



BE AWARE & TAKE CARE:
Talk to your pharmacist!

The Script

CALIFORNIA BOARD OF PHARMACY JANUARY 2005

Changes in Pharmacy Law for 2005

The Assembly and Senate bills listed in this article were enacted in 2004, and unless otherwise specified, took effect January 1, 2005. The new and amended statutes are paraphrased or summarized below, but you are urged to review the exact language of the statutes at the Board's Web site www.pharmacy.ca.gov.

AB 2184 (Plescia) Chapter 342, Statutes of 2004

Automated Drug Systems in Skilled Nursing and/or Intermediate Care Facilities (New)

B&PC 4119.1—allows a pharmacy to provide pharmacy services to a skilled nursing facility or an intermediate care facility through the use of an automated drug delivery system that need not be located at the same location as the pharmacy. Operation of the drug delivery system must be under supervision of a pharmacist who need not be physically present and is allowed to supervise the system electronically.

AB 2660 (Leno) Chapter 191, Statutes of 2004

Prescription Labeling Requirements (Amended)

B&PC 4040, 4052, 4060, 4076, 4111 and H&SC 11150—permits pharmacists to sign orders for controlled substances when initiating or adjusting drug regimens under protocol; requires pharmacists to register with the DEA **if** they are authorized to initiate or adjust drug therapy involving controlled substances under protocol; permits the possession of a controlled substance dispensed pursuant to a drug order signed by a pharmacist;

requires a prescription label to include the name of the practitioner, including a pharmacist, who ordered the drug; permits pharmacists to order controlled substances pursuant to a protocol; no longer requires the name of the supervising physician (of certified nurse midwives, nurse practitioners, physician assistants) to be on prescription labels.

AB 2682 (Negrete McLeod) Chapter 887, Statutes of 2004

Out-of-State Distributor to Become Nonresident Wholesaler and Exemptee-in-Charge to Become Designated Representative-in-Charge (New)

B&PC 4161—requires any person located outside California that ships, mails, or delivers dangerous drugs or devices into this state at wholesale to be considered an “**out-of-state distributor**” and be licensed by the Board. An out-of-state distributor's license may not be issued or renewed until the out-of-state distributor identifies and notifies the Board of the designation of an exemptee-in-charge. The exemptee-in-charge will be responsible for the company's compliance with all laws governing wholesalers. The nonresident wholesaler must notify the Board of a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be the exemptee-in-charge. This section is in effect until January 1, 2006.

On and after January 1, 2006, an out-of-state distributor will be known as a “**nonresident wholesaler**” and still require a license issued by the Board. A

separate license will be required for each place of business owned or operated by a nonresident wholesaler. The license must be renewed annually and is non-transferable. At the time of initial application or renewal of a nonresident wholesaler license, the applicant must submit in writing to the Board the following information or within 30 days of any change in the specified information:

- Its agent for service of process in this state;
- Its principal corporate officers, if any, as specified by the Board;
- Its general partners, if any, as specified by the Board; and
- Its owners if the applicant is not a corporation or partnership.

A nonresident wholesaler must comply with all directions or requests for information from the Board, or regulatory or licensing

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President's Message

By Stanley W. Goldenberg, R. Ph.
President, Board of Pharmacy

Editor's Update: President Goldenberg adds the following notice to his President's Message, which is current as of press time (January 21, 2005):

On January 5, 2005, Governor Schwarzenegger proposed to merge all autonomous boards within the Department of Consumer Affairs directly into the department's structure, and abolish the 279 board member positions on all these boards. This action would dissolve the Board of Pharmacy. Under this plan, boards will become bureaus under the Department of Consumer Affairs, and the executive officer and all staff would report to the director of the Department of Consumer Affairs. Unless the Legislature votes to deny the Governor's reorganization plan, the consolidation is scheduled to occur by July 1, 2005. Therefore, the current board may be the last Board of Pharmacy for California. The Board will maintain its current activities and involvement in consumer protection until any and all actions take place through the legislative process. More information about the process can be obtained at the Little Hoover Commission's Web site:
<http://www.lhc.ca.gov/lhc.html>.

For the first 25 years of my career, I worked in and owned pharmacies in California. The Board of Pharmacy was never on my "radar screen" until inspection time. But my perspectives changed in 2001 when I became a Board member and again more recently when I was elected president of the Board. I now want to "give back" to the profession of pharmacy, and I am seeking your help.

I now know that I missed opportunities, both entrepreneurial and professional, by not making time to be more involved. For these reasons, I am dedicating a major portion of my first presidential message to encourage you to become involved. There are a number of ways for you to do so.

Emerging pharmacy and political issues face the Board, the professionals it oversees and the consumers of California. In my opening message at our quarterly board meeting in July, I stressed the importance of well-informed, evidence-based decisions by the members.

First and foremost, the Board's mandate is to protect the public. To do this, the Board seeks to create policies and requirements that advance the pharmacist care available to patients, while minimizing the costs of regulatory compliance on licensees. So your involvement is important and desired.

Even with our current budget constraints, there are a number of ways you can participate in and keep abreast of Board activities and priorities. Listed below are avenues and opportunities for you to interact with us.

Public Meetings of the Board

The Board actively seeks the participation of interested individuals in emerging policy areas. There are a number of public meetings annually where public comment is sought. A description of these committees is provided here.

A. Board of Pharmacy quarterly meetings

At these meetings, the Board takes action to achieve its purpose of consumer protection. Topics are

divided into five major areas that correspond to a Board committee (see below), and six hours of continuing education is awarded for attending one full day of a Pharmacy Board meeting. Committee activities are reviewed and public input on all topics is an integral part of each segment. Space is included in the agenda to encourage open discussion of new and old business. Copies of the Board meeting agenda and materials are available on the Board's Web site.

Meetings for 2005 are scheduled for the following months and areas:

- January—Los Angeles
- April—Sacramento
- July—San Diego
- October—Bay Area

B. Committee Meetings

Committee meetings are held three to six weeks before the quarterly Board meetings and provide opportunities for information gathering and discussions on emerging topics. An example of how communicating at these meeting can impact pharmacy practice occurred at the June meeting of the Enforcement Committee. A written request was discussed to use new technology to replace the pharmacist's having to initial the prescription label of a medication prepared by a technician. Biometric identifiers were suggested in place of initialing, a recommendation that was approved by the Committee, and subsequently by the full Board, and added to the Board's Omnibus legislation. If enacted, the new provision allowing this technology will be in effect in January 2005.

Meeting agendas and materials are available on the Board's Web site.

Organizational Development Committee

Coordinates strategic planning, budget management and staff development activities to ensure the

efficient achievement of the Board's mission and goals.

John Tilley, *R. Ph.*, Chair
Stanley W. Goldenberg, *R. Ph.*

Communication and Education Committee

Promotes and develops educational materials for the public and licensees. For example, material developed for the public encourages patients to discuss their medication with their pharmacist and emphasizes the importance of patients complying with their medication treatment regimens. Other materials developed by the Committee assist pharmacists in understanding Pharmacy Law (e.g., *The Script*).

Andrea Zinder, *Public Member*, Chair
Richard L. Benson, *Public Member*
William Powers, *Public Member*
Kenneth H. Schell, *Pharm. D.*

Enforcement Committee

Pursues policies that protect the public by preventing violations and effectively enforcing federal and state pharmacy laws when violations occur.

William Powers, *Public Member*, Chair
David J. Fong, *Pharm. D.*
Stanley W. Goldenberg, *R. Ph.*

Licensing Committee

Ensures that the professional qualifications of those entering the practice of pharmacy, as well as those continuing to practice, meet minimum requirements for education, experience, and knowledge and ensures that facilities licensed by the Board meet minimum standards.

Ruth Conroy, *Pharm. D.*, Chair
Richard L. Benson, *Public Member*
Clarence Hiura, *Pharm. D.*

Legislation and Regulation Committee

Pursues legislation that ensures better patient care and that provides effective regulation of the individuals and firms who handle, dispense,

furnish, ship and store prescription drugs and devices in California.

John Jones, *R. Ph.*, Chair
James E. Acevedo, *Public Member*
Kenneth H. Schell, *Pharm. D.*

The Board's Web site

The Web site is the Board's main platform for disseminating information. We now have a system in place for e-mailing updated information to those who have requested (or subscribed) to receive it. The Web site contains a wealth of information, including:

- All meeting dates, times, locations, materials and agendas of Board and committee meetings
- All applications and other forms
- Help for complying with new regulatory requirements (e.g., questions and answers on the new controlled substances dispensing requirements);
- Board publications (*The Script*, *Health Notes*)

Newsletter (*The Script*)

The Script, currently published twice per year, provides information about new Board policies and pharmacy law changes and is mailed by the Board to all California licensed **pharmacies**. In partnership with the Board, the Pharmacy Foundation of California publishes and mails the *The Script* to all licensed **pharmacists**.

Continuing Education Outreach Programs

The Board has developed an outreach presentation about the Board and new pharmacy laws. A Board member and a Supervising Inspector present this information. The Board will schedule these presentations to groups of 50 pharmacists:

- Timely topics covered
- Question and answer periods
- Two hours of CE awarded

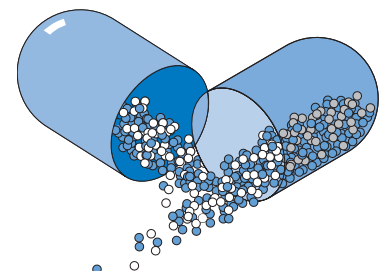
- Examples of recent outreach programs include (1) new prescribing and dispensing requirements for controlled substances and (2) information about the Board programs and new laws impacting pharmacy

To schedule an outreach program for your group, send a written request describing your organization and requested date(s) to the Board or contact Patricia Harris at (916) 445-5014.

Emerging issues being discussed by the Board

- Importation of drugs from other countries—the pursuit of “affordable” medication by individuals and states—has challenged our drug distribution system. The final solution will require federal and state actions.
- Terrorism—We must remember that the United States and the world changed after September 11, 2001. A letter, dated August 12, 2004, by FDA Commissioner Lester Crawford warned of “terrorist chatter” indicating that terrorists could target the United States food and drug supply—particularly prescription drugs imported illegally. Let us not forget the 1982 incident where Tylenol was removed from shelves, filled with cyanide and returned for sale, causing seven deaths.

Let us make this year one in which we address our goals with interaction to create a more dynamic profession and focus on our #1 mission—THE SAFETY OF CALIFORNIA CONSUMERS.



SB 151

Requirements for Prescribing and Dispensing Controlled Substances

Senate Bill 151 has brought changes in controlled substance prescribing and dispensing requirements. A major change is the elimination of the triplicate forms used for prescribing Schedule II controlled substances and use of easier to order tamper-resistant prescription forms that are purchased from designated security printing companies.

The Board has a number of educational materials on its Web site to aid pharmacists, prescribers and patients in understanding the new requirements, which will be in effect January 1, 2005.

To help you in finding answers to prescribing questions regarding these changes, an annotated index for the contents of the key prescribing laws (Health & Safety Code) is offered below. This index provides a quick overview of where in law particular provisions can be found. The exact text of SB 151 can be found at the Board's Web site, www.pharmacy.ca.gov, and a question and answer segment is also at that site.

Tamper-resistant prescription forms

H&SC 11029.5 Defines "security printer"

A person approved to produce controlled substance prescription forms pursuant to Section 11161.5.

H&SC 11161.5 Applying to become an approved security printer

Contains the requirements for applying for approval by the Department

of Justice and the Board of Pharmacy to print tamper-resistant prescription forms, delivery of forms to the prescriber, and record-keeping requirements for printers.

H&SC 11162.1 Requirements for tamper-resistant prescription forms

Describes all the features required for tamper-resistant forms and information to be entered on the forms by the prescriber. Included is a requirement that the form contains either (A) a statement printed on the bottom of the prescription blank that the "Prescription is void if more than one controlled substance prescription is written per blank" or (B) contain a space for the prescriber to specify the number of drugs prescribed on the prescription and a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."

Details tamper-resistant prescription form requirements for the designated prescriber of a *licensed health care facility*.

Prescribing Schedules II – V controlled substances

H&SC 11159.2 Exception to triplicate prescription requirements; terminally ill patient

Includes retention of requirements for a Schedule II prescription written on a regular plain prescription form for a "terminally ill" patient—must still include notation "11159.2 exemption."

H&SC 11164 Requirements for writing and dispensing Schedule II-V prescriptions

Includes all entries required on a controlled substance prescription. Directions for handling a Schedule II prescription that contains errors or uncertainties are found in Title 16 of the California Code of Regulations section 1761(a).

H&SC 11164.1 Controlled substance prescriptions written by out-of-state prescribers

Allows filling such prescriptions when delivered to out-of-state patients and requires the reporting of Schedules II and III prescriptions to the Department of Justice

B&PC 4170 Dispensing by the prescriber: requirements and restrictions

Includes definition of "prescriber" and details labeling and packaging requirements

Oral and faxed prescriptions

H&SC 11164 Faxing of prescriptions for Schedule III-V controlled substances

Permits Schedule III-V controlled substances to be dispensed upon an oral or electronically transmitted prescription. Note: Faxing a prescription written on the tamper-resistant forms will produce the word "VOID" across the face of the prescription, so prescribers are encouraged to use a regular form when faxing.

H&SC 11167 Faxing of Schedule II controlled substance prescriptions allowed in an emergency

Describes the emergency circumstances that allow the faxing of a Schedule II controlled substance prescription. This section lists all the requirements for a pharmacist who receives an oral, electronic data transmission, or a written order not made on a tamper-resistant prescription form.

H&SC 11167.5 Faxing of Schedule II controlled substance prescriptions for specified inpatients, residents, and home hospice patients

Contains pharmacists' procedures upon receipt of an oral or faxed

Schedule II prescription for a patient of a licensed skill nursing facility, a licensed intermediate care facility, a licensed home health agency, or a licensed hospice.

See Article 1 (commencing with Section 1250) of Chapter 2 of Division 2 of the Health & Safety Code for definitions of “*licensed health care facility*.”

Controlled Substance Utilization, Review, and Evaluation System (CURES)

H&SC 11164.1 Schedule III added to CURES data collection

Beginning January 1, 2005, all Schedule II and III prescriptions must be reported to the CURES data collection vendor, Atlantic Associates (see below).

H&SC 11165 CURES

Fully describes the purpose of and procedures for pharmacies to report Schedules II and III prescriptions to the CURES data collection vendor. Questions regarding the reporting procedures should be directed to Atlantic Associates at 1-888-492-7341.

Dispensing physicians with questions regarding CURES should contact the Bureau of Narcotic Enforcement (BNE) at (916) 227-4051.

H&SC 11165.1 Obtaining patient’s medical history from CURES data

Allows prescribers to request patient’s history from the Department of Justice.

To request a patient history of controlled substance prescriptions from the CURES, pharmacists or physicians can download a Patient Activity Report (PAR) request form by visiting the Board of Pharmacy Web site, www.pharmacy.ca.gov/app_forms.htm. Complete the appropriate PAR form and fax it to the BNE at (916) 227-5079.

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agency of the state in which it is licensed. Nonresident wholesalers must maintain records in a readily retrievable form of dangerous drugs and devices sold, traded, or transferred to persons in California and must maintain a valid, unexpired license, permit or registration in the applicant’s state of residence.

The Board will not issue or renew a nonresident wholesaler license until the applicant identifies a “**designated representative-in-charge**” (previously called an exemptee-in-charge) and notifies the Board in writing of that person’s identity and license number. Additionally, the Board must be notified within 30 days of a change in the designated representative-in-charge. The designated representative-in-charge will be responsible for the company’s compliance with all laws governing wholesalers. The Board may issue a temporary license under certain conditions and for periods of time that the Board determines to be in the public interest.

Surety Bond for Nonresident Wholesaler License (New)

B&PC 4162.5—effective January 1, 2006, requires an applicant for the issuance or renewal of a nonresident wholesaler license to submit a surety bond of \$100,000 for each site to be licensed, or other equivalent means of security acceptable to the Board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The Board may accept a surety bond of \$25,000 if the nonresident wholesaler’s annual gross receipts of the previous tax year are \$10 million or less, but the surety amount would revert to \$100,000 if the nonresident wholesaler has been

disciplined by any state or federal agency or has been issued an administrative fine pursuant to this section. The Board may make a claim against the bond if the licensee fails to pay a fine with 30 days of the issuance of the fine or when the costs become final. A single surety bond or other equivalent means of security acceptable to the Board will satisfy the bond requirement for all licensed sites under common control as defined in Section 4126.5. This section repeals on January 1, 2011, unless an enacted statute repeals or extends those dates.

SB 1159 (Vasconcellos) Chapter 608, Statutes of 2004 Furnishing Hypodermic Needles and Syringes Without Prescription (New)

B&PC 4145, 4147 and H&SC 11364—until December 31, 2010, authorizes a pharmacist to sell or furnish 10 or fewer hypodermic needles or syringes to a person for human use without a prescription if the pharmacy is registered with a local health department in the Disease Prevention Demonstration Project, which would be created to evaluate the long-term desirability of allowing licensed pharmacies to sell or furnish nonprescription hypodermic needles or syringes to prevent the spread of blood-borne pathogens, including HIV and hepatitis C. Detailed records of nonprescription sales of hypodermic needles and syringes are no longer required.

SB 1307 (Figuroa) Chapter 857, Statutes of 2004 Electronic Pedigree for Dangerous Drugs (New)

B&PC 4034—requires an electronic “pedigree” by January 1, 2007. The pedigree will contain information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a

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manufacturer, through acquisition and sale by a wholesaler, until final sale to a pharmacy or other person furnishing, administering, or dispensing the drug. The application of the pedigree requirement in pharmacies will be subject to review during the Board's sunset review in 2008. (Extension provisions for activation of this requirement exist in sections 4163.5 and 4163.6)

Records of Manufacture, Sale, Acquisition and Disposition of Dangerous Drugs or Devices (New)

B&PC 4081—existing law requires all records of manufacture, sale, acquisition, or disposition of dangerous drugs or devices to be open to inspection during business hours and retained for at least three years from the making. A current inventory must be kept by every manufacturer, wholesaler, pharmacy, veterinarian, laboratory, clinic, hospital, or institution who maintains a stock of dangerous drugs or devices. The name "exemptee-in-charge" will be changed to "designated representative-in-charge" on January 1, 2006. After that date, the owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible with the pharmacist-in-charge or representative-in-charge for maintaining the records and inventory. The pharmacist-in-charge or representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

Embargoed Dangerous Drugs or Devices (New)

B&PC 4084 and 4085—allows Board inspectors to embargo dangerous drugs or devices that are suspected of being adulterated or counterfeit by affixing a tag or other marking to the drug. If a Board inspector determines that an embargoed dangerous drug or device is not adulterated or counterfeit, the inspector may remove the tag or marking. It is unlawful for any person to remove, sell, or dispose of an embargoed dangerous drug or device without the Board's permission.

Furnishing Dangerous Drugs to Specified Entities and Violation Penalty (New)

B&PC 4126.5—permits pharmacies to furnish dangerous drugs only to:

- A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired;
- The pharmaceutical manufacturer from whom the dangerous drug was acquired;
- A licensed wholesaler acting as a reverse distributor;
- Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.
- A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law;
- A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs; and
- Another pharmacy under common control.

Violation of this section by either a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities or a person engaged in a prohibited transaction with such a pharmacy

may result in a fine of \$5,000 for each occurrence.

Surety Bond for Wholesalers (New)

B&PC 4162—requires applicants for the issuance or renewal of a wholesaler license to submit a surety bond of \$100,000 or other equivalent means of security to the Board. The purpose of the bond is to secure payment of any administrative fine imposed by the Board and any cost recovery ordered. If the applicant's annual gross income for the previous tax year is less than \$10 million a surety bond for \$25,000 will be accepted. Additionally, a surety bond of \$100,000 may be required for any licensee who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to the Pharmacy Law. This section becomes effective January 1, 2006.

Pedigree Required (New)

B&PC 4163—presently allows manufacturers and wholesalers to acquire or furnish dangerous drugs or devices only from or to those authorized by law to possess or furnish those dangerous drugs or devices. This section is in effect until January 1, 2007, when it will be repealed unless a later enacted statute is enacted before that date. If this section is repealed, the new section will prohibit a wholesaler or pharmacy from selling, trading, or transferring a dangerous drug at wholesale without a pedigree. Additionally, a wholesaler or pharmacy may not acquire a dangerous drug without receiving a pedigree. This section becomes operative on January 1, 2007.

Extension May be Allowed for Implementing Pedigree Requirement for Wholesalers (New)

B&PC 4163.5—authorizes the Board to extend the time allowed for implementing electronic

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technologies to track the distribution of dangerous drugs within the state if the Board determines that manufacturers or wholesalers cannot meet the requirement by January 1, 2007. The pedigree requirement compliance date may then be extended until January 1, 2008.

Extension May be Allowed for Implementing Pedigree Requirement for Pharmacies (New)

B&PC 4163.6—authorizes the Legislature to extend the time allowed for pharmacies to implement electronic tracking the distribution of dangerous drugs within the state if the Legislature determines that it is not economically and technically feasible for pharmacies to comply with the requirement by January 1, 2007. The date for compliance with the requirement may be extended to January 1, 2009.

Wholesaler Tracking System of Individual Sales of Dangerous Drugs (Amended)

B&PC 4164—effective January 1, 2006, will require licensed wholesalers that distribute controlled substances, dangerous drugs or devices within or into California to report all sales of those products that are subject to abuse. Wholesalers will be required to develop and maintain a system for tracking individual sales of dangerous drugs at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities.

No Business License for any Wholesaler Not Licensed by the Board (New)

B&PC 4168—prohibits a county or municipality from issuing a business license to a wholesaler who does

not have a current wholesaler license issued by the Board.

Wholesaler Sales Requirements (New)

B&PC 4169—prohibits the following:

- The purchase, trade, sale, or transfer of dangerous drugs or devices at wholesale to a person or entity that is not licensed with the Board as a wholesaler or pharmacy;
- The purchase, trade, sale, or transfer of dangerous drugs that the person knew or should have known were adulterated or misbranded;
- The purchase, trade, sale, or transfer of dangerous drugs or devices after the beyond use date on the label; and
- The failure to maintain records of the acquisition or disposition of dangerous drugs or devices for at least three years.

Violation of this section may result in a fine for each violation.

Excessive Furnishing of Dangerous Drugs by a Wholesaler to a Pharmacy (Amended)

B&PC 4301—defines acts of unprofessional conduct and authorizes the Board to take action against a wholesaler who clearly excessively furnishes dangerous drugs to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term facilities.

Fee Bases Increased (Amended)

B&PC 4400—authorizes an increase in the fee bases for initial and renewal license applications and penalties.

SB 1913 (Business and Professions Committee) Chapter 695, Statutes of 2004 Omnibus Measure

Delivery of Dangerous Drugs or Devices (New)

B&PC 4059.5—requires dangerous

drugs or devices delivered to a pharmacy to be signed for by and delivered to a pharmacist but also authorizes a pharmacy to take delivery of dangerous drugs or devices when the pharmacy is closed and no pharmacist is on duty if:

- The drugs are placed in a secure storage facility in the same building as the pharmacy;
- Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or devices have been delivered;
- The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or devices have been delivered;
- The pharmacy maintains written policies and procedures for the delivery of dangerous drugs or devices to a secure storage facility; and
- The agent delivering dangerous drugs or devices leaves documents indicating the name and amount of each dangerous drug or device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and devices delivered to the secure storage facility and for obtaining and maintaining records relating to the delivery.

Prescriber Dispensing Dangerous Drug to Emergency Room Patient (New)

B&PC 4068—permits a prescriber to dispense a dangerous drug, including a controlled substance, to an emergency room patient if **all** of the following apply:

- The hospital pharmacy is closed and there is no pharmacist available in the hospital;
- The dangerous drug is acquired by the hospital pharmacy;
- The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens;

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- The hospital pharmacy retains the dispensing information and, if the drug is Schedule II or III controlled substance, reports the dispensing information to the Department of Justice pursuant to H&SC 11165;
- The prescriber determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and
- The prescriber reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patient.

Site Licenses (New)

B&PC 4107—prohibits the Board from issuing more than one site license to a single premise except to issue a veterinary food-animal drug retailer license to a wholesaler or to issue a license to compound sterile injectable drugs to a pharmacy.

Environment for Compounding Sterile Injectable Products (New)

B&PC 4127.7—as of July 1, 2005, requires a pharmacy to compound sterile injectable products in one of the following environments:

- An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom with a positive air pressure differential relative to adjacent areas;
- An ISO class 5 cleanroom; or
- A barrier isolator that provides an ISO class 5 environment for compounding.

Veterinary Teaching Hospital (New)

B&PC 4170.5—permits veterinarians in a veterinary teaching hospital operated by an accredited veterinary medical school to dispense and administer dangerous drugs and devices and controlled substances from a common stock.

Foreign Graduates (Amended)

B&PC 4200—adds certification by the Foreign Pharmacy Graduate Examination Committee as an application requirement for foreign-educated pharmacists seeking licensure as a pharmacist in California.

Pharmacist/Intern Ratio and Intern Hours Requirement Changed (New)

B&PC 4208 and 4209— defines “intern,” details requirements for registration and qualifying for pharmacist licensure examinations. Intern affidavits (hours and experience) must be certified under penalty of perjury by a pharmacist under whose supervision such experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience. Interns must have at least 1,500 hours of intern experience before applying to take the pharmacist licensure examination. Section **4114** authorizes pharmacists to **supervise two intern pharmacists at one time**.

Compounding by Pharmacy Technicians (Amended)

Health & Safety Code 11207—clarifies language that permits a pharmacy technician to compound or prepare a prescription for a controlled substance when assisting a pharmacist.

Join Our E-mail List

The Board has recently established a service to notify anyone who is interested in receiving e-mail alerts about major updates to the Board’s Web site. The updates would include information related to when:

- Regulations are implemented or released for public comment
- Board newsletters are published
- Agendas about public meetings are released
- Questions and answers about new laws are added
- Board actions from Board meetings are available
- Drug recalls have occurred

There is no charge for this service, and you can subscribe to receive the e-mail alerts by accessing the Board’s Web site, www.pharmacy.ca.gov, and clicking on “Join Our E-mail List” under “Online Services.” Then submit your name and e-mail address in the provided spaces.

To confirm your identity, a message requesting confirmation will be sent to the e-mail address you provide. It will be necessary for you to keep your e-mail address current on this list.

Regulation Update Summaries

This article contains information relating to new and amended sections of Division 17, Title 16, of the California Code of Regulations. The noted regulations have been paraphrased or summarized below, but you are urged to review the exact language of the regulations at the Board's Web site www.pharmacy.ca.gov.

1709.1 – Designation of Pharmacist-In-Charge (Amended)

Effective October 3, 2004, a pharmacist may serve as pharmacist-in-charge at a second pharmacy if that pharmacy is located within 50 driving miles of the first pharmacy. The regulation allows a pharmacist to refuse to act as pharmacist-in-charge at a second pharmacy and prohibits the employer from taking disciplinary action or discriminating against the pharmacist for such a refusal.

1710 – Inpatient Hospital Pharmacy (Amended)

Effective October 22, 2004, this regulation authorizes the use of central fill pharmacies in hospitals.

1711 – Quality Assurance Programs (Amended)

Effective October 22, 2004, this regulation clarifies the patient and prescriber prescription error notification requirements of the existing regulation. Prescribers must be informed of a prescription error only when the drug was administered to the patient.

1717.1 – Common Electronic Files (Amended)

Effective October 22, 2004, this section clarifies that pharmacies employing common electronic prescription files must secure those files from unauthorized disclosure of confidential medical information and establish written policies and procedures to prevent unauthorized disclosures.

1717.4 – Electronic Transmission of Prescriptions (Amended)

Effective October 22, 2004, this regulation clarifies that pharmacists must ensure the authenticity of a prescription.

1720 – Application for Examination and Registration (Amended)

Effective October 22, 2004, applicants for a pharmacist license must comply with the requirements established by the administrators of the pharmacist licensure examinations and requires applicants to complete the licensing examinations within one year of being approved by the board to take the examinations.

1721 – Dishonest Conduct During Examination (Amended)

Effective October 22, 2004, candidates cheating on the pharmacist licensure examinations are prohibited from retaking the examinations for one year and may not become licensed as a pharmacy technician in that time period.

1723.1 – Confidentiality of Examination Questions (Amended)

Effective October 22, 2004, text was rewritten to clarify existing requirements.

1724 – Passing Grade in Examination

Effective October 22, 2004, text was rewritten to clarify existing requirements.

1749 – Fee Schedule

Effective October 22, 2004, fees for discontinued applications were deleted, keeping the Board's fee schedule current.

1793 – Definitions

Effective October 22, 2004, text was rewritten to clarify existing requirements.

1751 – Compounding Area for Parenteral Solutions (Amended)

Effective October 29, 2004, changes to this section update standards for compounding areas, delete obsolete language, reflect changes in referenced code section numbers and revise standards for certifying clean rooms and other compounding environments.

1751.01 – Facility and Equipment Standards for Sterile Injectable Compounding from Non-Sterile Ingredients (New)

Effective October 29, 2004, this section establishes additional facility and procedure requirements for compounding sterile injectable drug products from non-sterile ingredients. These standards are based on standards adopted by the United States Pharmacopeia and the American Society of Health System Pharmacists that reflect good professional practice.

1751.02 – Policies and Procedures (New)

Effective October 29, 2004, this section incorporates existing requirements for policies and procedures and adds new policy and procedure requirements for compounding from non-sterile ingredients. These policies and procedures are drawn from standards adopted by United States Pharmacopeia and the American Society of Health System Pharmacists that reflect good professional practice.

1751.2 – Labeling Requirements (Amended)

Effective October 29, 2004, this section is amended to update the terminology and conform to the usage in other portions of the regulation.

1751.3 – Recordkeeping Requirements (Amended)

Effective October 29, 2004, this section is amended to eliminate

Regulation Update

Continued from Page 9

recordkeeping requirements that are duplicated in other board regulations and to establish additional recordkeeping requirements for pharmacies compounding sterile injectable products from non-sterile ingredients. These recordkeeping requirements are drawn from standards adopted by United States Pharmacopeia and the American Society of Health System Pharmacists that reflect good professional practice.

1751.4 – Attire (Amended)

Effective October 29, 2004, this section amends existing requirements for protective clothing and establishes attire standards for pharmacy personnel compounding sterile injectable drugs from non-sterile ingredients. These requirements are drawn from standards adopted by United States Pharmacopeia and the American Society of Health System Pharmacists that reflect good professional practice.

1751.5 – Training of Staff, Patient, and Caregiver (Amended)

Effective October 29, 2004 This section is amended to establish additional training standards for pharmacy staff involved in the compounding of sterile injectable drug products from non-sterile ingredients. These training standards are drawn from standards adopted by United States Pharmacopeia and the American Society of Health System Pharmacists that reflect good professional practice.

1751.6 – Disposal of Waste Material (Amended)

Effective October 29, 2004, this section is amended to make the terminology consistent with other aspects of the regulation and to eliminate obsolete provisions.

1751.7 – Quality Assurance (Amended)

Effective October 29, 2004, this section updates existing quality assurance requirements and adds process

validation requirements for pharmacies compounding sterile injectable drug products from non-sterile ingredients. The process validation requirements are drawn from standards adopted by United States Pharmacopeia and the American Society of Health System Pharmacists that reflect good professional practice.

1751.8 – Policies and Procedures (Repealed)

Effective October 29, 2004, this section is repealed and elements of its former provisions are incorporated in section 1751.02.

1751.9 – Reference Materials (Amended)

Effective October 29, 2004, this section is amended to update the requirements for reference materials in pharmacies compounding sterile injectable drug products.

1793.3 – Ancillary Personnel (Amended)

Effective October 2, 2004, there is no limit on the number of clerk/typists that may be supervised by a pharmacist. The regulation allows a pharmacist to limit the number of clerk/typists that they supervise and prohibits the employer from taking disciplinary action or discriminating against the pharmacist for exercising that right.



Mandatory Reporting of Child and Elder Abuse

Under California law, all licensed health practitioners are “mandated reporters” for child or elder abuse.

Reporting Child Abuse

California Penal Code 11166 requires that all mandated reporters make a report to an agency specified in Penal Code 11165.9 (generally law enforcement agencies) whenever the mandated reporters, in their professional capacity or within the scope of their employment, have knowledge of or observe a child whom the mandated reporters know or reasonably suspect has been the victim of child abuse or neglect. The report must be telephoned to the appropriate agency as soon as possible and a written report sent within 36 hours of the receiving the information concerning the incident. Failure to comply with the requirements of Section 11166 is a misdemeanor, punishable by up to six months in a county jail, by a fine of \$1,000, or both.

Reporting Elder Abuse

Welfare and Institutions Code sections 15630-15632 designate persons (including health practitioners) who have assumed full or intermittent responsibility for the care or custody of an elder or dependent adult as mandated reporters. These practitioners are those who, in their professional capacity, or within the scope of their employment, observe or have knowledge of an incident that appears to be physical abuse, abandonment, abduction, isolation, financial abuse, or neglect. A report of the known or suspected abuse must be made by telephone immediately or as soon as possible. A written report must be submitted within two working days. Section 15630 details the appropriate agencies to whom the abuse must be reported.

Necessity for Pharmacist to Check Automation/Robotic Dispensing

The Board of Pharmacy recently reviewed a request from McKesson Automation, Inc. (McKesson) to approve a proposed protocol for use in hospital and institutional pharmacies that would not require licensed pharmacists to check every medication dispensed by its automated dispensing system, ROBOT-Rx. McKesson proposed a protocol whereby a pharmacist would check 100 percent of the medications packaged by the ROBOT-Rx on a daily basis for at least 30 days after the ROBOT-RX is deployed. After the 30 days, the pharmacist would then taper off to sampling only 5-10 percent of the doses dispensed.

Pharmacy Law is silent on the question about how a pharmacist must check medication dispensed from automated delivery systems, aside from those provisions relating to placement of such a system in nonprofit or free clinics (Business & Professions Code [B&PC] section 4186). There is no statute or regulation specifically requiring that a pharmacist check every dose dispensed by an automated drug delivery system located in an inpatient setting, nor is there any statute or regulation absolving the dispensing pharmacist of this responsibility. Because of this silence, McKesson concluded that it is within the Board's discretion to approve a protocol that would apply specifically to ROBOT-Rx technology.

In denying McKesson's request, the Board considered the opinions of its counsel, which follow, in relevant part:

The Board has no relevant statutory authority to approve a protocol, and to do so may constitute an impermissible underground regulation. Under current law, it is the responsibility of individual licensees to determine the level of error risk they are willing to assume, and the steps they take to reduce or eliminate that risk.

Pharmacy Law is violated where a prescription is dispensed in an insufficiently or inaccurately labeled

container (B&PC sections 4076-4078), where the drug dispensed deviates from requirements of a prescription (Title 16, California Code of Regulations [CCR] section 1716), or where the prescription is dispensed containing significant errors, omissions, irregularities, uncertainties, ambiguities, or alterations (CCR section 1761). These provisions apply to all dispensing, regardless of the setting.

Any licensee that chooses to implement a reduced-error-checking protocol like that suggested by McKesson is assuming the risk of any errors that result. Even if such errors are less likely with the ROBOT-Rx system, the licensee is responsible for any errors that do occur. It may therefore be a risk for licensees to implement a protocol that increases the chance of such an error, however minor, by eliminating 100 percent of the human double-checking that could perhaps catch and correct those few errors made by the machine(s). Any licensee implementing such a protocol will be subject to discipline for any errors that do occur (as would any licensee responsible for errors from any other delivery system). It is possible the severity of the violation may even be greater where the error could have been caught had not such a sampling protocol been in place.

In the absence of any statutes or regulations exempting a dispensing pharmacist or pharmacy working with an automated drug delivery system from the general requirements pertaining to prescription accuracy and propriety of drug delivery, it is the responsibility of

the dispensing pharmacist and pharmacy to ensure 100 percent accuracy of the dispensing. Licensees electing to save costs by reducing their level of error checking do so at their own risk and that of the patient.

Naturopathic Doctors Added to Prescriber List

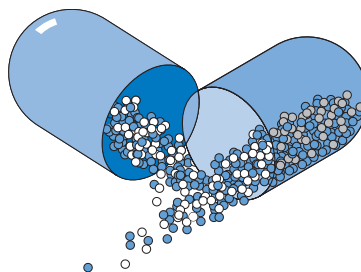
Section 3640.5 of the Business & Professions Code authorizes naturopathic doctors (NDs) to furnish or order Schedule III-V drugs, and emergency regulations authorizing NDs to prescribe have recently been approved.

Licensing of NDs by the Bureau of Naturopathic Medicine has begun and will be limited to those who have completed educational and other licensing requirements. Licensed NDs will function in accordance with standardized procedures or protocols developed with his or her supervising physician and surgeon.

Prescriptions written by NDs must contain:

- The printed or stamped name, license number and **furnishing number** of the ND,
- The ND's federal controlled substances registration number, if the prescription is for a controlled substance. This requirement may be met by stamping the ND's federal registration number on the prescription.
- The signature of the ND.

Updated information regarding this issue will be published in this newsletter when it becomes available.



PRESERVE A TREASURE



Antibiotics are precious resources but they are not cure-alls for all that ails your patients. Let us help you keep antibiotics potent resources that you and your patients can count on.

Contact FDA for bulk copies of "**Preserve a Treasure: Know When Antibiotics Work**" an easy-to-read brochure of frequently asked questions to help your patients understand the importance of prudent antibiotic use.

dpapubs@cder.fda.gov or 1-888-INFO-FDA



U.S. Department of Health and Human Services
Food and Drug Administration

Contact Your Doctor Again if:

- Your symptoms get worse.
- Your symptoms last a long time.
- After feeling a little better, you develop signs of a more serious problem. Some of these signs are a sick-to-your-stomach feeling, vomiting, high fever, shaking chills, chest pain.



U.S. Department of Health and Human Services
Food and Drug Administration

(FDA) 05-1513A

A message from the
"Get Smart: Know When Antibiotics Work"
campaign.

For more information:
http://www.fda.gov/oc/opacom/hottopics/anti_resist.html


U.S. Department of Health and Human Services
Food and Drug Administration

PRESERVE A TREASURE



Know When
Antibiotics Work

Cough? Sore throat? Runny nose?



You or a loved one feels miserable and you've come to the doctor looking for help.

Q: I'm sick. Don't I need a prescription for an antibiotic?

A: Your doctor has examined you and determined that your illness is caused by a viral infection. Antibiotics do NOT treat viral illnesses like colds, flu and most sore throats.

Q: If antibiotics don't treat viral illnesses like cold and flu, what do they treat?

A: Antibiotics are used to treat illnesses caused by bacteria. Examples of illnesses caused by bacteria include strep throat, tuberculosis and many types of pneumonia.

Q: Even though my illness may be caused by a virus, what harm can it do to take an antibiotic?

A: Taking antibiotics when they aren't needed contributes to the serious problem of antibiotic resistance.

Q: What is antibiotic resistance?

A: This is when bacteria cannot be killed by antibiotics. The bacteria have become resistant. If this continues, over time some recurring infections may have to be treated with different and stronger antibiotics and the very real possibility that eventually no antibiotic will be effective in killing the bacteria.

Q: If antibiotics will not help me, what will?

A: There are many over-the-counter products available to treat the symptoms of your viral infection. These include cough suppressants which will help control coughing and decongestants to help relieve a stuffy nose. Read the label and ask your pharmacist or doctor if you have any questions about which will work best for you.



Help Yourself Feel Better While You Are Sick

A cold usually lasts only a couple of days to a week. Feeling tired from the flu may continue for several weeks.

To feel better while you are sick:

- Drink plenty of fluids.
- Get plenty of rest.
- Use a cool mist vaporizer or a humidifier — an electric device that puts water into the air.
- Use saline nose spray to ease dry nasal passages.
- Use a fever reducer when needed.

Schedule III controlled substance prescriptions added to CURES reporting requirements

Since September 1998, all California pharmacies dispensing Schedule II controlled substances have been required to submit that prescription data electronically to the Controlled Substance Utilization Review and Evaluation Systems (CURES). Effective January 1, 2005, all Schedule III prescriptions must also be reported. The Bureau of Narcotic Enforcement (BNR) within the Department of Justice has made arrangements for collection of CURES data with the vendor, Atlantic Associates, Inc. For most pharmacies, compliance with this directive means that their **software must be modified so that Schedule III prescription information, as well as Schedule II**

prescription information, can be transmitted to Atlantic Associates, Inc.

Atlantic Associates, Inc.
Phone: (888) 492-7341
New FAX: (877) 508-6704

Prescribers who dispense Schedule II and III medications are also required to submit prescription information to the Department of Justice. Section 11165 of the H&SC requires both pharmacies and dispensing prescribers to submit the following information for each Schedule II and III prescription filled:

- Full name, address, gender, and date of birth of the patient;
- Prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility;
- Pharmacy prescription number, license number, and federal controlled substance registration number;
- NDC (National Drug Code) number of the controlled substance dispensed;
- Quantity of the controlled substance dispensed;
- ICD-9 (diagnosis code), if available;
- Date of issue of the prescription; and
- Date of dispensing of the prescription.

Delayed Renewal Notices and Licenses Please renew your license early

All Board of Pharmacy licenses, permits and license renewal notices (as well as those of all other health professions) are printed and mailed by the California State Employment Development Department (EDD). In the past, EDD was able to mail renewal notices approximately six weeks before a license's expiration date. Unfortunately, budget constraints at EDD are impacting these mailings. As a result, the renewal notices are being received by licensees only three to four weeks before the license expiration date. Then, because it takes an additional three to four weeks to process renewals once the Department of Consumer Affairs receives the renewal application and fee, some licenses expire before the renewed licenses are actually processed.

A similar delay occurs in the mailing of issued and renewed licenses. Whereas updating the Board's Web site information (relating to new and

renewed licenses) generates the printing of the licenses, it actually takes two to three weeks longer to mail the licenses. An additional week is then required for delivery by the US Postal Service.

mail your renewal notice and fee immediately upon receiving the notice

To alleviate some of the delay, the Board has requested EDD to print license renewal notices earlier. Another important step is for you to mail your renewal notice and fee immediately upon receiving the notice.

The longer you wait to submit the renewal, the greater the chances are that you will not receive your license before your old one expires.

If you have submitted your renewal application and fee, but your present license has expired before receiving the renewed license, interested parties may verify your licensure status by checking the Board's Web site (www.pharmacy.ca.gov/verify_lic.htm). However, since it now takes at least three weeks for the department to process your renewal, the Web site may not reflect that you have renewed your license.

Again, avoid problems by renewing your license as soon as you receive your renewal application. And use the license verification site (www.pharmacy.ca.gov/license_lookup.htm) to ascertain whether or when your license was renewed.

www.pharmacy.ca.gov

New Look for DEA Controlled Substance Registration Certificates

The Drug Enforcement Administration's (DEA), Office of Diversion Control, has changed the style and appearance of the DEA Controlled Substance Registration Certificate. As of October 1, 2004, the revised Certificate Registration consists of two parts (see below). The certificate has an embedded watermark logo, which will provide authentication of the certificate and also deter counterfeiting.

Registrants that are currently allowed to renew their DEA registration via the Diversion Control Program's Web site (i.e., retail pharmacies, hospitals, practitioners, mid-level practitioners and teaching institutions) may print their registration certificate upon completion of the registration renewal process as long as no changes have been made to their registration since their last renewal. The Diversion Control Program's Web site may be accessed at www.DEAdiversion.usdoj.gov. New registrants and all other renewing registrants will receive their certificates through the mail.

<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="font-size: small;">DEA REGISTRATION NUMBER</th> <th style="font-size: small;">THIS REGISTRATION EXPIRES</th> <th style="font-size: small;">FEE PAID</th> </tr> <tr> <td style="text-align: center;">BR0123456</td> <td style="text-align: center;">12-31-2007</td> <td style="text-align: center;">PAID</td> </tr> </table>	DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID	BR0123456	12-31-2007	PAID	<p style="text-align: center; font-weight: bold; font-size: small;">CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE UNITED STATES DEPARTMENT OF JUSTICE DRUG ENFORCEMENT ADMINISTRATION WASHINGTON, D.C. 20537</p> <p style="font-size: x-small;">Sections 304 and 1008 (21 U.S.C. 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacturer, distribute, dispense, import or export a controlled substance.</p> <p style="font-weight: bold; font-size: small;">THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, BUSINESS ACTIVITY, OR VALID AFTER THE EXPIRATION DATE.</p> <p style="text-align: right; font-size: x-small;">Form DEA-223 (11/03)</p>
DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID					
BR0123456	12-31-2007	PAID					
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="font-size: x-small;">SCHEDULES</th> <th style="font-size: x-small;">BUSINESS ACTIVITY</th> <th style="font-size: x-small;">DATE ISSUED</th> </tr> <tr> <td style="text-align: center;">2,2N 3,3N,4,5</td> <td style="text-align: center;">PRACTITIONER</td> <td style="text-align: center;">11-23-2004</td> </tr> </table>	SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED	2,2N 3,3N,4,5	PRACTITIONER	11-23-2004	
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<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td colspan="3" style="padding: 5px;"> JANE D REGISTRANT 1234 MAIN AVE PO BOX 1234 </td> </tr> <tr> <td style="width: 33%; padding: 5px;">ANYCITY</td> <td style="width: 33%; text-align: center; padding: 5px;">US</td> <td style="width: 33%; text-align: right; padding: 5px;">12345-0123</td> </tr> </table>	JANE D REGISTRANT 1234 MAIN AVE PO BOX 1234			ANYCITY	US	12345-0123	
JANE D REGISTRANT 1234 MAIN AVE PO BOX 1234							
ANYCITY	US	12345-0123					

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON, D.C. 20537

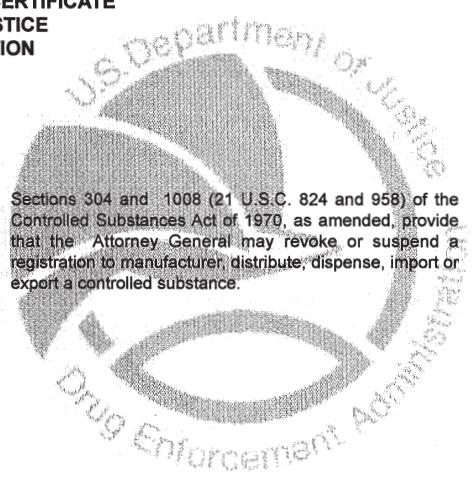
DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
BR0123456	12-31-2007	PAID

SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
2,2N 3,3N,4,5	PRACTITIONER	11-23-2004

JANE D REGISTRANT
1234 MAIN AVE
PO BOX 1234

ANYCITY US 12345-0123

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, BUSINESS ACTIVITY, OR VALID AFTER THE EXPIRATION DATE.



Sections 304 and 1008 (21 U.S.C. 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacturer, distribute, dispense, import or export a controlled substance.

Form DEA-223 (11/03)

What to Look for on the New Tamper-Resistant Prescription Forms

Beginning January 1, 2005, written prescriptions for controlled substances must be on tamper-resistant security prescription forms that have been printed by a Board-approved printing company. To prevent fraud or diversion, these forms must contain specific security features (Health & Safety Code section 11162.1 et seq.). There is no one specific format, size or color for the security prescription forms, so pharmacists need to be aware of the required features.

Security Features

The law requires that the list or description of the required security features must be printed on the security

prescription form. The list/description may be printed **anywhere on the form** (e.g., in warning bands along the edges of the form's face or listed on the back of the form). The description should tell what and where the features are on the form and how to test them.

Examples of what a new security form might look like are on the following pages. These are examples only—actual form designs and security feature application will vary significantly from form to form and from printer to printer. However, all forms are required to have specific security features and preprinted prescriber information.

More specific information about the security features required on these

forms, as well as other new requirements for prescribing and dispensing controlled substances can be found on the Board's Web site at www.pharmacy.ca.gov.

If the form does not contain the proper features, it may indicate that it was not printed by a Board-approved printer. Such prescriptions should be reported to the Bureau of Narcotic Enforcement at (916) 319-9062.

Important Note: If you have questions concerning the validity of a prescription, treat it like any other questionable prescription—call the prescriber to verify the prescription.

SINGLE PRESCRIBER OR GROUP PRACTICE SECURITY PRESCRIPTION FORM SAMPLE

VOID APPEARS WHEN COPIED	REVERSE RX	MICROPRINT SIGNATURE LINE	CA WATERMARK
Group Practice Name _____ Address _____ City, State Zip _____ Telephone Number _____		<input type="checkbox"/> Prescriber Name, Category of Licensure, DEA Number, State License Number Prescriber Name, Category of Licensure, DEA Number, State License Number Prescriber Name, Category of Licensure, DEA Number, State License Number Prescriber Name, Category of Licensure, DEA Number, State License Number	
Name _____ DOB _____ Address _____ Sex: <input type="checkbox"/> M <input type="checkbox"/> F		Z999999-0001 	
<h2 style="color: #0056b3; margin: 0;">SAMPLE ONLY – ACTUAL FORM DESIGNS MAY VARY SIGNIFICANTLY</h2>			
Quantity: <input type="checkbox"/> 1 24 <input type="checkbox"/> 25 49 <input type="checkbox"/> 50 74 <input type="checkbox"/> 75 100 <input type="checkbox"/> 101 150 <input type="checkbox"/> 151 over Unit _____ Refills: 0 1 - 2 3 - 4 - 5 <input type="checkbox"/> Do Not Substitute Initials _____		Date _____ Prescription is void if more than one controlled substance is written per blank	
THERMOCHROMIC INK SYMBOL	QUANTITY CHECK BOXES	CHEMICAL VOID PROTECTION	

Batch/Lot Numbers
Unique batch and sequential lot numbers assigned by approved security printers. Not tracked by the State,

Opaque Writing
fades or disappears when photocopied repeatedly

Six quantity check boxes allow quick confirmation that the quantity prescribed has not been altered.

Refills CII drugs cannot be refilled, only CIII V can be refilled.

Do Not Substitute prescriber must check box and initial

Statement that identifies form as a **single drug** prescription form


Thermochromic ink feature changes color or disappears temporarily with hot breath or when rubbed briskly. It slowly returns to normal as it cools.

Microprint signature line seen only with a magnifier and becomes a solid line when copied, faxes or scanned.

Description of security features in warning bands on face or listed on back of prescription.

INSTITUTION OR FACILITY SECURITY PRESCRIPTION FORM SAMPLE

Institution forms can only be used by health care facilities licensed under Health & Safety Code section 1250. Generally, these are 24-hour acute care hospitals, skilled nursing facilities, etc. The forms are preprinted with the facility and the facility's "designated prescriber" information as indicated below. The actual prescriber information will be printed, handwritten, or stamped on the form when the prescription is written.

VOID APPEARS WHEN COPIED		REVERSE RX	MICROPRINT SIGNATURE LINE	CA WATERMARK
Institution's State License Number Institution Name Address City, State Zip Designated Prescriber: Designated Prescriber Name, Category of Licensure, DEA Number, State License Number				9999999-0001
Prescriber Name & Category of Licensure		DEA Number	State License Number	Telephone Number
	Name _____	DOB _____	Rx	
	Address _____	Sex: <input type="checkbox"/> M <input type="checkbox"/> F		
1)	Quantity: <input type="checkbox"/> 1-24 <input type="checkbox"/> 25-49 <input type="checkbox"/> 50-74 <input type="checkbox"/> 75-100 <input type="checkbox"/> 101-150 <input type="checkbox"/> 151 - over		Unit _____ Refills: 0 - 1 - 2 - 3 - 4 - 5	
2)	SAMPLE ONLY – ACTUAL FORMS MAY VARY SIGNIFICANTLY		Quantity: <input type="checkbox"/> 1-24 <input type="checkbox"/> 25-49 <input type="checkbox"/> 50-74 <input type="checkbox"/> 75-100 <input type="checkbox"/> 101-150 <input type="checkbox"/> 151 - over	
3)	Unit _____ Refills: 0 - 1 - 2 - 3 - 4 - 5		<input type="checkbox"/> Do Not Substitute Initials _____	
X		Date _____	Prescription is void if the number of drugs is not noted: _____	
THERMOCHROMIC INK SYMBOL		QUANTITY CHECK BOXES		

- **Batch/Lot Numbers** – Unique batch and sequential lot numbers assigned by approved security printers. Numbers are not tracked by the State.
- **Actual Prescriber** – the prescription is not valid without the actual prescriber information filled in.
- **Opaque Writing** fades or disappears when photocopied repeatedly to lighten.
- **Six quantity check boxes** allow quick confirmation that the quantity prescribed has not been altered.
- **Do Not Substitute** –prescriber must check box and initial
- **Refills** – CII drugs cannot be refilled, only CIII – V can be refilled.
- **Description of security features** in warning bands on face or listed on back of prescription. (see sample of backside)

- **Thermochromic ink** feature changes color or disappears temporarily with hot breath or when rubbed briskly. It slowly returns to normal as it cools.
- **Microprint signature line** – seen only with a magnifier, which becomes a solid line when copied.
- **Statement** allows multiple prescriptions on one form.) Prescribers must note the number of drugs prescribed.

Alternatively, prescribers may order a form designed to write only single drug prescriptions. See the previous form sample using a single drug prescription format.

SAMPLE BACKSIDE OF SECURITY PRESCRIPTION FORMS

SAMPLE ONLY ACTUAL FORM DESIGNS MAY VARY

- Security Features:**
- RX logo disappears or changes color temporarily with hot breath or when rubbed briskly with finger.
 - Opaque Rx fades or disappears with repeated attempts to lighten prescription on copier.
 - Microprinted text signature line becomes solid line when copied.
 - California Security Prescription watermark on back.
 - Repetitive VOID pattern appears across face when copied.
 - VOID pattern or stain appears where attempts are made to chemically alter the prescription.
 - Quantity range checked confirms quantity prescribed.
 - Unique batch number and each form sequentially numbered.
 - Order not to substitute.
 - Single drug prescription format.
 - Preprinted prescriber information.

- **California Security Prescription Watermark** printed in opaque ink—hold at an angle to view.
- **Description of Security Features** may be on the face of prescription in warning bands instead, see blue bands on sample forms



Letter to California Pharmacists and Physicians and Surgeons

From: **Patricia F. Harris**
Executive Officer
State Board of Pharmacy

David T. Thornton
Executive Director
Medical Board of
California

Re: Schedule II Prescriptions and Section 11167 of the Health & Safety Code

Effective January 1, 2005, all written prescriptions for Schedule II-V controlled substances must be on tamper-resistant prescription forms that are purchased from state-approved, designated security printing companies.

Prescribers who do not have the tamper-resistant prescription forms may have difficulty providing good patient care when that care necessitates prescribing a Schedule II controlled substance. Prescriptions for Schedule III-V can be dispensed upon an oral or electronically transmitted prescription. Prescribers can also fax a regular prescription form for Schedule III-V drugs.

With regard to Schedule II prescriptions, prescribers without the required security forms may in limited emergency circumstances use the exception to the security form requirement offered by Section 11167 (copied below) of the Health and Safety Code to prescribe a Schedule II controlled substance for a patient in need.

The Board of Pharmacy and the Medical Board of California are most concerned that the healthcare needs of legitimate patients be met during the implementation period for the new security prescription forms. Pharmacists receiving prescriptions with the 11167 notation should exercise their professional judgment in filling these prescriptions, with the highest priority given to evaluating whether a prescription is authentic and issued for a legitimate medical purpose. This may require contacting the prescriber's office to verify the prescription. In addition, if pharmacists have reason to believe that a prescriber is delaying or avoiding use of security prescription forms, relying on Section 11167 for non-emergent Schedule II prescriptions, or otherwise misusing the limited emergency authority given by Section 11167, pharmacists may choose to file a complaint with the appropriate licensing board for the prescriber in question.

For their part, physicians need to make a good faith effort to obtain the new tamper-resistant security forms in compliance with the law and provide the written prescription on the new form by the seventh day after the initial order. The boards are concerned that patient care is not interrupted as long as both the prescribers and pharmacists are making good faith efforts to comply with this new law. There are nearly 50 approved printers with more than 1,000 distributors, so obtaining the new security forms should not be a problem.

Additional information on SB 151 is available on the Board of Pharmacy Web site: www.pharmacy.ca.gov and the Medical Board of California's Web site: www.caldocinfo.ca.gov.

11167. Notwithstanding subdivision (a) of Section 11164, in an emergency where failure to issue a prescription may result in loss of life or intense suffering, an order for a controlled substance may be dispensed on an oral order, an electronic data transmission order, or a written order not made on a controlled substance form as specified in Section 11162.1, subject to all of the following requirements:

(a) The order contains all information required by subdivision (a) of Section 11164.

(b) Any written order is signed and dated by the prescriber in ink, and the pharmacy reduces any oral or electronic data transmission order to hard copy form prior to dispensing the controlled substance.

(c) The prescriber provides a written prescription on a controlled substance prescription form that meets the requirements of Section 11162.1, by the seventh day following the transmission of the initial order; a postmark by the seventh day following transmission of the initial order shall constitute compliance.

(d) If the prescriber fails to comply with subdivision (c), the pharmacy shall so notify the Bureau of Narcotic Enforcement in writing within 144 hours of the prescriber's failure to do so and shall make and retain a hard copy, readily retrievable record of the prescription, including the date and method of notification of the Bureau of Narcotic Enforcement.

(e) This section shall become operative on January 1, 2005.

Pharmacists prescribing controlled substances must apply for personal DEA registration

Effective January 1, 2005, any pharmacist who is authorized to write or issue prescriptions for a Schedule II through V controlled substance, pursuant to a protocol with a physician, must now apply for personal registration as a Mid-Level Practitioner with the Drug Enforcement Administration (DEA). (Business and Professions Code 4052.) If the protocol does not include controlled substance therapy, the pharmacist is not required to obtain DEA registration.

You may apply online for DEA registration as a new Mid-Level Practitioner (DEA Form 224) at www.deadiversion.usdoj.gov. Any questions related to registration must be directed to the DEA:

Los Angeles area (213) 621-6960
San Diego area (858) 616-4542
San Francisco area (888) 304-3251

Board Competency Committee to be restructured—item writers needed

The Board’s Competency Committee develops and oversees the administration of the California Pharmacist Jurisprudence Examination or CPJE. This exam consists of 90 multiple-choice items that assess minimal competency in patient communication skills, pharmacy law and clinical knowledge in practice situation in California.

The Board is restructuring the Competency Committee into two groups: 1) a core committee that selects and refines the items for the examination, selects a cut-score and oversees the administration of the examination and 2) item writers. The Board is now seeking new members for both committees, and pharmacists are encouraged to apply.

1. Core Committee

Besides the main functions of the committee described above, related duties of the committee include the oversight of a job analysis of the pharmacist profession every five years to assure that the exam remains valid for entry-level pharmacist practice. From this analysis, the committee develops the content outline for the examination.

Appointment to the core committee is an honor, but the work required is demanding. There are six two-day meetings annually, and attendance at the committee meetings is a requirement. Those members who cannot attend all meetings each year may become item writers where attendance at periodic meetings is not required.

The committee will consist of 19 members and will be structured to ensure a balance of practitioners from all practice settings:

Schools of Pharmacy	
(1 member each)	6 members
Community Practice	6 members
Institutional Practice	5 members
Board Member:	1 member
Board Inspector	1 member

2. Item Writers

Item writers will meet only once annually for an item-writing workshop and training. Then throughout the year, assignments to write questions in specific areas of the content outline will be distributed to the item writers. The finished questions will be reviewed by the core committee for inclusion in future examinations. No other meetings are required for item writers.

How to Apply

The Board’s president appoints all committee members to terms of four years, with reappointment possible for another four years. Practicing California pharmacists who have been licensed within the last five years are especially encouraged to apply. Applications must include your curriculum vitae, a cover letter describing your area of pharmacy experience or practice, and three letters of reference from pharmacists who are familiar with your work. Please submit applications to:

Competency Committee Appointments
 Board of Pharmacy
 400 R Street, Suite 4070
 Sacramento CA 95814

NOTE: The National Association of the Boards of Pharmacy (NABP) also is seeking item writers. If you are a pharmacy practitioner, educator, or regulator, the NABP can use your expertise as an item writer for the North American Pharmacist Licensure Examination, Foreign Pharmacy Graduate Equivalency Examination, and the Disease State Management Examination. Those interested should send or fax a letter of interest and a current resume or curriculum vitae to:

NABP
 Executive Director/Secretary, Carmen A. Catizone
 700 Busse Highway, Park Ridge IL 60068
 (fax: 847-698-0124)

Item writers may write questions for either the California Board of Pharmacy or the NABP—not both.



Pharmacist Protocol for Dispensing Emergency Contraception

Pharmacists may furnish emergency contraception drug therapy based on a statewide protocol adopted by the California State Board of Pharmacy and the Medical Board of California. Development of the protocol was authorized by Senate Bill 490 (Chapter 651, Statutes of 2003). The protocol is located in section 1746 of the Code of Regulations and also can be viewed at www.pharmacy.ca.gov.

The Board-approved protocol was prepared with the intent to keep it simple and to comply with the statutory requirements established by Senate Bill 490. Statutory provisions for pharmacists furnishing emergency contraception drug

therapy are found in section 4052 of the Business & Professions Code.

Pharmacists may use this protocol after they have completed and been awarded one hour of continuing education credit in emergency contraception (a requirement of the new law).

Prior legislation (Senate Bill 1169, Chapter 900, Statutes of 2001) permits pharmacists to furnish emergency contraception medications to patients, based on a protocol with a single licensed prescriber. Protocols developed with a prescriber under these requirements remain valid.

Who can sign pharmacist intern affidavits?

The Board is finding that newly licensed pharmacists are acting as preceptors by signing pharmacy intern hours and experience affidavits for periods of time *before* they were actually licensed as pharmacists. For example, an intern's training began in 2002, but the preceptor signing the affidavit did not become a licensed pharmacist until 2003. In most of the cases, these newly licensed individuals are pharmacy managers and mistakenly required by company policy to sign off on all intern affidavits. California pharmacy law prohibits such action.

Section 1726 of the California Code of Regulations defines a "preceptor" as a licensed pharmacist whose license "...is not revoked, suspended or on probation in any state in which he or she is now or has been registered." Preceptors are responsible for the supervision and training of interns and ultimately confirm that training by signing off the interns' hours and experience affidavits—those signatures being affixed under penalty of perjury.

Another problem is that preceptors are signing off on intern hours affidavits, based on the intern's employment dates. However, occasionally individuals are hired initially as pharmacy clerks and begin their internship training at a later date. The dates on the intern hours affidavit should include only the actual dates the individual worked and trained as an intern and not be based on hiring and termination dates.

The consequences of erroneously signed affidavits include (1) seriously interfering with an intern's ability to complete his or her application for the Board's licensure exam; (2) being viewed as performing unlicensed activity and subject to citation and fine; and (3) criminal penalties for perjury.

How does wholesalers' electronic billing affect pharmacies' drug purchase recordkeeping?

The Board was recently asked for clarification of a pharmacy's recordkeeping duties when a wholesale supplier decides to convert from paper to electronic invoices. Specifically, is the pharmacy permitted to store invoices electronically and no longer required to keep paper copies of invoices on file? If so, how long is the pharmacy required to keep electronic invoices available for inspection?

California law requires that records of the manufacture, sale, acquisition and distribution of dangerous drugs and devices be available on the licensed premises for three years from the date of making (Business & Professions Code sections 4081, 4105 and 4333). Also, records may be kept electronically so long as a hard copy and an electronic copy can always be produced (B&PC 4105).

The answer is that pharmacies can keep drug purchase records from wholesalers electronically rather than on paper so long as these records are retained on site, immediately available for inspection for a period of three years, and can at all times be produced in both hard copy and electronic form by an on-duty pharmacist.



Ignoring restrictions on ephedrine sales can lead to disciplinary action and criminal conviction

In 2000, California laws restricted the sales of over-the-counter (OTC) medications for allergy, asthma, colds, sinus, and weight loss—products that could be used in the illicit manufacture of methamphetamine. Sales of these products must be reported to the Bureau of Narcotic Enforcement (BNE) on forms furnished by the BNE. The reporting requirements apply to sales by manufacturers, wholesalers, pharmacies and other unlicensed retailers.

Failure to comply with these requirements (Health & Safety Code 11100-11107.1) led to the conviction and of a San Jacinto pharmacist, Jae Gab Kim, for the distribution of pseudoephedrine to manufacture methamphetamine in May 2004.

Retail sales of products containing ephedrine, pseudoephedrine, norpseudoephedrine or phenylpropanolamine are limited to **no more than three packages or no more than nine grams (or 150 60 mg. pills) in a single transaction.** However, since most of these products are packaged in quantities of less than three grams per package, three packages of commercial products containing these substances will not ordinarily exceed the nine grams limit. Prescriptions for such products are exempt from the limit and reporting requirements.

Though abiding by the letter of the 9-gram-per-transaction limit, Kim's sales of pseudoephedrine skyrocketed more than 20 times during the first seven months of 2000. He regularly sold consumers generically labeled, 100-count bottles of 60 mg. pseudoephedrine pills that typically are used by pharmacists to fill prescriptions. His average sales rose to about 24 of these bottles per day. Employee testimony revealed that about half the people purchasing a bottle would also purchase two 24-count boxes of 60 mg. pseudoephedrine tablets and little else,

and some customers bought pseudoephedrine almost daily.

The evidence further showed that while Kim sold 5,000 bottles of 60 mg 100-count pseudoephedrine in 2000, 15 other pharmacies in the region had purchased a total of only two 60 mg. 100-count bottles during the same time period.

For more details regarding the laws relating to the limiting and reporting of ephedrine products and the sales and reporting exceptions, visit the Board's Web site, www.pharmacy.ca.gov and click on Written Information & Research Tools, then select the January 2000 *The Script* newsletter. An in-depth article begins on page 6 and is followed by questions and answers.

Can retired physicians prescribe?

The Medical Board of California recently asked the Board of Pharmacy to advise pharmacists that physicians with retired licenses cannot write prescriptions.

After July 1, 2004, a physician who is licensed as a physician in retired status with the Medical Board of California is no longer eligible to practice medicine and consequently may not write prescriptions.

Pharmacists with questions about the license status of a physician should contact the Medical Board of California at (916) 263-2382 or via the Internet at www.medbd.ca.gov.



Reporting Misconduct by Health Practitioners

The Medical Board of California Chief of Enforcement Joan Jerzak has requested that the Board of Pharmacy publish the following letter:

As chief of enforcement for the Medical Board of California, I am extremely interested in advancing the board's mission of consumer protection. Recently, a nurse in a California hospital was quoted in a major newspaper article stating that she knew (without naming anyone) of many physicians who deserved to have their licenses revoked by this board. The context for this was within a story about a licensee whose license was being revoked by our board. Such a statement is of concern to us because we rely in part on peer review and input from allied health professionals to help us in doing our job of patient protection. In my opinion, healthcare workers are in a uniquely

qualified position of trust and obligation to report to regulatory agencies problems they see with other healthcare providers that lead to or could lead to patient harm.

I am asking those "on the front line" to recognize and act on this obligation by informing the Medical Board of physician misconduct of which they become aware. While we can take complaints anonymously, they are impossible to pursue if we cannot find witnesses to corroborate the allegations. I cannot guarantee your name will not surface, but we will work with you to avoid that if possible. I can guarantee you that you will be doing the right thing by your patients and your profession. We, at the board, are deeply committed to our mission of consumer protection and the proper licensing and regulation of physicians in California. We hope you will work with us and your constituencies toward that end.

Please call our toll-free complaint line at (800) 633-2322, or download our complaint form from our Web site at www.caldocinfo.ca.gov or www.medbd.ca.gov. Thank you on behalf of the consumers of the state of California.

Changes at the Board

New Board officers were elected at the April 2004 meeting:

Stanley W. Goldenberg, *R. Ph.*,
President
William Powers, *Public Member*,
Vice President
David J. Fong, *Pharm D.*, Treasurer

Additionally, Ms. Andrea Zinder, *Public Member*, was recently reappointed to the Board by Speaker of the Assembly Fabio Nunez. Mr. William Powers was reappointed by Senate President Pro Tempore John Burton.



www.pharmacy.ca.gov

Clerk/Typist ratio for pharmacist is eliminated

Section 1793.3 of the California Code of Regulations was recently amended to remove the limits on the number of clerk/typists that may be supervised by a pharmacist. The regulation now allows a pharmacist to determine the number of clerk/typists the pharmacist will supervise. Employers are prohibited from taking disciplinary action or discriminating against the pharmacist for exercising this right. This amended regulation became effective October 2, 2004.





Board of Pharmacy needs inspectors

The Board of Pharmacy has inspector vacancies statewide and is seeking to fill these positions with self-starting pharmacists who have a solid understanding of pharmacy practice and pharmacy law.

Board inspectors from all over California are assigned to work in teams, and each inspector's duties are divided between those performed in a home office environment (e.g., report writing) and those requiring travel. Travel, including both local and statewide, is approximately 20-25 percent of the workweek. Inspectors are provided the use of home office equipment (telephone, cell phone, computer, etc.), a state car and business and travel expense reimbursement.

To be considered, you must be a California-registered pharmacist with at least two years' experience in the practice of pharmacy and possess a valid California driver's license. This is a civil service classification, so you will be required to participate in a qualifications assessment interview. The results of the interview will determine your ranking on a civil service hiring list. Based on this ranking, you may be called to appear for the Board's employment interview and writing skills evaluation.

To obtain an application for examination and employment, access the Board's Web site, www.pharmacy.ca.gov and click on What's New. Your completed examination application and résumé must be mailed to the address below and **postmarked no later than 2/8/05**.

Department of Consumer Affairs
P. O. Box 980428
West Sacramento CA 95798-0428

Six hours of CE for attending one full day of a Pharmacy Board meeting

Continuing education (CE) hours are being awarded to encourage pharmacists to learn more about the issues and operation of the Board. You may acquire six hours once a year by attending one full day of the Board's quarterly meetings. The meetings are held at different sites throughout the state to give as many licensees as possible the opportunity to attend. All interested parties are urged to attend. Board members are not eligible for this CE.

To attend a Board meeting, no reservations are needed. You simply arrive at the meeting location at the start of the business session. The business day eligible for CE is designated on the agenda.

Meeting dates for **2005** are:

April 27 & 28

Sacramento
Department of Consumer Affairs
400 R Street, 1st Floor Hearing
Room Sacramento, CA 95814

July 20 & 21

San Diego

October 25 & 26

Bay Area

Additional information regarding sites and agendas will be posted on the Board's Web site, www.pharmacy.ca.gov, approximately 10 days prior to the meetings. Also, you may download information packets for the meeting; these packets contain action items and background information that will be discussed during the meeting. The materials are placed on the Board's Web site about five days before a meeting.

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Pharmacy Law 2005 is available

The 2005 edition of the California Pharmacy Law book can be purchased for \$26.41 each. That amount includes tax and shipping charges.

For credit card orders or quantity discount pricing, call (800) 498-0911, extension 5, or visit www.Lawtechpublishing.com.

Purchase orders for over \$100 can either be mailed to:

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