



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

# The Script

CALIFORNIA BOARD OF PHARMACY MARCH 2003

## Changes in Pharmacy Law for 2003

Each year, a number of California laws are created, amended or sometimes repealed. Listed below are major changes in California's statutes. Unless otherwise specified, the following laws took effect on January 1, 2003. The exact language of the new and amended statutes noted below can be found in "Forms and Publications" on the Board's Web site, [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov).

**Assembly Bill 2045 (Matthews)  
Chapter 562, Statutes of 2002**

**Pharmacist-In-Charge**

Business and Professions Code (B&PC) 4306.6—If specified conditions are met, requires the Board to consider a good faith report of a pharmacy violation by a pharmacist-in-charge to the Board as a mitigating factor in any disciplinary action against the pharmacist-in-charge resulting from the report.

**Assembly Bill 2191 (Migden)  
Chapter 853, Statutes of 2002**

**Medical Records Confidentiality**

Civil Code 56.05, 56.101, 56.11, 56.12 & 56.102—Prohibits drug manufacturers, in most instances, from disclosing confidential medical information without prior patient authorization and prohibits, in most circumstances, requiring patients to permit disclosure of confidential medical information as a condition of obtaining prescription drugs.

**Assembly Bill 2655 (Matthews)  
Chapter 345, Statutes of 2002**

**CURES**

Health and Safety Code (H&SC) 11165 & 11165.1—Extends the Controlled Substance Utilization Review and Evaluation System (CURES) program for five years (until 2008) and permits physicians and pharmacists to request CURES profiles for their patients from the Department of Justice. This legislation also permits the Department of Justice to send CURES profiles to the physicians and pharmacists providing care to patients whose CURES profiles indicate the possibility of prescription drug abuse. Procedures to implement the process of requesting patient profiles are being developed by the Department of Justice.

**Assembly Bill 2935  
(Strom-Martin)  
Chapter 1138, Statutes of 2002**

**Pharmacy Scholarships**

Business and Professions Code (B&PC) 4406 and H&SC 128198—Establishes the California Pharmacist Scholarship and Loan Repayment Program, funded by a voluntary \$25 contribution by pharmacists, to pay for the educational expenses of pharmacy students and to repay qualifying educational loans of pharmacists who agree to practice in medically underserved areas. The Board will change its renewal notice to allow for such a donation.

*See Changes in Pharmacy Law, Page 5*

***The Script is being mailed only to pharmacies***

Because of budget constraints and lack of staff, the Board of Pharmacy newsletter, *The Script*, usually published quarterly, will now be published biannually (in January and July) for the foreseeable future. The reduction in service also limits the number of newsletters the Board can publish and mail. Consequently, this and future issues of the newsletter will be mailed only to pharmacies, where we hope they will be shared among all pharmacy employees. The newsletter can also be read or downloaded at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov).

The Board appreciates the wide support of this newsletter and regrets having to take this action. In the coming months the Board will greatly expand the information available on its Web site and encourages licensees to bookmark our Web site address.

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## President's Message

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

In this issue of *The Script*, I will review a number of current concerns and initiatives your Board of Pharmacy has dealt with over the past few months: Budget Constraints, Sunset Review and Quality Assurance Programs.

### Budget Constraints

The greatest challenge to the Board and its continued operations stem from the current state fiscal constraints that have resulted in funding cuts for all state agencies. The cuts have presented the Board and its staff with difficult decisions. We have had to assess each of our usual services and prioritize them to be sure that those services most critical to consumer protection are still supported by Board activities.

Our core responsibilities include timely investigation and resolution of consumer complaints, performing routine pharmacy inspections and assuring proper licensure of pharmacists and pharmacies. With our budgeting challenges, these areas will be first to receive resources in order to adequately protect consumers.

The Board has had to reduce some services due to our inability to hire replacement staff. Indeed, we have had to decrease the publication of *The Script* from quarterly to every six months and limit its distribution to each licensed pharmacy in order to afford the cost of circulation. We also are unable to fund publishing and mailing the Pharmacy Law book to all pharmacies this year. We anticipate that these measures will be temporary and hope

to resume normal services when the state's fiscal situation is improved.

We appreciate the patience of California pharmacists when dealing with the Board and its staff while the state works through its funding challenges.

### Sunset Review

California law requires that certain state agencies, including professional regulatory boards, go through what is known as a "sunset review" of their governing laws every four to six years to determine whether the laws and the state agency that enforces them are still useful and needed. This year, the laws governing pharmacy and the Board of Pharmacy are undergoing sunset review.

The Board has worked hard to evaluate its governing laws and its overall effectiveness in performing its duties concerning consumer protection. The Legislature will review the Board's evaluation of its programs and statistical analysis of its effectiveness, and it will hear testimony from interested parties during the review process. The Board participated in sunset review hearings before the Legislature in November 2002, and recommendations from the Legislature will be released in late March 2003.

The Board's Sunset Review Report can be read or downloaded at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov) or purchased from the Board for \$20. This volume contains a wealth of information about Board activities over the past year.

### Quality Assurance Program

California's Quality Assurance Program for pharmacies was implemented when Board regulations became effective on January 14, 2002. The Board decided to ease into the enforcement of the new regulations by having a six-month initial period where it would focus on education of pharmacists rather than other enforcement options to gain compliance. To aid pharmacies in developing successful and meaningful quality assurance

programs, the Board's 6th issue of *Health Notes* is on Quality Assurance Programs. Additional copies can be downloaded at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov).

Many pharmacies have implemented quality assurance programs, and our inspectors have noticed on routine inspections that there are some strong efforts in place to comply. Quality assurance should be central to the practice of pharmacy in every setting. No pharmacist wants to make mistakes and certainly none wants to repeat the same mistake over and over. The quality assurance regulation was designed to help prevent repetitive errors from occurring.

The desired outcome of the quality assurance program will be a reduction in medication errors. This outcome should be accompanied by improved patient well-being and a corresponding reduction in professional liability. Preventing future errors will have the direct effect of preventing lawsuits when the errors would have resulted in injury to the patient.

The quality assurance process need not be complicated, time consuming or burdensome. Adequately reviewing and correcting the circumstances that resulted in a simple error situation can take a short time, but it must follow the quality assurance program in place at the pharmacy and it must be documented. And to assure that a thorough and meaningful review takes place, the Board worked closely with patient advocates, interested pharmacists and pharmacy organizations to provide that these reviews could not be subpoenaed for use in civil litigation.

I encourage all pharmacists to actively embrace this required change in pharmacy practice.



## Licensees' addresses of record go online September 1, 2003

**IMPORTANT NOTE:** A licensee's address of record is the address to which all licenses, permits, license renewal notifications, newsletters, other publications, and correspondence from the Board is mailed. This information is considered public information. Your address of record is the address printed on your license, unless you have subsequently notified the Board of a change in your address after the license was mailed to you.

All Board licensees' addresses of record will become available to the public on the Board's Web site on September 1, 2003. This is the same information provided online by other health profession (physicians, dentists, therapists) regulatory boards, pursuant to the Information Practices Act (Civil Code section 1798 et seq.) and the Public Records Act (Government Code section 6250 et seq.).

## Changing Your Address of Record

If your address of record with the Board is your residence address, and you don't wish it to be available to the public, you may change it by providing the Board with a post office box number or a personal mail box (PMB). However, if you change your address of record to a box number, you must also provide your residence address, which will not be available to the public.

If you list your business address as your address of record, remember that all mailings from the Board will go to that address. For some, depending on a business address for licensee renewal notifications, licenses, and other mailings from the Board may be problematic, especially for receiving personal mail. For example, if you are employed in a large hospital complex with several pharmacies, opportunities for lost mail could exist. Also, using a business address would require you to change your address of record with the Board every time you change your place of employment.

To change your address of record, please complete and fax the following form to (916) 327-6308 or mail to the Board of Pharmacy, 400 R Street, Suite 4000, Sacramento CA 95814-6237.

### CHANGE OF ADDRESS (Please print)

Name: \_\_\_\_\_ License # \_\_\_\_\_  
(Please include license type: RPH, TCH, INT, etc.)

Social Security Number: \_\_\_\_\_  
(For purposes of identification only)

Old Address: \_\_\_\_\_  
\_\_\_\_\_

#### Address of Record

New address: \_\_\_\_\_  
\_\_\_\_\_

Note: If the new address of record is a PO box, PMB, or a business address, please enter residence address below. Your address of record will not be changed if no current residence address is entered.

#### Residence Address

Address: \_\_\_\_\_  
\_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Telephone: \_\_\_\_\_ E-mail address: \_\_\_\_\_  
(For address change acknowledgment)

## Answers to Quality Assurance Program Questions

**Q** How long must I keep reports of medication errors that occurred in my pharmacy? Should I send a copy of the report to the Board of Pharmacy?

**A** Quality assurance records must be kept immediately retrievable in the pharmacy and available for inspection for one year from the date of the incident. Copies should not be sent to the Board of Pharmacy.

**Q** If I catch an error before the patient receives the medication, is it reportable under Title 16 of the California Code of Regulations (CCR) section 1711?

**A** No, "near misses" are not reportable under 16 CCR section 1711. However, you should analyze why a near miss occurred, so it will not result in future harm to a patient.

**Q** Do I have to advise a patient and the prescriber that an error occurred?

**A** Yes, according to 16 CCR section 1711(c), the pharmacist is responsible for immediately contacting the patient and the prescriber in the event of a medication error, unless they both already notified you of the error. You should document on the monitoring form the results of the communication with both parties.

**Q** Can I utilize a quality assurance plan commercially offered for sale by various groups and societies, or do I have to develop my own?

**A** You can use any version you choose as long as the elements of 16 CCR section 1711 are included. You may need or want to customize it for your pharmacy.

**Q** If a medication error is discovered during the consultation process and the patient never leaves the pharmacy with the incorrect drug, should this be reported to the prescriber?

**A** No. An error occurs when the patient (or the patient's agent) is "furnished" with an erroneous medication, but since the drugs are not furnished until the consultation is complete, no error occurred within the definition of the regulation, 16 CCR section 1711.

**Q** In a hospital, medication errors are reported on an Incident Report. We are instructed by the risk management office to never make a copy. How can I maintain a record of the error in the hospital pharmacy and be compliant with 16 CCR section 1711?

**A** Nothing in the regulations states you are required to maintain a copy of the hospital incident report in the pharmacy. The regulation requires a record of the error. The hospital pharmacy may develop its own monitoring form for purposes of complying with the Board's regulation. Check with your Risk Management office. Remember, under Business & Professions Code section 4125, the quality assurance record is protected in most instances from discovery.

**Q** If a nurse administers an incorrect medication to a hospital patient even though the pharmacy placed the correct drug in the automated dispensing device or in a unit dose cart, is this reportable under 16 CCR section 1711?

**A** No, only errors committed by the pharmacy or its personnel are reportable. However, medication errors committed by other healthcare providers should be investigated as part of an overall hospital medication error prevention and reduction plan.

**Q** Must I have a written plan in addition to a monitoring/reporting form for medication errors?

**A** Yes, 16 CCR section 1711 requires written quality assurance policies and procedures and a monitoring/reporting form that you can use to track and document efforts to prevent medication errors.

**Q** What type of findings and determinations should be documented as a result of the investigation of a medication error?

**A** The goals of the quality assurance program are to identify the cause of and prevent medication errors. Errors are the result of individuals processing prescriptions. They could be system/process oriented. Analysis by the pharmacist-in-charge should include an analysis of what went wrong in the filling/dispensing process, what changes or corrections were made and ultimately, the effectiveness of the changes. Replies such as, "We will try to do better," "human error," or "I won't let it happen again," are not adequate responses or reasons for an error. Careful analysis of processes and/or the staff performance is paramount to consumer protection and prevention of future errors.

**Q** Who needs to know about our quality assurance program?

**A** All pharmacy staff members need to know about the program, just like any major policy or procedure. Even a relief pharmacist should know where the forms and plan are stored. If an error is brought to the relief pharmacist's attention, he or she can respond appropriately.

## Answers to Quality Assurance . . .

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**Q** In pharmacies where they have contracted with a qualified outside entity or their administrative offices conduct quality assurance review, must records and summaries of quality assurance review be available in the pharmacy?

**A** Yes, a record of quality assurance review must be immediately retrievable. If the record is not maintained in the pharmacy, it must be immediately retrievable by fax or by e-mail. If it would not at all times be immediately retrievable, then it would have to be maintained in the pharmacy. The record must contain the following:

1. Date, location and participants of the quality assurance review.
2. The pertinent data and the other information relating to the medication error(s) reviewed and documentation of any patient contact required by 16 CCR section 1711(c).
3. The findings and determinations generated by the quality assurance review.
4. Recommended changes to pharmacy policy, procedure, systems or processes, if any.

## Changes in the Board

### Departing Member

The Board wishes to extend its best wishes and appreciation to a departing public member, Mr. Robert Elsner, B.A., who was appointed by Governor Pete Wilson and served with the Board from April 4, 1998 to June 1, 2002. During his tenure with the Board, Mr. Elsner served as president and vice president and was instrumental in forming the Pharmacy Manpower Task Force. The task force brought together members of all areas of pharmacy practice to seek solutions to the pharmacist shortage in California. He also represented the Board with the SMART Coalition, an Agency on Aging group seeking ways to educate senior citizens regarding the importance of medication compliance. Additionally, Mr. Elsner was a member of the Board's Citation and Fine Committee.

Mr. Elsner's dedication, determination, and most certainly, his sense of humor will be sorely missed. Thank you, Bob.

### New Officers

New Board officers were elected at the April 2002 meeting: John Jones, R.Ph., *President*; Donald W. Gubbins, Jr., Pharm.D., *Vice President*; and Caleb K. Zia, Ed.D., Public Member, *Treasurer*.

## Changes in Pharmacy Law

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### Senate Bill 1278 (Speier) Chapter 542, Statutes of 2002

#### Medicare Drug Discount

Business and Professions Code (B&PC) 4425—Makes permanent provisions in existing law that require pharmacies to provide prescription drugs, not covered by insurance, at Medi-Cal prices to Medicare beneficiaries. The new law also requires pharmacies to post a notice of the availability of this discount; the notice will be provided by the Department of Health Services.

### Senate Bill 1558 (Figueroa) Chapter 263, Statutes of 2002

#### Drug Samples

Business and Professions Code (B&PC) 4061—Permits nurse practitioners, certified nurse-midwives, and physician assistants to request and receive drug samples authorized by a physician.

### Senate Bill 2019 (Speier) Chapter 683, Statutes of 2002

#### Student Loans

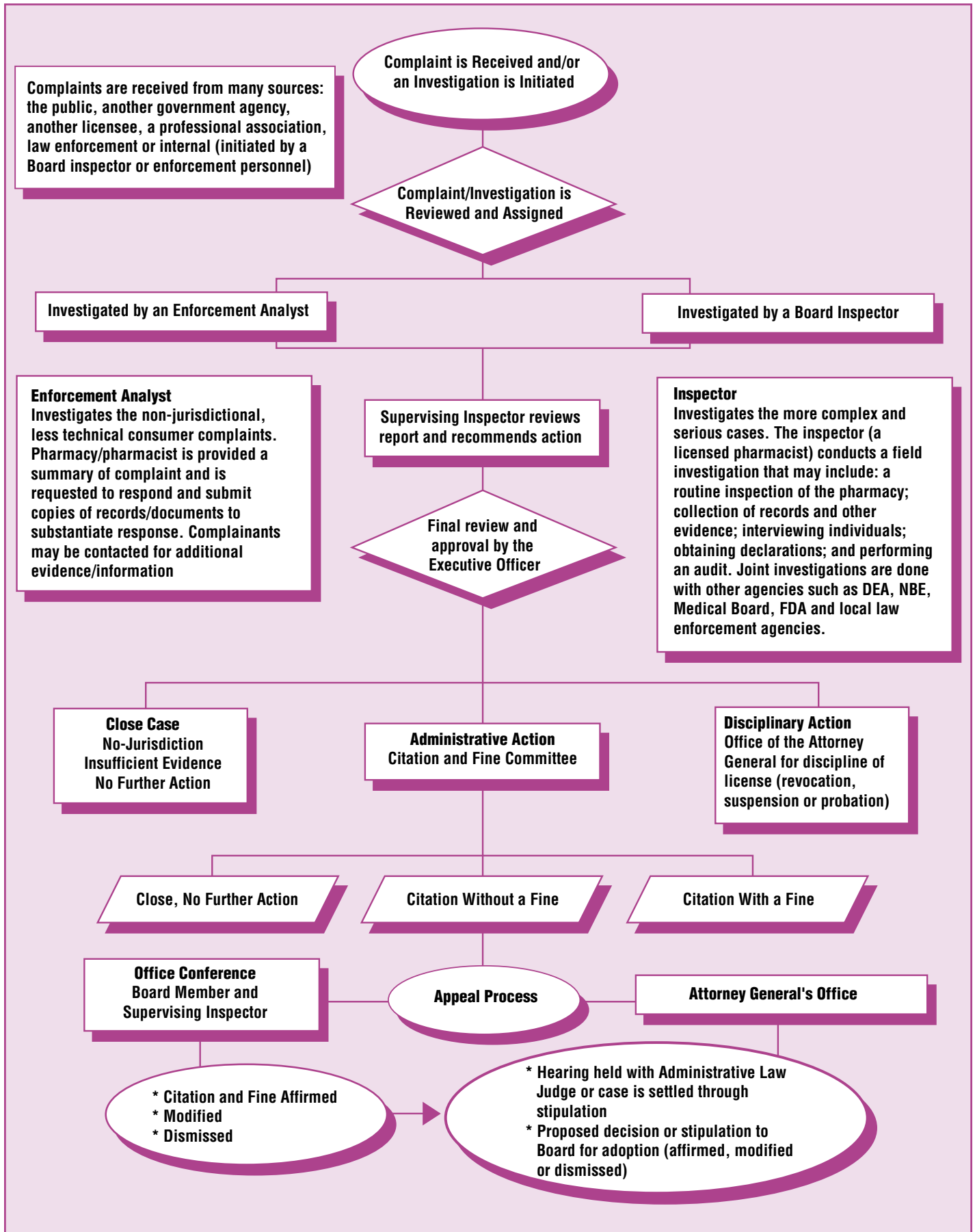
Business and Professions Code (B&PC) 685—Under specified circumstances, permits a licensing board to cite, fine, and deny the license renewal of a health care practitioner, or reject the license application of a prospective practitioner, who is in default on HEAL loans or other educational loans made by the Department of Health and Human Services.

### Senate Bill 2026 (Committee on Business and Professions) Chapter 1013, Statutes of 2002

#### Omnibus Measure

H&SC 11150 et seq.—Conforms state controlled substance schedules to federal controlled substance schedules. It also repeals obsolete statute relating to the licensing of controlled substance warehouses.

# Citation and Fine Investigation Process



# Citation and Fine Committee: Citation and Fine Process

The Board may assess fines for violation of the Pharmacy Law. The following information details the investigation and enforcement processes of the Board's Cite and Fine regulations.

## 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 a factor in 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 the notification process. This notification will simply notify the licensee of the violations of law that the inspector or enforcement analyst believes occurred. This notification is not the Board's final or formal determination regarding the matter. It is also neither a citation nor is it a disciplinary action.

At this time, the licensee is provided another opportunity to respond in writing to the alleged violation. In the written response, the licensee may address the specifics of the violation, as well as provide any mitigatory information that the licensee wishes to have included in the investigation report.

After the investigation is completed and there is a determination by the inspector or an 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 as to not merit any action, then the case may be closed 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 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. That may occur when the executive officer determines that there was no violation, that the violation was so minor as to not merit an action, or that the mitigating circumstances were such that it would be best not to pursue an action. The matter then ends. A disciplinary action will not be sought nor will the case be sent to the Citation and Fine Committee for the possible issuance of a citation and fine.

### \* **Further Investigation**

The executive officer may decide that there is insufficient evidence to determine if a violation occurred or if any action is warranted. The executive officer may then send the matter back for further investigation.

### \* **Referral to the Citation and Fine Committee**

After review, the executive officer may forward the matter to the Board's Citation and Fine Committee. After its review, the committee may issue a citation, with or without a fine. The citation will be issued to the licensee and will include a reference to the statute or regulation violated. It will also include a description of the nature and facts of the violation, as well as a notice to the licensee of available appeal rights.

Alternatively, the committee may decide to either close the matter and take no action (in the same manner as the executive officer under the Case Closure option above), or seek to obtain further information (by sending the matter back to the Board's staff for additional investigation and/or by requesting that the licensee appear before it).

Also, alternatively, the committee may decide that the violation is substantial and warrants discipline of the licensee. The committee may then send the matter back to the executive officer for referral to the Attorney General.

\* **Disciplinary Action** The executive officer may determine that the violation is substantial and warrants discipline of the licensee. The matter is then referred to the Attorney General, where, if appropriate, an accusation identifying the alleged violations is prepared.

## Issuance of the Citation and Fine

The Board's two-member Cite and Fine Committee issues most citations and fines (except for those citations and fines that the executive officer is authorized to issue). The Citation and Fine Committee will consider the following factors when issuing a citation with or without a fine:

- \* 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.
- \* Recognition by the licensee of the licensee's wrongdoing and demonstration of corrective action to prevent recurrence, e.g., new policies and procedures, protocol, hiring of additional staff, etc.
- \* Extent to which the cited person or entity has cooperated with the Board's investigation and other law enforcement or regulatory agencies.

## Citation and Fine Committee . . .

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- \* Extent to which the cited person or entity has mitigated or attempted to mitigate any damage or injury caused by the violation.
- \* If the violation involved multiple licensees, the relative degree of culpability of each licensee. In the case where the staff pharmacist failed to consult, the pharmacist-in-charge and the pharmacy may also be issued a citation and fine, if warranted by the circumstances.
- \* Any other relevant matters that may be appropriate to consider.

### Fine Amount

The Board's regulation provides that a fine can be up to a maximum of \$2,500 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), then 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 Citation and Fine Committee will consider the amount of the fine on a case-by-case basis.

### Request for an Office Conference

A licensee has 14 calendar days after service of the citation and fine to request an office conference, pursuant to Title 16 of the California Code of Regulations (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 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 and Government Code section 11150, et seq.

## Transfer of pharmacy ownership requires both temporary permit and permanent license

No one can operate a pharmacy in California unless he or she has obtained authorization through licensure by the Board. A new pharmacy license must be obtained before the ownership of a pharmacy is transferred from one person or entity to another, and the license must be issued before the new owners can legally operate the pharmacy. The previous owner's license cannot be transferred to the new owner (Business & Professions Code (B&PC) section 4201(f)).

Note: Section 1709 of the California Code of Regulations requires an application

for a change of ownership for: "any transfer of a beneficial interest in a business entity licensed by the board, in a single transaction or in a series of transactions, to any person or entity, which transfer results in the transferee's holding 50% or more of the beneficial interest in that license."

Business circumstances sometime require a pharmacy to open for business before the application for a new license has been completed. Consequently, B&PC section 4110 was recently amended to give the Board, at its discretion, the authority to issue a temporary permit when the ownership of a pharmacy will change. The temporary pharmacy permit allows the new owner to operate the pharmacy while the permanent license application is continuing through the review process. A pharmacist-in-charge is also required for the temporary permit.

New pharmacy owners who have not received a new pharmacy license from the Board before the ownership is transferred to them must now submit both an application for a change of ownership (\$340) and a fee for a temporary pharmacy

permit (\$175)-at the same time. The application can be downloaded from [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov).

The temporary permit must be applied for before the ownership changes. Once the Board receives the application, the new owner will be notified within 15 working days of any deficiencies in the temporary permit application, and those deficiencies must be resolved before the temporary permit can be issued. During this period the new owners cannot operate the pharmacy. The temporary permit may be issued for up to 180 days.

During the temporary permit period, the change of ownership application will continue through the review process for consideration of a permanent license. Applicants will be notified during this period of any deficiencies that must be corrected before the permanent license will be issued.

Operating a pharmacy without a valid temporary permit or permanent license constitutes unlicensed activity and may result in the immediate shutdown of the pharmacy as well as disciplinary action.





## Rx for Good Practice

In day-to-day pharmacy practice, unusual situations sometimes occur, generating questions. So to help our licensees with questions whose answers may or may not be found in the pharmacy law book, "Rx for Good Practice" will be featured in each issue of *The Script*. If you have questions you would like to see answered in this column, please fax your question to *The Script* at (916) 327-6308.

**Q** This is a two part question: First, practitioners often write prescription dosages for certain drug strengths that do not exist or that are not in our pharmacy's stock on that particular day. For example, if the prescription is written "Lotensin 20 mg, one tablet every day," can I substitute "Lotensin 10 mg, two tablets every day" without calling the prescribing practitioner?

The second question relates to substituting dosage forms between liquid and tablets. For example, if the prescriber writes "Sulfatrim two teaspoons twice a day," is it possible to substitute with "Bactrim DS, 1/2 tablet twice a day"? Sulfatrim has 200 mg of sulfamethoxazole and 40 mg of trimethoprim per teaspoon. Bactrim DS has 800 mg of sulfamethoxazole and 160 mg of trimethoprim per tablet. So two teaspoons of Sulfatrim has 400 mg of sulfamethoxazole and 80 mg of trimethoprim, which is equivalent to half of a Bactrim DS tablet in terms of their active ingredients. Again, can I substitute these two without calling the prescriber?

**A** The answer to both questions is Yes. Section 4052.5 of the Business & Professions Code (B&PC) authorizes pharmacists to use their professional judgment and allows them to "...select a different form of medication with the same active chemical ingredients of equivalent strength and duration of therapy as the prescribed product when the change will improve the ability of the patient to comply with the prescribed drug therapy." Of course, no changes can be made if the prescriber indicates either orally, in writing, or in a check-off box on the prescription "Do Not Substitute." Additionally, if a different form of medication is used, the patient must be informed, and the name of the dispensed drug must be indicated on the prescription label.

**Q** Is it legal to dispense a prescription that was telephoned to the pharmacy and recorded on an answering machine or voice mail system? I am told by my supervisor that it is not legal.

**A** The law does not address the issue of telephonically recorded prescription orders specifically. However, since the B&PC section 4070 requires an oral prescription (excluding Schedule II drugs) to be reduced to writing by the pharmacist and contain all the elements of a prescription (B&PC section 4040), it follows that the same procedures would apply to a recorded telephone message. Reasonable effort must be made to confirm that the person who left the message is authorized to do so, and that person's name must be recorded with the prescription information. As always, the pharmacist's professional judgment should be used to assure that the prescription is legitimate and ordered by an authorized prescriber or the prescriber's authorized agent.

**Q** After confirming with the prescribing physician by telephone that a refill for a controlled substance is approved, is the pharmacist required to reduce the refill prescription to writing?

**A** This question has two answers. (1) No, if the refill prescription complies with all requirements of the Health & Safety Code section 11200:

(a) No person shall dispense or refill a controlled substance prescription more than six months after the date thereof.

(b) No prescription for a Schedule III or IV substance may be refilled more than five times and in an amount, for all refills of that prescription taken together, exceeding a 120-day supply.

(c) No prescription for a Schedule II prescription may be refilled.

(2) Yes, the refill prescription must be reduced to writing after confirmation by the prescriber if the prescription does not meet any of the above requirements. (B&PC section 4070(a), Title 16 of the California Code of Regulations (16 CCR) section 1717(c), and Title 21 of the Code of Federal Regulations (21 CFR) section 1306.21(a))

**Q** Can a pharmacy clerk (or any other non-licensed personnel) assist the pharmacist by removing drugs from stock?

**A** No. Only a pharmacist, an intern, or a pharmacy technician is authorized to remove drugs from stock. The duties of a pharmacy clerk are detailed in 16 CCR section 1793.3.

**Q** If a Schedule II (triplicate) prescription cannot be filled entirely because my pharmacy does not have the needed amount in stock. Can I dispense a partial amount?

**A** Yes. Partial filling of a Schedule II controlled substance is permitted when the pharmacist is unable to supply the full amount for which the prescription is written or for which an emergency prescription is orally transmitted. The pharmacist must document on the face of the prescription the quantity dispensed. The balance of the prescription may be filled within 72 hours of the first partial filling. If the pharmacist is unable to fill the remaining portion within 72 hours, the prescriber must be notified. Nothing may be dispensed beyond the 72 hours unless a new prescription (triplicate) is obtained. See 21 CFR section 1306.13(a).

**Q** Can a prescription for a controlled substance be transferred more than once?

**A** No. According to 21 CFR section 1306.26, a prescription for a C-III thru C-V medication may be transferred only once, but permits pharmacies electronically sharing a real time, online database to transfer up to the maximum refills permitted by law. This section also provides the requirements for documenting transferred controlled substance prescriptions.

**Q** What should I do if presented with a forged prescription? Do I notify the Board?

**A** No, do not notify the Board. Call your local police department.

## Canadian Drug Imports to the United States

Who would have thought that upholding the law would be so complicated? Yet, when it comes to the hot-button issue of importing drugs from Canada into the United States, enforcement authorities on both sides of the border are finding themselves struggling to correctly interpret and enforce the laws.

In essence, the situation as some consumers explain stands thus: Prescription drug prices in the United States are higher than in any other country; high enough that some patients have trouble affording necessary drug regimens. Drug prices are lower in Canada, where price controls and the country's health system mandate lower purchasing prices from manufacturers. It is becoming increasingly popular and socially acceptable for US residents to purchase their medications either from Canadian pharmacies in person by crossing the border, or by ordering from an Internet pharmacy. Companies touting the later alternative are springing up and advertising their services in national publications; and while they imply that such activities are completely legal, they are not. In fact, importing or reimporting medications from Canada and other jurisdictions outside the US is almost always illegal, for a variety of reasons:

- \* Drugs shipped to US consumers must be approved by the US Food and Drug Administration (FDA); most imported drugs are not. The FDA grants drug approvals specific to manufacturers and products, and takes into consideration a host of other requirements, including manufacturing location and processing methods, formulation, source of active ingredients, and more. As David J. Horowitz, acting director of the FDA's Office of Compliance for the Center for Drug Evaluation and Research, notes, "Frequently, drugs sold outside of the US are not from a manufacturer that has FDA approval for that drug. Moreover, even if the manufacturer has FDA approval for a drug, the version produced for foreign markets usually

does not meet all of the requirements of the US approval."

- \* Labels must comply with FDA requirements.
- \* Drugs are often dispensed without a valid prescription, a problem with many Internet drug transactions.
- \* It is illegal for a Canadian pharmacy to reimport prescription drugs originally manufactured in the United States.
- \* At the state level, 42 states require non-resident pharmacies to be registered with or licensed by the state board of pharmacy in order to ship drugs to resident consumers.

With drug importation clearly illegal in most situations, why the confusion among law enforcement agencies? In large part, the political climate and mixed messages from lawmakers are responsible. Popular opinion strongly favors legalizing importation of drugs as a solution to high prices in the United States, and politicians seem to agree. They do not necessarily support current law. As reported in a recent issue of Newsweek, for example, Vermont Governor Howard Dean encourages Vermonters to buy drugs from Canada.

Moreover, Congress has voted on more than one occasion to legalize the importation of medications from Canada for personal use, a move that keeps both consumers and regulators uncertain about imminent changes in the law. In July 2002, the Senate passed H.R. 5186 approving the legalization of such imports with the proviso that it becomes law only if Secretary of Health and Human Services Tommy Thompson finds that such imports are safe. Given the Bush administration's stated opposition to such a measure, it seems likely that the bill will meet the fate of its predecessors in past years and not be implemented. In the meantime, the ambiguity of such an action causes more confusion among consumers and regulators alike, and fuels misleading advertisements.

"The US Senate and House of Representatives voted overwhelmingly in

favor of allowing you and your doctor to order your prescription drugs directly from Canada," trumpets one advertisement for a "pharmacy guide" that assists US consumers in ordering medications from across the border.

Confusion also stems in part from enforcement decisions made in the past by the FDA. The FDA has allowed individuals and their physicians to bring under strictly defined circumstances certain drugs that are otherwise illegal into the United States. In its written guidance to compliance officers, the agency states, "FDA personnel may use their discretion to allow entry of shipments of violative FDA-regulated products when the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the user."

This Personal Importation Policy outlines the agency's enforcement priorities, which may have been more relevant in a time when international commerce was less common, and certainly the Internet not so pervasive. The language is broad enough that some Internet operations have apparently used it to help justify their promotion of current importations.

### Enforcing the Law

As a result of these mixed messages flying about, both US and Canadian pharmacists and regulatory authorities find themselves caught in the middle, and not always sure of the correct course of action. But stripped of its popular and political trappings, the issue is fairly simple: Can a US pharmacy send a prescription to a Canadian pharmacy to have it filled and then returned to the US pharmacy? No. Can a US consumer order a prescription online from a Canadian pharmacy? Again, no. Does the responsibility rest with the pharmacy or the consumer? Both. But since pharmacies are fewer in number and are already professionally regulated, they are the ones sought out by enforcers.

In fact, regulatory agencies are actively addressing the issue. The FDA has sent warning "cyber-letters" to a number of

## Canadian Drug Imports . . .

*Continued from Page 10*

pharmacies that operate on the Internet, advising them that they may be violating the law. The agency continues to monitor these sites. Some US state boards of pharmacy have also begun to advise those pharmacists under their jurisdiction of the illegality of such imports.

Enforcement naturally becomes more complicated when international borders are involved. Canadian boards of pharmacy may find themselves scrambling to research US federal and state laws on the topic, and how their own laws intersect with US law. Like the US boards of pharmacy, the Canadian boards enforce existing rules. If drug exportation to the US is not illegal under Canada's national or provincial law or regulations, the board has little ability to act. Moreover, privacy issues can prevent boards from sharing information with other jurisdictions that could act.

Indeed, cooperation is the key to addressing the issue. "If it's an issue that has to be addressed because of patient care and legalities, then we need to take a multi-party approach," says Ronald Guse, registrar of the Manitoba Pharmaceutical Association. While Guse has been attempting to establish the legalities of the

situation within both Canada and the United States, "Clear legal definitions have not been forthcoming," he says.

Establishing clear laws that are coordinated across provincial, state, and international boundaries would obviously help, even if politics make it unlikely. And effective enforcement requires cooperation as well, particularly as drug importation becomes a multi-million dollar business and enforcement resources remain small.

Meanwhile, within the scope of their mandate, Canadian authorities are not ignoring the issue. The Ontario College of Pharmacists recently brought charges against an Internet pharmacy, the Canadian Drug Store, Inc, and several individuals and entities associated with the online pharmacy. The company had unlawfully set up and operated an unaccredited pharmacy, filling prescriptions written by US doctors for US residents. Provincial boards, including the Manitoba Pharmaceutical Association, have been active in ascertaining US law so those pharmacies under its jurisdiction can be properly notified about the issue. Nonetheless, clear national guidance on a policy level has been lacking from both countries.

## A Role for VIPPS?

One concern touted by opponents of legalizing drug imports from Canada is the possibility that companies could transport drugs that appear authentic, but are, in fact, counterfeit or of lower quality. NABP launched the successful Verified Internet Pharmacy Practice Sites(tm) (VIPPS(tm)) program in 1999 to address similar concerns in regard to US-based Internet pharmacies. The Association is now working with Canada's National Association of Pharmacy Regulatory Authorities to establish a similar program there. Such a move would help put to rest at least some public health concerns.

Ultimately, the fate of drug importation lies with politicians, who will need to weigh competing pressures for affordable medications and drug company profits sufficient to support research and development of new drugs. Until this complex issue is resolved, regulators must continue to uphold the laws as they stand, not as what they may someday become.

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## Department of Justice to provide patient CURES profiles

On August 31, 2002, Governor Davis signed Assembly Bill 2655 (Chapter 345, Statutes of 2002) which extends the Controlled Substance Utilization Review and Evaluation System (CURES) program for five years and makes a number of changes related to the CURES program. Most notably, this bill permits physicians and pharmacists to request and receive CURES profiles for their patients from the Department of Justice. This legislation also permits the Department of Justice to send CURES profiles to the physicians and pharmacists providing care to patients whose CURES profiles indicate the possibility of prescription drug abuse.

The patient CURES profile request form is available at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov). Pharmacists may download the form, follow the instructions and submit the request to the fax number listed on the form. The CURES profile will be mailed to the address of the pharmacy listed on the request form.

## Changes at my pharmacy: Which form do I use?

Whenever there is a change in any of the following, the appropriate form must be completed and submitted to the Board of Pharmacy within 30 days.

### If there is a change in:

Pharmacist-in-Charge  
Exemptee-in-Charge  
Corporate Officer/Administrator/  
Medical Director  
Change of Ownership

### Complete this form:

Change of Pharmacist-in-Charge  
Change of Exemptee-in-Charge  
Change of Permit Request  
Community Pharmacy Application or  
Hospital Pharmacy Application or  
Clinic Permit Application

If you are closing your pharmacy: Discontinuance of Business

Please visit [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov) to obtain important information, updates on pharmacy law, and the proper forms to make the above changes.

## Compliance Guidelines: Electronically Transmitted Prescriptions

### Computer-to-Computer — Computer-to-Fax

California pharmacies can accept computer to fax prescriptions for controlled substances (except for Schedule II prescriptions) and these electronically transmitted prescriptions are not required to be in the handwriting of the prescriber. However, these prescriptions must contain the electronic signature of the prescriber.

Pharmacies that accept electronically transmitted prescriptions (computer-to-fax, or computer-to-computer) must ensure the authenticity, integrity, non-repudiation and confidentiality of the document. Authentication means ensuring that the prescriber is the person he or she purports to be. Integrity means ensuring that both the document and the signature have not been altered in the course of the transmission. Non-repudiation means ensuring that a party to the transaction cannot later disclaim it. Moreover, a pharmacist has an affirmative obligation to verify a prescription when appropriate to do so.

The pharmacy must also ensure that a prescription has been electronically transmitted to the pharmacy of the patient's choice. This may be done a number of ways, including, but not limited to, an affirmative statement on the prescription that the prescriber advised the patient of this right.

While pharmacies may, under certain circumstances, accept computer-generated

prescriptions for controlled substances (excluding Schedule II) that are electronically transmitted, Health and Safety Code section 11164(b)(1), still requires that prescriptions for controlled substances in Schedules III and IV must, except in emergencies, "be wholly written in ink or indelible pencil in the handwriting of the prescriber" if they are not electronically transmitted to the pharmacy.

**Editor's Note:** There has been no change in the federal regulations that allow fax or data transmission of prescriptions. However, in a letter dated September 28, 2001, Patricia M. Good, Chief of the Liaison and Policy Section, Office of Diversion Control for the U.S. Department of Justice, Drug Enforcement Administration, states that current DEA regulations allow for Schedules III, [IV], or V controlled substances that are electronically created and transmitted, either directly to a computer or via a facsimile machine, to be treated as oral prescriptions. This means that the prescription must be reduced to writing and retained for at least three years from the time of making. A pharmacist that receives an electronically transmitted prescription, via a facsimile machine or by other methods, must ensure the validity of the prescription prior to dispensing the controlled substance. (Title 21 Code of Federal Regulations section 1306.21)

### Computer-Generated Prescription for Non- Controlled Substances

California pharmacies can accept computer-generated paper prescriptions for non-controlled substances that contain the electronic signature of the prescriber. These are paper prescriptions that are printed at the prescriber's office and given to the patient.

Pharmacies that accept these paper prescriptions that contain the prescriber's electronic signature must ensure the authenticity, integrity, non-repudiation and confidentiality of the document.

Authentication means ensuring that the prescriber is the person he or she purports to be. Integrity means ensuring that both the document and the signature have not been altered. Non-repudiation means ensuring that a party to the transaction cannot later disclaim it. Moreover, a pharmacist has an affirmative obligation to verify a prescription when appropriate to do so.

The prescriber is also responsible for ensuring the authenticity, integrity, non-repudiation and confidentiality of the printed prescription that contains his or her electronic signature. This includes, but is not limited to, the printing of the prescription document on security paper that will void the prescription document should it be altered or reproduced.

### Non-Repudiation

The requirement of non-repudiation is consistent with, and is an integral part of, ensuring the security, integrity and confidentiality of a prescription that is transmitted from a computer to a facsimile machine. Moreover, it is consistent with the pharmacist's affirmative obligation to verify a prescription when appropriate to do so, regardless of how the prescription is transmitted.

It is likely that a different method might be needed to ensure the non-repudiation of a prescription transmitted from computer-to-fax than the method needed for a prescription transmitted from computer-to-computer. Depending on the circumstances, such a computer-to-fax transmission method might not necessarily require the high-tech approach needed for computer-to-computer transmissions.

The California Board of Pharmacy does not provide specific directions or technological requirements on how to ensure the authenticity, integrity, non-repudiation and confidentiality of prescriptions. It is up to the involved parties to meet those requirements in whatever way best suits the circumstances in question.



## Now, more than ever, use of the Board's Web site is crucial to good practice . . . [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)

The current State budget crisis compels all State agencies to function with fewer staff members and resources. During these times of budget constraints, the Board of Pharmacy will continue to seek ways to protect and provide services to California consumers, while developing ways to expedite services to its licensees. One of those ways is to devote the Board's limited resources to keeping its Web site current, with as much information as possible. Correspondingly, the Board strongly encourages licensees to take time out from busy schedules to peruse the Board's Web site to become familiar with all the information offered there. Many questions can be answered promptly, and applications can be obtained instantly.

### Pharmacy Law

Each day, the Board receives dozens of requests to speak to inspectors for answers or interpretations regarding the Pharmacy Law. However, inspectors are no longer available to take such calls. Nonetheless, many of these inquiries can be answered, and printed material can be obtained quickly by researching [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov).

To look up sections of the law, click on "About the Board," then click on "Board Authority." There, you will find the Table of Contents of California Pharmacy Law with links to the sites where you can view the text of various sections. Also included are selected sections of the Health and Safety Code and a revised subject index to aid in locating sections of pharmacy law. Additionally, LawTech Publishing Co., Inc. will continue to offer for sale a book of 2003 pharmacy laws, which may be purchased by contacting LawTech at (949) 498-4815.

### Miscellaneous Inquiries

Answers to many of the day-to-day inquiries can be found through the following links:

- \* Board Meeting Dates, Sites and Agendas

- \* Prior Board Exam Pass Rates
- \* The Complaint Process
- \* Patient Consultation
- \* Public Disclosure Policy
- \* Disciplinary Guidelines
- \* Compliance Guidelines:
- \* Electronic Signatures
- \* Citation and Fine Process
- \* Pharmacy Law Interpretations
- \* Drug Expiration Dates
- \* Frequently Asked Questions
- \* Legislation/Regulations
- \* Board Newsletters
- \* Sunset Review

### Applicant Info

The Board receives close to 100 daily requests for applications, forms, and publications. To streamline the process and eliminate the delays caused by mailing, those persons requesting applications or forms are now directed to [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov). All Board applications, forms and publications can be downloaded at "Forms and Publications." Board applications, related instructions, experience affidavits, the Request for Live Scan Form (for electronic fingerprinting) and instructions for personal and site permit licenses can also be downloaded from "Applicant Info."

### Personal Licenses

Registered Pharmacist link—contains Board licensure examination and experience requirements, application, dates and deadlines, and information on postponing a scheduled examination, issuance of licenses, wall certificates and reciprocity. The Candidates Review Guide can also be downloaded there.

Intern Pharmacist link—contains the intern pharmacist application, intern hours affidavits and requirements, and the Intern Preceptor Manual details the duties and responsibilities of an intern.

Pharmacy Technician link—contains the application for registration, instructions

for qualifying, experience affidavits and requirements, and the Request for Live Scan Form and instructions.

Foreign Graduate link—contains the Foreign Pharmacy Graduate Equivalency Commission information, intern/pharmacist licensure requirements, Foreign Graduate Application, and subsequent Board examination information.

### Site Permit/Licenses link

All applications, instructions and requirements, related affidavits, forms, and the Request for Live Scan Form can be downloaded for:

Community and Hospital Pharmacies (Pharmacy Self-Assessment Forms can be downloaded from the "Forms and Publication Section")

Clinic

Wholesaler and Exemption Certificates (Wholesaler/Drug Manufacturer)

Out-of-State Distributor

Non-Resident Pharmacy Requirements

### Forms and Publications link

Documents to be viewed and/or downloaded at this site include:

- \* Issues of The Script (from January 1999 to present)
- \* Health Notes (six issues)
- \* Pharmacy Self-Assessment Forms
- \* Disciplinary Guidelines
- \* Intern/Preceptor Manual
- \* Candidates Review Guide
- \* Additional Multiple Choice Questions
- \* Additional Short-Answer Essay Questions

Now, more than ever, the Board's Web site can save you valuable time.

# Pharmacy Law Interpretations

## Pharmacy Technician Badges

While on duty in a pharmacy, a person employed as a pharmacy technician must wear some identification (a badge), which clearly identifies him or her as a pharmacy technician, even on those occasions when he or she might not be performing the specific duties of a pharmacy technician. (See Title 16 California Code of Regulations [16 CCR] section 1793.7(d).)

## Pharmacy Technician Duties

A pharmacy technician may only perform the duties of a pharmacy technician while assisting, and while under the direct supervision and control of, a registered pharmacist. (See Business & Professions Code [B&PC] section 4115(a), (b), (f) and (h); and 16 CCR sections 1793.2 and 1793.7(b) and (c).)

The duties of a pharmacy technician include packaging, manipulative, repetitive, or other nondiscretionary tasks. Such tasks include, but are not limited to, removing drugs from stock; counting, pouring or mixing pharmaceuticals; placing the product in a container; affixing labels to containers; and packaging and repackaging. (See B&PC section 4115(a), (b) and (c); and 16 CCR section 1793.2.) The pharmacy should have a job description, policies and procedures regarding the pharmacy technician's duties and responsibilities available for review. (See 16 CCR section 1793.7(e).)

## Pharmacy Technician Ratios

When performing an inspection, the inspector will determine compliance with the pharmacist/pharmacy technician ratio requirements in B&PC section 4115(g) and 16 CCR section 1793.7(f). In making the determination, the inspector will consider the number of pharmacists working in the pharmacy and the setting in which the pharmacy technician is employed, because

the ratio for dissimilar settings may be different. (i.e., a community pharmacy setting, a hospital setting, a state operated facility, a skilled nursing facility, etc.)

In determining compliance with the ratio requirements, the inspector may observe the pharmacy's operation, review the pharmacy's daily work schedule, interview the pharmacist(s) and other pharmacy employees, interview the pharmacy's customers, and review the pharmacy's job description, policies and procedures regarding the pharmacy technician's duties and responsibilities. The inspector is not limited to the above and may make such other inquiries as is reasonable under the circumstances.

## Prescription Vial Return to Stock

Pharmacies sometimes prepare prescription medication vials that for one reason or another are never dispensed to the patient. California law allows such medications, so long as they do not leave the pharmacy, to be returned to the pharmacy's stock. Civil Code section 56.10 prohibits a pharmacy from disclosing medical information regarding a patient to another patient or the public. Accordingly, when a prescription vial that has been returned to stock is re-dispensed to a new patient, the original patient's name and any other identifying information must be completely blacked out (or removed) from the label to ensure the original patient's confidentiality. The original patient's name or identifying information must be indecipherable.

After the labeled vial has been returned to stock and before it has been re-dispensed to a new patient, it is generally not necessary to conceal the original patient's identity, so long as no unauthorized person has access to, or can readily view, that vial. (See also 16 CCR section 1764.)

Pharmacies, if they choose to do so, may accept returned medication containers that have been opened by the patient, but

the medication cannot be returned to the pharmacy's stock. Opened containers cannot assure against contamination or alteration.

## Requirement for a Counseling Area

All pharmacies (except hospital inpatient pharmacies which meet certain requirements) must contain an area that is suitable for confidential patient counseling. (See 16 CCR section 1714.)

There are no statutory or regulatory guidelines that detail the structural requirements for a patient counseling area. All that is required is that consultation occurs in an area that provides confidentiality.

The inspector can determine the suitability of the consultation area by observing patient consultation taking place, interviewing the pharmacist and other pharmacy employees, interviewing the pharmacy's customers, and generally evaluating the consultation area's location and construction. The inspector is not limited to the above and usually makes such other inquiries and observations.

## Access to Pharmacy Records Outside the Pharmacy

Under certain circumstances and conditions, a pharmacy may store its records off-site if a waiver from the Board has been issued. (See B&PC section 4105 and 16 CCR section 1707.) One of the conditions for off-site storage of records is that the confidentiality of any patient related information be maintained.

Generally, Civil Code section 56.10 prohibits a pharmacy from disclosing medical information regarding a patient. This prohibition extends to patient-related information a pharmacy maintains off-site. Accordingly, the pharmacy may not allow access to such patient records unless disclosure of such records is allowed under one or more of the exceptions to Civil Code

## Pharmacy Law Interpretations

*Continued from Page 14*

section 56.10, found in that sections subdivisions (b) and (c). One of the exceptions that would allow disclosure of such records is for billing purposes. (See Civil Code section 56.10(c).)

There is no statutory or regulatory requirement that access to the records must only occur within the licensed pharmacy area or that a pharmacist must directly supervise the access. However, regardless of how or where the access occurs, the pharmacy and pharmacist-in-charge may still be responsible for any disclosures of confidential patient information that occur in violation of Civil Code section 56.10.

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## Pharmacy Self-Assessment Forms must be completed by July 1, 2003

Since there will not be another *The Script* published until July of this year, the Board wants to remind all pharmacists-in-charge (PICs) that section 1715 of the California Code of Regulations requires PICs to complete a self-assessment of their pharmacy before July 1 of each odd-numbered year.

Additionally, completion of a self-assessment is required within 30 days of a new pharmacy permit being issued or whenever there is a change of PIC.

The Board of Pharmacy will not be mailing forms to each pharmacy this year. The forms can be downloaded by clicking on "Forms and Publications" at the Board's Web site, [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov).

And please remember: **DO NOT MAIL THE COMPLETED FORM TO THE BOARD.** It must be retained in the pharmacy for three years after the assessment is completed and readily available for review.

## Board to begin issuing Sterile Compounding Licenses to California and Nonresident Pharmacies

Effective July 1, 2003, a pharmacy may not compound sterile injectable drug products in California unless:

1. The pharmacy is specially licensed with the Board as a sterile compounding pharmacy, OR:
2. The pharmacy has a current accreditation from the Joint Commission on Accreditation of Healthcare Organizations or another accreditation agency approved by the Board (at this time, there is no other agency).

All pharmacies that compound sterile injectable drug products must follow Board regulations for sterile compounding. These regulations are found in Title 16 of the California Code of Regulations as Article 8, beginning with section 1751. Additionally, the Board is promulgating revised

regulations for compounding sterile injectable drug products.

Note: If a nonresident pharmacy is shipping sterile injectable drug products into California, this pharmacy must also comply with Board regulations for sterile compounding. It also must be separately licensed with the Board to compound sterile injectable drug products unless it possesses current accreditation from the Joint Commission on Accreditation or Healthcare Organizations or another accreditation agency approved by the Board. A separate application form for nonresident pharmacies is required.

Watch the Board's Web site for the compounding pharmacy license application forms (expected near the beginning of April) and for the Board's amended regulations.



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

Continuing education 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, and all interested parties are urged to attend. Board members are not eligible for this CE.

The remaining meeting dates and sites for 2003 are:

**April 29 (Board meeting) –30 (Strategic Planning), 2003**

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

**July 21–22, 2003**

San Diego (Specific site to be determined)

**October 29–30, 2003**

San Francisco/Bay Area (Specific site to be determined)

Additional information regarding sites and agendas will be posted on the Board's Web site approximately 10 days prior to meetings, or you may contact the Board at (916) 445-5014, Ext. 4006.

## Notice to Consumers

The new English language "Notice to Consumers" has been mailed to all pharmacies—to be posted in the pharmacy where it is conspicuous to and can be read easily by consumers. Pharmacies must display the poster distributed by the Board or print the exact wording of the notice on the back of customer receipts (Business & Professions Code section 4122). Pharmacies cannot produce their own posters.

For pharmacies with special language needs, the Board's Web site, [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov), now has an 8.5" X 11" version of the new notice available for downloading in five additional languages: Chinese, Vietnamese, Spanish, Korean, and Russian.