Changes in Pharmacy Law for 2000

Effective January 1, 2000, enacted legislation has made both substantial and minor changes to pharmacy law. Many of these changes are summarized here. Most of these changes are to the Business & Professions Code (B&PC), Health & Safety Code (H&SC).

AB 136 (Mazzoni), Chapter 762, 1999

Needle Exchange Programs

11364.7 H&SC—now exempts public entities, their agents, and their employees from criminal prosecution for distributing hypodermic needles or syringes to participants in clean needle and syringe exchange programs. Such programs must be authorized by the public entity pursuant to a declaration of emergency by the public entity. This bill does not exempt local programs from all other laws and regulations governing the distribution of hypodermic needles and syringes, including sections 4140-4149 B&PC.

Pharmacists participating in any needle exchange program sponsored by a city or county government must still comply with the record keeping requirements in Section 4146 of the Business and Professions Code.

AB 162 (Runner), Chapter 978, 1999

Restrictions on Ephedrine Sales

11100 H&SC—now limits over-the-counter (OTC) sales of products containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine (excluding liquid pediatric products for children) to three (three-ounce) packages or nine grams for each single transaction. Exceeding the OTC sales limit is a misdemeanor. The provisions of this section preempt all local ordinances related to the sale of ephedrine products. Prescription sales of ephedrine products may exceed the three package limit imposed on OTC sales, but must be reported to the Department of Justice/Bureau of Narcotic Enforcement.

11106 H&SC—requires those who engage in the sale or distribution of ephedrine products and who are not licensed by the Board of Pharmacy or the Department of Health Services to obtain a business permit from the Department of Justice and be registered with the DEA.

(See "Information and Answers to Questions About Ephedrine Sales Restrictions" on page 6.)

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President's Message

by Richard Mazzoni, R.Ph. President, California Board of Pharmacy

With the new millennium upon us, it is appropriate to reflect on some of the major forces that are poised to shape health care in the future. Many of these influences are outside our traditional health care

universe, but their potential impact on our practice cannot be ignored. All concerned must consider these factors if we are to fulfill our obligations to the patients we serve. Consider, for example, just a few:

- THE INTERNET: This is, by far, the most significant change in the health care delivery system in history. The online world has changed the way products and services are delivered. Information that was previously virtually impossible to obtain is now available for anyone to access. Your patients now are better informed about their own conditions and expect a higher level of expertise from the health care teams that treat them. Patients are also aware that there are alternative methods of obtaining products, both over-the-counter and prescription. This presents a challenge to both practitioners and regulators like the Board of Pharmacy.
- **ALTERNATIVE THERAPIES:** The herbal medicine explosion presents another challenge to the pharmacy

profession. We must educate ourselves on the products that our patients are using. Some of these products have definite therapeutic uses, and, in some cases, significant drug interactions. For example, a leading consumer magazine recently surveyed a number of pharmacies as to the safety of taking ginko biloba with warfarin. Sadly, only a few pharmacists correctly identified the interaction. Alternative therapies are pervasive in our society; it is vital that all of us in practice be knowledgeable about their potential benefits as well as potential harm.

• INCREASED PRESCRIPTION VOLUME: It is predicted that the number of prescriptions filled will almost double between 1998 and 2003. This fact, coupled with pharmacy school enrollments that are not increasing at anywhere near the same rate, combine to create a difficult situation for practitioners and regulators. It is imperative that boards of pharmacy consider regulations in light of these facts. Pharmacists must take an active role in reengineering the dispensing process to add efficiency and reduce wasted time.

These are just a few of the forces at work in our profession. Consider how they influence your practice and the patients with whom you interact every day.

Please accept my best wishes for a healthy, happy, and prosperous New Year!



Law for 2000 Continued from Page 1

AB 261 (Lempert), Chapter 375, Statutes of 1999

Pharmacist Scope of Practice

4052 B&PC—now permits pharmacists to perform the following patient management functions in all settings pursuant to a written protocol with a physician:

- Ordering or performing routine patient assessment procedures (e.g. temperature, pulse, and respiration).
- Ordering drug therapy related laboratory tests.
- Administering drugs and biologicals by injection.
- Adjusting the drug regimen of a patient.

The bill also requires that patient records be made available to the pharmacist and that the procedures performed by the pharmacist relate to a condition for which the patient has seen a physician.

AB 924 (Committee on Public Safety), Chapter 975, 1999

Gamma-Butyrolactone (GBL)

11055, 11100 & 11377 H&SC—amends section 11055 H&SC to add gamma-hydroxybutyrate, including its immediate precursors—one of which is gamma-butyrolactone (GBL)—to the list of Schedule II controlled substances. Sections 11100 and 11377 have been amended to conform to the requirements of section 11055.

AB 1234 (Shelley), Chapter 393, 1999

Posting Public Meeting Notices on the Internet

11125 of the Government Code—as of July 1, 2000, requires all state bodies to notice regularly scheduled public hearings at least 10 days in advance on the Internet. This requirement will apply to the Board of Pharmacy. [Note: the Board of Pharmacy is finalizing a new website, which will be in place before July 1, 2000.]

AB 1545 (Correa), Chapter 914, 1999

Nurse Practitioners and Physician Assistants

4076 B&PC—changes labeling requirements for prescriptions if dispensed from a drug order written by a nurse practitioner or physician assistant (under protocol with a supervising physician and surgeon). In such cases, pharmacists must include the name of the nurse practitioner or physician assistant ordering the drug on the container label of any prescription.

2725.1 B&PC—permits nurse practitioners to dispense Schedule III through Schedule V controlled substances in licensed clinics. However, nurse practitioners are prohibited by their practice act from furnishing Schedule II drugs.

Other amendments of this bill permits nurse practitioners and physician assistants to:

- 4061 B&PC—sign for drug samples ordered by their supervising physicians.
- 4170 B&PC—hand drug samples to patients.

SB188 (Leslie), Chapter 900, 1999

Authority to Require Pharmacy to Remain Open During RPh's Meal/Rest Breaks

4116 B&PC—requires the Board of Pharmacy to adopt regulations permitting a pharmacy to remain open under certain conditions while the pharmacist takes the lunch and rest breaks that are mandated by orders of the Industrial Welfare Commission and section 512 of the Labor Code.

4115 B&PC—permits pharmacy technicians to remain in the pharmacy during the pharmacist's absence and perform non-discretionary tasks.

Hospital Drug Purchases and Regulatory Mandate

4056 B&PC—Existing law permits small hospitals (100 beds or less) that do not employ a full-time pharmacist to purchase drugs wholesale for use by patients in the hospital. However, each hospital using this exemption must retain a pharmacist consultant to monitor and review dispensing activity in the hospital. This bill provides that these hospitals may dispense these drugs, in limited quantities, to outpatients if the prescriber feels that it is in the best interest of patient to commence therapy immediately,

Law for 2000 Continued from Page 3

and the hospital is located in a rural area (as defined), and no pharmacy is available within 30 minutes or 30 miles. The prescriber may dispense only enough to continue therapy—not to exceed a 72-hour supply—until a community pharmacy is readily available.

SB 393 (Speier), Chapter 946, 1999

Prescription Drugs for Medicare Beneficiaries

4425 B&PC—requires pharmacies participating in the Medi-Cal program to sell prescription drugs to Medicare beneficiaries at the same price charged to Medi-Cal patients.

4426 B&PC—requires the Department of Health Services to study the adequacy of Medi-Cal pharmacy reimbursement rates, and track Medi-Cal participation changes that may be caused by providing prescription drugs to Medicare beneficiaries at Medi-Cal rates. All of these provisions are to be repealed on January 1, 2003, if there is no legislative action to extend the program.

SB 651 (Burton), Chapter 190, 1999

Pharmacist Wage Orders and Medi-Cal Reimbursement

1186 Labor Code—requires mandatory lunch and rest breaks for pharmacists. However, pharmacists who qualify as administrative or executive staff are exempted from these requirements. Prior to this bill, pharmacists were excluded from mandatory breaks because they were considered "professional" staff. This change in law precipitated the provisions in SB 188 requiring the Board of Pharmacy to adopt regulations (see Law Update, Page 10) establishing conditions under which a pharmacy may remain open while the pharmacist is on break. Questions related to 1186 Labor Code should be directed to the California Labor Commission at (916) 323-4920.

14105.337 Welfare and Institutions Code—requires the Department of Health Services to increase the Medi-Cal dispensing fee by .25¢ per prescription beginning January 1, 2000, and by .15¢ per prescription effective July 1, 2002.

SB 765 (Schiff), Chapter 748, 1999

Biological Specimens

651 B&PC—requires biological specimens for clinical testing be secured in a labeled, locked box when in public and out of control of the licensee collecting the specimen or his/her agents, and permits licensing boards to fine violators up to \$1,000.

SB 816 (Escutia), Chapter 949, 1999

Nurse Practitioners and Physician Assistants to Obtain Drug Orders

2836.1 and 3502.1 B&PC—recasts the existing authority of nurse practitioners and physician assistants to furnish drugs and permits them to issue a drug order for individual patients. The bill specifies that these drug orders are to be treated as prescriptions and must conform to the same B&PC and H&SC requirements as prescriptions from any other provider. The nurse practitioner's or physician assistant's signature on a drug order will be considered to be the signature of the prescriber.

2836.2 B&PC—requires all nurse practitioners authorized pursuant to section 2831.1 B&PC to furnish or issue drug orders for controlled substances to obtain a Drug Enforcement Administration (DEA) registration number. Without the amendments provided in SB 816, the DEA would not issue DEA registration numbers to nurse practitioners and physician assistants.

SB 1308 (Senate Business and Professions Committee), Chapter 655, 1999

Annual Omnibus Bill, provisions sponsored by the Board of Pharmacy

- **4022 B&PC**—conforms California law to the new federal definition of dangerous drugs to be designated by "Rx Only" instead of "Caution: federal law prohibits dispensing without prescription".
- **4040.5 B&PC**—expanded wholesaler categories licensed by the Board of Pharmacy to include "reverse distributors," who arrange for and manage the disposal of outdated drugs and devices.

- 4043 B&PC—includes reverse distributor in the definition of "wholesaler" among those who sell for
 resale, or negotiates for distribution, or takes possession of, any drug or device included in Section
 4022.
- **4057 B&PC**—moves the lists of dangerous drugs and devices exempted for licensed providers and repeals the Board's authority to amend the items included in those lists. These exemptions are to be taken up by the Board of Pharmacy in regulation.
- 4078 B&PC—amended to permit false or misleading labeling of drugs for the purpose of clinical studies and prescribing placebos. Such misleading labels can be made only at the specific direction of the prescriber. Both the prescriber and furnisher must retain record of the false label for 3 years.
- 4102 B&PC—expands the pharmacist's authority to perform skin puncture to include laboratory tests categorized as "waived" or "moderate" under Clinical Laboratory Improvement Amendments of 1988 (42 United States Code section 263a). These tests must be part of drug regimen management, as allowed under 4052 B&PC. The pharmacist is required to report the test results to the patient and the patient's physician if the patient requests it.
- 4115.5 B&PC—extends the window for completing a pharmacy technician externship from 6 months to 12 if the externship includes a hospital pharmacy rotation.
- **4200.5 B&PC**—removes the requirement of returning the pharmacist wall certificate to the Board before receiving a retired pharmacist license.
- **4202 B&PC**—requires pharmacy technician applicants for registration with the Board to possess a high school diploma or general education development equivalent (GED).
- 4402 B&PC—changes the disposition of any Board-issued license—other than a pharmacist license—that has expired. Under current law, expired licenses are cancelled automatically after three years, but this section grants the Board of Pharmacy discretion to cancel an expired license after 60 days. However, expired licenses are still automatically cancelled after three years if the Board of Pharmacy has taken no action.
- 11165 H&SC—extends the CURES program for tracking prescribed and dispensed Schedule II drugs to July 1, 2003.



Information and Answers to Questions About Sales Restrictions on Ephedrine Products

Limitations imposed on the sale of OTC medications for allergy, asthma, colds, sinus, and weight loss

Health & Safety Code (H&SC) sections 11100 and 11106 have been amended to strengthen existing restrictions on the sale and reporting requirements of medication products that contain ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, and the changes became effective January 1, 2000.

California laws limiting the sales and requiring the reporting of sales of certain substances that can be used in the illicit manufacture of drugs and controlled substances are found in H&SC sections 11000-11107.1, and regulations applicable to these code sections are located in sections 800-808 of Title 11 of the California Code of Regulations (CCR). These laws relate to certain sales by manufacturers, wholesalers, pharmacies and other, unlicensed retailers and applies to, among other substances, products containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine—substances found in common allergy, asthma, cold, and sinus medications and

some weight loss products. In large quantities, the ephedrine, etc. in these products can be used in the illicit manufacture of methamphetamine.

Sales Limitations

Section 11100 now limits the retail sale of over-the-counter (OTC) medication products containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine to **no more** than three packages or no more than nine grams in a single transaction, except as discussed below. Since, in accordance with the federal Comprehensive Methamphetamine Control Act, most of these products are packaged in quantities of less than three grams per package, three packages of commercial products containing these substances will ordinarily not exceed the nine grams limit.

Note: a retail sale in violation of the three packages/ nine grams limit is punishable as a misdemeanor.

Reporting Requirements

Section 11100 requires that manufacturers, wholesalers, retailers or other persons or business entities who sell, transfer, or



furnish products containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine report those transactions to the Bureau of Narcotic Enforcement (BNE) on forms furnished by the BNE, except as noted below.

Sales Limit Exceptions and Reporting Exemptions

Sales limits and reporting requirements do not apply:

- To a pharmacist dispensing such products pursuant to a prescription
- To certain liquid products labeled and intended for exclusive use by children and infants. "Pediatric liquid" is defined as a nonencapsulated liquid where the dosage limits do not exceed 15 milligrams of phenylpropanolamine or pseudoephedrine per 5 milligrams of liquid product or, for liquid products primarily intended for administration to children under two years of age, for which the recommended dosage does not exceed one fluid ounce (new subsection (h)(4) of Section 11100)
- Wholesalers registered with the DEA and licensed by the Board of Pharmacy and manufacturers registered with the DEA and licensed for pharmaceuticals by the Department of Health Services, provided that the wholesaler or manufacturer obtains a letter from the purchaser or recipient which includes the purchasing or recipient company's current business address, and a description of how the product is to be used.

Permit Requirements

Section 11106 requires any manufacturer, wholesaler, retailer, or any other person or business entity who sells, transfers or furnishes solid or liquid ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine to obtain a **Precursor Business Permit** from the BNE—of the Department of Justice (DOJ). Along with the permit, the permittee will be provided with forms and instructions for reporting those transactions to the BNE.

Note: Engaging in such transactions without a permit may be punished as either a misdemeanor or a felony.

Exceptions to Permit Requirement

The following persons and entities are not required to obtain a Precursor Business Permit (but are subject to sales limits and reporting requirements, except as described below):

- Pharmacies licensed by the Board
- Warehouses and wholesale facilities which are currently registered with the Drug Enforcement Administration and with the Board of Pharmacy
- Retailers (grocery stores, convenience stores, etc.) whose sales are confined to OTC, face-to-face transactions with walk-in customers; provided that sales are within the three packages/nine grams sales limit per single transaction

Note: the above requirements and restrictions are intended to preempt any local ordinances or regulations governing such transactions by retailers.

Some Questions and Answers:

Q. Does my pharmacy need a Precursor Business Permit to sell or dispense products containing ephedrine?

See Ephedrine Q and A, Page 8



Ephedrine Q and AContinued from Page 7

- A. No, because the pharmacy is already licensed by the Board of Pharmacy and registered with the DEA.
- Q. Can my pharmacy sell more than three packages/nine grams OTC to the same customer in a single transaction?
- A. No, unless there is a valid prescription for a greater amount/number of packages.
- Q. Is a pharmacist who dispenses more than the three packages/nine grams limit, pursuant to a prescription, required to report the transaction to the BNE?
- A. No.
- Q. Is a wholesaler licensed by the Board of Pharmacy required to report to the BNE transactions that exceed the limit?
- A. No, if the sale is to an entity or business that is licensed by the Board of Pharmacy or by the DHS for drug products. However, if the sale is to an individual or entity that is not licensed by the Board or DHS, the wholesaler would be required to report the sale. In addition, any sale or transfer that is suspicious in nature must be reported to the DEA.
- Q. Where should I call to obtain information about or an application for a Precursor Business Permit and/or the reporting requirements?
- A. Contact the BNE at (916) 227-3955.
- Q. What do I do if I am suspicious that an individual is purchasing precursor products for the manufacture of methamphetamine?
- A. Report any suspicious inquiries or



transactions involving precursor products to your local law enforcement officials, and provide records of any suspicious transactions to the DEA. Additionally, if you know that the purchase is for illegal purposes, to sell the product to that individual is a violation of both federal and state laws.

Q. What does nine grams mean in a practical sense?

- A. Since there are 1,000 milligrams to one gram, threshold quantities of pseudoephedrine, for example, would be:
 - Three packages of 50, 60mg. tablets equal 9,000mg. or nine grams (3 X 50 X 60 =9,000mg. (1,000 = nine grams)
 - Three packages of 100, 30mg. tablets equal 9,000mg. or nine grams
 - Three packages of 12, 240mg. tablets equal 8,640mg.—8.64 grams

- Q. Does the nine grams limit mean that the amount of ephedrine in the product being sold must not exceed that amount, or does the limit refer to the amount of the total product?
- A. The limit of nine grams in a single transaction refers to the active amount of ephedrine in the product, not the product's total weight.

Q. What should I tell my cashiers about the sales of such products?

- A. Because "retailer" includes anyone who represents the owner of, or operation of, a business enterprise dealing with the sale or transfer of ephedrine, etc., you should ensure that your cashiers are all aware of products containing such substances and amounts (or numbers of packages) that will exceed the limit or threshold.
- Q. Am I required to post a sign limiting purchases of ephedrine products in the cough and cold section of the store, or anywhere in the store?

- No. A sign is not required by law; the individual business may post a sign if it so chooses.
- Q. Must I pull all OTC products containing ephedrine, etc. off the OTC shelves and keep them behind the pharmacy counter?
- A. No. The law does not require that such products be placed behind the counter; however, the prudent pharmacy will obviously monitor their stock of these products for any significant theft or disappearance, and take appropriate precautions as warranted.
- Q. I work in a pharmacy within a large supermarket where OTC cough and cold medications are often, even usually, sold at the front check-out lanes, rather than at the pharmacy counter. How can I control these sales?
- A. The pharmacist is not responsible for those sales. It is the responsibility of the retailer—the supermarket owner and operator—to ensure that the sales/reporting laws are followed, including restrictions on sales to minors, much as is required for and done with cigarette and alcohol sales.

Q. Who enforces the sales/reporting law, including the new provisions?

A. Primary enforcement and administration of the law is still done by the BNE; however, any violation of the sales/reporting laws by a licensee of the Board of Pharmacy is subject to citation, disciplinary action, or other action by the Board (because the Pharmacy Law provides that Board licensees may be disciplined, etc. for violations of controlled substances laws.)

Want a job with great benefits? Be a pharmacy inspector for the Board of Pharmacy

If you are an innovative, highly motivated individual who is looking for an exciting career that puts you on the front line of changes in the pharmacy practice, the Board of Pharmacy is looking for you! Applications for employment as a pharmacy inspector for the Board are accepted on an ongoing basis. You must be a registered pharmacist in California with two years' experience in the practice of pharmacy. You also must have a valid California driver's license.

The Board has inspector vacancies statewide and is seeking selfstarting pharmacists with experience in the new practice areas of pharmacy, such as automated drug dispensing, clinical case management, specialty clinic management, and patient education.

There are plenty of perks. Inspectors, under general direction, work from home offices where they are provided equipment (telephone, cell phone, computer, printer, fax machine), a state car, business and travel expense reimbursement, a salary range of \$5,085 - \$5,774 per month, and all the health and retirement benefits of state civil service.

To obtain an application, you may access the Internet at www.spb.ca.gov/jobgen/app.htm, and for general information, www.spb.ca.gov/bullback.htm. Or you may contact the Board at (916) 445-5014.

Your completed application and résumé should be mailed to:

Department of Consumer Affairs

P. O. Box 980428

West Sacramento CA 95798-0428

Attention: Human Resources

Pharmacy Manpower

Forum held in Sacramento

In September 1999, the Board of Pharmacy held a forum in Sacramento where more than 35 speakers expressed their opinions on whether there is a pharmacist shortage in California, and suggested ways to resolve pharmacystaffing issues. To allow interested parties in southern California to also participate, another forum was held at the Mission Inn in Riverside on January 25, 2000. This article summarizes only the comments made at the Sacramento meeting: the comments made at the Riverside meeting were not available in time to be included here, but will be detailed in the April issue of The Script.

All areas of the pharmacy profession were represented in Sacramento via written and/or oral comments: chain and individual pharmacies, pharmacist associations and unions, pharmacy schools and students, pharmacy attorneys, and individual pharmacists and pharmacy technicians.

There was a diversity of opinions expressed concerning the existence of a pharmacist shortage, and if such a shortage could be relieved through pharmacist licensure reciprocity with other states or by increasing the pharmacy technician/pharmacist ratio.

A frequent comment heard was that there is no actual shortage of pharmacists, but that the appearance of a shortage can be attributed to:



- * a reluctance of pharmacists to work 12-14 hour shifts with no breaks, weekend and evening hours with no additional compensation;
- * heavy third-party payer responsibilities for the pharmacist without commensurate compensation;
- * the preponderance of female pharmacists, many of whom are unavailable for full-time duty; and
- * an inability to recruit pharmacists to work in rural area pharmacies.

Chain pharmacy representatives

encouraged the Board to consider reciprocity of pharmacist licensure between California and other states to help relieve pharmacy-staffing problems. However, a large number of speakers were against reciprocity. A suggestion was made that instead of lowering California testing standards by reciprocating with other states, the Board might consider increasing the number of pharmacist licensure examinations given per year.

Some speakers suggested increasing the ratio of pharmacy technicians to pharmacists in community pharmacy settings.
Others stated that although increas-

ing the number of pharmacy technicians would appear to give the pharmacist more time to review patient medication profiles and perform patient consultation, it would actually add to their already supervisory-heavy responsibilities. Additionally, the point was made that better-trained pharmacy technicians are needed, and the Board was encouraged to raise pharmacy technician registration standards and standardize training programs.

Another area of concern was the third-party payer responsibilities of the pharmacist and the lack of sufficient reimbursement for those activities. To stay competitive, chain pharmacies often accept third-party payer contracts with reimbursement to the pharmacy so low that they often do not cover costs, much less provide a profit. One speaker suggested that the Board to propose legislation regulating such contracts. However, the Board has no jurisdiction over profit-making decisions by pharmacies unless laws are violated.

The Board wishes to express its gratitude to all those who participated in the Sacramento and Riverside forums. Many took time off from work and some traveled across the state to participate. Your ideas and opinions are important to the Board and are vital to any future regulations proposed by the Board.

Law Update

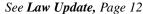
This article contains the exact language of additions and/or amendments to Chapter 9, Division 2 of the Business & Professions Code; Chapter 17, Title 16 of the California Code of Regulations; and Chapter 2, Division 10 of the Health & Safety Code; and others. Amended text is underlined, and asterisks indicate text that is unchanged and not included here.

For your convenience, these added and amended sections are included here so that they may be cut out and saved until the next publication of the Pharmacy Law.

Business & Professions Code

(New) 681. (a) Commencing July 1, 2000, every person licensed pursuant to this division who collects human biological specimens for clinical testing or examination, shall secure, or ensure that his or her employees, agents, or contractors secure, those specimens in a locked container when those specimens are placed in a public location outside of the custodial control of the licensee, or his or her employees, agents, or contractors. (b) Containers used for human biological specimens put into use on or after January 1, 2001, shall be marked "Caution: Biohazardous Material -Please Do Not Touch or Handle," or words of similar meaning. (c) This section shall not apply where the biological specimens have been placed in the mail in compliance with all applicable laws and regulations. (d) The licensing board having jurisdiction of the licensee may impose appropriate sanctions for violations of this section, including, if otherwise authorized by the licensing act, the imposition of a fine not to exceed one thousand dollars (\$1,000). (e) As used in this section, "locked container" means a secure container that is fully enclosed and locked by a padlock, key lock, combination lock, or similar locking device.

(New) 1220.5. (a) The Department of Health Services shall develop, and provide to all licensed clinical laboratories, a form in triplicate to be used by employees, agents, and couriers of licensed clinical laboratories to give notice when a specimen storage container has been improperly secured pursuant to Section 681. (b) The three copies of the triplicate form shall each contain instructions so that one copy is to be attached to the unlocked specimen storage container, one copy is mailed to the Department of Consumer Affairs to be forwarded to the appropriate licensing entity pursuant to Section 1288.3, and one copy is kept by the licensed clinical laboratory for its records. (c) This form





Continued from Page 11

shall be provided to all licensed clinical laboratories on and after January 1, 2001.

(New) 1288.3. (a) If a clinical laboratory employee, agent, or courier retrieves biological specimens located in a public place outside of the custodial control of a licensee, or his or her employee, agent, or contractor, and those specimens are not secured in a locked container, the clinical laboratory employee, agent, or courier, utilizing the form provided by the State Department of Health Services pursuant to Section 1220.5, shall (1) notify the licensee by attaching the appropriate copy of the form to the unlocked storage container, and (2) mail the appropriate copy of the form to the Department of Consumer Affairs. The Department of Consumer Affairs shall forward all forms received to the appropriate licensing entity. (b) This section shall not apply where the biological specimens have been received by mail in compliance with all applicable laws and regulations. (c) For purposes of this section: (1) "locked container" means a secure container that is fully enclosed and locked by a padlock, key lock, combination lock, or similar locking device. (2) "Licensee" means a person licensed pursuant to this division 2 (commencing with Section 500), who collects human biological specimens for clinical testing or examination. (d) A violation of this section is not subject to Section 1287. (e) This section shall become operative on January 1, 2001. Nothing in this section shall be construed to require clinical laboratory employees, agents, or couriers to notify licensees or the Department of Consumer Affairs of an unsecured specimen if the State Department of Health Services has not provided the appropriate forms.

(Amended) 2725.1. Notwithstanding any other provision of law, a registered nurse may dispense drugs or devices upon an order by a licensed physician and surgeon when 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 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 3.5 (commencing with Section 4063) of Chapter 9.

- (Amended) 2836.1 Neither this chapter nor any other provision of law shall be construed to prohibit a nurse practitioner from furnishing or ordering drugs or devices when all of the following apply:
- (a) The drugs or devices are furnished <u>or ordered</u> by a nurse practitioner in accordance with standardized procedures or protocols developed by the nurse practitioner and his or her supervising physician and surgeon under any of the following circumstances:
 - (1) When furnished <u>or ordered</u> incidental to the provision of family planning services.
 - (2) When furnished <u>or ordered</u> incidental to the provision of routine health care or prenatal care.
 - (3) When rendered to essentially healthy persons.
- (b) The nurse practitioner is functioning pursuant to standardized procedure, as defined by Section 2725, or protocol. The standardized procedure or protocol shall be developed and approved by the supervising physician and surgeon, the nurse practitioner, and the facility administrator or his or her designee.
- (c) The standardized procedure or protocol covering the furnishing of drugs or devices shall specify which nurse practitioners may furnish or order drugs or devices, which drugs or devices may be furnished or ordered, under what circumstances, the extent of physician and surgeon supervision, the method of periodic review of the nurse practitioner's competence, including peer review, and review of the provisions of the standardized procedure.
- (d) The furnishing or ordering of drugs or devices by a nurse practitioner occurs under physician and surgeon supervision. Physician and surgeon supervision shall not be construed to require the physical presence of the physician, but does include (1) collaboration on the development of the standardized procedure, (2) approval of the standardized procedure, and (3) availability by telephonic contact at the time of patient examination by the nurse practitioner.
- (e) For purposes of this section, no physician and surgeon shall supervise more than four nurse practitioners at one time.
- (f) Drugs or devices furnished <u>or ordered</u> by a nurse practitioner may include Schedule III through Schedule V controlled substances under the California Uniform Controlled Substances Act (Division 10 (commencing with

Section 11000) of the Health and Safety Code) and shall be further limited to those drugs agreed upon by the nurse practitioner and physician and surgeon and specified in the standardized procedure. When Schedule III controlled substances, as defined in Section 11056 of the Health and Safety Code, are furnished or ordered by a nurse practitioner, the controlled substances shall be furnished or ordered in accordance with a patient-specific protocol approved by the treating or supervising physician. A copy of the section of the nurse practitioner's standardized procedure relating to controlled substances shall be provided upon request, to any licensed pharmacist who dispenses drugs or devices, when there is uncertainty about the nurse practitioner furnishing the order.

- (g) The board has certified in accordance with Section 2836.3 that the nurse practitioner has satisfactorily completed (1) at least six month's physician and surgeon-supervised experience in the furnishing or ordering of drugs or devices and (2) 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 subdivision.
- (h) Use of the term "furnishing" in this section, in health facilities defined in subdivisions (b), (c), (d), (e), and (i) of Section 1250 of the Health and Safety Code, shall include (1) the ordering of a drug or device in accordance with the standardized procedure and (2) transmitting an order of a supervising physician and surgeon.
- (i) Nothing in this section, nor any other provision of law, shall be construed to authorize a nurse practitioner in solo practice to furnish drugs or devices, under any circumstances.
- (j) "Drug order" or "order" for purposes of this section means an order for medication which is dispensed to or for an ultimate user, issued by a nurse practitioner as an individual practitioner, within the meaning of Section 1306.02 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 nurse practitioners; and (3) the signature of a nurse practitioner 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.

(Amended) 2836.2. Furnishing or ordering of drugs or devices by nurse practitioners is defined to mean the act of making a pharmaceutical agent or agents available to the patient in strict accordance with a standardized procedure. All nurse practitioners who are authorized pursuant to Section 2831.1 to furnish or issue drug orders for controlled substances shall register with the United States Drug Enforcement Administration.

- (Amended) 3502.1. (a) In addition to the services authorized in the regulations adopted by the board, and except as prohibited by Section 3502, while under the supervision of a licensed physician and surgeon or physicians and surgeons approved by the board, a physician assistant may administer or provide medication to a patient, or transmit orally, or in writing on a patient's record or in a drug order, an order to a person who may lawfully furnish the medication or medical device pursuant to subdivisions (c) and (d). (1) A supervising physician and surgeon who delegates authority to issue a drug order to a physician assistant may limit this authority by specifying the manner in which the physician assistant may issue delegated prescriptions.
- (2) Each supervising physician and surgeon who delegates the authority to issue a drug order to a physician assistant shall first prepare and adopt a written, practice specific, formulary and protocols that specify all criteria for the use of a particular drug or device, and any contraindications for the selection. The drugs listed shall constitute the formulary and shall include only drugs that are appropriate for use in the type of practice engaged in by the supervising physician and surgeon. When issuing a drug order, the physician assistant is acting on behalf of and as an agent for a supervising physician and surgeon.
- (b) "Drug order" for purposes of this section means an order for medication which is dispensed to or for a patient, issued and signed by a physician assistant acting as an individual practitioner within the meaning of Section 1306.02 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 or order of the supervising physician, (2) all references to "prescription" in this code and the Health and Safety Code shall include drug orders issued by physician assistants pursuant to authority granted by their supervising physicians, and (3) the signature of a physician assistant on a drug order shall be deemed to be the signature of a prescriber for purposes of this code and the Health and Safety Code.

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- (c) A drug order for any patient cared for by the physician assistant that is issued by the physician assistant shall either be based on the protocols described in subdivision (a) or shall be approved by the supervising physician before it is filled or carried out.
- (1) A physician assistant shall not administer or provide a drug or issue a drug order for a drug other than for a drug listed in the formulary without advance approval from a supervising physician and surgeon for the particular patient. At the direction and under the supervision of a physician and surgeon, a physician assistant may hand to a patient of the supervising physician and surgeon a properly labeled prescription drug prepackaged by a physician and surgeon, manufacturer as defined in the Pharmacy Law, or a pharmacist.
- (2) A physician assistant may not administer, provide or issue a drug order for Schedule II through Schedule V controlled substances without advance approval by a supervising physician and surgeon for the particular patient.
- (3) Any <u>drug order issued</u> by a physician assistant shall be subject to a reasonable quantitative limitation consistent with customary medical practice in the supervising physician and surgeon's practice.
- (d) A written drug order issued pursuant to subdivision (a), except a written drug order in a patient's medical record in a health facility or medical practice, shall contain the printed name, address, and phone number of the supervising physician and surgeon, the printed or stamped name and license number of the physician assistant, and the signature of the physician assistant. Further, a written drug order for a controlled substance, except a written drug order in a patient's medical record in a health facility or a medical practice, shall include the federal controlled substances registration number of the physician assistant. The requirements of this subdivision may be met through stamping or otherwise imprinting on the supervising physician and surgeon's prescription blank to show the name, license number, and if applicable, the federal controlled substances number of the physician assistant, and shall be signed by the physician assistant. When using a drug order, the physician assistant is acting on behalf of and as the agent of a supervising physician and surgeon.
- (e) The medical record of any patient cared for by a physician assistant for whom the supervising physician and surgeon's drug order has been issued or carried out shall be reviewed and countersigned and dated by a supervising physician and surgeon within seven days.

- (f) All physician assistants who are authorized by their supervising physicians to issue drug orders for controlled substances shall register with the United States Drug Enforcement Administration (DEA).
- **4009** (This section was repealed and replaced with the following:) The board may not adopt or amend any rule or regulation that thereby would conflict with Section 1186 of the Labor Code.
- (Amended) 4022. "Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use, except veterinary drugs that are labeled as such, and includes the following: (a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.
- (b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a _____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.
- (c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.
- (Amended) 4040. (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 physician assistant or nurse practitioner who issues a drug order pursuant to Section 3512.1 or 2836.1.

(2) Issued by a physician, dentist, optometrist, podiatrist, or veterinarian, or, if a drug order is issued pursuant to Section 3502.1 or 2836.1, by a physician assistant or nurse practitioner licensed in this state. * * *

(New) 4040.5. "Reverse distributor" means every person who acts as an agent for pharmacies, drug wholesalers, manufacturers, and other entities by receiving, inventorying, and managing the disposition of outdated or nonsalable dangerous drugs.

(New) 4043. "Wholesaler" means and includes every person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, or agent, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022. Unless otherwise authorized by law, a wholesaler may not store, warehouse, or authorize the storage or warehousing of drugs with any person or at any location not licensed by the board.

The following contains only the amended portion of this section. The remaining portions of the section can be found in the Pharmacy Law book. The overall information contained in this section remains the same; however, the formatting was changed.

(Amended) 4052 (a) Notwithstanding any other provision of law, a pharmacist may: * * *

- (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 therapyrelated 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) 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 Section 4073.
- (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. * * *

(Amended) 4056. (a) Notwithstanding any provision of this chapter, a licensed hospital that contains 100 beds or fewer, and that does not employ a full-time pharmacist, may purchase drugs at wholesale for administration, under the direction of a physician, or for dispensation by a

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physician, to persons registered as inpatients of the hospital, to emergency cases under treatment in the hospital, <u>or</u>, <u>under the conditions described in subdivision (f)</u>, to <u>persons registered as outpatients in a rural hospital as defined in Section 124840 of the Health and Safety Code</u>. The hospital shall keep records of the kind and amounts of drugs so purchased and administered or dispensed, and the records shall be available for inspection by all properly authorized personnel of the board. ***

(f) A physician himself or herself may dispense drugs to outpatients directly pursuant to subdivision (a) only if the physician determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the physician reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensation to the patient within 30 minutes of the hospital pharmaceutical services or within a 30-mile radius from the hospital pharmaceutical services by means of the method of transportation the patient states that he or she intends to use. The quantity of drugs dispensed to any outpatient pursuant to this subdivision shall be limited to that amount necessary to maintain uninterrupted therapy during the period when pharmaceutical services outside the hospital are not readily available or accessible, but shall not exceed a 72-hour supply. The physician shall ensure that the label on the drug contains all the information required by Section 4076. ***

(Amended) 4060. 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 physician assistant pursuant to Section 3502.1 or a nurse practitioner pursuant to Section 2836.1. This section shall not apply to the possession of any controlled substance by a manufacturer, wholesaler, pharmacy, physician, podiatrist, dentist, veterinarian, physician assistant, or nurse practitioner, when in stock in containers correctly labeled with the name and address of the supplier or producer. Nothing in this section authorizes a nurse practitioner or a physician assistant to order his or her own stock of dangerous drugs and devices.

(Amended) 4061. 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 nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or

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 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.

(Amended) 4074. (a) A pharmacist shall inform a patient orally or in writing of the harmful effects of a drug dispensed by prescription if the drug poses substantial risk to the person consuming the drug when taken in combination with alcohol or if the drug may impair a person's ability to drive a motor vehicle, whichever is applicable, and provided the drug is determined by the board pursuant to subdivision (b) to be a drug or drug type for which this warning shall be given.

- (b) The board may by regulation require additional information or labeling.
- (c) This section shall not apply to drugs furnished to patients in conjunction with treatment or emergency services provided in health facilities or, except as provided in subdivision (d), to drugs furnished to patients pursuant to subdivision (a) of Section 4056.
- (d) A health facility shall establish and implement a written policy to ensure that each patient shall receive information regarding each medication given at the time of discharge and each medication given pursuant to subdivision (a) of Section 4056. This information shall include the use and storage of each medication, the precautions and relevant warnings, and the importance of compliance with directions. This information shall be given by a pharmacist or registered nurse, unless already provided by a patient's prescriber, and the written policy shall be developed in collaboration with a physician, a pharmacist, and a registered nurse. The written policy shall be approved by the medical staff. Nothing in this subdivision or any other provision of law shall be construed to require that only a pharmacist provide this consultation.

- (Amended) 4076. (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 nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or 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 <u>and</u>, <u>if applicable</u>, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or 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 nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or physician assistant who functions pursuant to Section 3502.1.

- (Amended) 4078. (a) (1) No person shall place a false or misleading label on a prescription. (2) No prescriber shall direct that a prescription be labeled with any information that is false or misleading.
- (b) Notwithstanding subdivision (a), a person may label a prescription, or a prescriber may direct that a prescription be labeled, with information about the drug that is false under either of the following circumstances: (1) If the labeling is a necessary part of a clinical or investigational drug program approved by the federal Food and Drug Administration or a legitimate investigational drug project involving a drug previously approved by the federal Food and Drug Administration. (2) If, in the medical judgment of the prescriber, the labeling is appropriate for the proper treatment of the patient.
- (c) The furnisher of a prescription labeled pursuant to subdivision (b) shall make, and retain for three years from the date of making, a record stating the manner in which the information on the prescription label varies from the actual drug in the container and documenting the order of the prescriber to so label the container. The prescriber shall make, and retain for at least three years, a record of his or her order to so label the container.
- (Amended) 4102. Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures. 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, and (b) clinical laboratory tests that are classified as waived or moderate 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) and paragraph (13) of subdivision (b) of Section 1206.5. A pharmacist performing these functions shall, at the direction of the patient, report the results obtained from a blood test to the patient and the patient's physician of choice. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.
- (New) 4115 * * * (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

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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). * * *

(Amended) 4115.5.* ** (d) An externship in which a pharmacy technician trainee may participate as described in subdivision (a) shall be for a period of no more than six consecutive months in a community pharmacy and for a total of no more than 12 months if the externship involves rotation between a community and hospital pharmacy. The externship shall be completed while the trainee is enrolled in a course of instruction at the institution. * * *

(New) 4170.*** (8) 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.

(Amended) 4174. Notwithstanding any other provision of law, a pharmacist may dispense drugs or devices upon the drug order of a nurse practitioner functioning pursuant to Section 2836.1 or a certified nurse midwife functioning pursuant to Section 2746.51, a drug order of a physician assistant functioning pursuant to Section 3502.1, or the order of a pharmacist acting under Section 4052.

(Amended) 4175. (a) The California State Board of Pharmacy shall promptly forward to the appropriate licensing entity, including the Medical Board of California, the Board of Dental Examiners 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, 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, nurse practitioners, or physician assistants pursuant to Section 4170 shall be handled by the Medical Board of California, the Board of Dental Examiners of California, the State Board of Optometry, the Osteopathic

Medical Board of California, the <u>Board of Registered</u> <u>Nursing</u>, or the Physician Assistant Committee as a case of greatest potential harm to a patient.

(Amended) 4202. (a) An applicant for registration as a pharmacy technician shall be issued a certificate of registration if he or she is a high school graduate or possesses a general education development equivalent, and meets any one of the following requirements: (1) Has obtained an Associate of Arts degree in a field of study directly related to the duties performed by a pharmacy technician.

- (2) Has completed a course of training specified by the board.
- (3) Is eligible to take the board's pharmacist licensure examination, but has not been licensed by the board as a pharmacist. Once licensed as a pharmacist, the pharmacy technician registration is no longer valid and the pharmacy technician certificate of registration must be returned to the board within 15 days.
- (4) Has provided satisfactory proof to the board of one year's experience performing the tasks specified in subdivision (a) of Section 4115 while employed or utilized as a pharmacy technician to assist in the filling of prescriptions for an inpatient of a hospital, for an inmate of a correctional facility, or experience deemed equivalent by the board. * * *
- (Amended) 4402. (a) Any pharmacist license that is not renewed within three years following its expiration may not be renewed, restored, or reinstated and shall be canceled by operation of law at the end of the three-year period. * * *
- (e) Any other license issued by the board <u>may</u> be canceled by the board if the license is not renewed within 60 days after its expiration. Any license canceled under this subdivision may not be reissued. Instead, a new application will be required.
- (New) 4425. (a) As a condition of a pharmacy's participation in the Medi-Cal program pursuant to Chapter 7 (commencing with Section 14000) of Division 9 of the Welfare and Institutions Code, the pharmacy, upon presentation of a valid prescription for the patient and the patient's Medicare card, shall charge Medicare beneficiaries a price that does not exceed the Medi-Cal reimbursement rate for prescription medicines, and an amount, as set by the State Department of Health Services to cover electronic transmission charges. However, Medicare beneficiaries shall not be allowed to use the Medi-Cal

reimbursement rate for over-the-counter medications or compounded prescriptions. (b) The State Department of Health Services shall provide a mechanism to calculate and transmit the price to the pharmacy, but shall not apply the Medi-Cal drug utilization review process for purposes of this section. (c) The State Department of Health Services shall monitor pharmacy participation with the requirements of subdivision (a) and report to the Legislature annually on that participation. The report shall include, but shall not be limited to, information on any pharmacies that discontinue participation in the Medi-Cal program, and the reasons given for the discontinuance. (d) If prescription drugs are added to the scope of benefits available under the federal Medicare program, the Senate Office of Research shall report that fact to the appropriate committees of the Legislature. It is the intent of the Legislature to evaluate the need to continue the implementation of this article under those circumstances.

(New) 4426. The State Department of Health Services shall conduct a study of the adequacy of Medi-Cal pharmacy reimbursement rates including the cost of providing prescription drugs and services.

(New) 4427. This article shall remain in effect only until January 1, 2003, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2003, deletes or extends that date.

Health & Safety Code

(Amended) 11100. (a) Any manufacturer, wholesaler, retailer, or other person in this state who sells, transfers, or otherwise furnishes any of the following substances to any person or business entity in this state or any other state shall submit a report to the Department of Justice of all of those transactions: (1) Phenyl-2-propanone. * * * (34) Gamma-butyrolactone. * * *

- (c) (1) Any manufacturer, wholesaler, retailer, or other person in this state, prior to selling, transferring, or otherwise furnishing any substance specified in subdivision (a) to any person or business entity in this state or any other state, shall require
 - (A) a letter of authorization from that person or business entity that includes the currently valid business license number or federal Drug Enforcement Administration (DEA) registration number, the address of the business, and a full description of how the substance is to be used, and

- (B) proper identification from the purchaser. The requirement for a full description of how the substance is to be used does not require the person or business entity to reveal their chemical processes that are typically considered trade secrets and proprietary information. * * *
- (e) This section shall not apply to any of the following:
 - (1) Any pharmacist or other authorized person who sells or furnishes a substance upon the prescription of a physician, dentist, podiatrist, or veterinarian.
 - (2) Any physician, dentist, podiatrist, or veterinarian who administers or furnishes a substance to his or her patients.
 - (3) Any manufacturer licensed by the State Department of Health Services or wholesaler licensed by the California State Board of Pharmacy who sells, transfers, or otherwise furnishes a substance to a licensed pharmacy, physician, dentist, podiatrist, veterinarian, or retail distributor as defined in subdivision (h), provided that the manufacturer or wholesaler submits records of any suspicious sales or transfers as determined by the Department of Justice.
 - (4) (A) Any sale, transfer, furnishing, or receipt of any drug which contains ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine and which is lawfully sold, transferred, or furnished over the counter without a prescription pursuant to the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) or regulations adopted thereunder. However, this section shall apply to preparations in solid or liquid dosage form, except pediatric liquid forms, as defined, containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine where the individual transaction involves more than three packages or nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, norpseudoephedrine, or phenylpropanolamine. * *
- (g) (1) Except as otherwise provided in subparagraph (A) of paragraph (4) of subdivision (e), it is unlawful for any manufacturer, wholesaler, retailer, or other person to sell, transfer, or otherwise furnish a substance specified in subdivision (a) to a person under 18 years of age.
 - (2) Except as otherwise provided in subparagraph (A) of paragraph (4) of subdivision (e), it is unlawful for any person under 18 years of age to possess a substance specified in subdivision (a).

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- (3) Notwithstanding any other law, it is unlawful for any retail distributor to (i) sell in a single transaction more than three packages of a product that he or she knows to contain ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, or (ii) knowingly sell more than nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, other than pediatric liquids as defined. Except as otherwise provided in this section, the three package per transaction limitation or nine gram per transaction limitation imposed by this paragraph shall apply to any product that is lawfully sold, transferred, or furnished over the counter without a prescription pursuant to the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.), or regulations adopted thereunder, unless exempted from the requirements of the federal Controlled Substances Act by the federal Drug **Enforcement Administration pursuant to Section** 814 of Title 21 of the United States Code.
- (4) A violation of this subdivision is a misdemeanor.(h) For the purposes of this article, the following terms have the following meanings:
 - "Drug store" is any entity described in Code 5912 of the Standard Industrial Classification (SIC)
 Manual published by the United States Office of Management and Budget, 1987 edition.
 - (2) "General merchandise store" is any entity described in Codes 5311 to 5399, inclusive, and Code 5499 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.
 - (3) "Grocery store" is any entity described in Code 5411 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.
 - (4) "Pediatric liquid" means a nonencapsulated liquid whose unit measure according to product labeling is stated in milligrams, ounces, or other similar measure. In no instance shall the dosage units exceed 15 milligrams of phenylpropanolamine or pseudoephedrine per five milliliters of liquid product, except for liquid products primarily intended for administration to children under two years of age for which the recommended dosage unit does not exceed two milliliters and the total package content does not exceed one fluid ounce.

- (5) "Retail distributor" means a grocery store, general merchandise store, drugstore, or other related entity, the activities of which, as a distributor of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products, are limited exclusively to the sale of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products for personal use both in number of sales and volume of sales, either directly to walkin customers or in face-to-face transactions by direct sales. "Retail distributor" includes an entity that makes a direct sale, but does not include the parent company of that entity if the company is not involved in direct sales regulated by this
- (6) "Sale for personal use" means the sale in a single transaction to an individual customer for a legitimate medical use of a product containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine in dosages at or below that specified in paragraph (3) of subdivision (g). "Sale for personal use" also includes the sale of those products to employers to be dispensed to employees from first-aid kits or medicine chests.
- (i) It is the intent of the Legislature that this section shall preempt all local ordinances or regulations governing the sale by a retail distributor of over-the-counter products containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine.
- (Amended) 11106. (a) (1) Any manufacturer, wholesaler, retailer, or any other person or business entity in this state who sells, transfers, or otherwise furnishes any substance specified in subdivision (a) of Section 11100 to a person or business entity in this state or any other state or who obtains from a source outside of the state any substance specified in subdivision (a) of Section 11100 shall submit an application to, and obtain a permit for the conduct of that business from, the Department of Justice. An intracompany transfer does not require a permit if the transferor is a permittee. Transfers between company partners or between a company and an analytical laboratory do not require a permit if the transferor is a permittee and a report as to the nature and extent of the transfer is made to the Department of Justice pursuant to Section 11100 or 11100.1. This paragraph shall not apply to any manufacturer, wholesaler, retailer, or other person who is licensed by either the State Department of Health Services or the California State Board of Pharmacy, and is also registered

with the federal Drug Enforcement Administration of the United States Department of Justice.

- (2) Except as provided in paragraph (3), no permit shall be required of any manufacturer, wholesaler, retailer, or other person for the sale, transfer, furnishing, or obtaining of any product which contains ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine and which is lawfully sold, transferred, or furnished over the counter without a prescription or by a prescription pursuant to the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) or regulations adopted thereunder.
- (3) A permit shall be required for the sale, transfer, furnishing, or obtaining of preparations in solid or liquid dosage form containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, unless (A) the transaction involves the sale of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products by retail distributors as defined by this article over the counter and without a prescription, or (B) the transaction is made by a person or business entity exempted from the permitting requirements of this subdivision under paragraph (1).
- (b) The department shall provide application forms, which are to be completed under penalty of perjury, in order to obtain information relating to the identity of any applicant applying for a permit, including, but not limited to, the business name of the applicant or the individual name, and if a corporate entity, the names of its board of directors, the business in which the applicant is engaged, the business address of the applicant, a full description of any substance to be sold, transferred, or otherwise furnished or to be obtained, the specific purpose for the use, sale, or transfer of those substances specified in subdivision (a) of Section 11100, the training, experience, or education relating to this use, and any additional information requested by the department relating to possible grounds for denial as set forth in this section, or by applicable regulations adopted by the department. The requirement for the specific purpose for the use, sale, or transfer of those substances specified in subdivision (a) of Section 11100 does not require an applicant or permittee to reveal their chemical processes that are typically considered trade secrets and proprietary business information.
- (c) Applicants and permittees shall authorize the department, or any of its duly authorized representatives, as a condition of being permitted, to make any examination of the books and records of any applicant, permittee, or other person, or visit and inspect the business premises of any

- applicant or permittee during normal business hours, as deemed necessary to enforce this chapter.
- (d) An application may be denied, or a permit may be revoked or suspended, for reasons which include, but are not limited to, the following:
- (1) Materially falsifying an application for a permit or an application for the renewal of a permit.
- (2) If any individual owner, manager, agent, representative, or employee for the applicant who has direct access, management, or control for any substance listed under subdivision (a) of Section 11100, is or has been convicted of a misdemeanor or felony relating to any of the substances listed under subdivision (a) of Section 11100, any misdemeanor drug-related offense, or any felony under the laws of this state or the United States. * * *
 - (8) If any individual owner, manager, agent, representative, or employee for the applicant who has direct access, management, or control for any substance listed under subdivision (a) of Section 11100, willfully violates or has been convicted of violating, any federal, state, or local criminal statute, rule, or ordinance regulating the manufacture, maintenance, disposal, sale, transfer, or furnishing of any of those substances.
 - (e) Notwithstanding any other provision of law, an investigation of an individual applicant's qualifications, or the qualifications of an applicant's owner, manager, agent, representative, or employee who has direct access, management, or control of any substance listed under subdivision (a) of Section 11100, for a permit may include review of his or her summary criminal history information pursuant to Sections 11105 and 13300 of the Penal Code, including, but not limited to, records of convictions, regardless of whether those convictions have been expunged pursuant to Section 1204.5 of the Penal Code, and any arrests pending adjudication. * * *

(Amended) 11026 "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

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of Part 3 of Division 107, 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. **

(Amended) 11150 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 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 out-of-state prescriber acting pursuant to Section 4005 of the Business and Professions Code shall write or issue a prescription.

(Amended) 11165 (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds, establish the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II controlled substances by all practitioners authorized to prescribe or dispense these controlled substances. CURES shall be implemented as a pilot project, commencing on July 1, 1997, to be administered concurrently with the existing triplicate prescription process, to examine the comparative efficiencies between the two systems. * * *

(c) The Department of Justice, in consultation with the Board of Pharmacy, shall submit a report to the Legislature by January 1, 1999, with annual updates also due January 1, 2000, 2001, and 2002, on the CURES pilot project. Specifically, these reports shall assess the ability of CURES to provide complete, accurate, and timely data on Schedule II controlled substances prescribed and dispensed in California, the effectiveness of this information in investigating and prosecuting individuals suspected of diversion activities, and the feasibility of replacing the current triple-copy prescription form with a single-copy

serialized prescription form to reduce existing administrative burdens. Further, the report shall make recommendations regarding the replacement of the existing triplicate prescription process with CURES, and funding alternatives for ongoing system support. * * *

(e) This section shall become inoperative on July 1, 2003, and, as of January 1, 2004, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2004, deletes or extends the dates on which it becomes inoperative and is repealed.

California Code of Regulations

(New) 1714.1 Pharmacy Operations During the Temporary Absence of a Pharmacist

This section is to ensure that pharmacists are able to have duty free breaks and meal periods to which they are entitled under Section 512 of the Labor Code and the orders of the Industrial Welfare Commission, without unreasonably impairing the ability of a pharmacy to remain open.

(a) In any pharmacy that is staffed by a single pharmacist, the pharmacist may leave the pharmacy temporarily for breaks and meal periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy and removing ancillary staff from the pharmacy if the pharmacist reasonably believes that the security of the dangerous drugs and devices will be maintained in his or her absence.

If in the professional judgment of the pharmacist, for reasons of security or otherwise, the pharmacist determines that the pharmacy should close during his or her absence, then the pharmacist shall close the pharmacy and remove all ancillary staff from the pharmacy during his or her absence.

- (b) During the pharmacist's temporary absence, no prescription medication may be provided to a patient or to a patient's agent unless the prescription medication is a refill medication that the pharmacist has checked, released for furnishing to the patient and was determined not to require the consultation of a pharmacist.
- (c) During such times that the pharmacist is temporarily absent from the pharmacy, the ancillary staff may continue to perform the non-discretionary duties authorized to them by pharmacy law. However, any

- duty performed by any member of the ancillary staff shall be reviewed by a pharmacist upon his or her return to the pharmacy.
- (d) During the temporary absence of a pharmacist as authorized by this section, an intern pharmacist shall be considered ancillary staff, and may not perform any discretionary duties nor otherwise act as a pharmacist.
 - (e) In pharmacies where there are two or more pharmacists on duty, the pharmacists shall stagger their breaks and meal periods so that the pharmacy is not left without a pharmacist for a temporary period.
 - (f) The temporary absence authorized by this section shall be limited to the minimum period authorized for pharmacists by section 512 of Labor Code or orders of the Industrial Welfare Commission, and any meal shall be limited to 30 minutes. The pharmacist who is on break shall not be required to remain in the pharmacy area during the break period.
 - (g) The pharmacy shall have written policies and procedures regarding the operations of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods. The policies and procedures shall include the authorized duties of ancillary staff, the pharmacist's responsibilities for checking all work performed by ancillary staff and the pharmacist's responsibility for maintaining the security of the pharmacy. The policies and procedures shall be open to inspection by the board or its designee at all times during business hours.
- (h) A pharmacist who takes a break in compliance with this section shall not be subject to California State Board of Pharmacy disciplinary action or board citation for acts that he or she did not authorize and that he or she, by the exercise of reasonable care, could not have prevented during his or her absence.

(New) 1748.3 Medical Device Retailer Location Restriction

- (a) No person shall conduct a medical device retailer in California from a private residence.
- (b) A warehouse owned by a medical device retailer, the primary purpose of which is storage, not dispensing of dangerous devices to patients, shall not be located at a private residence.

(New) 1783 Manufacturer or Wholesaler Furnishing Drugs and Devices

- (a) A manufacturer or wholesaler shall furnish dangerous drugs or devices only to an authorized person; prior to furnishing dangerous drugs and devices to a person not known to the furnisher, the manufacturer or wholesaler shall contact the board or, if the person is licensed or registered by another government entity, that entity, to confirm the recipient is an authorized person.
- (b) "Authorized person" means a person to whom the board has issued a permit which enables the permit holder to purchase dangerous drugs or devices for use within the scope of its permit. "Authorized person" also means any person in this state or in another jurisdiction within the United States to the extent such furnishing is authorized by the law of this state, any applicable federal law, and the law of the jurisdiction in which that person is located. The manufacturer or wholesaler furnishing to such person shall, prior to furnishing the dangerous drugs and devices, establish the intended recipient is legally authorized to receive the dangerous drugs or devices.
- (c) Dangerous drugs or devices furnished by a manufacturer or wholesaler shall be delivered only to the premises listed on the permit; provided that a manufacturer or wholesaler may furnish drugs to an authorized person or an agent of that person at the premises of the manufacturer or wholesaler if (1) the identity and authorization of the recipient is properly established and (2) this method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person. Dangerous drugs or devices may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the dangerous drugs or devices so received. Any discrepancy between the receipt and the type and quantity of dangerous drugs and devices actually received shall be reported to the delivering manufacturer or wholesaler by the next business day after the delivery to the pharmacy receiving area.
- (d) A manufacturer or wholesaler shall not accept payment for or allow the use of an entity's credit to establish an account for the purchase of dangerous drugs or devices from any person other than: (1) the owner(s) of record, chief executive officer, or chief

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financial officer listed on the permit for the authorized person; and (2) on an account bearing the name of the permittee.

(e) All records of dangerous drugs or devices furnished by a manufacturer or wholesaler to an authorized person shall be preserved by the authorized person for at least three years from the date of making and shall, at all times during business hours, be open to inspection by authorized officers of the law at the licensed premises. The manufacturer or wholesaler shall also maintain all records of dangerous drugs or devices furnished pursuant to this section for at least three years from the date of making and shall, at all times during business hours, keep them open to inspection by authorized officers of the law at the premises from which the dangerous drugs or devices were furnished.

Labor Code

(New) 1186 A person employed in the practice of pharmacy is not exempt from coverage under any provision of the orders of the Industrial Welfare Commission unless he or she individually meets the criteria established for exemption as executive or administrative employees. No person employed in the practice of pharmacy may be subject to any exemption from coverage under the orders of the Industrial Welfare Commission established for professional employees.

Welfare and Institutions Code

(New) 14105.337 (a) Effective January 1, 2000, the department shall increase reimbursement to pharmacists by twenty-five cents (\$.25) per prescription for all drug prescription claims reimbursed through the Medi-Cal program. (b) Effective July 1, 2002, the department shall increase reimbursement to pharmacists by an additional fifteen cents (\$.15) per prescription for all drug prescription claims reimbursed through the Medi-Cal program.



Disciplinary Actions by the Board

PHARMACISTS/PHARMACIES

JEROME PIEPMEYER, RPH 27303, Davenport, CA

Violation: For purposes of settlement only, respondent admitted that shortages of a controlled substance occurred during his tenure as pharmacist-in-charge (PIC) at Dominican Santa Cruz Hospital Pharmacy.

Action: Revoked, stayed; three years'

probation to 11/30/00

Effective: December 1, 100

Effective: December 1, 1997

CARLYLE WASHBURN, RPH 24637, Watsonville, CA

Violation: For purposes of settlement only, respondent admitted that shortages of a controlled substance occurred during his tenure as PIC at Dominican Santa Cruz Hospital Pharmacy.

Action: Revoked, stayed; three years' probation to 11/30/00; may not be PIC

Effective: December 1, 1997

DOMINICAN SANTA CRUZ HOSPITAL, HSP 14013, Santa Cruz, CA

Violation: For purposes of settlement only, respondent admitted that shortages of a controlled substance occurred at the pharmacy.

Action: Revoked, stayed; three years' probation to 11/30/00; maintain weekly perpetual inventory of all Schedule II and III controlled substances; payment of \$10,326 costs

Effective: December 1, 1997

SAFEWAY PHARMACY #1192, PHY 36014, Concord, CA

Violation: For purposes of settlement only, respondent admitted to failing to notify either the DEA or Board of Pharmacy of employee's diversion/theft of controlled substance.

Action: Revoked, stayed; three years' probation, one day's suspension of operation; provide free community service; payment of \$5,553 in costs

Effective: October 20, 1998

YOUNG MI JUNG, RPH 41568, Cupertino, CA

Violation: For purposes of settlement only, respondent admitted she was convicted of a

crime for violation of Penal Code (PC) 666, petty theft with prior conviction for theft; PC 484/488, petty theft; and 273a(1), child endangerment.

Action: Revoked, stayed; two years' probation; psychiatric evaluation; may not be PIC, supervisor or preceptor of interns; payment of \$1,409 costs

Effective: October 20, 1998

JACK WELBY PARKER, JR., RPH 24562, Martinez, CA

Violation: For purposes of settlement only, respondent admitted to administering and furnishing controlled substances to himself without a prescription or authorization and obtaining a controlled substance from employer by fraud, deceit, or subterfuge.

Action: Revoked, stayed; five years' probation; 45 days' suspension; mandatory participation in the Pharmacist Recovery Program with random fluid testing; abstain from alcohol and drug use; no ownership or beneficial interest in any entity licensed by the Board; may not be PIC, supervisor, or preceptor of interns; payment of \$2,500 in costs

Effective: October 22, 1998

PRYDE MANGA FONBAH, RPH 47835, Fresno, CA

Violation: Deviating from the requirements of a prescription without the prior consent of the prescriber.

Action: Revoked, stayed; two years' probation; may not be PIC, supervisor, or preceptor of interns; take and pass law exam within one year of decision date; no ownership or interest in any business licensed by the Board; payment of \$4,000 in costs

Effective: October 23, 1998

ARSEN MIKRTCHYN, RPH 44841, Glendale, CA and SUNSET PHARMACY and 1/2 HR. PHOTO, PHY 37937, Los Angeles, CA

Violation: For purposes of settlement only, respondents admitted to having a significant shortage of drugs and failing to have adequate policies and procedures for maintaining records of dangerous drug

disposition to detect drug losses pursuant to the responsibilities of a PIC.

Action: RPH-90 days' suspension, stayed; one year's probation; may not supervise or be a preceptor of interns; may be a PIC, but must retain an independent consultant to review pharmacy operations; payment of \$5,000 in costs. PHY-90 days' suspension, stayed; one year's probation

Effective: October 24, 1998

BENNY MAGDAEL, RPH 31933, Stockton, CA

Violation: Ordering controlled substances without authorization or medical indications; trading the drugs for street cocaine for self-use; altering a DEA controlled substance registration certificate for shipping drugs to him; failing to maintain controlled substance inventory records; being convicted of possession of a controlled substance; and failing to notify the Board of his termination as PIC.

Action: Revoked; payment of \$4,765.37 in

COSIS

Effective: October 24, 1998

GENE R. YONEMOTO, RPH 27503, Whittier, CA

Violation: Helping to secure registration for a pharmacy technician by making a false representation.

Action: Letter of Reproval; payment of

\$1,425.25 in costs

Effective: October 28, 1998

JOSEPH THOMAS KUSCHELL, JR., RPH 29081, Redding, CA

Violation: Through a stipulated settlement, respondent admitted to falsifying documents and filling prescriptions for dangerous drugs for self-use and taking said filled prescriptions without payment; unlawfully taking money and personal property; falsifying affidavit for employee to register as a pharmacy technician.

Action: Revoked, stayed; three years' probation; 60 days' suspension beginning January 1, 1999; take and pass law section of the licensure examination; if recommended by a psychiatrist or psychotherapist, the respondent shall undergo psycho-

Disciplinary Actions

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therapy at respondent's expense; may not be PIC; payment of \$6,000 in costs **Effective:** December 4, 1998

RONALD STANTON DEPPER, RPH 20816, Los Alamitos, CA

Violation: For purposes of settlement, respondent admitted to being convicted of a crime of grand theft of pharmacy items, nonprescription drugs, and at least one prescription drug.

Action: Revoked, stayed; 30 days' suspension; take and pass law section of the licensure examination within six months; no ownership or interest in any business licensed by the Board; payment of \$1,923.25 in costs

Effective: December 4, 1998

KIRK C. BOLAS, RPH 45427, Auburn, CA

Violation: Issuing false prescriptions for unknown quantities of a controlled substance for personal use; making false statements in prescriptions by using fictitious information; and taking unknown quantities of drugs from employer for respondent's own use.

Action: Revoked

Effective: December 4, 1998

ROBERT STEPHEN OLSEN, RPH 29784, Covina, CA

Violation: Allowing a nonpharmacist access to controlled substances which allowed theft of controlled substances by a technician, and failing to inventory and audit controlled substances and notify the Board of the theft.

Action: Revoked, stayed; three years' probation; 45 days' suspension; share payment of \$19,656.18 in costs with Armando M. Chacon

Effective: December 11, 1998

ARMANDO MATA CHACON, RPH 28976, San Gabriel, CA

Violation: Allowing a nonpharmacist access to controlled substances which allowed theft of controlled substances by a technician and failing to inventory and audit controlled substances and notify the Board of the theft.

Action: Revoked, stayed; 60 days' suspension; three years' probation; share payment of \$19,656.18 in costs with Robert S. Olsen

Effective: December 11, 1998

VITO DOMINIC FABRIZIO, RPH 25019, Lodi, CA

Violation: Furnishing excessive amounts of controlled substances to another person. Action: Revoked, stayed; five years' probation; 90 days' suspension; may continue as PIC at K-Mart #7486, but cannot be a preceptor or supervise intern pharmacists; retain an independent consultant for review of pharmacy operations; no ownership or interest in any business licensed by the Board; payment of \$18,832.10 in costs

Effective: January 3, 1999

SAINT JOSEPH HOSPITAL PHAR-MACY, HSP 3169, Orange, CA

Violation: While denying guilt of allegations of failing to prepare and maintain proper records and to train and/or supervise a technician with respect to compounding, respondent understands that this public reproval constitutes disciplinary action against the license by the Board.

Action: Letter of Reprimand; payment of

\$8,000 in costs

Effective: January 20, 1999

JOSEPH I. SKURO, RPH 14753, Tarzana, CA

Violation: For purposes of settlement only, the respondent admitted to failing to consult; dispensing medication in a container that was not childproof; and repackaging prescription medications improperly labeled.

Action: 90 days' suspension, stayed; one year's probation; may not supervise or be a preceptor of interns or serve as PIC of any pharmacy licensed by the Board; payment of \$1,500 in costs

Effective: January 20, 1999

JAYNE RITZ, RPH 40419, Laguna Beach, CA

Violation: Being convicted of crimes which included knowingly making a false

statement or misrepresentation for the purpose of obtaining workers compensation insurance benefits and failing to submit satisfactory proof of continuing education for license renewal.

Action: Revoked

Effective: February 13, 1999

BEOM MO ANH, RPH 36388, Canoga Park, CA and VALLEY PHARMACY, PHY 30560, Reseda, CA

Violation: For purposes of settlement only, respondents admitted to failing to account for acquisition and disposition of dangerous drugs and controlled substances; excessive furnishing of dangerous drugs without prescriptions; storing dangerous drugs and controlled substances in an unsecured and unlicensed location; and storing drugs requiring refrigeration in a nonrefrigerated bin.

Action: RPH and PHY both revoked; payment of \$11,510 in costs prior to granting reinstatement or issuance of any license

Effective: February 20, 1999

DIEU HUYEN VO, RPH 47458, San Diego, CA

Violation: For purposes of settlement only, respondent admitted to failing to maintain and produce records of drugs ordered and dispensed.

Action: Six months' suspension, stayed; one year's probation; pass pharmacy law exam; payment of \$1,000 in costs

Effective: February 20, 1999

PHARMACY INTERNS

MICHAEL WILLIAM BARBER, INT 4015, Redding, CA

Violation: Obtaining, possessing, and using alcohol, marijuana, and cocaine. **Action:** Revoked; payment of \$5,472.25 in

costs

Effective: December 24, 1998

PHARMACY TECHNICIANS

SONDRA IMANI DOUGLAS, TCH 11225, Bakersfield, CA

Violation: Convicted of delivering a package containing marijuana for mailing. Action: Revoked, stayed; one year's probation; take and pass the Pharmacy Technician Certification Board examination; abstain from the use of controlled substances and dangerous drugs and from association with those who use controlled substances

Effective: October 22, 1998

BRIAN DAVID GLOBERMAN, TCH 5288, Los Angeles, CA

Violation: Securing a pharmacy technician registration by making a false statement. Action: Letter of Reproval; payment of

\$1,450 in costs

Effective: October 28, 1998

ELISA NICOLE CORREA. TCH 18992, Red Bluff, CA

Violation: In a stipulated settlement, respondent admitted to submitting to the Board a false certification of hours worked to be registered as a pharmacy technician. Action: Revoked; payment of \$1,195 in costs

Effective: December 4, 1998

STEPHANIE ANN BOYLE, TCH 6276, Oceanside, CA

Violation: Possessing and being under the influence of methamphetamine, a controlled substance.

Action: Revoked

Effective: January 20, 1999

JEFFREE STITH BROWN, TCH 16480, San Jose, CA

Violation: Attempting to purchase an illegal drug and convicted of driving under the influence of alcohol or drugs.

Action: Revoked; payment of \$2,921.25 in

Effective: February 13, 1999

STATEMENT OF ISSUES

EARL STROTMAN, Long Beach, CA, applicant for exemption certificate

Violation: Being convicted of crimes substantially related to the qualifications, functions, or duties of the holder of an exemption certificate.

Action: Application denied Effective: October 1, 1998

VOLUNTARY SURRENDER OF LICENSE

GREGGORY LEE QUICK, TCH 4770, Yuba City, CA

Violation: For purposes of settlement only, respondent admitted to failing to have a pharmacist check his repackaging work which resulted in patient injury. **Action:** Voluntary surrender of his pharmacy technician registration; not

permitted to practice as a pharmacy technician in California

Effective: January 20, 1999

IN-PHARM, INC. dba IN-PHARM, PHY 40793, Escondido, CA and RES PHARM, INC. dba RES PHARM, PHY 40809, Fallbrook, CA

Violation: While not admitting guilt of accusations of securing a license for pharmacy, but actually conducting a wholesale business; submitting false and misleading statements on application; failing to produce pharmacies' records; and allowing nonpharmacists to sell dangerous drugs to third parties. against her licenses, respondent agreed that surrender of the licenses constitutes disciplinary action against the licenses by the Board.

Action: Voluntary surrender of licenses, payment of \$10,000 in costs prior to granting reinstatement of pharmacy or issuance of any license

Effective: February 20, 1999



Explanation of Disciplinary Language

- 1. Revoked means the license is canceled, voided, annulled, rescinded. The right to practice or operate a Board of Pharmacylicensed business is ended.
- 2. Revoked, stayed; 60 days' suspension; three years' probation-"Stayed" means the revocation is postponed, put off. Professional practice or operation may continue so long as the licensee complies with specified probationary terms and conditions, which in this example includes 60 days' actual suspension from practice or operation. Violation of probation may result in the lifting of the stay and the implementation of the revocation that was stayed.
- 3. Stipulation indicates a form of "plea-bargaining." The case is negotiated and settled prior to hearing (similar to an "out-of-court settlement" in civil court).
- 4. Voluntary Surrender of *License*-The licensee returns his or her license to the Board, subject to specific conditions of surrender and acceptance by the Board
- 5. *Effective* indicates the date the disciplinary decision goes into operation.
- 6. Statement of Issues refers to the initial or accusatory pleading (filed by the Board) which commences the administrative procedure for denial of licensure to an applicant.
- 7. Letter of Reprimand (or Reproval) is a public document reproving a licensee for violations of Pharmacy Law.

California Counts Census 2000

Every 10 years the Census Bureau is required by the U.S. Constitution to count every person in the United States. In mid-March, you will be mailed the official census questionnaire, and April 1, 2000 is Census Day. The census is one of America's most significant historical events. Thomas Jefferson was responsible for the first census conducted in 1790, so this coming March and April you will be participating in the 22nd census of the United States.

The census is important. Census information about the population of your community and the State of California is used to make major decisions, including expenditures and services for businesses, shopping centers, roads, and schools. In the previous census in 1990, California had the largest "undercount" (people missed by the census) compared to all other states in the nation. As a result, we lost an estimated \$2.2 billion in federal funds that rightfully should have been spent in California, primarily on health care for the elderly.

If Californians do not fully participate in the 2000 census, we could lose over \$3 billion in federal funds during the next decade. Because of the seriousness of the problem, Governor Davis signed legislation to promote the census throughout California. In addition, Governor Davis appointed a task force, the California Complete Count Committee, to help maximize the number of Californians counted in the 2000 census.

The census is safe. Your census information is absolutely 100% confidential. The U.S. Census Bureau is strictly prohibited from sharing personal census information with any other individuals or organizations, public or private. By law, your answers on the census questionnaire cannot be given to anyone, including the Internal Revenue Service, courts, police, welfare agencies or the Immigration and Naturalization Service. Confidentiality is guaranteed.

It's your future. Don't leave it blank. The 2000 census will involve the government's largest peacetime commitment of human resources in the history of America. California and the U.S. Census Bureau are making unprecedented efforts to encourage everyone to participate in the census. But these efforts will only make a difference if we respond. So, please, when you receive your official census questionnaire in March, take a few

minutes to complete the form and then mail it back promptly. (Make sure to mail your questionnaire back to the U.S. Census Bureau so census takers won't need to come to your door.)

For additional information, call the California Complete Count Campaign in Los Angeles (323) 965-2943 or Sacramento (916) 323-3301, or visit California's web site at HYPERLINK http://www.census.ca.gov. And for more information, visit the U.S. Census Bureau's web site at HYPERLINK http://www.census.gov.



MarinolTM is still Schedule II in California

Federal regulations have changed Marinol's designation from a Schedule II controlled substance to a Schedule III substance, allowing pharmacies to purchase Marinol from wholesalers without using the federal DEA 222 order form.

However, the California Health & Safety Code (H&SC) still lists Marinol as a Schedule II controlled substance, and as such requires a triplicate prescription unless the prescription is written pursuant to H&SC section 11159.2 for a terminally ill patient. As a Schedule II controlled substance, Marinol prescriptions may not be refilled.

Legislation (Senate Bill 550, authored by Pat Johnston) to change Marinol to a Schedule III controlled substance is being held in the Senate for review when the legislative session begins again in January 2000.



Major law changes affecting pharmacy technicians

An emergency regulation, section 1714.1 of the California Code of Regulations took effect January 1, 2000, and the Board is seeking permanent adoption. This regulation ensures that pharmacists in single-pharmacist pharmacies will receive work free breaks and meal breaks without requiring the pharmacy to close. The pharmacist will determine whether to close the pharmacy and remove all ancillary staff during his/her absence. If the pharmacy remains open during the pharmacist's absence, only refill medication that the pharmacist has checked and that does not require pharmacist consultation may be handed to patients by ancillary staff. Any duties performed by ancillary staff during the pharmacist's absence must be reviewed upon the pharmacist's return to the pharmacy. Additionally, during the pharmacist's absence, no ancillary staff will be allowed to perform any discretionary duties or act as a pharmacist.

Beginning January 1, 2000, an applicant for pharmacy technician registration with the Board must be a high school graduate or possess a general education development equivalent pursuant to section 4202(a) Business & Professions Code (B&PC).

Section 4115.5 B&PC expands the amount of time from six to twelve months in which a "pharmacy technician student" (a person who is enrolled in a pharmacy technician training program operated by a California public postsecondary education institution or by a private postsecondary vocational institution approved by the Bureau for Private Postsecondary and Vocational Education) may complete an externship that includes both community and hospital pharmacies. This statute is also effective January 1, 2000.

(The exact language of these sections is included in "Law Update" beginning on Page 17.)

Pharmacy Board meetings are open to the public

Pharmacy Board meetings are open to the public, and the Board encourages all interested parties to participate in these meetings. The remaining Board meeting dates and sites for 2000 are:

- April 12-13, 2000
 Department of Consumer Affairs
 400 R Street, Suite 1030
 Sacramento CA 95814-6237
- ◆ July 26-27, 2000 Westgate Hotel 1055 Second Avenue San Diego CA 92101
- October 18-19, 2000
 Embassy Suites
 150 Anza Boulevard
 Burlingame CA 94010

Agendas with meeting times, locations and information regarding Board committee meetings may be obtained by calling the Board at (916) 445-5014.





What's happening at the Board?

Do you ever wonder what goes on at the Board? Well, we thought it might be interesting for our licensees to know a little of what we have done in the last 12 months. The Board received 199,432 incoming calls and made 197,012 outgoing calls. And, in between the calls, among our other duties, we processed 48,841 pieces of incoming mail, mailed out 55,406 pieces, processed approximately 8,500 applications of all sorts, and provided approximately 152,000 newsletters, 12,000 pharmacy self-assessment forms, and 5,000 pharmacy law books. Whew...!

But help is here for the Board and for our callers. We now have an automated answering telephone service. The staff no longer has individual telephone numbers, so all calls to the Board must be directed to (916) 445-5014 and an extension number. A directory with names and extension numbers will be provided by the automated system.

Because we know your calls are important, callers will not be cast adrift with only a recording to talk to-there will always be a live person available to help direct your call!

First Retired Pharmacist licenses issued

The Board of Pharmacy is proud to list those California pharmacists who have been issued a Retired Pharmacist license and the number of years each was registered with the Board. The Board wishes to publicly congratulate and acknowledge these individuals for providing pharmaceutical care and service to the people of California and helping them attain an improved quality of life for so many years. Thank you all!

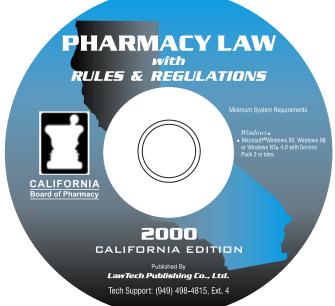
	Years*		Years*
Fred A. Caldeira	60	Myra J. Katz	41
Annette S. Kaplan	57	Thomas R. Pickhardt	40
Cathleen Blake Braun	55	Walter B. Nisbet, Jr., Pharm.	D. 40
Joseph L. Gardella	50	Francis R. Brendis	40
Elvus D. Regalia	50	Allan G. Bond	39
Doris C. Wais	49	Eberhard J. Schneider	39
Richard M. Beebe	48	Irwin H. Woloshin	39
Richard A. Parent	47	Gary L. Aukes, Pharm.D.	36
Norman Carabet	45	James K. Nishio, Pharm.D.	36
Walter K. Cook	44	William H. Pipkin	34
Richard N. Yamagishi	43	Charles A. Brandt, Pharm.D.	22

*Years Registered with the Board of Pharmacy



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Has your name or address changed?

Section 4100 of the Business and Professions Code requires all holders of personal Board-issued licenses (pharmacists, interns, pharmacy technicians and exemptees) to report name or address changes to the Board within 30 days of the change. Such changes must be mailed or faxed to the Board.

When notifying the Board of a change in your name, please include the following:

- A copy of legal documentation (marriage license, divorce decree, or legal name change) of your name change or
- Copies of your driver license and Social Security card (both reflecting the new name).

For address changes, please include your full name, license number, old address, and new address. Your "address of record" is accessible to the public, pursuant to the Information Practices Act and the Public Records Act. If you choose to use a post office box or business address as your address of record, section 1704 of the Business and Professions Code requires you to also provide your residence address which is *not* accessible to the public.

Please mail or fax all change information to:

California State Board of Pharmacy 400 R Street, Suite 4070 Sacramento CA 95814 FAX: (916) 327-6308

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