision in state law.</p>
<b>Hospice patients</b>	
<p><b>21 CFR 1306.11(g)</b> A pharmacy may dispense a C II narcotic prescription, based on a fax of the original prescription, for a patient residing in a hospice certified by Medicare or licensed by the state. The practitioner or practitioner's agent shall note on the prescription that the patient is a hospice patient.</p>	<p><b>H&amp;SC 11167.5</b> For a patient of a licensed home health agency providing hospice care, a pharmacist may dispense a Schedule II controlled substance on a prescription transmitted orally or electronically from the prescriber. The pharmacist must reduce the prescription to writing on a pharmacy-generated triplicate prescription form. The person receiving the controlled substance at the home health agency providing hospice care must sign the pharmacy-generated prescription. The pharmacy must obtain a copy of any original signed order from the facility.</p> <p>Note: The federal DEA considers the use of pharmacy-generated triplicate prescriptions as the original written prescriptions to be in violation of federal law.</p>

Federal	State
<b>Terminally ill patients</b>	
<p>There is no parallel provision for terminally ill patients under federal law; however, the process authorized by the state for terminally ill patients would meet the basic federal requirements for any C II prescription.</p>	<p><b>H&amp;SC 11159.2</b> A prescription for a terminally ill patient may be issued using an ordinary written prescription form, provided the prescription is signed and dated by the prescriber and contains the name of the drug, the quantity prescribed, and directions for its use—all of which must be written in ink or indelible pencil, all in the prescriber’s handwriting. Other required information need not be in the prescriber’s handwriting. The prescription must contain the words “11159.2 exemption” to indicate the physician’s certification that the patient is terminally ill. Where the certification is technically in error (but not missing), the pharmacist may fill the prescription if he or she has personal knowledge that the patient is terminally ill and if the pharmacist returns the prescription to the prescriber for correction within 72 hours. “Terminally ill” in this context refers to a patient who, in the reasonable medical judgment of the prescriber, is suffering from an illness that is incurable and irreversible and that the illness will, if it follows its normal course, bring about the patient’s death within one year. It also means that the prescriber’s treatment is primarily for the control of pain, symptom management, or both, rather than for cure of the illness.</p>
<b>Chart orders for hospital patients</b>	
<p>Federal law has no provision that is directly parallel to the state’s provision.</p>	<p><b>H&amp;SC 11159</b> An order for use by a patient in a licensed hospital is exempt from all requirements for controlled substances but must be in writing on the patient’s record. The order must be signed by the prescriber, dated, and shall state the name and quantity of the controlled substances ordered and the quantity actually administered. The record must be maintained by the hospital for seven years.</p>
<b>Partial filling: drugs unavailable</b>	
<p><b>21 CFR 1306.13(a)</b> A C II prescription may be partially filled if the pharmacist is unable to supply the full quantity. The pharmacist must make a notation of the quantity supplied on the face of the written prescription. The remaining portion of the prescription must be filled within 72 hours of the first partial filling. No further quantity may be supplied beyond 72 hours without a new prescription. If the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist must notify the prescriber.</p>	<p>There is no similar provision in state law.</p>
<b>Partial filling: long term care facility (LTCF) or terminally ill patients</b>	
<p><b>21 CFR 1306.13(b)</b> A C II prescription written for a patient in an LTCF or for a patient diagnosed as terminally ill may be partially filled. The pharmacist must record on the prescription whether the patient is “terminally ill” or an “LTCF patient.” For each partial filling, the pharmacist must record on the prescription the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity dispensed in all partial fillings must not exceed the total quantity prescribed. The fractionated C II prescription may be valid for a period not to exceed 60 days from the issue date unless terminated sooner by the discontinuance of medication.</p>	<p><b>16 CCR 1745</b> A triplicate prescription for a C II controlled substance written for an inpatient of a SNF or for a terminally ill patient may be partially filled. The prescription must be tendered and at least partially filled within seven days following the date of issue. The pharmacist must record the date and amount of each partial filling and the initials of the pharmacist dispensing the prescription. No portion of the prescription may be dispensed more than 30 days from the prescription’s date of issuance. Regardless of how many times the prescription is partially filled, the total amount dispensed shall not exceed that written on the face of the prescription. The original triplicate prescription must be forwarded to the Department of Justice at the end of the month in which the prescription has been completely filled or in which the prescription had been canceled by death of the patient or otherwise, whichever comes first.</p>

## Law Update

This article contains additions and amendments to the Business & Professions Code, Health & Safety Code, Insurance Code and Public Resources Code. For your convenience, these sections are included here so that they may be cut out and saved until the next publication of the Pharmacy Law.

### Business & Professions Code

#### 1206.5. (Amended)

(a) Notwithstanding subdivision (b) of Section 1206 and except as otherwise provided in Section 1241, no person shall perform a clinical laboratory test or examination classified as waived under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:

(1) A licensed physician and surgeon holding a M.D. or D.O. degree.

(2) A licensed podiatrist or a licensed dentist if the results of the tests can be lawfully utilized within his or her practice.

(3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.

(4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.

(5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or Section 3535.

(6) A person licensed under Chapter 6 (commencing with Section 2700).

(7) A person licensed under Chapter 6.5 (commencing with Section 2840).

(8) A perfusionist if authorized by and performed in compliance with Section 2590.

(9) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).

(10) A medical assistant, as defined in Section 2069, if the waived test is performed pursuant to a specific authorization meeting the requirements of Section 2069.

(11) A pharmacist, as defined in Section 4036, if ordering drug therapy-related laboratory tests in compliance with clause (ii) of subparagraph (A) of paragraph (5) of , or subparagraph (B) of paragraph (4) of, subdivision (a) of Section 4052, or if performing skin puncture in the course of performing routine patient assessment procedures in compliance with Section 4052.1.

(12) Other health care personnel providing direct patient care.

(b) Notwithstanding subdivision (b) of Section 1206, no person shall perform clinical laboratory tests or examinations classified as of moderate complexity under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:

(1) A licensed physician and surgeon holding a M.D. or D.O. degree.

(2) A licensed podiatrist or a licensed dentist if the results of the tests can be lawfully utilized within his or her practice.

(3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.

(4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.

(5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or Section 3535.

(6) A person licensed under Chapter 6 (commencing with Section 2700).

(7) A perfusionist if authorized by and performed in compliance with Section 2590.

(8) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).

(9) A person performing nuclear medicine technology if authorized by and performed in compliance with Article 6 (commencing with Section 107115) of Chapter 4 of Part 1 of Division 104 of the Health and Safety Code.

(10) Any person if performing blood gas analysis in compliance with Section 1245.



(11) (A) A person certified or licensed as an “Emergency Medical Technician II” or paramedic pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code while providing prehospital medical care, a person licensed as a psychiatric technician under Chapter 10 (commencing with Section 4500) of Division 2, as a vocational nurse pursuant to Chapter 6.5 (commencing with Section 2840) of Division 2, or as a midwife licensed pursuant to Article 24 (commencing with Section 2505) of Chapter 5 of Division 2, or certified by the department pursuant to Division 5 (commencing with Section 70001) of Title 22 of the California Code of Regulations as a nurse assistant or a home health aide, who provides direct patient care, if the person is performing the test as an adjunct to the provision of direct patient care by the person, is utilizing a point-of-care laboratory testing device at a site for which a laboratory license or registration has been issued, meets the minimum clinical laboratory education, training, and experience requirements set forth in regulations adopted by the department, and has demonstrated to the satisfaction of the laboratory director that he or she is competent in the operation of the point-of-care laboratory testing device for each analyte to be reported.

(B) Prior to being authorized by the laboratory director to perform laboratory tests or examinations, testing personnel identified in subparagraph (A) shall participate in a preceptor program until they are able to perform the clinical laboratory tests or examinations authorized in this section with results that are deemed accurate and skills that are deemed competent by the preceptor. For the purposes of this section, a “preceptor program” means an organized system that meets regulatory requirements in which a preceptor provides and documents personal observation and critical evaluation, including review of accuracy, reliability, and validity, of laboratory testing performed.

(12) Any other person within a physician office laboratory if the test is performed under the supervision of the patient’s physician and surgeon or podiatrist who shall be accessible to the laboratory to provide onsite, telephone, or electronic consultation as needed, and shall: (A) ensure that the person is performing test methods as required for accurate and reliable tests; and (B) have personal knowledge of the results of the clinical laboratory testing or examination performed by that person before the test results are reported from the laboratory.

(13) A pharmacist, if ordering drug therapy-related laboratory tests in compliance with clause (ii) of subparagraph (A) of paragraph (5) of, or subparagraph (B) of paragraph (4) of, subdivision (a) of Section 4052. (c) Notwithstanding subdivision (b) of Section 1206, no person shall perform clinical laboratory tests or examinations classified as of high complexity under CLIA unless the clinical laboratory test or examination is

performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:

(1) A licensed physician and surgeon holding a M.D. or D.O. degree.

(2) A licensed podiatrist or a licensed dentist if the results of the tests can be lawfully utilized within his or her practice.

(3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory if the test or examination is within a specialty or subspecialty authorized by the person’s licensure.

(4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code if the test or examination is within a specialty or subspecialty authorized by the person’s certification.

(5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or Section 3535.

(6) A perfusionist if authorized by and performed in compliance with Section 2590.

(7) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).

(8) A person performing nuclear medicine technology if authorized by and performed in compliance with Article 6 (commencing with Section 107115) of Chapter 4 of Part 1 of Division 104 of the Health and Safety Code.

(9) Any person if performing blood gas analysis in compliance with Section 1245.

(10) Any other person within a physician office laboratory if the test is performed under the onsite supervision of the patient’s physician and surgeon or podiatrist who shall: (A) ensure that the person is performing test methods as required for accurate and reliable tests; and (B) have personal knowledge of the results of clinical laboratory testing or examination performed by that person before the test results are reported from the laboratory.

(d) Clinical laboratory examinations classified as provider-performed microscopy under CLIA may be personally performed using a brightfield or phase/contrast microscope by one of the following practitioners:

(1) A licensed physician and surgeon using the microscope during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or employee.

(2) A nurse midwife holding a certificate as specified by Section 2746.5, a licensed nurse practitioner as specified in Section 2835.5, or a licensed physician assistant acting under the supervision of a physician pursuant to Section 3502 using the microscope during the patient's visit on a specimen obtained from his or her own patient or from the patient of a clinic, group medical practice, or other health care provider of which the certified nurse midwife, licensed nurse practitioner, or licensed physician assistant is an employee.

(3) A licensed dentist using the microscope during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee.

#### **2028. (New)**

(a) The Medical Board of California shall consult with the California State Board of Pharmacy and commission a study and report its results to the Legislature on or before January 1, 2003, on the electronic transmission of prescriptions by physicians and surgeons.

(b) This report shall include recommendations on the following matters:

(1) Whether the electronic transmission of prescriptions should be encouraged.

(2) Methods to encourage physicians and surgeons, health care providers specified in subdivision (a) of Section 4024, and persons licensed to prescribe in another state who meet the requirements described in subdivision (b) of Section 4005 to issue prescriptions by electronic transmission.

(3) Identification of systems to protect confidential personal and medical information of patients for whom prescriptions are issued using electronic transmission, including, but not limited to, the issuance of digital certification to physicians and surgeons, health care providers specified in subdivision (a) of Section 4024, and persons licensed to prescribe in another state who meet the requirements described in subdivision (b) of Section 4005 to use when transmitting prescriptions electronically."

(c) "Digital certification" is an electronic signature verifying the identity of the physician and surgeon, health care provider specified in subdivision (a) of Section 4024, or person licensed to prescribe in another state who meets the requirements described in subdivision (b) of Section 4005 who is transmitting the prescription electronically.

#### **2725.1. (Amended)**

Notwithstanding any other provision of law, a registered nurse may dispense drugs or devices upon an order by a licensed physician and surgeon if the nurse is functioning within a licensed clinic as defined in paragraphs (1) and (2) of subdivision (a) of Section 1204 of, or within a clinic as defined in subdivision (b) or (c) of Section 1206, of the Health and Safety Code. No clinic shall employ a registered nurse to perform dispensing duties exclusively. No registered nurse shall dispense drugs in a pharmacy, keep a pharmacy, open shop, or drugstore for the retailing of drugs or poisons. No registered nurse shall compound drugs. Dispensing of drugs by a registered nurse, except a certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51 or a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, shall not include substances included in the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code). Nothing in this section shall exempt a clinic from the provisions of Article 13 (commencing with Section 4180) of Chapter 9.

#### **2746.51. (Amended)**

(a) Neither this chapter nor any other provision of law shall be construed to prohibit a certified nurse-midwife from furnishing or ordering drugs or devices, including controlled substances classified in Schedule III, IV, or V under the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code), when all of the following apply:

(1) The drugs or devices are furnished or ordered incidentally to the provision of any of the following:

(A) Family planning services, as defined in Section 14503 of the Welfare and Institutions Code.

(B) Routine health care or perinatal care, as defined in subdivision (d) of Section 123485 of the Health and Safety Code.

(C) Care rendered to essentially healthy persons within a facility specified in subdivision (a), (b), (c), (d), (i), or (j) of Section 1206 of the Health and Safety Code, a clinic as specified in Section 1204 of the Health and Safety Code, a general acute care hospital as defined in subdivision (a) of Section 1250 of the Health and Safety Code, a licensed birth center as defined in Section 1204.3 of the Health and Safety Code, or a special hospital specified as a maternity hospital in subdivision (f) of Section 1250 of the Health and Safety Code.

(2) The drugs or devices are furnished or ordered by a certified nurse-midwife in accordance with standardized procedures or protocols. For purposes of this section,

standardized procedure means a document, including protocols, developed and approved by the supervising physician and surgeon, the certified nurse-midwife, and the facility administrator or his or her designee. The standardized procedure covering the furnishing or ordering of drugs or devices shall specify all of the following:

(A) Which certified nurse-midwife may furnish or order drugs or devices.

(B) Which drugs or devices may be furnished or ordered and under what circumstances.

(C) The extent of physician and surgeon supervision.

(D) The method of periodic review of the certified nurse-midwife's competence, including peer review, and review of the provisions of the standardized procedure.

(3) If Schedule III controlled substances, as defined in Section 11056 of the Health and Safety Code, are furnished or ordered by a certified nurse-midwife, the controlled substances shall be furnished or ordered in accordance with a patient-specific protocol approved by the treating or supervising physician and surgeon.

(4) The furnishing or ordering of drugs or devices by a certified nurse-midwife occurs under physician and surgeon supervision. For purposes of this section, no physician and surgeon shall supervise more than four certified nurse-midwives at one time. Physician and surgeon supervision shall not be construed to require the physical presence of the physician, but does include all of the following:

(A) Collaboration on the development of the standardized procedure or protocol.

(B) Approval of the standardized procedure or protocol.

(C) Availability by telephonic contact at the time of patient examination by the certified nurse-midwife.

(b) (1) The furnishing or ordering of drugs or devices by a certified nurse-midwife is conditional on the issuance by the board of a number to the applicant who has successfully completed the requirements of paragraph (2). The number shall be included on all transmittals of orders for drugs or devices by the certified nurse-midwife. The board shall maintain a list of the certified nurse-midwives that it has certified pursuant to this paragraph and the number it has issued to each one. The board shall make the list available to the California State Board of Pharmacy upon its request. Every certified nurse-midwife who is authorized pursuant to this section to furnish or issue a drug order for a controlled substance shall register with the United States Drug Enforcement Administration.

(2) The board has certified in accordance with paragraph (1) that the certified nurse-midwife has satisfactorily completed at least six month's physician and surgeon supervised experience in the furnishing or ordering of drugs or devices and a course in pharmacology covering the drugs or devices to be furnished or ordered under this section. The board shall establish the requirements for satisfactory completion of this paragraph.

(3) A copy of the standardized procedure or protocol relating to the furnishing or ordering of controlled substances by a certified nurse-midwife shall be provided upon request to any licensed pharmacist who is uncertain of the authority of the certified nurse-midwife to perform these functions.

(c) Drugs or devices furnished or ordered by a certified nurse-midwife may include Schedule II controlled substances under the California Uniform Controlled Substances Act, (Division 10 (commencing with Section 11000) of the Health and Safety Code) under the following conditions:

(1) The drugs and devices are furnished or ordered in a hospital as described in subdivision (a) of Section 1250 of the Health and Safety Code and are furnished or ordered in accordance with requirements referenced in paragraphs (2) to (4), inclusive, of subdivision (a) and in paragraphs (1) to (3), inclusive, of subdivision (b).

(2) When Schedule II controlled substances, as defined in Section 11055 of the Health and Safety Code, are furnished or ordered by a certified nurse-midwife, the controlled substances shall be furnished or ordered in accordance with a patient-specific protocol approved by the treating or supervising physician and surgeon. (d) Furnishing of drugs or devices by a certified nurse-midwife means the act of making a pharmaceutical agent or agents available to the patient in strict accordance with a standardized procedure or protocol. Use of the term "furnishing" in this section shall include the following:

(1) The ordering of a drug or device in accordance with the standardized procedure or protocol.

(2) Transmitting an order of a supervising physician and surgeon.

(e) "Drug order" or "order" for purposes of this section means an order for medication or for a drug or device that is dispensed to or for an ultimate user, issued by a certified nurse-midwife as an individual practitioner, within the meaning of Section 1306.03 of Title 21 of the Code of Federal Regulations. Notwithstanding any other provision of law, (1) a drug order issued pursuant to this section shall be treated in the same manner as a prescription of the supervising physician; (2) all references to "prescription" in this code and the Health and Safety Code shall include drug orders issued by certified nurse-

midwives; and (3) the signature of a certified nurse-midwife on a drug order issued in accordance with this section shall be deemed to be the signature of a prescriber for purposes of this code and the Health and Safety Code.

(f) Nothing in this section, nor any other provision of law, shall be construed to authorize a nurse-midwife in solo practice to furnish drugs or devices, under any circumstances.

#### **4033. (Amended)**

(a) "Manufacturer" means and includes every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer.

(b) Notwithstanding subdivision (a), "manufacturer" shall not mean a pharmacy compounding a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy for the purpose of delivering or administering the drug to the patient or patients named in the prescription, provided that neither the components for the drug nor the drug are compounded, fabricated, packaged, or otherwise prepared prior to receipt of the prescription.

(c) Notwithstanding subdivision (a), "manufacturer" shall not mean a pharmacy that, at a patient's request, repackages a drug previously dispensed to the patient, or to the patient's agent, pursuant to a prescription.

#### **4040. (Amended)**

(a) "Prescription" means an oral, written, or electronic transmission order that is both of the following:

(1) Given individually for the person or persons for whom ordered that includes all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the condition for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, or physician assistant who issues a drug order pursuant to Section 2746.51, 2836.1, or 3502.1.

(2) Issued by a physician, dentist, optometrist, podiatrist, or veterinarian or, if a drug order is issued pursuant to Section 2746.51, 2836.1, or 3502.1, by a certified nurse-midwife, nurse practitioner, or physician assistant licensed in this state. (b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner consistent with paragraph (3) of subdivision (b) of Section 11164 of the Health and Safety Code, the name and quantity of the drug prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code, Section 11164 of the Health and Safety Code shall prevail.

(c) "Electronic transmission prescription" includes both image and data prescriptions. "Electronic image transmission prescription" means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(e) Nothing in the amendments made to this section (formerly Section 4036) at the 1969 Regular Session of the Legislature shall be construed as expanding or limiting the right that a chiropractor, while acting within the scope of his or her license, may have to prescribe a device.

#### **4050. (Amended)**

(a) In recognition of and consistent with the decisions of the appellate courts of this state, the Legislature hereby declares the practice of pharmacy to be a profession.

(b) Pharmacy practice is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes.

#### **4051. (Amended)**

(a) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section

4040 of a prescriber unless he or she is a pharmacist under this chapter.

(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section 4052, and otherwise provide clinical advice or information or patient consultation if all of the following conditions are met:

(1) The clinical advice or information or patient consultation is provided to a health care professional or to a patient.

(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

#### 4052. (Amended)

(a) Notwithstanding any other provision of law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded medication to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.

(4) Perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:

(A) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(B) Ordering drug therapy-related laboratory tests.

(C) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(D) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.

(5) (A) Perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a

physician, in accordance, as applicable, with policies, procedures, or protocols of that facility, the home health agency, the licensed clinic, the health care service plan, or that physician, in accordance with subparagraph (C):

(i) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(ii) Ordering drug therapy-related laboratory tests.

(iii) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(iv) Initiating or adjusting 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 policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.

(B) A patient's prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(C) The policies, procedures, or protocols referred to in this paragraph shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and, at a minimum, meet all of the following requirements:

(i) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(ii) Require that the medical records of the patient be available to both the patient's prescriber and the pharmacist.

(iii) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(iv) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures

to be performed 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 shall be provided in writing to the treating or supervising physician within 24 hours.

(6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(7) Provide consultation to patients and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals.

(8) Initiate emergency contraception drug therapy in accordance with standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice. Prior to performing any procedure authorized under this paragraph, a pharmacist shall have completed a training program on emergency contraception, which includes, but is not limited to, conduct of sensitive communications, quality assurance, referral to additional services, and documentation.

(b) (1) Prior to performing any procedure authorized by paragraph (4) of subdivision (a), a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

(2) Prior to performing any procedure authorized by paragraph (5) of subdivision (a), a pharmacist shall have either (1) successfully completed clinical residency training or (2) demonstrated clinical experience in direct patient care delivery.

(3) For each emergency contraception drug therapy initiated pursuant to paragraph (8) of subdivision (a), the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized fact sheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.

(c) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

(d) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

#### 4052.1 (New)

Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5. For purposes of this section, "routine patient assessment procedures" means: (a) procedures that a patient could, with or without a prescription, perform for himself or herself, or (b) clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, as authorized by paragraph (11) of subdivision (a) of Section 1206.5. A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

#### 4052.5 (Amended)

(a) In addition to the authority allowed under Section 4073, a pharmacist filling a prescription order for a drug product may select a different form of medication with the same active chemical ingredients of equivalent strength and duration of therapy as the prescribed drug product when the change will improve the ability of the patient to comply with the prescribed drug therapy.

(b) In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "Do not substitute" or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked "Do not substitute" if the prescriber personally initials the box or checkmark.

(c) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (b). The pharmacist who selects the drug product to be dispensed pursuant to this section shall assume the same responsibility for selecting the dispensed drug product as would be incurred in filling a prescription for a drug product using the prescribed form of medication. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a drug product pursuant to this section.

(d) This section shall apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the California Medical Assistance Program set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.

(e) When a substitution is made pursuant to this section, the use of the different form of medication shall be communicated to the patient, and the name of the dispensed drug product shall be indicated on the prescription label, unless the prescriber orders otherwise.

(f) This section shall not permit substitution between long-acting and short-acting forms of a medication with the same chemical ingredients or between one drug product and two or more drug products with the same chemical ingredients.

#### 4052.7. (Amended)

(a) A pharmacy may, at a patient's request, repackage a drug previously dispensed to the patient or to the patient's agent pursuant to a prescription.

(b) Any pharmacy providing repackaging services shall have in place policies and procedures for repackaging these drugs and shall label the repackaged prescription container with the following:

(1) All the information required by Section 4076.

(2) The name and address of the pharmacy repackaging the drug and the name and address of the pharmacy that initially dispensed the drug to the patient.

(c) The repackaging pharmacy and the pharmacy that initially dispensed the drug shall only be liable for its own actions in providing the drug to the patient or the patient's agent.

#### 4053. (Amended)

(a) Subdivision (a) of Section 4051 shall not apply to a manufacturer, veterinary food-animal drug retailer, or wholesaler if the board shall find that sufficient, qualified supervision is employed by the manufacturer, veterinary food-animal drug retailer, or wholesaler to adequately safeguard and protect the public health, nor shall Section 4051 apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).

(b) An individual employed by a manufacturer, veterinary food-animal drug retailer, or wholesaler may apply for an exemption from Section 4051. In order to obtain and maintain that exemption, the individual shall meet the following requirements:

(1) He or she shall be a high school graduate or possess a general education development equivalent.

(2) He or she shall have a minimum of one year of paid work experience related to the distribution or dispensing of dangerous drugs or dangerous devices or meet all of the

prerequisites to take the examination required for licensure as a pharmacist by the board.

(3) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

(A) Knowledge and understanding of state and federal law relating to the distribution of dangerous drugs and dangerous devices.

(B) Knowledge and understanding of state and federal law relating to the distribution of controlled substances.

(C) Knowledge and understanding of quality control systems.

(D) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage and handling of drugs.

(E) Knowledge and understanding of prescription terminology, abbreviations, dosages and format.

(4) The board may, by regulation, require training programs to include additional material.

(5) The board may, by regulation, require training programs to include additional material.

(6) The board shall not issue a certificate of exemption until the applicant provides proof of completion of the required training to the board.

(c) The manufacturer, veterinary food-animal drug retailer, or wholesaler shall not operate without a pharmacist or an individual in possession of a certificate of exemption on its premises.

(d) Only a pharmacist or an individual in possession of a certificate of exemption shall prepare and affix the label to veterinary food-animal drugs.

#### 4060. (Amended)

No person shall possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, or veterinarian, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, or a physician assistant pursuant to Section 3502.1. This section shall not apply to the possession of any controlled substance by a manufacturer, wholesaler, pharmacy, physician, podiatrist, dentist, veterinarian, certified nurse-midwife, nurse practitioner, or physician assistant, when in stock in containers correctly labeled with the name and address of the supplier or producer. Nothing in this section authorizes a certified nurse-

midwife, a nurse practitioner, or a physician assistant to order his or her own stock of dangerous drugs and devices.

#### **4061. (Amended)**

No manufacturer's sales representative shall distribute any dangerous drug or dangerous device as a complimentary sample without the written request of a physician, dentist, podiatrist, or veterinarian. However, a certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or a physician assistant who functions pursuant to Section 3502.1, may sign for the delivery or receipt of complimentary samples of a dangerous drug or dangerous device that has been requested in writing by his or her supervising physician. Each written request shall contain the names and addresses of the supplier and the requester, the name and quantity of the specific dangerous drug desired, the name of the certified nurse-midwife, nurse practitioner, or physician assistant, if applicable, receiving the samples pursuant to this section, the date of receipt, and the name and quantity of the dangerous drugs or dangerous devices provided. These records shall be preserved by the supplier with the records required by Section 4059.

#### **4076. (Amended)**

(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or the physician assistant who functions pursuant to Section 3502.1 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber and, if applicable, the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or the physician assistant who functions pursuant to Section 3502.1.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or the physician assistant who functions pursuant to Section 3502.1.

#### **4102. (Repealed)**

#### **4110. (Amended)**

(a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred.

(b) The board may, at its discretion, issue a temporary permit, when the ownership of a pharmacy is transferred from one person to another, upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary permit fee shall be established by the board at an amount not to exceed the annual fee for renewal of a permit to conduct a pharmacy. A temporary permit may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary permit was issued by mistake or denies



the application for a permanent license or registration, the temporary license or registration shall terminate upon either personal service of the notice of termination upon the permit holder or service by certified mail, return receipt requested, at the permit holder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary permit nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary permit holder be deemed to have a vested property right or interest in the permit.

#### 4115. (Amended)

(a) Notwithstanding any other provision of law, a pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, only while assisting, and while under the direct supervision and control of, a pharmacist.

(b) This section does not authorize the performance of any tasks specified in subdivision (a) by a pharmacy technician without a pharmacist on duty, nor does this section authorize the use of a pharmacy technician to perform tasks specified in subdivision (a) except under the direct supervision and control of a pharmacist.

(c) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.

(d) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the direct supervision and control of a pharmacist. Any pharmacy that employs a pharmacy technician to perform tasks specified in subdivision (a) shall do so in conformity with the regulations adopted by the board pursuant to this subdivision.

(e) (1) No person shall act as a pharmacy technician without first being registered with the board as a pharmacy technician as set forth in Section 4202.

(2) The registration requirements in paragraph (1) and Section 4202 shall not apply during the first year of employment for a person employed or utilized as a pharmacy technician to assist in the filling of prescriptions for an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, or for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

(f) The performance of duties by a pharmacy technician shall be under the direct supervision and control of a pharmacist. The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician. A pharmacy

technician may perform the duties, as specified in subdivision (a), only under the immediate, personal supervision and control of a pharmacist. Any pharmacist responsible for a pharmacy technician shall be on the premises at all times, and the pharmacy technician shall be within the pharmacist's view. A pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient. This subdivision shall not apply to a person 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. Notwithstanding the exemption in this subdivision, the requirements of subdivisions (a) and (b) shall apply to a person 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.

(g) (1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, and for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

(2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117.

(3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of his or her professional judgment, that permitting the second pharmacy technician to be on duty would interfere with the effective performance of the pharmacist's responsibilities under this chapter. A pharmacist assigned to supervise a second pharmacy

technician shall notify the pharmacist in charge in writing of his or her determination, specifying the circumstances of concern with respect to the pharmacy or the pharmacy technician that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule. No entity employing a pharmacist may discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this paragraph.

(h) Notwithstanding subdivisions (b) and (f), the board shall by regulation establish conditions to permit the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy. During these temporary absences, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. The pharmacist shall be responsible for a pharmacy technician and shall review any task performed by a pharmacy technician during the pharmacist's temporary absence. Nothing in this subdivision shall be construed to authorize a pharmacist to supervise pharmacy technicians in greater ratios than those described in subdivision (g).

#### **4119.2 (New)**

(a) Notwithstanding any other provision of law, a pharmacy may furnish epinephrine auto-injectors to a school district or county office of education pursuant to Section 49414 of the Education Code if all of the following are met:

(1) The epinephrine auto-injectors are furnished exclusively for use at a school district site or county office of education.

(2) A physician and surgeon provides a written order that specifies the quantity of epinephrine auto-injectors to be furnished.

(b) Records regarding the acquisition and disposition of epinephrine auto-injectors furnished pursuant to subdivision (a) shall be maintained by both the school district or county office of education for a period of three years from the date the records were created. The school district or county office of education shall be responsible for monitoring the supply of auto-injectors and assuring the destruction of expired auto-injectors.

#### **4126. (New)**

(a) Notwithstanding any other provision of law, a covered entity may contract with a pharmacy to provide pharmacy services to patients of the covered entity, as defined in Section 256b of Title 42 of the United States Code, including dispensing preferentially priced drugs obtained pursuant to Section 256b of

Title 42 of the United States Code. Contracts between those covered entities and pharmacies shall comply with guidelines published by the Health Resources and Services Administration and shall be available for inspection by board staff during normal business hours.

(b) Drugs purchased pursuant to Section 256b of Title 42 of the United States Code and received by a pharmacy shall be segregated from the pharmacy's other drug stock by either physical or electronic means. All records of acquisition and disposition of these drugs shall be readily retrievable in a form separate from the pharmacy's other records.

(c) Drugs obtained by a pharmacy to be dispensed to patients of a covered entity pursuant to Section 256b of Title 42 of the United States Code that cannot be distributed because of a change in circumstances for the covered entity or the pharmacy shall be returned to the distributor from which they were obtained. For the purposes of this section, a change in circumstances includes, but is not limited to, the termination or expiration of the contract between the pharmacy and the covered entity, the closure of a pharmacy, disciplinary action against the pharmacy, or closure of the covered entity.

(d) A licensee that participates in a contract to dispense preferentially priced drugs pursuant to this section shall not have both a pharmacy and a wholesaler license.

(e) Neither a covered entity nor a pharmacy shall be required to obtain a license as a wholesaler based on acts reasonably necessary to fully participate in the drug purchase program established by Section 256b of Title 42 of the United States Code.

#### **4127. (New)**

The board shall adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy.

##### **4127.1 (New)**

(a) A pharmacy shall not compound injectable sterile drug products in this state unless the pharmacy has obtained a license from the board pursuant to this section. The license shall be renewed annually and is not transferable.

(b) A license to compound injectable sterile drug products may only be issued for a location that is licensed as a pharmacy. Furthermore, the license to compound injectable sterile drug products may only be issued to the owner of the pharmacy license at that location. A license to compound injectable sterile drug products may not be issued until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

(c) A license to compound injectable sterile drug products may not be renewed until the location has been inspected by the board and found to be in compliance with this article and regulations adopted by the board.

(d) Pharmacies operated by entities that are licensed by either the board or the State Department of Health Services and that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board, are exempt from the requirement to obtain a license pursuant to this section.

(e) The reconstitution of a sterile powder shall not require a license pursuant to this section if both of the following are met:

(1) The sterile powder was obtained from a manufacturer.

(2) The drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection pursuant to this division.

(f) This section shall become effective on the earlier of July 1, 2003, or the effective date of regulations adopted by the board pursuant to Section 4127.

#### **4127.2 (New)**

(a) A nonresident pharmacy may not compound injectable sterile drug products for shipment into the State of California without a license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.

(b) A license to compound injectable sterile drug products may only be issued for a location that is licensed as a nonresident pharmacy. Furthermore, the license to compound injectable sterile drug products may only be issued to the owner of the nonresident pharmacy license at that location. A license to compound injectable sterile drug products may not be issued or renewed until the board receives the following from the nonresident pharmacy:

(1) A copy of an inspection report issued by the pharmacy's licensing agency, or a report from a private accrediting agency approved by the board, in the prior 12 months documenting the pharmacy's compliance with board regulations regarding the compounding of injectable sterile drug products.

(2) A copy of the nonresident pharmacy's proposed policies and procedures for sterile compounding.

(c) Nonresident pharmacies operated by entities that are licensed as a hospital, home health agency, or a skilled nursing facility and have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board, are

exempt from the requirement to obtain a license pursuant to this section.

(d) This section shall become effective on the earlier of July 1, 2003, or the effective date of regulations adopted by the board pursuant to Section 4127.

#### **4127.3. (New)**

(a) Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that a pharmacy compounding injectable sterile drug products poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the pharmacy to immediately cease and desist from compounding injectable sterile drug products. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.

(b) Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue the owner a notice setting forth the acts or omissions with which the owner is charged, specifying the pertinent code section or sections.

(c) The order shall provide that the owner, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the owner's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five days from the date the request of the owner is received by the board. The president shall render a written decision within five days of the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision of the president of the board may be sought by the owner or person in possession or control of the pharmacy pursuant to Section 1094.5 of the Code of Civil Procedure. (d) Failure to comply with a cease and desist order issued pursuant to this section shall be unprofessional conduct.

#### **4127.4 (New)**

Notwithstanding any other provision of law, a violation of this article, or regulations adopted pursuant thereto, may subject the person or entity that committed the violation to a fine of up to two thousand five hundred dollars (\$2,500) per occurrence pursuant to a citation issued by the board.

#### **4127.5 (New)**

The fee for the issuance of a license, or renewal of a license, to compound sterile drug products shall be five hundred dollars (\$500) and may be increased to six hundred dollars (\$600).

**4127.6 (New)**

This article shall become operative upon the allocation of positions to the board for the implementation of the provisions of this article in the annual Budget Act.

**4160. (Amended)**

(a) No person shall act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board. Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.

(b) No selling or distribution outlet, located in this state, of any out-of-state manufacturer, that has not obtained a license from the board, that sells or distributes only the dangerous drugs or the dangerous devices of that manufacturer, shall sell or distribute any dangerous drug or dangerous device in this state without obtaining a wholesaler's license from the board.

(c) A separate license shall be required for each place of business owned or operated by a wholesaler. Each license shall be renewed annually and shall not be transferable.

(d) The board shall not issue or renew a wholesaler license until the wholesaler designates an exemptee-in-charge and notifies the board in writing of the identity and license number of that exemptee. The exemptee-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. Each wholesaler shall designate, and notify the board of, a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be exemptee-in-charge. A pharmacist may be designated as the exemptee-in-charge.

(e) For purposes of this section, "exemptee-in-charge" means a person granted a certificate of exemption pursuant to Section 4053, or a registered pharmacist, who is the supervisor or manager of the facility.

**4161. (Amended)**

(a) No person shall act as an out-of-state manufacturer or wholesaler of dangerous drugs or dangerous devices doing business in this state who has not obtained an out-of-state dangerous drug or dangerous device distributor's license from the board. Persons not located in this state selling or distributing dangerous drugs or dangerous devices in this state only through a licensed wholesaler are not required to be licensed as an out-of-state manufacturer or wholesaler or have an out-of-state dangerous drug or dangerous device distributor's license.

(b) Applications for an out-of-state dangerous drug or dangerous device distributor's license shall be made on a form furnished by the board. The board may require any information as the board deems is reasonably necessary to carry out the purposes of the section. The license shall be renewed annually.

(c) The Legislature, by enacting this section, does not intend a license issued to any out-of-state manufacturer or wholesaler pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any out-of-state manufacturer or wholesaler.

(d) The Legislature, by enacting this section, does not intend a license issued to any out-of-state manufacturer or wholesaler pursuant to this section to serve as any evidence that the out-of-state manufacturer or wholesaler is doing business within this state.

**4170. (Amended)**

(a) No prescriber shall dispense drugs or dangerous devices to patients in his or her office or place of practice unless all of the following conditions are met:

(1) The dangerous drugs or dangerous devices are dispensed to the prescriber's own patient, and the drugs or dangerous devices are not furnished by a nurse or physician attendant.

(2) The dangerous drugs or dangerous devices are necessary in the treatment of the condition for which the prescriber is attending the patient.

(3) The prescriber does not keep a pharmacy, open shop, or drugstore, advertised or otherwise, for the retailing of dangerous drugs, dangerous devices, or poisons.

(4) The prescriber fulfills all of the labeling requirements imposed upon pharmacists by Section 4076, all of the recordkeeping requirements of this chapter, and all of the packaging requirements of good pharmaceutical practice, including the use of childproof containers.

(5) The prescriber does not use a dispensing device unless he or she personally owns the device and the contents of the device, and personally dispenses the dangerous drugs or dangerous devices to the patient packaged, labeled, and recorded in accordance with paragraph (4).

(6) The prescriber, prior to dispensing, offers to give a written prescription to the patient that the patient may elect to have filled by the prescriber or by any pharmacy.

(7) The prescriber provides the patient with written disclosure that the patient has a choice between obtaining the prescription from the dispensing prescriber or obtaining the prescription at a pharmacy of the patient's choice.

(8) A certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or a physician assistant who functions pursuant to Section

3502.1, may hand to a patient of the supervising physician and surgeon a properly labeled prescription drug prepackaged by a physician and surgeon, a manufacturer as defined in this chapter, or a pharmacist.

(b) The Medical Board of California, the State Board of Optometry, the Dental Board of California, the Osteopathic Medical Board of California, the Board of Registered Nursing, and the Physician Assistant Committee shall have authority with the California State Board of Pharmacy to ensure compliance with this section, and those boards are specifically charged with the enforcement of this chapter with respect to their respective licensees.

(c) "Prescriber," as used in this section, means a person, who holds a physician's and surgeon's certificate, a license to practice optometry, a license to practice dentistry, or a certificate to practice podiatry, and who is duly registered as such by the Medical Board of California, the State Board of Optometry, the Dental Board of California, or the Board of Osteopathic Examiners of this state.

#### **4175. (Amended)**

(a) The California State Board of Pharmacy shall promptly forward to the appropriate licensing entity, including the Medical Board of California, the Dental Board of California, the State Board of Optometry, the Osteopathic Medical Board of California, the Board of Registered Nursing, or the Physician Assistant Committee, all complaints received related to dangerous drugs or dangerous devices dispensed by a prescriber, certified nurse-midwife, nurse practitioner, or physician assistant pursuant to Section 4170.

(b) All complaints involving serious bodily injury due to dangerous drugs or dangerous devices dispensed by prescribers, certified nurse-midwives, nurse practitioners, or physician assistants pursuant to Section 4170 shall be handled by the Medical Board of California, the Dental Board of California, the State Board of Optometry, the Osteopathic Medical Board of California, the Board of Registered Nursing, or the Physician Assistant Committee as a case of greatest potential harm to a patient.

#### **4186. (New)**

(a) Automated drug delivery systems, as defined in subdivision (h), may be located in any clinic licensed by the board pursuant to Section 4180. If an automated drug delivery system is located in a clinic, the clinic shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. All policies and procedures shall be maintained at the location where the automated drug system is being used.

(b) Drugs shall be removed from the automated drug delivery system only upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. Drugs removed from the automated drug delivery system shall be provided to the patient by a health professional licensed pursuant to this division.

(c) The stocking of an automated drug delivery system shall be performed by a pharmacist.

(d) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the clinic. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

(e) The automated drug delivery system used at the clinic shall provide for patient consultation pursuant to Section 1707.2 of Title 16 of the California Code of Regulations with a pharmacist via a telecommunications link that has two-way audio and video.

(f) The pharmacist operating the automated drug delivery system shall be located in California.

(g) Drugs dispensed from the automated drug delivery system shall comply with the labeling requirements in Section 4076.

(h) For purposes of this section, an "automated drug delivery system" means a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

#### **4196. (Amended)**

(a) No person shall conduct a veterinary food-animal drug retailer in the State of California unless he or she has obtained a license from the board. A license shall be required for each veterinary food-animal drug retailer owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a veterinary food-animal drug retailer in more than one location. The license shall be renewed annually and shall not be transferable.

(b) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be

in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct a veterinary food-animal drug retailer.

(c) No person other than a pharmacist, an intern pharmacist, an exempt person, an authorized officer of the law, or a person authorized to prescribe, shall be permitted in that area, place, or premises described in the permit issued by the board pursuant to Section 4041, wherein veterinary food-animal drugs are stored, possessed, or repacked. A pharmacist or exemptee shall be responsible for any individual who enters the veterinary food-animal drug retailer for the purpose of performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the veterinary food-animal drug retailer.

(d) The board shall not issue or renew a veterinary food-animal retailer license until the veterinary food-animal drug retailer designates an exemptee-in-charge and notifies the board in writing of the identity and license number of that exemptee. The exemptee-in-charge shall be responsible for the veterinary food-animal drug retailer's compliance with state and federal laws governing veterinary food-animal drug retailers. Each veterinary food-animal drug retailer shall designate, and notify the board of, a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be exemptee-in-charge. A pharmacist may be designated as the exemptee-in-charge.

(e) For purposes of this section, "exemptee-in-charge" means a person granted a certificate of exemption pursuant to Section 4053, or a registered pharmacist, who is the supervisor or manager of the facility.

#### 4200.5. (Amended)

(a) The board shall issue, upon application and payment of the fee established by Section 4400, a retired license to a pharmacist who has been licensed by the board. The board shall not issue a retired license to a pharmacist whose license has been revoked.

(b) The holder of a retired license issued pursuant to this section shall not engage in any activity for which an active pharmacist's license is required. A pharmacist holding a retired license shall be permitted to use the titles "retired pharmacist" or "pharmacist, retired."

(c) The holder of a retired license shall not be required to renew that license.

(d) In order for the holder of a retired license issued pursuant to this section to restore his or her license to active status, he or she shall pass the examination that is required for initial licensure with the board.

#### 4301. (Amended)

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

(a) Gross immorality.

(b) Incompetence.

(c) Gross negligence.

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

(h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.

(i) Except as otherwise authorized by law, knowingly selling, furnishing, giving away, or administering or offering to sell, furnish, give away, or administer any controlled substance to an addict.

(j) The violation of any of the statutes of this state or of the United States regulating controlled substances and dangerous drugs.

(k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.



(l) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

(m) 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 or of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program. The record of the compromise is conclusive evidence of unprofessional conduct.

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter.

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board.

(p) Actions or conduct that would have warranted denial of a license.

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.

(r) The selling, trading, transferring, or furnishing of drugs obtained pursuant to Section 256b of Title 42 of the United States Code to any person a licensee knows or reasonably should have known, not to be a patient of a covered entity, as defined in paragraph (4) of subsection (a) of Section 256b of Title 42 of the United States Code.

#### 4400. (Amended)

The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be three hundred forty dollars (\$340) and may be increased to four hundred dollars (\$400).

(b) The fee for a nongovernmental pharmacy or medical device retailer annual renewal shall be one hundred seventy-five dollars (\$175) and may be increased to two hundred fifty dollars (\$250).

(c) The fee for the pharmacist examination shall be one hundred fifty-five dollars (\$155) and may be increased to one hundred eighty-five dollars (\$185).

(d) The fee for regrading an examination shall be seventy-five dollars (\$75) and may be increased to eighty-five dollars (\$85). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifteen dollars (\$115) and may be increased to one hundred fifty dollars (\$150).

(f) The fee for a wholesaler license and annual renewal shall be five hundred fifty dollars (\$550) and may be increased to six hundred dollars (\$600).

(g) The fee for a hypodermic license and renewal shall be ninety dollars (\$90) and may be increased to one hundred twenty-five dollars (\$125).

(h) The fee for application and investigation for an exemptee license under Sections 4053 and 4054 shall be seventy-five dollars (\$75) and may be increased to one hundred dollars (\$100), except for a veterinary food-animal drug retailer exemptee, for whom the fee shall be one hundred dollars (\$100).

(i) The fee for an exemptee license and annual renewal under Sections 4053 and 4054 shall be one hundred ten dollars (\$110) and may be increased to one hundred fifty

dollars (\$150), except that the fee for the issuance of a veterinary food-animal drug retailer exemptee license shall be one hundred fifty dollars (\$150), for renewal one hundred ten dollars (\$110), which may be increased to one hundred fifty dollars (\$150), and for filing a late renewal fifty-five dollars (\$55).

(j) The fee for an out-of-state drug distributor's license and annual renewal issued pursuant to Section 4120 shall be five hundred fifty dollars (\$550) and may be increased to six hundred dollars (\$600).

(k) The fee for registration and annual renewal of providers of continuing education shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).

(l) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars (\$40) per course hour.

(m) The fee for evaluation of applications submitted by graduates of foreign colleges of pharmacy or colleges of pharmacy not recognized by the board shall be one hundred sixty-five dollars (\$165) and may be increased to one hundred seventy-five dollars (\$175).

(n) The fee for an intern license or extension shall be sixty-five dollars (\$65) and may be increased to seventy-five dollars (\$75). The fee for transfer of intern hours or verification of licensure to another state shall be fixed by the board not to exceed twenty dollars (\$20).

(o) The board may, by regulation, provide for the waiver or refund of the additional fee for the issuance of a certificate where the certificate is issued less than 45 days before the next succeeding regular renewal date.

(p) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change is thirty dollars (\$30).

(q) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, is sixty dollars (\$60) and may be increased to one hundred dollars (\$100).

(r) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(s) The fee for any applicant for a clinic permit is three hundred forty dollars (\$340) and may be increased to four hundred dollars (\$400) for each permit. The annual fee for renewal of the permit is one hundred seventy-five dollars (\$175) and may be increased to two hundred fifty dollars (\$250) for each permit.

(t) The board shall charge a fee for the processing and issuance of a registration to a pharmacy technician and a separate fee for the biennial renewal of the registration. The registration fee shall be twenty-five dollars (\$25) and may be increased to fifty dollars (\$50). The biennial renewal fee shall be twenty-five dollars (\$25) and may be increased to fifty dollars (\$50).

(u) The fee for a veterinary food-animal drug retailer license shall be four hundred dollars (\$400). The annual renewal fee for a veterinary food-animal drug retailer shall be two hundred fifty dollars (\$250).

(v) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty dollars (\$30).

## California Code of Regulations

### 1711. (New)

(a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

(b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in this section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

(c) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form. Unless the pharmacist has already been notified of a medication error by the prescriber or the patient, the pharmacist shall immediately communicate to the patient and the prescriber the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record



of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:

1. the date, location, and participants in the quality assurance review;
2. the pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);
3. the findings and determinations generated by the quality assurance review; and,
4. recommended changes to pharmacy policy, procedure, systems, or processes, if any.

The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.

(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created.

(g) The pharmacy's compliance with this section will be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.

(h) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.

(i) This section shall become operative on January 1, 2002.

## Health & Safety Code

### 1363.03. (New)

(a) Every health care service plan that covers prescription drug benefits and that issues a card to enrollees for claims processing purposes shall issue to each of its enrollees a uniform card containing uniform prescription drug information. The uniform prescription drug information card shall, at a minimum, include the following information:

(1) The name or logo of the benefit administrator or health care service plan issuing the card, which shall be displayed on the front side of the card.

(2) The enrollee's identification number, or the subscriber's identification number when the enrollee is a dependent who accesses services using the subscriber's identification number, which shall be displayed on the front side of the card.

(3) A telephone number that pharmacy providers may call for assistance.

(4) Information required by the benefit administrator or health care service plan that is necessary to commence processing the pharmacy claim, except as provided for in paragraph (5).

(5) A health care service plan shall not be required to print any of the following information on a member card:

(A) Any number that is the same for all of its members, provided that the health care service plan provides this number to the pharmacy on an annual basis.

(B) Any information that may result in fraudulent use of the card.

(C) Any information that is otherwise prohibited from being included on the card.

(b) Beginning July 1, 2002, the new uniform prescription drug information card required by subdivision (a) shall be issued by a health care service plan to an enrollee upon enrollment or upon any change in the enrollee's coverage that impacts the data content or format of the card.

(c) Nothing in this section requires a health care service plan to issue a separate card for prescription drug coverage if the plan issues a card for health care coverage in general and the card is able to accommodate the information required by subdivision (a).

(d) This bill shall not apply to a nonprofit health care service plan with at least 3.5 million enrollees that owns or operates its own pharmacies and that provides health care services to enrollees in a specific geographic area through a mutually exclusive contract with a single medical group.

(e) "Card" as used in this section includes other technology that performs substantially the same function as a card.

(f) For purposes of this section, if a health care service plan delegates responsibility for issuing the uniform prescription drug information card to a contractor or agent, then the contract between the health care service plan and its contractor or agent shall require compliance with this section.

### 11026. (Amended)

"Practitioner" means any of the following:

(a) A physician, dentist, veterinarian, podiatrist, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, a registered nurse acting within the

scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, a certified nurse-midwife acting within the scope of Section 2746.51 of the Business and Professions Code, a nurse practitioner acting within the scope of Section 2836.1 of the Business and Professions Code, or a physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or Section 3502.1 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code.

(b) A pharmacy, hospital, or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer, a controlled substance in the course of professional practice or research in this state.

(c) A scientific investigator, or other person licensed, registered, or otherwise permitted, to distribute, dispense, conduct research with respect to, or administer, a controlled substance in the course of professional practice or research in this state.

#### **11150. (Amended)**

No person other than a physician, dentist, podiatrist, or veterinarian, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, a registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, a certified nurse-midwife acting within the scope of Section 2746.51 of the Business and Professions Code, a nurse practitioner acting within the scope of Section 2836.1 of the Business and Professions Code, a physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or Section 3502.1 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code, or an out-of-state prescriber acting pursuant to Section 4005 of the Business and Professions Code shall write or issue a prescription.

#### **Insurance Code**

##### **10123.194. (New)**

(a) Every disability insurer that covers hospital, medical, or surgical expenses, and, as part of that coverage, also covers prescription drug benefits, and that issues a card to insureds for claims processing purposes, shall issue to each of its insureds a uniform card containing uniform prescription drug information. The uniform prescription drug information card shall, at a minimum, include the following information:

(1) The name or logo of the benefit administrator or disability insurer issuing the card, which shall be displayed on the front side of the card.

(2) The insured's identification number, or the policyholder's identification number when the insured is a dependent who accesses services using the policy holder's identification number, which shall be displayed on the front side of the card.

(3) A telephone number that pharmacy providers may call for assistance.

(4) Information required by the benefit administrator or disability insurer that is necessary to commence processing the pharmacy claim, except as provided for in paragraph (5).

(5) A disability insurer shall not be required to print any of the following information on an insured's card:

(A) Any number that is the same for all of its insured, provided that the disability insurer provides this number to the pharmacy on an annual basis.

(B) Any information that may result in fraudulent use of the card.

(C) Any information that is otherwise prohibited from being included on the card.

(b) Beginning July 1, 2002, the new uniform prescription drug information card required by subdivision (a) shall be issued by an insurer to an insured upon enrollment or upon any change in the insured's coverage that impacts the data content or format of the card.

(c) Nothing in this section requires an insurer to issue a separate card for prescription drug coverage if the insurer issues a card for health care coverage in general and the card is able to accommodate the information required by subdivision (a).

(d) "Card" as used in this section includes other technology that performs substantially the same function as a card.

(e) For purposes of this section, if a disability insurer delegates responsibility for issuing the uniform prescription drug information card to a contractor or agent, then the contract between the disability insurer and its contractor or agent shall require compliance with this section.

#### **Public Resources Code**

##### **15025. (New)**

For purposes of this article, the following terms have the following meanings:

(a) "Mercury-added novelty" means a mercury-added product intended mainly for personal or household enjoyment or

adornment. A “mercury-added novelty” includes, but is not limited to, any item intended for use as a practical joke, figurine, adornment, toy, game, card, ornament, yard statue or figure, candle, jewelry, holiday decoration, and item of apparel, including footwear.

(b) “Mercury fever thermometer” means a mercury-added product that is used for measuring body temperature. Mercury fever thermometer does not include a digital thermometer that uses mercuric oxide button cell batteries.

(c) “School” means any school used for the purpose of the education of more than 12 children in kindergarten or any of grades 1 to 12, inclusive.

### 15026. (New)

(a) On and after July 1, 2002, no person, other than a person licensed pursuant to Article 9 (commencing with Section 4140) of Chapter 9 of Division 2 of the Business and Professions Code, may sell at retail, or otherwise supply, a mercury fever thermometer to a consumer or patient in this state. A mercury fever thermometer may be sold at retail, or otherwise supplied to a consumer or patient only upon the prescription of a physician, dentist, veterinarian, or podiatrist. A mercury fever thermometer sold at retail shall be accompanied by clear written instructions concerning careful handling to avoid breakage and proper cleanup should breakage occur.

(b) A violation of subdivision (a) is a violation of the requirements of Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code and the California State Board of Pharmacy shall enforce the requirements of subdivision (a) in accordance with Chapter 9.



### From *Budget Woes*, Page 1

telephone calls, preparing the newsletter, processing and mediating consumer complaints, providing support to the field inspectors, and educating the public through consumer outreach programs. Due the hiring freeze, those positions cannot be filled. Consequently, the Board has had to make some difficult decisions as to its priorities and services to its licensees.

First and foremost, the Board’s priority is to protect the public. To do this, it is important that consumer complaints and investigations are completed timely, pharmacies and other Board-licensed facilities are inspected periodically, and cases at the Attorney General’s office for egregious violations of pharmacy law are prosecuted. Moreover, it is also important that the Board does not impede pharmacist and pharmacy services to the public. It must ensure that applications for pharmacists, pharmacy technicians and pharmacies are processed timely and efficiently.

To meet these priorities, the following routine services provided in the past to applicants and licensees must be suspended indefinitely:

- There will no longer be a “duty inspector” to answer routine calls from licensees. These calls usually are pharmacy law questions. Answers to these questions can be found by reading the California pharmacy law book (which was provided to each pharmacy by the Board), reviewing the pharmacy self-assessment forms and previously published newsletters, accessing the Board’s website at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov), calling your professional association or contacting your own private attorney for advice.

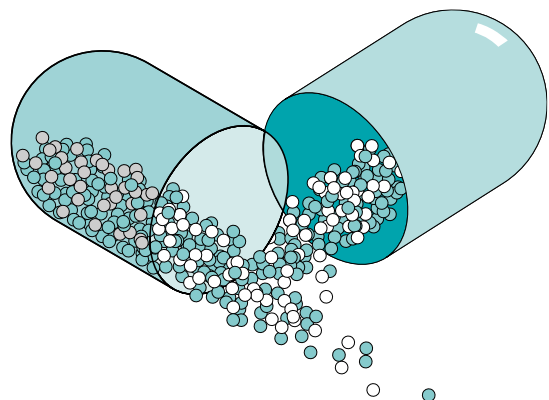
Meanwhile, the Board is actively inspecting pharmacies on a routine basis, and pharmacists are encouraged to ask questions of the inspector during these inspections. The goal of the routine inspections is to educate licensees to promote voluntary compliance of pharmacy law.

- There will no longer be an interactive website where licensees can contact the Board with questions. Again, many of the questions received on the website are law questions that can be answered as described above.

- The Board can no longer publish a quarterly newsletter (The Script). This will be the last newsletter for at least one year. For the latest Board information, access the website.

- The Board can no longer provide application status information over the telephone. Applicants for the pharmacist licensure examination, pharmacy technician registration, pharmacy interns, and foreign graduate evaluations will hear a voice mail message advising that calls requesting application status will not be returned. Such inquiries must be faxed to (916) 322-3561, and every effort will be made to try to respond on a weekly basis.

The Board of Pharmacy regrets having to implement these changes and apologizes for any inconvenience and appreciates your understanding and patience during this difficult time.



From *Quality Assurance, Page 1*

- The findings of the quality assurance program must be used to develop pharmacy systems and workflow processes to prevent medication errors.
- The investigation and review of each medication error shall commence as soon as is reasonably possible, but no later than two business days from the date the medication error is discovered.
- Every review of a medication error must include:
  1. Date, location, and participants in the review.
  2. Pertinent data and other information relating to the medication error(s) reviewed.
  3. Documentation of patient and prescriber notification.
  4. Findings and determinations generated by the quality assurance review.
  5. Recommended changes to pharmacy policy, procedure, systems, or processes, if any.
- Records of the quality assurance review must be retained in the pharmacy for at least one year from the date the record was created.
- Pharmacies may contract with qualified outside entities to develop and/or conduct their quality assurance program.

Records generated in a pharmacy quality assurance program are exempt from discovery based on a provision included in the legislation requiring pharmacies to implement quality assurance programs. This exemption can be found in Section 4125 of the Business & Professions Code.

## Enforcement Policy

The Board expects that this regulation may require pharmacies to implement important changes in their operations. Accordingly, during the first six months of implementation (until July 1, 2002), the principal focus of the Board's enforcement efforts will be to educate pharmacists about this new regulation. Quality assurance programs will be reviewed during Board inspections. If, during the first six months, a pharmacy does not have a quality assurance program, the inspector will issue a written correction notice on the inspection report. Inspectors will follow-up to assure compliance with the correction notice. If during the follow-up inspection, the pharmacy still does not have a quality assurance program, then a notice of violation will be issued. A notice of violation can result in a range of enforcement actions from reprimand to citation and fine, to a disciplinary hearing. The Board regards failure to implement quality assurance programs in compliance with this regulation as an extremely serious violation.

The Board does not intend to use documents from a quality assurance program when investigating medication error complaints. However, when the investigation of a medication error is complete, the inspector will return to review the pharmacy's quality assurance program and the review of specific errors.

After July 1, 2002, failure to have a quality assurance program in place and/or failure to complete a quality assurance review in compliance with the regulation will result in the issuance of a notice of violation and enforcement action for the failure to comply with the quality assurance requirements.

## Health Insurance Portability and Accountability Act

### Did you know?

**The Health Insurance Portability and Accountability Act of 1996 (or HIPAA) will go into effect over the next few years. It sets requirements for providing for patient privacy and obtaining patient consent before electronic health records and information are shared with other entities.**

**This act is a complex body of federal requirements with a series of implementation dates. The first deadline relates to the Transactions and Code Sets Rule and requires covered entities (excluding some small health plans) to submit a compliance plan to the Secretary of the U.S. Department of Health and Human Services by October 2003. The plan must include a budget, schedule, work plan, and an implementation strategy for achieving compliance. For more information, please contact the U. S. Department of Health and Human Services.**

**The following websites provide information on different aspects of HIPAA implementation:**

<http://aspe.hhs.gov/admnsimp/Index.htm>

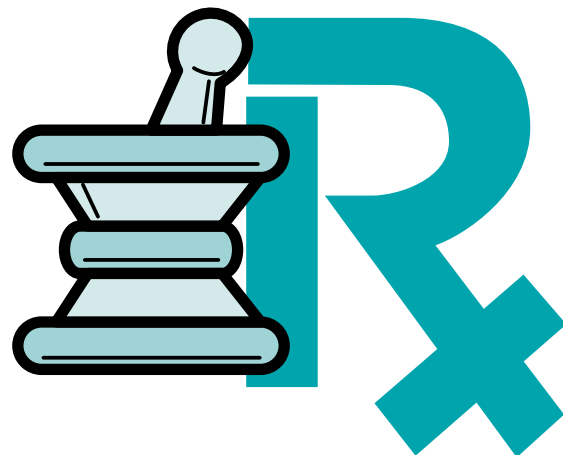
<http://www.hhs.gov/ocr/hipaa/>

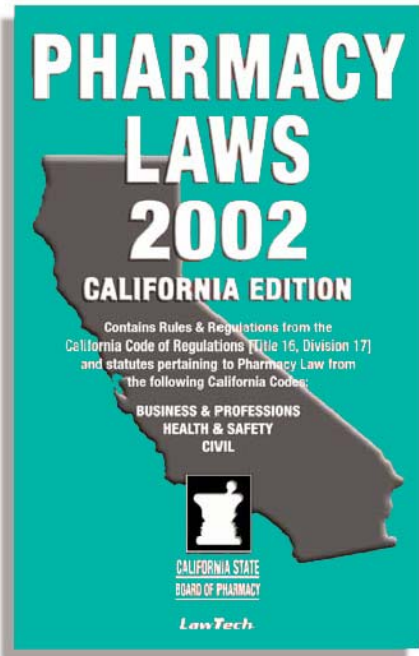
<http://www.ncvhs.hhs.gov/>

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Signature (Required) \_\_\_\_\_

*This newsletter is published by the*  
**California State Board of Pharmacy**  
**Department of Consumer Affairs**  
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## **Pharmacy Board meetings are open to the public...**

... and the Board encourages all interested parties to attend.  
The remaining meeting date and site for 2002 are:

**April 24–26, 2002**  
Dept. of Consumer Affairs  
400 R Street, 1st Floor Hearing  
Room  
Sacramento, CA 95814

**July 24–25, 2002**  
San Diego, California  
To be determined

**October 24–25, 2002**  
San Francisco, CA  
To be determined

Agendas are posted on the Board's website ([www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)) approximately 10 days prior to meetings, or you may contact the Board at (916) 445-5014, Ext. 4006.

*From President's Message, Page 2*

### **Bills to be Considered in the 2002 Legislative Session:**

**NAPLEX**—Assemblywoman Virginia Strom-Martin has amended AB 108 consistent with the Board's position on adopting NAPLEX at the July 25, 2001 Board meeting.

**TECH CHECK TECH**—The Board voted to support legislation that would allow a pharmacy technician to check another pharmacy technician's filling unit-dose cassettes in an inpatient hospital pharmacy. The hospital inpatient pharmacy would be required to apply to the Board for a special waiver that would be renewed annually, and the criteria for the waiver would be specified in legislation to include at least the following:

- The hospital has a clinical pharmacy program;
- The "checking" technician has specialized training and is certified by the Pharmacy Technician Certification Board;
- The pharmacy has an ongoing quality assurance review; and
- The Board performs an annual inspection of the pharmacy prior to renewing the waiver.

Available to consumers and licensees via the Board of Pharmacy's website [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov) is the licensure verification information, issues of The Script, summary of actions from Board meetings, applications, brochures, pharmacy self-assessment forms, and other valuable information sites, including California law.