BE AWARE & TAKE CARE:
Talk to your pharmacist!

The Script

CALIFORNIA BOARD OF PHARMACY MARCH 2004

Renewal Notices and Licenses Are Delayed

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

Please renew your license early

a result, the renewal notices are being received by the licensee only three to four weeks before the license renewal 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 processed.

A similar delay occurs in the mailing of new 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 more weeks to mail the licenses. An additional week is then required for delivery by the US Postal Service.

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 license 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. However, since it now takes two or three weeks for the department to process and cashier your renewal, the Web site may not reflect that you have renewed your license.

Please plan ahead and renew your license once you receive the renewal application.

New Requirements for Schedule II–V Drugs

On September 16, 2003, the Governor signed Senate Bill 151 (Burton, Chapter 406, Statutes of 2003), repealing California's longstanding requirement for state-issued triplicate prescription forms for Schedule II controlled substances. In place of the triplicate, prescribers will use a tamper-resistant prescription pad that will be available from private printing companies that have been approved by the Board of Pharmacy and the Department of Justice. These changes are a primary focus of this issue.

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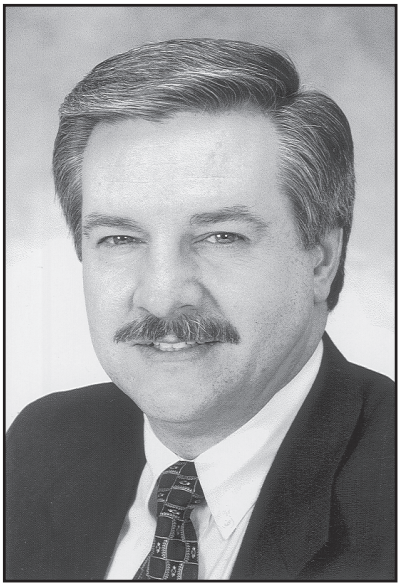


President's Message

By John D. Jones, R.Ph.
President, Board of Pharmacy

I am pleased to address you in this issue of *The Script*. Your board has worked hard to redirect scarce funding and obtain the needed resources to get it published.

As you can see from its content, the Board has been busy with new laws and is faced with challenges that transcend California's borders. The Board is also changing. We have two new professional members joining us, Ruth Conroy and Ken Schell. We also have two new public members; James Acevedo and Richard Benson. Finally, Clarence Hiura was reappointed for a fourth term as a professional member.

A new law signed by Governor Davis last year increases the size of the board to 13 by adding two public members. We will need the energy and wisdom of all of the members of the Board and the board's staff as we consider issues that test our ability to protect the consumers of California.

New Laws

In this issue, the Board updates you on major changes in the laws that affect your licensing and practice. The change to using the NAPLEX and a California Pharmacy Jurisprudence Examination (CPJE) has generated many questions about the process of examination, licensing and reciprocation of licenses. We attempt to answer in this issue many of the questions we have received over the past few months.

A major change in pharmacy practice is coming via the elimination of triplicate prescriptions for Schedule II controlled substances which will actually occur by January 2005. The section explaining the new law and the efforts of the Board to communicate it to the prescribing professions is detailed in this issue of *The Script*. The Board is working hard to break down barriers to the appropriate use of prescription controlled substances while strengthening modern and efficient means of tracking these drugs through the CURES program to prevent diversion and abuse.

The National Association of Boards of Pharmacy

Because California adopted the NAPLEX for testing applicants for pharmacist licenses, our state now becomes eligible to participate as an active member of the National Association of Boards of Pharmacy (NABP). Previously, the California board was an associate member of NABP, and as such, the Board did not have voting rights, could not serve on committees or run for its elected offices. Because NABP represents all of the boards of pharmacy nationwide on issues affecting pharmacy practice and regulation, it is important that our board be represented. A benefit of the change to use the NAPLEX is that our members and executive officer will have the opportunity to fully participate on par with the other 49 states in directing pharmacy policy at the national level.

Prescription Drug Importation

The Board has struggled over the past year to deal with the issue of prescription drug importation from outside of the United States. This has been a contentious and controversial issue, and the Board has been tasked with balancing consumer access to affordable prescriptions against the safety and effectiveness of drugs obtained from foreign sources. The Board has heard from many interested parties on this issue during its committee meetings and at its quarterly board meetings. Already in 2004, a number of legislation proposals on this issue have been introduced in the California Legislature.

I hope that you enjoy this issue of *The Script* and find it useful in answering your questions on new laws and issues before the Board. The newsletter is also available on the Board website at *www.pharmacy.ca.gov*.

Changes in Pharmacy Law for 2004

Each year, a number of California laws are created, amended or repealed. Listed below is a summary of last year's legislative changes to pharmacy law. Unless otherwise specified, these laws became effective on January 1, 2004. The exact language of the new and amended statutes noted below can be found in "California Pharmacy Law and Index" on the Board's Web site, *www.pharmacy@ca.gov,* and in the *2004 California Pharmacy Lawbook,* available for purchase through *www.LawTechPublishing.com*. Some of the changes brought by these bills are detailed in other articles in this newsletter.

Assembly Bill 186 (Correa)
Chapter 426, Statutes of 2003

Furnishing Dangerous Drugs to Optometrists by Pharmacists

Amends sections 4059, 4060 and 4061 of the Business & Professions Code (B&PC) and sections 11250 and 11251 of the Health & Safety Code (H&SC)—Adds optometrists to the healing arts practitioners who can receive dangerous drugs and devices from manufacturers, wholesalers and pharmacies without a prescription when accompanied by sale and purchase records. This bill also authorizes the distribution of dangerous drugs or devices as complimentary samples only upon the written request of these persons. These amended sections also authorize a pharmacist to furnish therapeutic pharmaceutical agents to an optometrist (note this pertains to limited drugs—see B&PC section 3041).

Assembly Bill 1196 (Montanez)
Chapter 748, Statutes of 2003

Nurse Practitioners Can Furnish Schedule II Controlled Substances

Amends section 2836.1 of the B&PC and section 11165 of the H&SC—Authorizes nurse practitioners to furnish drugs or devices that are classified as Schedule II-V, subject to certain conditions.

Senate Bill 151 (Burton)
Chapter 406, Statutes of 2003

Elimination of the Triplicate Prescription Requirement

Adds sections 11029.5, 11161.5, 11161.7, 11162.1, 11164.1 and 11165.1 and amends and recasts sections 11159.2, 11161, 11162, 11162.6, 11164, 11165, 11166, 11167, 11167.5, 11168, 11169 and 11190 of the H&SC—Eliminates the triplicate prescription requirement for Schedule II control substances effective January 1, 2005, and requires prescriptions for any controlled substance to be issued on controlled prescription forms obtained from a security printer approved by the Board of Pharmacy. Between July 1, 2004, and January 1, 2005, prescribers of Schedule II drugs will be permitted to use either the triplicate form or the new security forms. Also, if adequate state funding is provided, the bill would add tracking of Schedule III drugs to the CURES program.

Senate Bill 175 (Kuehl)
Chapter 250, Statutes of 2003

Veterinary Drugs Defined as Dangerous Drugs

Amends sections 4022, 4067, 4170, 4171 and 4175 of the B&PC—Adds veterinary drugs to the definition of dangerous drugs. Previously, veterinary drugs labeled for use on animals were not considered dangerous drugs under California law.

Senate Bill 292 (Speier)
Chapter 544, Statutes of 2003

Prescription Labels to Have Drug Description

Amends section 4076 of the B&PC—Effective January 1, 2006, requires prescription labels to contain a physical description of the drug, including the color, shape, and any identification code appearing on the tablets or capsules. New drugs are exempt from these requirements for the first 120 days on the market.

Senate Bill 361 (Figueroa)
Chapter 539, Statutes of 2003

Orders of Correction, Letter of Admonishment, Issuance of Citations

Amends sections 4001, 4002, 4003, 4008, 4062, 4200, 4202, 4312, 4400 and 4403 of and adds sections 4083, 4106, 4200.2, 4200.3, 4200.4, 4314 and 4315 to the B&PC—Authorizes Board inspectors to issue a written order of correction and the executive officer to issue a letter of admonishment directing a licensee to comply with the Pharmacy Law or related regulations. The bill requires an order of correction or letter of admonishment to contain certain information, including the process for the licensee to contest the order or letter. The bill also authorizes the Board, when it issues citations with fines and orders of abatement, to direct a person to demonstrate how future compliance will be accomplished. Also contained in the bill are a number of other changes including revisions of the requirements for the pharmacist licensure examination and the requirements for pharmacy technician registration.

Continued on page 4

Requirements for Schedule II-V prescriptions are standardized

Existing law has disparate requirements for prescriptions in different schedules and for the various forms permitted by existing law. Senate Bill 151 standardizes these requirements across all schedules.

Specifically, **prescribers must sign and date the forms, but the remainder of the information required can be filled in by the prescriber's staff or printed on a form by any other means.** Pharmacies no longer need to mail copies of Schedule II prescriptions to the Department of Justice unless the prescriptions are submitted on a state-issued triplicate prescription form (which will no longer be valid after January 1, 2005).

As of January 1, 2004		
Prescription Element	**Schedule II**	**Schedules III-V**
Prescriber Signature	Prescriber	Prescriber
Date Issued	Prescriber or Agent	Prescriber
Prescriber Address	Preprinted	Prescriber or Agent
Prescriber Phone Number	Preprinted	Prescriber or Agent
Prescriber License Type	Preprinted	Prescriber or Agent
Prescriber License Number	Preprinted	Prescriber or Agent
Prescriber DEA Number	Preprinted	Prescriber or Agent
Patient Name	Prescriber or Agent	Prescriber or Agent
Patient Address	Prescriber or Agent	Prescriber or Agent
Drug Name	Prescriber or Agent	Prescriber or Agent
Quantity	Prescriber or Agent	Prescriber or Agent
Drug Strength	Prescriber or Agent	Prescriber or Agent
Directions for Use	Prescriber or Agent	Prescriber or Agent

As of January 1, 2005		
Prescription Element	**Schedule II**	**Schedules III-V**
Prescriber Signature	Prescriber	Prescriber
Date Issued	Prescriber	Prescriber
Prescriber Address	Preprinted	Preprinted
Prescriber Phone Number	Preprinted	Preprinted
Prescriber License Type	Preprinted	Preprinted
Prescriber License Number	Preprinted	Preprinted
Prescriber DEA Number	Preprinted	Preprinted
Patient Name	Prescriber or Agent	Prescriber or Agent
Patient Address	Prescriber or Agent	Prescriber or Agent
Drug Name	Prescriber or Agent	Prescriber or Agent
Quantity	Prescriber or Agent	Prescriber or Agent
Drug Strength	Prescriber or Agent	Prescriber or Agent
Directions for Use	Prescriber or Agent	Prescriber or Agent

Schedule II prescriptions written for patients with a terminal illness, pursuant to section 11159.2 of the Health & Safety Code, may be written on ordinary prescription forms. Only the prescriber's signature and date must be written by the prescriber, the other information may be added by the prescriber's agent.

Senate Bill 151 also establishes that all controlled substance prescriptions (Schedules II-V) are valid for six months from the date of issuance.

Changes in Pharmacy Law for 2004 *Continued from page 3*

Senate Bill 490 (Alpert)
Chapter 651, Statutes of 2003

Emergency Contraception Protocol
Amends section 4052 of the B&PC—Authorizes a pharmacist to furnish emergency contraception drug therapy in accordance with a standardized procedure or protocol developed and approved by both the Board of Pharmacy and the Medical Board of California.

Senate Bill 545 (Speier)
Chapter 652, Statutes of 2003

Emergency Contraception Administrative Fee
Amends section 4052 and adds section 682 to the B&PC—Authorizes pharmacists to furnish emergency contraception drug therapy subject to certain conditions and revises the pharmacist training requirement. This bill prohibits a pharmacist from requiring a patient to provide individually identifiable medical information, except as specified. A pharmacist is also prohibited from charging a separate consultation fee for the initiation of emergency contraception drug therapy, but is authorized to charge an administrative fee not to exceed $10 more than the retail cost of the drug.

Triplicates to be replaced with tamper-resistant prescription forms

The triplicate prescription form required to prescribe for Schedule II medications is being replaced. Effective July 1, 2004, a new form may be used to prescribe Schedule II medications, although triplicate forms can still be used for six more months. On January 1, 2005, all *written* controlled substance prescriptions (for Schedules II–V) must be on the new, tamper-resistant prescription form.

Phone and fax orders for Schedules III-V medications will still be permitted. Fax orders should not be on the tamper-resistant forms (use of the new forms will result in a prescription that reads "void") but on an ordinary prescription form. If the tamper-resistant form is used for a fax prescription, the pharmacy will have to assure the prescription's authenticity.

The tamper-resistant form will be available from private printers who must be approved by both the Board of Pharmacy and the Department of Justice. Prescribers can obtain these forms from any approved security printer in any quantity or format they desire.

The new forms must have a number of different security features:

- Void protection to prevent duplication or chemical washing to alter prescriptions;
- Watermark on the backside of the prescription with the text "California Security Prescription;"
- Thermo-chromic ink that changes color when exposed to heat;
- A description of the security features printed on each prescription form;
- Quantity check-off boxes; and
- The preprinted name, category of licensure, license number, and federal controlled substance registration number of the prescribing practitioner.

The pharmacy-generated triplicate for patients in skilled nursing, intermediate care, and hospice settings is also being replaced. Beginning July 1, 2004, pharmacies may replace the pharmacy-generated triplicate with a form of their own design. In addition, pharmacies may now take oral and electronic Schedule II orders for patients in any home health care setting and patients served by a licensed hospice.

Hospitals and other licensed health facilities will use a variation of the tamper-resistant forms for discharge medications filled by the hospital that does not require the prescriber's information (name, license number, etc.) to be preprinted on the form. Instead, these "institutional forms" require the prescriber to write, print or stamp that information on the form before they can be used for a valid prescription.

Approval Process for Printers of Tamper-Resistant Prescription Forms

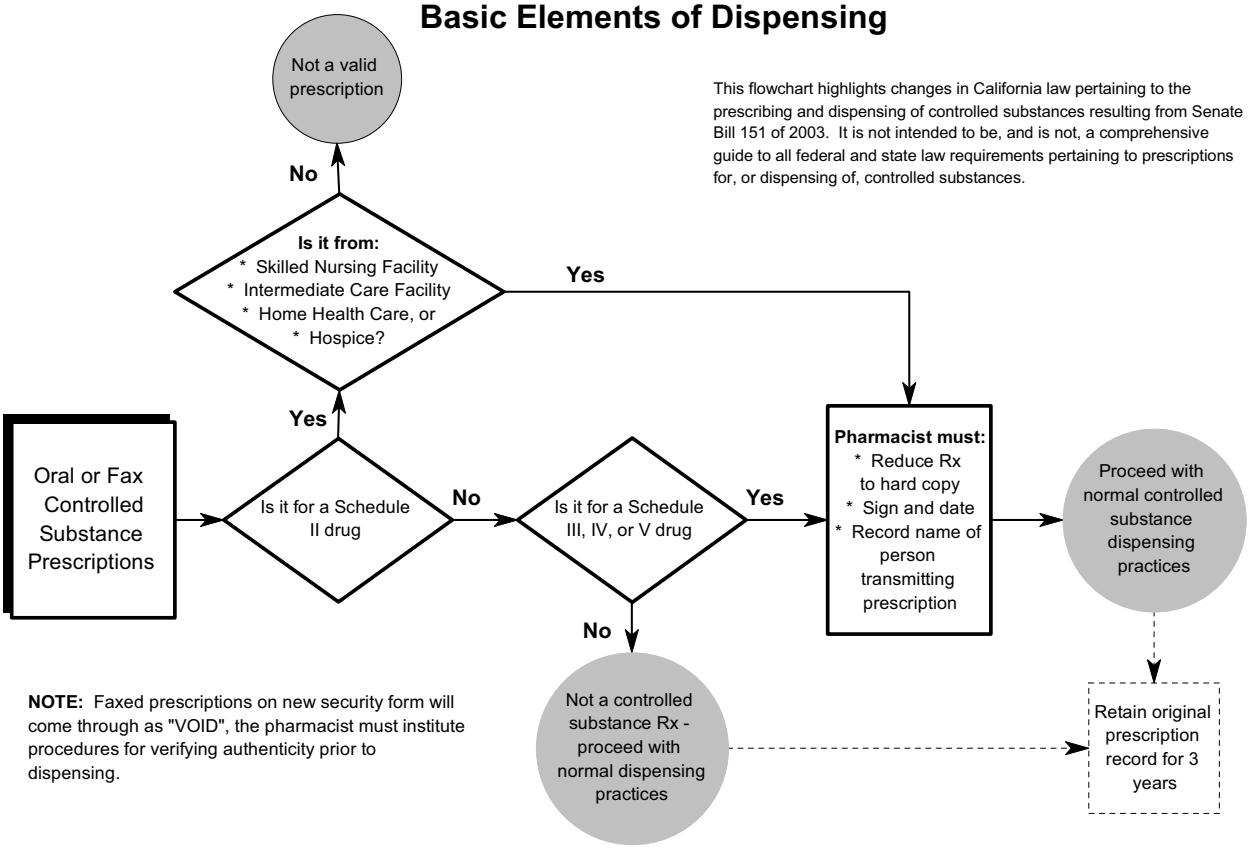
Senate Bill 151 (Burton, Chapter 406, Statutes of 2003) requires that the new, tamper-resistant prescription forms be produced by "security printers" who are approved by both the Board of Pharmacy and the Department of Justice. Applications for approval are available from the Board's Web site *(www.pharmacy.ca.gov)* with complete instructions attached.

To become a security printer, the printer must apply to the Board of Pharmacy. If approved, the application is then forwarded for consideration by the Department of Justice which has 30 days to approve or deny the application.

Generally, applicants are screened for prior criminal history and the adequacy of their policies and procedures to ensure that prescription forms are produced and distributed only to appropriately licensed practitioners. The new law requires that security printers confirm the licensure and prescribing privileges for any person requesting controlled substance prescription forms.

Once a security printer is approved, the printer is authorized to produce prescription forms for appropriately licensed practitioners. The Board of Pharmacy will maintain a list of approved security printers on its Web site.

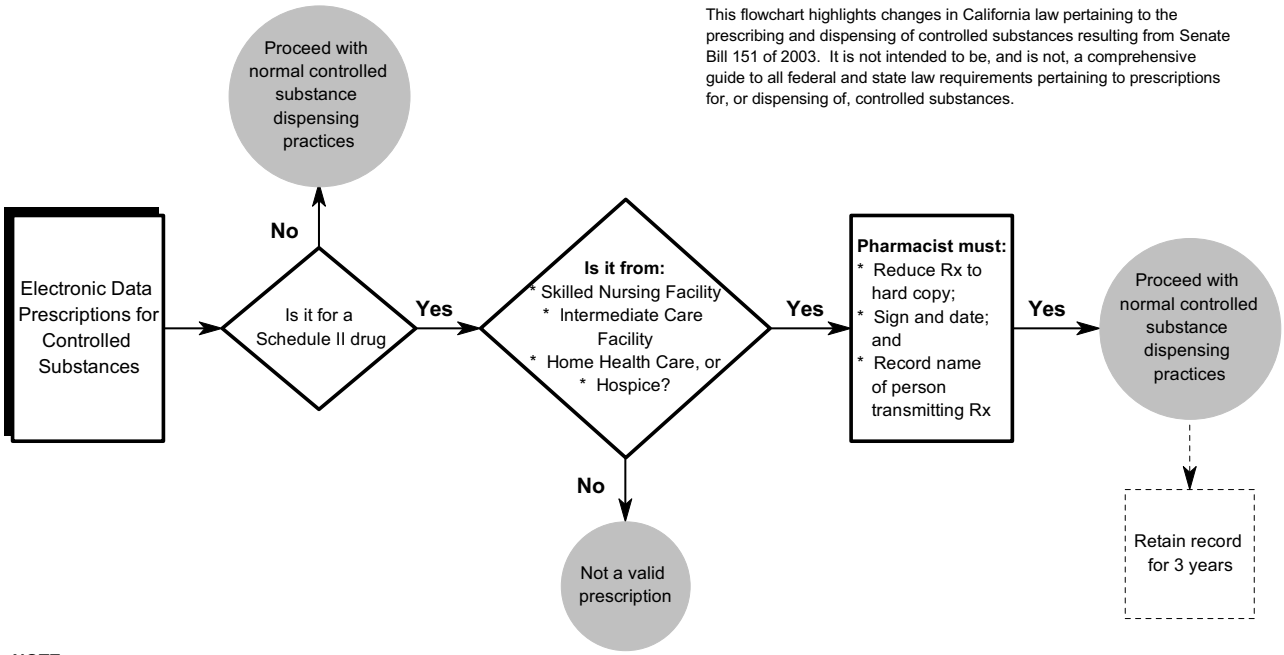
Effective July 1, 2004
Oral or Fax Prescriptions for Controlled Substances:
Basic Elements of Dispensing



This flowchart highlights changes in California law pertaining to the prescribing and dispensing of controlled substances resulting from Senate Bill 151 of 2003. It is not intended to be, and is not, a comprehensive guide to all federal and state law requirements pertaining to prescriptions for, or dispensing of, controlled substances.

NOTE: Faxed prescriptions on new security form will come through as "VOID", the pharmacist must institute procedures for verifying authenticity prior to dispensing.

Effective July 1, 2004
Electronic Data Prescriptions for Controlled Substances:
Basic Elements of Dispensing

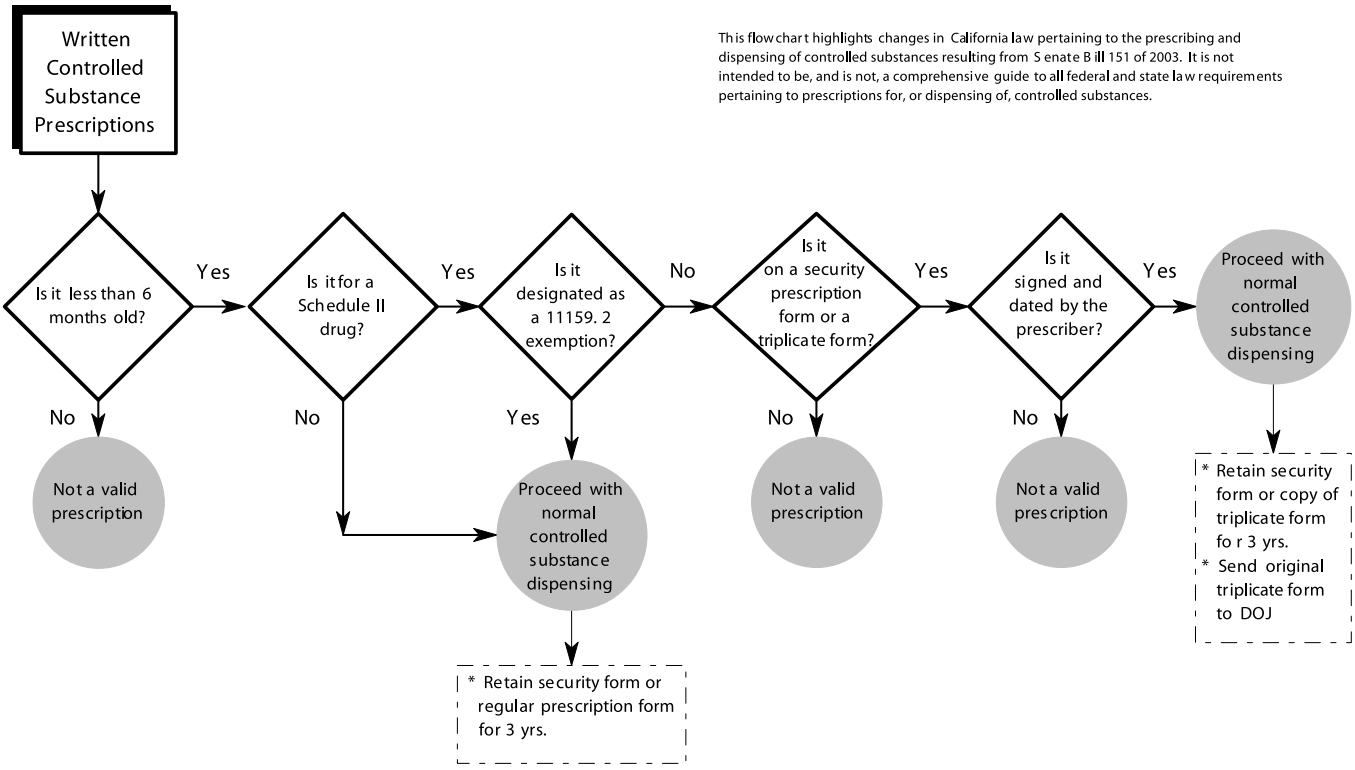


This flowchart highlights changes in California law pertaining to the prescribing and dispensing of controlled substances resulting from Senate Bill 151 of 2003. It is not intended to be, and is not, a comprehensive guide to all federal and state law requirements pertaining to prescriptions for, or dispensing of, controlled substances.

NOTE: Oral and fax transmitted controlled substance prescriptions are displayed in a separate flowchart.

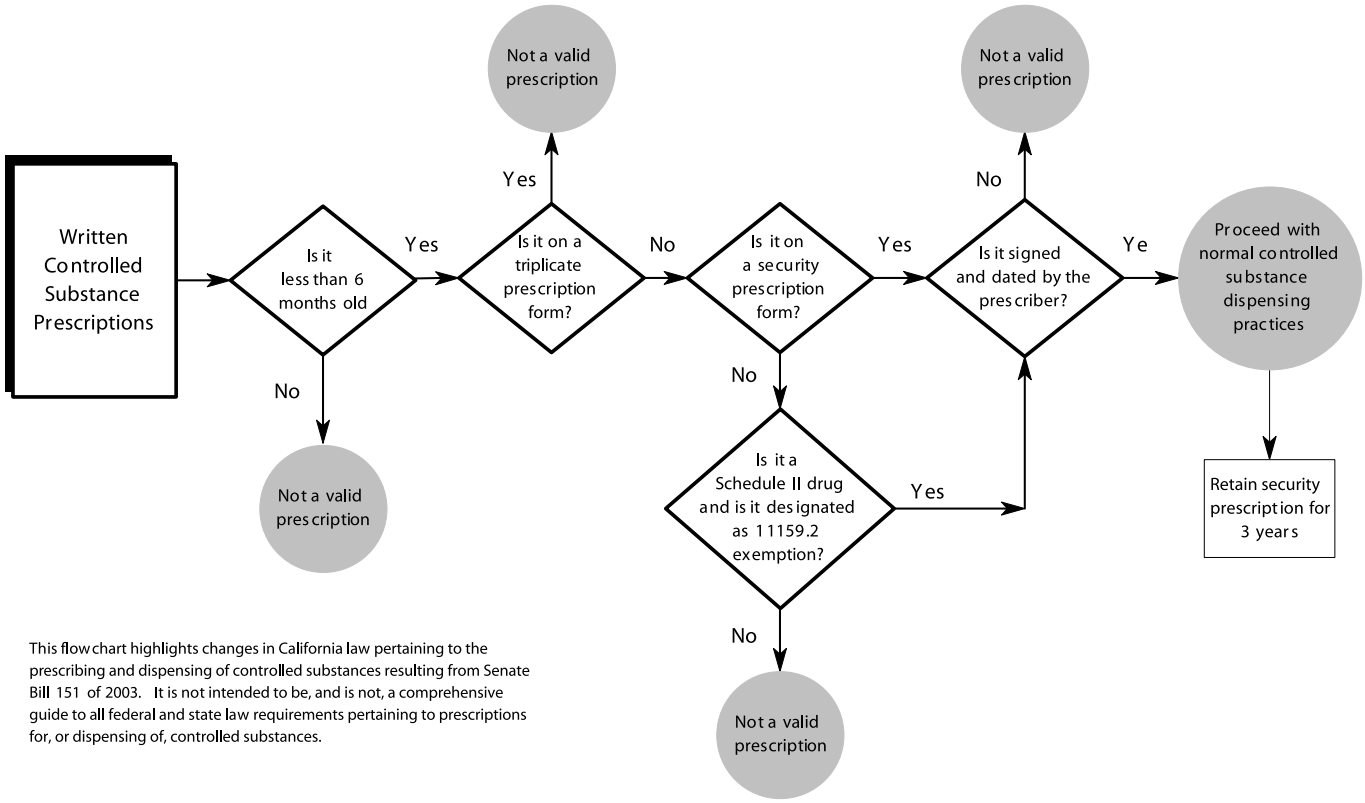
Effective July 1, 2004 through January 1, 2005

Written Controlled Substance Prescriptions: Basic Elements of Dispensing



Effective January 1, 2005

Written Controlled Substance Prescriptions: Basic Elements of Dispensing



Emergency Contraception

Under California law, pharmacists who are specially trained and provide emergency contraception must also provide patients with a fact sheet regarding emergency contraception. A previously published fact sheet has been revised by the Board and is included below. The new fact sheet is written at a lower reading level so that more individuals will understand the phrasing. Other changes included the removal of specific reference to dosing because different products have different dosing regiments.

Copies of the fact sheet are available on the Board's Web site in English and nine additional languages: Cambodian, Chinese, Farsi, Hmong, Korean, Russian, Spanish, Tagalog and Vietnamese.

Key Facts About Emergency Contraception

Emergency Contraception (EC) is a safe and effective way to prevent pregnancy after sex.

Consider using Emergency Contraception if:

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

What are Emergency Contraceptive pills?

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

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

Don't wait! Take EC as soon as possible.

- It is best to take EC within three days of unprotected sex.
- The sooner you take EC the more effective it is.
- For more information talk to your pharmacist or doctor.

EC is safe and effective.

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

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

EC won't cause an abortion.

- Emergency Contraceptive pills are NOT the same as RU-486 (the abortion pill).
- Emergency Contraceptive pills are not effective after pregnancy has occurred and cannot interrupt it.

EC won't harm a developing fetus.

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

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

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

Medical follow-up after taking Emergency Contraceptive pills

- If you don't get a normal period within three weeks, take a pregnancy test.
- It is important to visit your doctor or clinic if you need a regular birth control method or information about preventing sexually transmitted infections, such as HIV/AIDS.

In California all women and men with eligible incomes may receive free family planning services through the Family PACT program.

If you don't have a doctor or clinic, call 1-800-942-1054 to find a Family PACT provider near you.

emergency contraception

Revised October 2003

Timeline for Major Changes to California Prescribing Laws

Senate Bill 151 is a complex bill that makes substantial changes to California law regarding the prescribing of controlled substances, and these changes will be phased in over the next year:

Effective January 1, 2004

- Controlled substance prescriptions (Schedules II–V) are valid for six months.
- All pharmacies are required to report Schedule II controlled substance prescriptions to the CURES program in a time and manner established by the Department of Justice.
- Schedule II–IV controlled substance prescriptions are required only to be signed and dated by the prescriber, the other information required on a prescription form may be printed or written in by the prescriber's staff.

Effective July 1, 2004

- The Department of Justice will no longer produce or distribute triplicate prescription forms.
- Triplicate prescription forms may be used to prescribe Schedule II controlled substances.
- Prescribers may use the new controlled substance prescription forms for Schedule II controlled substance prescriptions.
- Oral and electronic orders for Schedule II controlled substance prescriptions for patients in skilled nursing facilities, intermediate care facilities, home health care programs, and hospice programs are permitted. Such orders must be reduced to hard copy form and signed by the pharmacist on a form of the pharmacy's design.
- Prescribers dispensing Schedule II controlled substances are required to begin reporting these prescriptions to the Department of Justice.

Effective January 1, 2005

- Triplicate prescriptions are no longer valid.
- All written controlled substance prescriptions (oral and fax orders for Schedules III–V are permitted) shall be on controlled substance prescription forms.
- **Pharmacies** must report Schedule III controlled substance prescription information to the CURES program.
- **Prescribers** dispensing Schedule III controlled substances must report those prescriptions to the Department of Justice.

Policy of Nondiscrimination on the Basis of Disability and Equal Employment Opportunity Statement

The California Board of Pharmacy does not discriminate on the basis of disability in employment or in the admission and access to its programs and activities.

An Americans with Disabilities Act (ADA) coordinator has been designated to coordinate and carry out this agency's compliance with the nondiscrimination requirements of Title II of the ADA. Information concerning the provisions of the ADA, and the rights provided thereunder, is available from:

Candy Place
ADA Coordinator
California Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814

New Requirements for Licensure as a California Pharmacist

California has new examination requirements for pharmacist licensure. Beginning January 1, 2004, applicants must pass the North American Pharmacist Licensure Examination (NAPLEX) and a California-specific examination—the California Pharmacist Jurisprudence Examination (CPJE).

Both these examinations are multiple-choice exams that are administered nationwide, six days per week.

The NAPLEX is developed by the National Association of Boards of Pharmacy, and is the primary licensing examination used by all other states. Candidates have approximately four hours to complete this examination, which assesses the knowledge, judgment and skills required of an entry-level pharmacist. The exam is comprised of 185 questions, 150 of which are graded, while the other 35 are pretest items.

The CPJE is developed by this board, and is used exclusively for pharmacist licensure in California. The examination assesses three primary areas:

1. The candidate's proficiency in patient communication skills.

2. Aspects of contemporary standards of practice for pharmacists in California, including pharmacists' care and the application of clinical knowledge to typical pharmacy practice situations that are not evaluated by the NAPLEX.

3. The candidate's knowledge of applicable state laws and regulations.

The CPJE is comprised of 90 questions, 75 of which are graded and the other 15 are pretest items. Candidates will have a maximum of two hours to take this examination.

Application Processes:

The NAPLEX and CPJE can be taken in any order, but both must be passed for licensure.

Applicants seeking a pharmacist license must meet California's requirements to be qualified to take the examinations. These requirements are detailed on the Board's Web site, and there is a $155 fee for this application.

Once qualified by California, an applicant is directed to contact both NABP and Experior Assessments (test administrator of the CPJE) to make arrangements to take the examinations at approved locations nationwide. There is a $40 fee to take the CPJE and $430 fee to take the NAPLEX.

Candidates will select their own testing location, date and time to take each examination. However, because different companies administer the two examinations, applicants will need to take the NAPLEX and CPJE at different locations.

Results:

Candidates will receive results directly from the California Board within two weeks of taking the NAPLEX and approximately four weeks after taking the CPJE. The Board will only mail results to candidates—it will not release them over the phone or via fax.

Candidates who pass both examinations and meet all other requirements will be licensed as pharmacists.

Candidates who fail either or both examinations must retake the failed examination(s). A candidate must wait 90 days before retaking either examination, and California must requalify each candidate before he or she can reschedule any examination.

Four Test Failures Require Additional Education

For several years, California law has required candidates who fail the pharmacist licensure exam four times to take 16 units of education in a school of pharmacy before they can retake the examination. This requirement remains in effect but requires some explanation:

- Candidates who have never taken the California licensure examination, will have a maximum of four attempts to pass the CPJE or the NAPLEX.

- Candidates who failed the prior California examination given before January 1, 2004, will have each of these failed exams count when determining the number of failed exams attempted. For example, if you failed the January 2002 and January 2003 California examinations, you will have two attempts to pass the CPJE and two attempts to pass the NAPLEX before you are required to take 16 units of pharmacy education.

For More Information

The Board's Web site (*www.pharmacy.ca.gov*) contains detailed information about the new examination and examination processes.

Information about the NAPLEX can be obtained from the NABP's Web site (*www.nabp.net*). The NAPLEX/MPJE Registration Bulletin that can be downloaded from this Web site contains information about the examination that will be helpful to applicants.

Information about the CPJE can be obtained from Board's Web site and in the CPJE Candidate Handbook.

NAPLEX Scores

Because the NAPLEX is used in all 50 states, there are three ways an applicant can take the NAPLEX or provide California with a NAPLEX score:

1. Apply to the California board for pharmacist licensure, using California as the primary or qualifying state—in which case the Board will advise the NABP when the applicant is eligible to take the pharmacist licensure examination. After taking the examination, California will be provided with the NAPLEX score directly from the NABP.

2. Apply to another state as your qualifying state—i.e., by applying to become a pharmacist in another state, taking the NAPLEX for this state, AND designating California as a score transfer state. A candidate must designate California as a score transfer state before taking the NAPLEX.

3. Use the NABP's license transfer program, which will enable a pharmacist to transfer a score earned on the NAPLEX to California after he or she is licensed as a pharmacist in another state. However, California can only accept a NAPLEX score taken after January 1, 2004. Scores earned before January 1, 2004, cannot be used for licensure in California.

Additionally all persons who wish to become pharmacists in California must pass the CPJE as well as the NAPLEX.

Clarence Hiura, Pharm.D., reappointed to the Board

Dr. Clarence Hiura was recently reappointed as a professional pharmacist member to the Board of Pharmacy. Dr. Hiura is currently serving as Chair of the Board's Licensing Committee, and his board tenure will expire in June 2007.

Schedule III is added to the CURES requirement

On January 1, 2005, all pharmacies will have to begin submitting Schedule III prescription information to the Controlled Utilization Review and Evaluation System (CURES) program. The CURES program compiles prescription data in a statewide database to assist state law enforcement and regulatory agencies in their efforts to reduce prescription drug diversion. That data is also available for prescribers and pharmacists who wish to obtain a patient drug history for someone under their care.

Currently, pharmacies are required to electronically transmit only Schedule II prescription information to the CURES program. New legislation, Senate Bill 151 (Burton, Chapter 406, Statutes of 2003), will require the same information be transmitted for Schedule III prescriptions. **For most pharmacies, this means that their software must be modified so that Schedule III (as well as Schedule II) prescription information is transmitted to the Department of Justice via their data collector, Atlantic Associates.**

In addition to requiring submission of Schedule III prescription information, the bill now requires prescribers dispensing these drugs also to submit prescription information to the CURES program beginning on July 1, 2004. Both pharmacies and dispensing prescribers must submit the following information for each prescription filled:

- Full name, address, gender, and date of birth of the patient;
- Prescriber's category of licensure, license number, and federal controlled substance registration number;
- 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.

California Pharmacist Scholarship and Loan Repayment Program

Pharmacists and pharmacies are able to contribute to a fund established to finance scholarships for pharmacy students willing to practice in underserved areas. Interested individuals may do this at the same time that they renew either their pharmacist or pharmacy licenses. Such a contribution is voluntary.

This provision has been in effect since January 2003 and was enacted to establish mechanisms for addressing pharmacist workforce shortages in medically underserved areas. Contributions made as part of the renewal process are limited to the $25 amount specified in statute. License renewal forms for pharmacists and pharmacies now contain information about how to make this contribution.

Pharmacists Recovery Program

For pharmacists or pharmacist interns who have a problem with drugs, alcohol or mental illness, or live or work with a pharmacist or intern who does, help is available from the Pharmacists Recovery Program by calling toll-free (800) 522-9198. The PRP is a **confidential source of treatment** and provides individuals with the help needed to face the problem, deal with it and, if possible, return to the profession as a contributing member.

While the PRP serves as a diversion program to which the Board may refer licensees, it is also for pharmacists and interns who, on a strictly voluntary basis and without the Board's knowledge, desire to avail themselves of its services.

Pharmacy Law 2004 can be ordered from LawTech

This year, budget constraints will not permit the Board of Pharmacy to provide new lawbooks to all pharmacies as it has done in the past. However, the lawbook may be purchased by contacting:

LawTech Publishing Co
1060 Calle Cordillera, Suite 105
San Clemente CA 92673
(949) 498-4815
E-mail: *sales@LawTechPublishing.com*

California pharmacy laws are also available on the Board's Web site, *www.pharmacy.ca.gov/pdfs/lawbook_2004.pdf*.

Legislation passed in 2003

Assembly Bill 1196 (Montanez, Chapter 748, Statutes of 2003) permits nurse practitioners to prescribe Schedule II controlled substances. Authority to prescribe Schedule II drugs must be included in the protocol established between the nurse practitioner and the supervising physician. Pharmacists can request a copy of protocol provisions relating to controlled substances when needed to clarify any uncertainty the pharmacist may have regarding a drug order issued by a nurse practitioner.

Registration requirements change for Pharmacy Technicians

Effective January 1, 2004, requirements changed for applicants seeking registration as pharmacy technicians in California. These changes were made by SB 361 (Figueroa, Chapter 361, Statutes of 2003).

Specifically, changes in Business & Professions Code section 4202(a) alter the qualifying methods an applicant must satisfy to become registered. To be issued a technician registration, an applicant must satisfy **one** of the following criteria:

- Obtain an associate's degree in pharmacy technology;
- Complete a course of training specified by the board;
- Be a graduate of a school of pharmacy accredited by the ACPE; or
- Be certified by the Pharmacy Technician Certification Board (PTCB).

Experience as a pharmacy clerk will no longer qualify an applicant for registration as a pharmacy technician.

Information on the PTCB examination can be obtained by contacting PTCB at (202) 429-7576. Also, a list of community colleges offering the associate's degree in pharmacy technology may be obtained by visiting the California Community Colleges Chancellor's Office Web site at *www.cccco.edu*. Details for the course of training specified by the board are found in California Code of Regulations Title 16, Section 1793.6.

Delivery of Dangerous Drugs after Pharmacy is Closed

At its July 2003 meeting, the Board agreed to the following interpretation of Business & Professions Code section 4059.5.

Dangerous drugs may be delivered to a secured area when a pharmacy is closed and no pharmacist is on duty **if**:

- The dangerous drugs are placed in a secure storage facility in the same building as the pharmacy;
- Only the pharmacist-in-charge (PIC) or a pharmacist designated by the PIC has access to the secure storage facility after the drugs have been delivered;
- The secure storage facility has a means of indicating that it has been entered after the dangerous drugs have been delivered;
- The pharmacy maintains written policies and procedures on these storage procedures; and
- The agent delivering the dangerous drugs leaves documentation indicating the name and quantity of drugs delivered.

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

The Board is sponsoring 2004 legislation to clarify this interpretation.

Investigation Process

Complaint Investigation

When the Board of Pharmacy receives a complaint or uncovers potential violations of the law through its own efforts, the matter may be assigned for investigation either to an enforcement analyst or to an inspector.

During the course of the investigation, evidence is obtained to determine if the alleged violation of law occurred. As part of the investigation, the licensee may be asked for documents (e.g., business records, patient records, and/or policies and procedures) and/or for statements regarding the events that allegedly transpired. Licensees are encouraged to respond in a timely and accurate manner, as the information is used as part of the investigative record. A licensee's responsiveness or non-responsiveness may be considered as mitigation or aggravation.

If it is believed that a violation of Pharmacy Law took place, the licensee may be advised of the alleged violation through an **Order of Correction** (Business & Professions Code [B&PC] section 4083) on the inspection report. This order simply notifies the licensee of the violations of law that the inspector believes occurred and directs the licensee to comply within 30 days by submitting a corrective action plan to the inspector.

After the investigation is completed and there is a determination by the inspector or enforcement analyst that the law was violated, the case is referred to a supervising inspector for review. If the supervising inspector determines that there was no violation or that the violation was so minor that it does not merit any action, the case may be closed with the Order of Correction only, and the matter goes no further.

Recommended Actions

If after review by a supervising inspector, it is determined that action may be warranted, the case is referred to the Board's executive officer. The executive officer, with the assistance of the supervising inspectors, reviews the matter and determines the appropriate course of action. The types of potential action include:

- **Case Closure—No Further Action** The executive officer may decide that no action is warranted. This may occur when the executive officer finds that there has been no violation, that the violation is so minor that it does not merit an action, or that the mitigating circumstances are such that it would be best not to pursue an action. The matter then ends.
- **Order of Correction** If an Order of Correction has been issued, the licensee can contest the order by requesting an office conference with the executive officer. However, if no office conference is requested, compliance with the order is not an admission of the noted violation. The order of correction is not the Board's final or formal determination regarding the matter, nor is it a citation or a disciplinary action. A copy of the order of correction and the corrective action plan must be maintained on the pharmacy premises for at least three years from the letter's date of issuance. The order of correction will not be considered a public record for purposes of disclosure.
- **Further Investigation** The executive officer may decide that there is insufficient evidence to determine whether a violation occurred or whether any action is warranted. The executive officer may then send the matter back for further investigation.
- **Letter of Admonishment** After review, the executive officer may issue a Letter of Admonishment to the licensee for failure to comply with Pharmacy Law. The letter will include a reference to the statute or regulation violated, a description of the nature and facts of the violation, and a notice to the licensee of available appeal rights. (See B&PC section 4315.)
- **Citation and Fine** (See next page.)
- **Refer to the Attorney General's Office**

Issuance of Orders of Abatement

The Board is authorized to issue an order of abatement, requiring a person or entity to whom a citation has been issued to demonstrate how future compliance with Pharmacy Law will be accomplished. In such cases a licensee may be required to do such things as submit a corrective action plan and complete up to six hours of continuing education courses in subject matter specified in the order of abatement. (Section 4314 B&PC)

Issuance of Citations and Fines

The executive officer issues citations and fines and considers the following factors:

- Gravity of the violation;
- Good or bad faith of the cited person or entity;
- History of previous violations;
- Evidence that the violations were or were not willful;
- Extent to which the cited person or entity has cooperated with the Board's investigation;
- Extent to which the cited person or entity has mitigated or attempted to mitigate any damage or injury caused by the violation;
- Other matters as may be appropriate; and
- The number of violations found in the investigation.

Fine Amount

The Board's regulation provides that a fine can be up to a maximum of $5,000 per licensee for each citation.

If an investigation involves multiple licensees (e.g., a staff pharmacist, the pharmacist-in-charge, a pharmacy technician, and the pharmacy), each licensee may be cited and fined. The amount of each fine will depend on which of the above factors are present and applicable to each licensee. The amount of the fine is determined on a case-by-case basis.

Request for an Office Conference

A licensee has 14 calendar days after service of a letter of admonishment or a citation and fine to request an office conference, pursuant to Title 16 of the California Code of Regulations (16 CCR) section 1775.4(b).

Appeal Process for Citation and Fines

If a hearing is not requested, payment of a fine does not constitute an admission of the violation charged. A licensee has 30 days after service of the citation and fine to file a written appeal (request for a hearing). Appeals are referred to the Attorney General's Office and proceed in accordance with the Administrative Procedure Act. For more complete description of the entire appeal process, please see 16 CCR sections 1775-1775.4 on the Board's Web site under "California Pharmacy Law and Index." and Government Code section 11150, et seq. at *www.leginfo.ca.gov/calaw*.

Routine Inspection Process

Section 4008 of the Business & Professions Code authorizes Board of Pharmacy inspectors to conduct routine inspections of pharmacies. Whereas Board policy is to inspect all pharmacies at least once every three years, Board staffing may not always permit this. This article provides information about what to expect during a routine inspection. (Investigative processes are detailed in another article of this issue.)

Routine inspections are unannounced. Upon arrival at the pharmacy, the inspector will, as unobtrusively as possible, typically review the pharmacy's operations, including the following:

- Completed self-assessment form **and** compliance with the form;
- Quality assurance program;
- Patient consultation compliance;
- CURES compliance/controlled substance recordkeeping;
- Compounding equipment;
- Acquisition and disposition records; prescription documents and inventory; and
- Security and sanitation practices.

Many pharmacists also use the inspection as an opportunity for asking questions of inspectors regarding Pharmacy Law.

If the inspector believes an infraction or violation of pharmacy law has taken place, an order of correction will be noted on the inspection report (Business & Professions Code [B&PC] section 4083). This order simply notifies the licensee of the violations of law that the inspector believes occurred and directs the licensee to comply within 30 days by submitting a corrective action plan to the inspector. Alternatively, the licensee can contest the order by requesting an informal office conference with the executive officer. However, if no office conference is requested, compliance with the order is not an admission of the noted violation. The order of correction is not a citation, nor is it a disciplinary action. A copy of the order of correction and the corrective action plan must be maintained on the pharmacy premises for at least three years from the date of issuance.

An investigation may be opened by the inspector if the violations are of a more serious nature.

Senate Bill 361 extends Board's operation and increases its membership

A number of changes to pharmacy law were enacted last year in SB 361 (Figueroa, Chapter 539, Statutes of 2003). One significant provision extends the operation of the Board of Pharmacy until 2007, when it will undergo a new legislative review. Failure to enact SB 361 would have resulted in the dissolution of the Board, and its regulatory operation would have merged into the Department of Consumer Affairs on July 1, 2004.

Another important element of the bill is the addition of two more public board members, raising the total membership of the Board to 13. Under the new structure, the Governor appoints seven pharmacists and four public members who are not licensees of the Board. At least five of the seven pharmacist appointees must be pharmacists who are actively engaged in the practice of pharmacy, and the membership of the Board must include at one pharmacist representative from each of the following practice settings:

- an acute care hospital,
- an independent community pharmacy,
- a chain community pharmacy,
- a long-term health care or skilled nursing facility, **and**
- a pharmacist who is a member of a labor union that represents pharmacists.

The Senate Committee on Rules and the Speaker of the Assembly each appoints one public member.

Where to Find Answers to Your Questions

Because of severe budget cuts to the staff of the Board of Pharmacy, callers to this office are no longer be able to speak with a "duty inspector" for answers to legal or routine pharmacy practice questions. Answers to most questions can be found by reviewing:

- The California Pharmacy Law which is available on the Board's Web site with an updated index or may be purchased from LawTech Publishing at (949) 498-4815;
- The pharmacy's completed self-assessment forms which are available for review in your pharmacy;
- Previously published Board newsletters (*The Script*);
- In this issue, an updated subject index of newsletter articles, including "Rx for Good Practice" questions and answers; and
- The Board's Web site, *www.pharmacy.ca.gov*.

If you are unable to resolve legal issues through the above means, you should contact your pharmacy's legal counsel.

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Rx for Good Practice

Please remember that changes in the law may have changed the answers to some of these questions since their originally publication.

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Disposal of drugs—expired or returned	Oct 2001
Faxed/electronic data transmissions differences	Nov 2000
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Must physician hand-write all C III-V Rxs	Oct 2001
PA or NP signing drug orders	Jul 2001
Patients with same name identified by birthdate	Jul 2001
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Refill Rx reduced to writing	Mar 2003
Rx amount written as "one bottle"	Jul 2001
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Transferring Rx by faxing Rx label	Oct 2001
Transferring Rx more than once	Mar 2003

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Department of Consumer Affairs
400 R Street, Suite 4070
Sacramento CA 95814
(916) 445-5014
Fax: (916) 327-6308
www.pharmacy.ca.gov

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

Continuing education (CE) hours are being awarded to encourage licensees 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.

The remaining meeting dates and sites for this year are:

April 21–22, 2004
Department of Consumer Affairs
400 R Street, 1st Floor Hearing Room
Sacramento CA 95814

July 21–22, 2004 — San Diego —To be determined

October 20–21, 2004—Bay Area—To be determined

Additional information regarding sites and agendas will be posted on the Board's Web site *(www.pharmacy.ca.gov)* approximately 10 days prior to 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. These materials are placed on the Board's Web site about five days before a meeting.

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