



BE AWARE & TAKE CARE:
Talk to your pharmacist!

The Script

C A L I F O R N I A B O A R D O F P H A R M A C Y F E B R U A R Y 2 0 0 9

Changes in Pharmacy Law for 2009

The Assembly and Senate bills listed in this article were enacted in 2008, and unless otherwise specified, took effect January 1, 2009. The new and amended Business and Professions Code (B&PC), Health and Safety Code (H&SC), and Streets and Highways Code (S&HC) laws are paraphrased or summarized below, but you are urged to review the exact language at www.pharmacy.ca.gov/laws_regs/new_laws.pdf.

SB 377 (Aanestad), Chapter 378, Statutes of 2008

Highway Signs: Pharmacies and Attractions

S&HC 101.7 (Amended)—requires the Department of Transportation to adopt regulations governing the placement and standards for roadway information signs identifying approved 24-hour pharmacy services. These regulations would allow sign placement, along with that of other roadside businesses, near freeway exits in rural areas.

SB 1307 (Ridley-Thomas), Chapter 713, Statutes of 2008

Background: A dangerous drug or dangerous device must have a “pedigree,” meaning an electronic record of each transaction resulting in a change of ownership of a given drug, from sale by a manufacturer, through acquisition and sale by one or more wholesalers, manufacturers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the

dangerous drug. The following new and amended provisions of this bill relate to pedigree requirements and implementation dates.

Manufacturer

B&PC 4033 (Amended)—amends the definition of “manufacturer,” for the purpose of meeting pedigree requirements, to include:

- A person who prepares, derives, manufactures, produces, or repackages a dangerous drug or device, or cosmetic;
- The holder of an approved New Drug Application, an Abbreviated New Drug Application, or a Biologics License Application;
- A private label distributor (including colicensed partners) for whom the private label distributor’s prescription drugs are originally manufactured and labeled and have not been repackaged; or
- The distributor agent for the manufacturer, contract manufacturer, or private label distributor.

Pedigree

B&PC 4034 (Amended)—adds “repackagers” to the list of those whose products must contain a pedigree and the requirement of a customer-specific shipping reference number linked to the sales invoice number if a sales invoice number is not immediately available. Repackagers must

serialize repackaged drugs, and a pedigree must be provided that references the pedigree of the original packages provided by the manufacturer. This section further requires that a pedigree must track each dangerous drug at the “smallest package or immediate container” distributed by the manufacturer for sale to pharmacies. It also defines “interoperable electronic system” as a system that electronically tracks and traces dangerous drugs that use a unique identification number and supplemented by a

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President's Message

By Kenneth Schell, Pharm. D.,
President, Board of Pharmacy

It's been a year of challenges and opportunities. There was an epic state budget negotiation and nationwide fiscal problems that have made it even more difficult to provide our state with the highest quality healthcare. Only through close collaboration between consumers, the profession, and the regulatory agencies will the public be assured of safe and effective medication therapy.

My goal as president of the Board is to establish, maintain, and enhance communication with the public, pharmacists, other regulatory bodies, the Legislature and the administration. To do this, my promise to all is simple: I will listen—not just listen but also actively engage in a meaningful dialogue so that issues important to the Board's key stakeholders are considered.

There are several specific opportunities on the Board's plate this year to strengthen its primary mission of consumer health safety and protection. We will again reach out to health care professionals and the public for assistance in developing a patient-centered prescription label that will minimize medication errors

and optimize positive therapeutic outcomes. I am hopeful all parties will participate as the Board responds to this legislative mandate.

On the subject of safety, the Board will continue to contribute to the effort to establish a system that ensures safe medication use. The e-pedigree initiative has been extended to allow the industry sufficient time to effect a system that will maximize the integrity of our medication supply chain while minimizing cost increases and medication supply disruptions. We are heartened that all parties, state and federal government, the health professions, and the public are fully engaged in this process. We will continue to evaluate new technologies and work to lower existing barriers so that we have the safest and best distribution chain of medications in the world.

Next on our plate is to review the Board's processes and operations. With recent budget shortcomings, the Board finds itself looking for ways to do more with less. Additionally, the Board will be reaching out to pharmacy professionals to ensure the partnership between the Board and licensees produces the highest quality pharmaceutical services our citizens have come to expect.

In closing, I would like to express my pride in being appointed to the California Board of Pharmacy and to serve this year as Board president. That role allows me to give back to the state and its citizens, for whom I feel a tremendous debt of gratitude. I want to assure everyone that my fellow board members and I will listen, learn, and help. Have a great year. I look forward to working with you all.

NEW— Important License Renewal Information

Beginning January 2009, all license renewal applications will include a red-lined box containing the following text, also in red:

Since you last renewed your license, have you had any license disciplined by a government agency or other disciplinary body; or have you been convicted of any crime in any state, the U.S.A. and its territories, military court or a foreign country?

You must check the box indicating Yes or No.

Check the box next to "YES" if, since your last renewal, you have had any license disciplined by a government agency or have been convicted or pled guilty to any crime. "Conviction" includes a plea of no contest and any conviction that has been set aside or deferred pursuant to Sections 1000 or 1203.4 of the Penal Code, including infractions, misdemeanors, and felonies. You do not need to report a conviction for an infraction with a fine of less than \$300 unless the infraction involved alcohol or controlled substances. You must, however, disclose any convictions in which you entered a plea of no contest and any convictions that were subsequently set aside pursuant to the aforementioned codes. "License" includes permits, registrations, and certificates. "Discipline" includes, but is not limited to, suspension, revocation, voluntary surrender of license, probation, or any other restriction.

FAILURE TO RESPOND TO THIS QUESTION WILL DELAY RENEWAL OF YOUR LICENSE.

July 1 Deadline for Completion of Updated Self-Assessment Forms

Section 1715 of Title 16 California Code of Regulations requires pharmacists-in-charge to complete a "Community Pharmacy & Hospital Outpatient Pharmacy Self-Assessment" on Form 17M-13 (Rev 10/08) or Form 17M-14 (Rev 10/08) entitled "Hospital Pharmacy and Self-Assessment" before July 1 of every odd year. Section 1784 directs

wholesaler designated representatives-in-charge to complete Form 17M-26 (Rev 10/08) entitled "Wholesaler Dangerous Drugs & Devices Self-Assessment"—also before July 1 of every odd year. Completed forms must be retained for three years.

Updated forms will be available on the Board's Web site, www.pharmacy.ca.gov in early May of this year.

New Data Collection Vendor for CURES

Atlantic Associates, Inc. has collected controlled substance data for CURES since 1998, but in line with California's competitive bid process, a new vendor for data collection was awarded the contract. Effective January 1, 2009, all controlled substance prescription data must be submitted on a weekly basis to Infinite Solutions, Inc., who will continue to support the ASAP 2005 format.

To begin transition to the new vendor, pharmacies, pharmacy corporations, pharmacy data management entities, and pharmacy software vendors must establish an account with Infinite Solutions, Inc. by contacting:

Main office: (916) 641-0500, or

Direct CURES support: (916) 679-5720, or

Technical Support:

E-mail: curessupport@4infinitesolutions.com, or

Address: 5 Parkcenter Dr., Suite 110
Sacramento, CA 95825.

You may also visit the Infinite Solutions, Inc. Web site at www.4infinitesolutions.com/cures, where you can find information about the submission of data to Bureau of Narcotic Enforcement (BNE) through Infinite Solutions, Inc.

If you have questions or need additional information, you may contact Ronna Kephart at Ronna.Kephart@doj.ca.gov, or contact the BNE CURES office at (916) 319-9062.

Notify the Franchise Tax Board if you move outside California!

Pharmacists who work in California are required to file income tax returns with both the Internal Revenue Service and the California Franchise Tax Board. No news there, but it may be news to you to learn that moving to another state without notifying the FTB of your move can generate tax trouble with serious consequences.

This is what happens when you move to another state and no longer file California tax returns: if you hold any kind of California professional license and have previously filed tax returns in California, the FTB assumes that you are still working in California but have failed to file subsequent tax returns. The FTB then calculates what your income should be, based on the earnings reported on your previous return, and sends letters advising that you must file a return and pay the tax for that amount and usually with accompanying penalties.

The problem then escalates because the FTB notifications are sent to the address contained in your last tax return submitted in California and most likely never reach you at your out-of-state address. Upon receiving no response to their letters, the FTB then takes steps to secure collection of the assumed tax amount. Those steps can include attaching a lien against your social security number, affecting your credit rating and even damaging your ability to secure a loan.

Again, the FTB obtains your address and income information from previous tax returns, **not from the Board of Pharmacy (online or otherwise)**.

So to preclude such tax problems after moving to another state, you should notify the FTB of your new address by submitting a Change of Address form (FTB 3533) directly to the FTB. (Post office address change cards are not accepted for this purpose.) You may order the form by calling 1-800-338-0505, or you may download the form at www.ftb.ca.gov/forms/07_3533.pdf, and mail the completed form to:

Franchise Tax Board
Sacramento, CA 95827

Pharmacists have reported serious tax and credit problems related to this issue and have had great difficulty trying to resolve them, so if your address changes, the law requires you to notify the Board of Pharmacy within 30 days, but think ahead—notify both the Board **AND** the FTB.

Changes in Pharmacy Law

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linked unique identification number in the event that drug is repackaged.

In addition to prior exemptions, this bill clarifies that the following transactions are exempt from the pedigree requirement:

1. An “intracompany” sale or transfer, meaning any transaction for any valid business purpose between a division, subsidiary, parent, or affiliated or related company under the common ownership and control of the same corporate or legal entity;
2. Dangerous drugs delivered by the federal government to a local or state government entity;
3. The sale, trade, or transfer of a radioactive drug between any two entities licensed by the Radiologic Health Branch of the State Department of Public Health, the federal Nuclear Regulatory Commission, or an Agreement state is exempt for two years after the compliance date for manufacturers unless the Board determines that the risk of counterfeiting or diversion of radioactive drugs is sufficient for requiring the pedigree;
4. The sale, trade, or transfer of drugs labeled by the manufacturer “for veterinary use only”;
5. The sale, trade, or transfer of compressed medical gas;
6. The sale, trade, or transfer of intravenous “solutions” intended for the replenishment of fluids and electrolytes, for dialysis, or for irrigation or reconstitution, as well as sterile water;
7. Dangerous drugs in a sealed package with a medical device or medical supplies at the point of first shipment by the manufacturers and the package remains sealed until the drug and device are used (surgical purposes only); and
8. A product that meets either of the following criteria:
 - A product comprised of two or more regulated components, such as a drug/device, biologic/device, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity; or
 - Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products or device and biological products.

Enactment of Federal Legislation Related to Pedigree

B&PC 4034.1 (New)—Upon enactment of federal legislation or adoption of a regulation addressing pedigree or serialization measures for dangerous drugs that is inconsistent with California statutes, the California statutes will become inoperative. Within 90 days of the enactment, the Board must publish a notice that the related statutes are inoperative and

adopt emergency regulations necessary to reflect the inoperation of state law.

Rerepackager

B&PC 4044 (New)—defines “repackager” as a person or entity that is registered with the federal Food and Drug Administration as a repackager and packages finished drugs from bulk or that repackages dangerous drugs into different containers, excluding shipping containers.

Third-Party Logistics Provider or Reverse Third-Party Logistic Provider

B&PC 4045 (New)—defines “third-party logistics provider” and “reverse third-party logistic provider” as entities licensed as wholesalers that contract with dangerous drug manufacturers to provide or coordinate warehousing, distribution, or other similar services on behalf of a manufacturer, but for which there is no change of ownership in the dangerous drugs. A third-party logistics provider will not be required to generate or update pedigree documentation, but must maintain copies of the pedigree. To be exempt from documentation for pedigrees, a reverse third-party logistic provider may accept only decommissioned drugs from pharmacies or wholesalers.

Wholesaler License Surety Bond Requirements

B&PC 4162 (Amended)—removes the repeal dates listed for California wholesalers bonding requirements.

Renewal of Nonresident Wholesaler License: Surety Bond

B&PC 4162.5 (Amended)—removes the repeal dates of this section for nonresident wholesalers bonding requirements.

Unauthorized Furnishing by Manufacturer or Wholesaler

B&PC 4163 (Amended)—Specifies that repackagers and pharmacies, as well as manufacturers and wholesalers, may not furnish dangerous drugs or dangerous devices to unauthorized persons. Additionally, the effective date on which a wholesaler or repackager cannot sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree, nor acquire a dangerous drug without a pedigree was changed from January 1, 2009, to July 1, 2016. Commencing on July 1, 2017, a pharmacy may not sell, trade, or transfer a dangerous drug without providing a pedigree, nor may a pharmacy or “pharmacy warehouse” acquire a dangerous drug without receiving a pedigree. In this section, a pharmacy warehouse is defined as a physical location, licensed as a wholesaler

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for prescription drugs, that acts as a central warehouse and performs intracompany sales or transfers those drugs to a group of pharmacies under common ownership and control.

Drop Shipment

B&PC 4163.1 (New)—defines “drop shipment” as the sale of a dangerous drug by the manufacturer whereby all of the following occur:

1. The pharmacy or person authorized by law to dispense or administer the drug receives delivery of the drug directly from the manufacturer;
2. The wholesale distributor takes ownership of, but not physical possession of, the drug; and
3. The wholesale distributor invoices the pharmacy or other person authorized by law to dispense or administer the drug in place of the manufacturer.

The Board may develop regulations to establish an alternative process to convey the pedigree information required for dangerous drugs that are sold by drop shipment.

Written Declaration (Grandfathering)

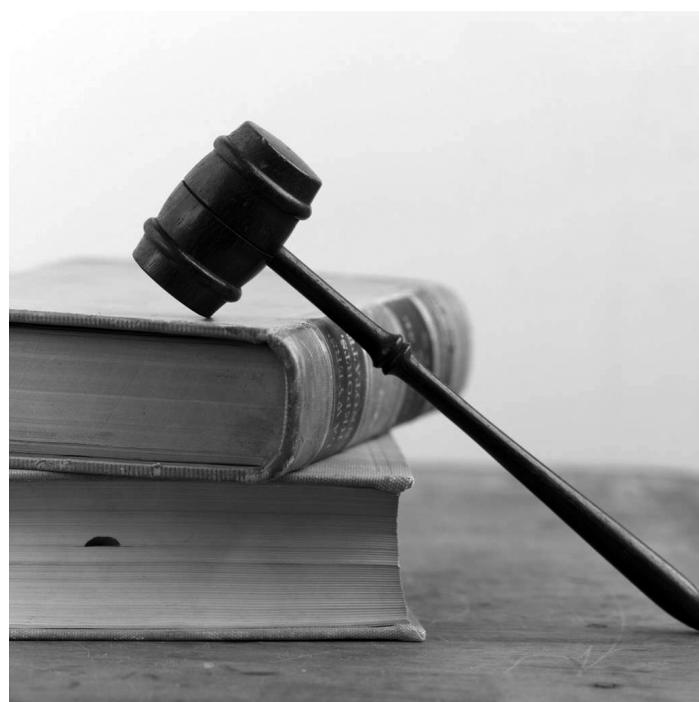
B&PC 4163.2 (New)—allows manufacturers, wholesalers, or pharmacies, who possess dangerous drugs that were manufactured or distributed prior to the operative date for pedigree requirements, to prepare a written statement under penalty of perjury designating these drugs as not subject to pedigree requirements. The written declaration must include the National Drug Code Directory lot number for each drug designated, and the declaration must be submitted to the Board no later than 30 days after the operative date of the pedigree requirements. The submitter must retain and make available for Board inspectors a copy of each declaration for three years. Drugs designated on a written declaration timely created and submitted to the Board may be purchased, sold, acquired, returned, or otherwise transferred without meeting pedigree requirements if the transfer complies with other requirements of the Pharmacy Law.

Pedigree Standard Operating Procedures Related to Content Inference

B&PC 4163.3 (New)—requires the Board to promulgate regulations that define the circumstances in which participants in the distribution chain may infer the contents of cases, pallets, etc. of dangerous drugs without opening each unit. Participants subject to such regulation would be required to document their processes and procedures in their standard operating procedures and make them available for Board review.

Holding Legal Title on Pedigree Requirement Effective Date (Grandfathering)

B&PC 4163.4 (New)—permits the exemption



from the pedigree requirement to wholesalers and pharmacies that have all units of dangerous drugs, for which the manufacturer does not hold legal title, in their possession on the effective date of the pedigree requirement. However, if any units of those drugs are subsequently returned to the manufacturer, they shall be subject to the pedigree requirement if the manufacturer distributes those units in California.

Implementation Dates of Pedigree Requirement

B&PC 4163.5 (New)—To encourage participants in the dangerous drug distribution chain to make the implementation as quickly as possible and ensure continued availability of prescription drugs in California, the Legislature has declared that before January 1, 2015, each manufacturer of dangerous drugs distributed in California must designate at least 50 percent of its drugs to be subject of its initial phase of compliance with the state’s serialized electronic pedigree requirements. The remaining 50 percent of the drugs must be comply with the pedigree requirements by January 1, 2016.

Each manufacturer shall notify the Board of Pharmacy of the designated drugs and the methods employed to achieve the serialized electronic pedigree requirements. The notification process for these actions may be specified by the Board.

For purposes of designating drugs to be serialized, manufacturers shall select from the following

Compliance dates extended for ePedigree requirements

To protect consumers from counterfeit, diverted or adulterated drugs, California adopted an electronic pedigree requirement to provide a system of tracking prescription drugs from the point of manufacture to the final destination, a pharmacy or hospital, by January 2007. However, because of the technological and production line complexities voiced by the pharmaceutical supply chain, the compliance date was delayed to 2009 and again to 2011. Subsequently, Senate Bill 1307 (Ridley-Thomas) was signed by Governor Schwarzenegger in September 2008, replacing the 2011 implementation date with a series of staggered implementation dates requiring total compliance throughout the supply chain by July 1, 2017.

The supply chain was very active in securing the modifications they needed to ensure successful implementation. In exchange, those supporting the bill agreed to no additional delays. This agreement was commemorated in a letter to the Senate Journal, August 25, 2008, by Senator Ridley-Thomas.

The implementation compliance dates are:

- 50 percent of a manufacturer's products by 2015;
- The remaining 50 percent of the manufacturer's products by 2016;
- Wholesalers and repackagers must accept and forward products with the ePedigree by July 1, 2016; and
- Pharmacy and pharmacy warehouses must accept pedigrees by July 1, 2017.

There is preemptive language in SB 1307 that would repeal California's provisions if federal law contrary to California's ePedigree law is enacted. There are also provisions defining drop shipments, third party logistics companies (3PLs), repackagers and manufacturers. More detailed information is included in "Changes in Pharmacy Law for 2009," beginning on Page 1.

In the coming year, as the implementation dates draw near, the Board will continue to hold public meetings to provide guidance to the supply chain for implementing the requirements. Additionally, the Board will promulgate regulations for a number of provisions (including inference, drop shipments, grandfathering) needed to implement the requirements.

The Board wishes to acknowledge and thank Senator Ridley-Thomas and the Senate Business, Professions and Economic Development Committee for their support of SB 1307.

Pharmacies and Returned Sharps: Board Policy

As of September 1, 2008, section 118286 of the Health & Safety Code (H&SC) made it illegal to dispose of sharps waste in the trash or recycling containers. "Sharps waste" is defined (H&SC 117750) as any device having acute rigid corners, edges, or protuberances capable of cutting or piercing, includes such items as hypodermic needles, hypodermic needles with syringes, blades, needles with attached tubing, syringes contaminated with biohazardous waste, acupuncture needles, and root canal files.

Because of needle pricks, cuts, etc. to subsequent handlers of sharps waste, that section further requires that all sharps waste be transported in an approved sharps container to a collection center, and the California Integrated Waste Management Board, on their Web

site, includes pharmacies among such collection centers. However, pharmacy law does not authorize pharmacies to take back sharps unless there is a county-

During the interim period until laws resolving this issue are updated, the Board of Pharmacy has adopted the following policy:



adopted exchange program in place. This contradiction leaves pharmacies and their patients confused about what to do with used or unwanted sharps waste.

California law does not authorize pharmacies to accept the return of sharps when appropriately contained in an approved sharps container. The Board reserves its enforcement discretion about whether to intervene with any pharmacy that takes back sharps containers inappropriately. However, until this matter is fully resolved, the Board does not anticipate intervening in such practices. This policy may change as a result of a complaint or public safety issue.

Preparation is Key to Dealing with Pharmacy Crime

The July 2008 issue of *The Script* included an article, "Is your pharmacy secure?" The following additional information regarding pharmacy robbery was prepared and provided by Purdue Pharma L.P.

This article discusses one of the most important elements of dealing with pharmacy crime—preparing for a pharmacy robbery. With the goal of keeping you, other employees and customers safe in the event of a robbery, experts recommend that you don't try to be a hero. Specifically, give the robber(s) what they ask for, get them out of the store, and with preparation, be the best witness you can be.

How to prepare for a pharmacy robbery:

Establish store policies to assist investigators

Wipe down pharmacy counters and doors at specific times during the day and night (such as the beginning of each shift) so that fingerprints may be recovered in the event of a robbery.

Do not stock controlled substances in areas of the pharmacy where customers can observe them. Consider storing controlled substances in a locked cabinet or safe.

Use an indelible marker to write the name or initials of the pharmacy and the store number on the bottom of bottles containing controlled substances. If the bottles are recovered, they may tie the evidence to the original robbery case.

Preparing self and staff

Develop policies and procedures for robbery and theft in the Pharmacy Department. Specific employees should be assigned to do the following in the event of a pharmacy robbery:

- Call 911 when safe to do so. Do not simply rely on an alarm system. Report the robbery and any injuries.
- Observe the getaway vehicle if it can be done without personal danger. Note license plate number, make, model, year, color and any distinguishing marks.
- Lock all doors. Do not allow anyone to enter or leave.
- Preserve the crime scene.
- Gather customers together, and make them as comfortable as possible.
- Give notepads or robbery report forms to customers and staff. Ask them to write down what they saw. This activity gives them something to focus on and may assist investigators.

Establish training and conduct regular "robbery drills."

As with fire drills, people tend to respond better during dangerous situations if they have practiced before the incident. Drills also allow you to identify areas where further training is needed.

What to do during a robbery:

Stay calm, do exactly what the robber(s) asks, and get them out of the store as quickly as possible. Your personal safety and the safety of your staff and customers are of the utmost importance.



Avoid developing tunnel vision. Note the robber's gender, body build, skin color, eye color, race, glasses, tattoos, scars and any other identifiable traits. Place a height reference tape near the store entrance and the pharmacy counter. Note how tall the individual is as they leave the premises. Notice how tall they are in relation to a fixed item in the store such as store shelving. Investigators will ask you to report anything you saw, heard or smelled. If possible, keep any note or written instructions left by the robber, and give it to the investigators.

What to do after a robbery:

Immediately after a robbery, each employee should perform their assigned tasks. Don't touch anything touched by the robber, and secure any area where the individual(s) may have been. Cooperate fully with law enforcement when they arrive. Refer all media inquiries to law enforcement. Contact your insurance carrier to report the robbery. (You are also required to submit a Theft or Loss Report [DEA Form 106] to the DEA and a copy of that report to the Board of Pharmacy.)

Training videos can be useful in educating pharmacy staff on what to do in case of a pharmacy robbery. The training video, *Pharmacy Safety – Robbery*, can be found on the RxPatrol® website.

In addition to the training video, consider registering with RxPatrol® (Rx Pattern Analysis Tracking Robberies and Other Losses) at www.RxPatrol.com. This program is funded by Purdue Pharma L.P. and is administered by Captain Richard Conklin, a 27-year veteran of the Stamford, CT Police Department. The program allows for law enforcement, pharmacists and store managers across the country to submit information about pharmacy crimes involving both prescription and over-the-counter drugs. Once verified, the information is entered into the RxPatrol® database by Captain Conklin. The database can be searched to see if similar offenses have occurred elsewhere in a specified region.

Medication Error Issues

One of the Board's primary goals is to elevate the California pharmacist's awareness of how to prevent and eliminate medication errors. In future editions of *The Script*, the Board will feature articles on medication errors. These articles will include errors that the Board has recently investigated and the processes that leading experts recommend for error prevention.

During 2007-2008, the top medication errors investigated by the Board were due to the wrong drug being dispensed, followed closely by wrong drug strength dispensed and incorrect directions for use.

Medication errors reported to the Board originate from a number of different processes. Dispensing the wrong drug occurs when the pharmacist dispenses a sound/look-alike drug instead of the prescribed drug and when the pharmacist misreads the prescriber's direction for use. Patients also are dispensed the wrong drug when the properly filled, labeled and checked medication is provided to another patient at the counter, a patient often with a similar name. The Board strongly advises pharmacies to ensure a second check by checking the patient's address or birth date.

Pharmacists are provided all sorts of information intended to be helpful in reducing dispensing errors, but often it is easier to understand how some of these errors occur, and more importantly, how to prevent them by reviewing actual case files. The cases outlined below are medication errors investigated by the Board.

Case 1. An eight-month-old child was given a prescription for Novahistine DH (Phenylhist DH), a codeine-containing product. The pharmacist incorrectly typed the directions on the prescription label as "Give 1½ teaspoonfuls by mouth every 6 hours" instead of the prescribed direction to give 1½ cc (ml) by mouth every 6 hours. This resulted in the dispensing of seven times the prescribed dose. The infant's mother, who was a nurse, caught the error before the child received any of the medication.

Case 2. An adult female asked the pharmacist to refill her prescription for Disopyramide 100mg. The pharmacist incorrectly filled the prescription with Desipramine 100mg. Subsequently, the patient began to experience difficulty in breathing, fainting spells, irregular or fast /pounding heartbeat, stomach pain, unusual tiredness, anxiety, constipation and/or diarrhea, drowsiness or dizziness, and dry mouth—all side effects of Desipramine. The patient contacted the pharmacy and was told by the PIC that the tablets were a generic replacement, and the symptoms could not be related to the generic drug.

Case 3. An adult female asked the pharmacist to refill her Norvasc (5mg once daily) prescription, a blood pressure-lowering drug, but the pharmacist incorrectly dispensed Lipitor, a drug for lowering cholesterol. Five days later, the patient suffered a stroke and was hospitalized. After six days in the hospital and six major procedures, she was released. One

of her discharge medications was Lisinopril 10mg, but the pharmacist incorrectly filled the prescription with Lisinopril 20mg. Fortunately, the patient subsequently received the correct medication, and her condition stabilized.

Case 4. A 58-year-old female patient was prescribed Prednisone 2.5mg tablets to be taken "1 tablet bid" (5mg daily). The pharmacist incorrectly dispensed Prednisone 50mg tablets to be taken as "½ tablet bid" (50mg/day). As a result of this error, the patient required hospitalization but recovered without permanent harm.

Case 5. A mature adult female was prescribed Climata 0.045-0.015mg Pro Patch. The pharmacist incorrectly dispensed Estradiol 0.0375mg patch. After seven months of taking the incorrect medication, the patient suffered a uterine build-up requiring a D & C medical procedure.

The following charts reflect the type and percent of citations related to California prescription errors from July 1, 2007 to June 30, 2008, and look/sound-alike drug errors from July 1, 2007, to July 1, 2008.

MEDICATION ERROR DATA

All pharmacy settings July 1, 2007 – July 1, 2008

Common Look-alike Sound-alike Errors	Prescribed	Dispensed
	Abilify	Adderall XR
	Augmentin	Amoxicillin
	Darvocet N	Darvon N
	Desipramine	Disopyamide
	Felodipine	Feldene
	Hydralazine	Hydroxyzine
	Lipitor	Lisinopril
	Lovastatin	Loratadine
	Lumigan	Lotemax
	Naproxen	Naprofen
	Metolazone	Metoclopramide
	Rispersal	Requip
	Parnate	Paxil
	Pepcid	Prilosec
	Pravachol	Prevacid
	Simvastatin	Sertraline
	Trazodone	Tramadol
	Zyrtec	Zantac
	Zyrtec	Zyprexa
	Zetia	Zyrtec

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Med Error Issues

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PRESCRIPTION ERRORS DATA

All pharmacy settings July 1, 2007 – June 30, 2008

Medication Error Category	Number	Percent of Total Citations
Wrong Drug	174	39%
Wrong Strength	72	16%
Wrong Instructions	77	17%
Wrong Patient	46	11%
Wrong Medication Quality	24	5%
Other Labeling Error	25	6%
Compounding/Preparation Error	11	2%
Refill Errors (frequency, timeliness)	1	<1%
Total # Citations of errors (May have more than one category listed)	445	

The Institute for Safe Medication Practices (ISMP) is dedicated to medication error prevention and works directly with the pharmaceutical industry to prevent errors, providing the following information online:

- ⌚ “Sound/Look-Alike Drug Names”
www.ismp.org/tools/confuseddrugnames.pdf.
- ⌚ ISMP also has a list of such drugs where “tall man” (upper case) letters have been used to draw attention to the dissimilarities of similar drugs and to help distinguish between them.
“Look-Alike Drug Name Sets with Recommended Tall Man Letters”
www.ismp.org/tools/tallmanletters.pdf.
- ⌚ “Error-Prone Abbreviations, Symbols, and Dose Designations”
www.ismp.org/tools/errorproneabbreviations.pdf.

DEA Clarification on Modification of Schedule II Controlled Substances Prescriptions

On November 19, 2007, the Drug Enforcement Administration (DEA) published in the Federal Register (FR) the Final Rule entitled *Issuance of Multiple Prescriptions for Schedule II Controlled Substances* (72FR 64921). In the preamble of that Rule, the DEA stated that “the essential elements of the (Schedule II) prescription written by the practitioner (such as the name of the controlled substance, strength, dosage form, and quantity prescribed)...may not be modified orally.”

However, in the DEA Web site Q & A section, pharmacists were advised that they “may change or add the dosage

form, drug strength, drug quality, directions for use, or issue date only after consultation with and agreement of the prescribing practitioner.”

The DEA recognizes the resultant confusion regarding this conflict and plans to resolve this matter through future rulemaking. Until that time, pharmacists are instructed to adhere to state regulations or policy regarding those changes that they may make to Schedule II prescriptions after oral consultation with the prescriber.

Without specific reference to Schedule II prescriptions, section 1716

of Title 16 of the California Code of Regulations prohibits a pharmacist from deviating from the requirements of a prescription (this means all prescriptions, including Schedule II) without prior consent of the prescriber, and section 1761(a) speaks to erroneous or uncertain prescriptions, stating that “the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.”

Questions related to this issue should be directed to the Liaison and Policy Section, Office of Diversion Control, DEA at (202) 307-7297.

Changes in the Board

The Board of Pharmacy welcomes a new public member, Ryan L. Brooks, and a new professional member, Randy B. Kajioka, Pharm.D. The Board also extends its best wishes and appreciation to departing professional members, Stanley W. Goldenberg, RPh, Ruth M. Conroy, Pharm.D., and public members, William "Bill" Powers and Henry "Hank" Hough.

New Members

Ryan Brooks of San Francisco was appointed by Governor Arnold Schwarzenegger to the Board on November 4, 2008, to fill the position formerly held by Public Member Henry Hough. Since 2002, Mr. Brooks has served as Vice President of Government Affairs for CBS Outdoor' Western Region, a leading global media company in broadcast and cable television, radio and outdoor advertising. During the previous years, he functioned as Director of Administrative Services for the city and county of San Francisco, Director of Business Development for EA Engineering, Director of Community and Public Relations for the U.S. Navy/Western Division, Director of Community Relations for the engineering firm, Planning Research Corporation (an environmental engineering firm now known as Tetra Tech), and Pentagon advisor to the deputy undersecretary of defense for environmental securities. He also served on the San Francisco Public Utilities Commission from 2003 to 2008, where he assumed the position of president in 2007. Mr. Brooks presently serves as a member of the New Motor Vehicle Board, the Little Hoover Commission, and the California International Relations Foundation.

Mr. Brooks' term will expire June 1, 2012.



Ryan Brooks

Randy Kajioka, of Elk Grove, was appointed to the Board by Governor Schwarzeneggar on December 7, 2008. Dr. Kajioka's employment at Kaiser Permanente began in 1984, where he served as a staff pharmacist, Assistant Chief Pharmacist and Outpatient Pharmacy Manager. Since 2003, he has held the position of Pharmacy Project Manager at Kaiser Permanente and Nuclear Pharmacist for Medi-Physics. He also functions as Director of Pharmacy Operations for RNRx Medical Staffing and works as a relief pharmacist for Bel Air Pharmacies and Walgreens. Dr. Kajioka also serves as Vice President of the Sacramento Asian Peace Officer's Association and on the Community Advisory Council for the Asian Pacific Community Counseling Center.

Dr. Kajioka's term will expire June 1, 2011.



Randy Kajioka

Departing Members

Upon his retirement from the Board, **Stanley Goldenberg** described his years (2001 to 2008) on the Board as one of the highlights of his professional career. He added, "The honor of working with past and present fellow board members and being elected for president for two terms, helped me to understand the real meaning and full value of *SERVICE*. I have often said that we all stand on each others' shoulders, and this is demonstrated by the dedication and service of the Board of Pharmacy administrative leadership. Patricia Harris and Virginia Herold, as well as the excellent staff, created a contagious atmosphere that motivated us all to strive for service excellence dedicated to consumer protection, as well as recognition and advancement of the profession of pharmacy. I'd also like to express my appreciation to John Jones, Bill Powers and Clarence Hiura for their mentoring and friendship. And I must add a special thanks to my wife, Suzyn, for her support while I was serving on the Board of Pharmacy. I am truly grateful for having been given the opportunity to serve."

Mr. Goldenberg was instrumental in promoting the "Tech Check Tech" program, the 50-year pharmacist certificate, and the pedigree regulation and its foundation for future implementation. He also championed the promotion of student involvement and was elected president of the Board for two years.

Ruth Conroy was appointed to the Board in 2003. Dr. Conroy was actively engaged with many Board projects, but her membership in the Licensing Committee was where her influence and direction was most manifest. She strove to assure that the Board's licensing processes and procedures were as timely and efficient as possible. Future licensees will certainly benefit from her efforts on their behalf.

William "Bill" Powers, a public member since 2000, served as president from 2006 -2008. Two of Mr. Power's priorities during his tenure as president were to continue and increase the Board's outreach programs aimed at senior citizens and to educate licensees in ways to reduce medication errors.

One of the Board's largest undertakings during his tenure has been to implement the ePedigree requirements for prescription drugs dispensed or shipped through California. Mr. Powers was very instrumental in the enactment of ePedigree and deeply involved in the implementation of SB 472, requiring the standardization of prescription container labels and SB 966 regarding "take back" programs for the collection and proper disposal of drug waste.

Mr. Powers was also active in the development and adoption of the Board's Disaster Response Policy Statement advising that pharmacy law can be waived during federal or

Changes in the Board

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local emergencies to provide care to patients and encourages health care providers to volunteer their time and expertise to assist and care for those whose lives are totally disrupted during disastrous events.

In his goodbye to the Board, Mr. Powers said, "It has been my great pleasure to work on such ambitious and wide-reaching programs, and to work with such a visionary group of board members and terrific staff. They are all dedicated to promoting the health and safety of all Californians."

Henry "Hank" Hough was appointed to the Board in 2006. While with the Board, Mr. Hough participated in the Communication and Public Education Committee and the Licensing Committee and the Enforcement Committee, where he advocated for consumer self-reliance and accountability in managing their medication therapies.

The Board wishes to express its gratitude to those wonderfully talented and dedicated members with whom we have been privileged to work.

Clarification

In the July 2008 issue of *The Script*, an article ("Licensees can be held accountable for drug delivery thefts") regarding the reporting of drug delivery theft or loss stated that section 11103 of the Health & Safety Code (H&SC) "requires that any theft, loss, or shipping discrepancy must be reported to the Department of Justice within three days after the discovery." However, it must be noted that this law is pursuant to H&SC 11100, which relates to manufacturers, wholesalers, retailers or other entities that sell, transfer, or otherwise furnishes the individual chemicals listed in H&SC section 11100. It does not apply to pharmacists or hospitals that sell, transfer or furnish the end products that contain the chemicals listed in section 11100.

Additionally, in the same article, Drug Enforcement Agency registrants were advised to report in-transit losses of controlled substances to the DEA upon discovery. Please note that the report must be submitted on DEA Form-106, which is available online at www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html. (21 Code of Federal Regulations sections 1301.74(c) and (e).

Frequently Asked Questions

Do you have a question that you would like to see addressed in the newsletter? If so, please e-mail them to
Hope_Tamraz@dca.ca.gov.

Q. Physician assistants, under a supervising physician, are authorized to write prescriptions, but when both names are on the prescription form, how does the pharmacist know who actually wrote the prescription?

A. Sections 3502.1(b), (d) of the Business & Professions Code (B&PC) require that a prescription written by a PA must contain the printed name, address, and phone number of the supervising physician and the printed or stamped name, license number and signature of the PA. The PA's signature identifies him or her as the prescriber, and any questions regarding the prescription should be directed to the prescribing PA. If a PA is authorized by the supervising physician to issue drug orders for controlled substances, PAs must have a separate DEA

registration number, and that number must be included on controlled substance prescription forms. Generally, PAs include the initials "PA" after their signed name.

Section 4040 of the B&PC requires the prescriber's signature on a written prescription. If the names of both the physician and the PA are printed on the prescription, but there is no signature, such a prescription is, pursuant to Title 16, California Code of Regulations section 1761(a), erroneous, uncertain, and contains an omission (the prescriber's signature). This section directs pharmacists to "contact the prescriber to obtain the information needed to validate the prescription."

Q. How long does a facility need to keep recall notices on the premises?

A. According to the FDA's recall coordinator, guidelines published in 21 Code of Federal Regulations, Part 7, do not establish a time frame for record retention of recall letters.



Senate Joint Resolution No. 19 (Ridley-Thomas) 2008

Professional health licensees' obligations related to torture and treatment of detainees

The American Medical Association defines "torture" as the deliberate, systematic or wanton administration of cruel, inhumane and degrading treatments or punishments during imprisonment or detainment." Section 2340 of Title 18 of the United States Code defines torture as "an act committed by a person acting under the color of law specifically intended to inflict severe physical or mental pain or suffering upon another person within his custody or physical control." The International Red Cross, The New England Journal of Medicine, The Lancet (a British medical journal), military records, and first-person accounts have reported that California-licensed health professionals have participated in torture or its coverup against detainees in United States custody.

Because health professionals' most basic obligations are to protect the health of and do no harm to others, the Senate and the Assembly of the State of California jointly resolved (Senate Joint Resolution 19) that all California health professions boards must notify their licensees that they are absolutely prohibited from knowingly planning, designing, participating in, or assisting in the use of condemned techniques at any time and may not enlist others to employ these techniques to circumvent that prohibition. And to that end, this resolution also requests the United States Department of Defense and the Central Intelligence Agency to remove all California-licensed health professionals from participation in prisoner and detainee interrogations.

The Legislature requests that when California-licensed health professionals have reason to believe that interrogations

are coercive or "enhanced" or involve torture or cruel, inhuman, or degrading treatment or punishment, they shall report their observations to the appropriate authorities. If the authorities are aware of those abusive interrogation practices but have not intervened, then those health professionals are ethically obligated to report those practices to independent authorities who have the power to investigate and adjudicate those allegations.

"Commit yourself to the noble struggle for human rights. You will make a greater person of yourself, a greater nation of your country and a finer world to live in."

Dr. Martin Luther King, Jr.
Nobel Peace Prize Laureate

This resolution applies to all relevant California licensees, including those licensed by but not limited to, the Board of Behavioral Sciences, the Dental Board of California, the Medical Board of California, the Osteopathic Medical Board of California, the Bureau of Naturopathic Medicine, the California State Board of Pharmacy, the Physician Assistant Committee of the Medical Board of California, the California Board of Podiatric Medicine, the Board of Vocational Nursing and Psychiatric Technicians, the Board of Psychology, and the Board of Registered Nursing.

California-licensed health professionals who participate in coercive or enhanced interrogation, or torture or other forms of cruel, inhuman, or degrading treatment or punishment may one day be subject to prosecution.

The exact language of the resolution can be viewed at:
http://www.leginfo.ca.gov/pub/07-08/bill/sen/sb_0001-0050/sjr_19_bill_20080818_chaptered.pdf

Optometric Scope of Practice Expanded

In September 2008, Senate Bill 1406 (Correa), Chapter 352, Statutes of 2008, made changes to section 3041 of the Business & Professions Code (B&PC). The bill expands optometrists' scope of practice to treat, among other disorders, glaucoma and eliminated some restrictions to optometric prescribing. Pursuant to B&PC sections 3041 and 3041.3, optometrists who are certified to use therapeutic pharmaceutical agents may prescribe the following for the treatment of eye disorders:

- All oral analgesics that are not controlled substances;
- Codeine and hydrocodone compounds (still restricted to three days' use);
- Topical and oral anti-allergy agents (no longer have time restrictions);
- Topical and prescription oral anti-inflammatories can now be prescribed for post-surgical pain with no time restrictions;
- Topical antibiotics;
- Oral antibiotics for treatment of ocular disease;
- All topical hyperosmotics;
- Topical anti-glaucoma agents; and
- All oral antihistamines.

Note: Topical and oral antivirals no longer have time restrictions.

To write a prescription for therapeutic pharmaceuticals, the optometrist's license must be classed "TPA," and those letters should appear directly to the right of the prescriber's license number. If such designation is not included with the license number on the prescription, the optometrist's license may be verified online at www.optometry.ca.gov. The license class can then be determined by clicking on the licensee's name and reviewing "License or Registration Class."



Changes in Pharmacy Law

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measures:

- Unit volume,
- Product package (SKU) type, or
- Drug product family.

AB 1141 (Anderson), Chapter 292, Statutes of 2008

Schedule II Controlled Substances

H&SC 11055 (Amended)—adds Khat and Cathinone to Schedule II controlled substances.

Schedule IV Controlled Substances

H&SC 11057 (Amended)—adds Cathine to Schedule IV controlled substances.

Unlawful Possession Controlled Substances

H&SC 11377 (Amended)—makes the unlawful possession of Khat, Cathinone and Cathine a misdemeanor.

I'm opening a Pharmacy—What do I do?

That's a big question, and the following simplified steps are detailed to help you get through all the necessary application processes.

Step 1.

Apply for a Board of Pharmacy pharmacy license by downloading the application and instructions for its completion at www.pharmacy.ca.gov/forms/phy_app_pkt.pdf.

Step 2.

DEA registration is required for the purchase and distribution of controlled substances, but you may not apply for registration until after the pharmacy license number is issued. A DEA registration application may be obtained by downloading www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm.

Note: Although the DEA will not begin processing the registration application until a Board license number has been issued, applying for DEA registration online greatly reduces DEA's processing time.



Step 3.

A National Provider Identifier (NPI) number is required when applying for a Medi-Cal provider number. To apply for the NPI, download the application at www.med.umich.edu/medschool/gme/npi/NPI_Form_cms.pdf.

Step 4.

To obtain a Medi-Cal provider number from the Department of Health Care Services, download the application at http://files.medi-cal.ca.gov/pubsdoco/provappsenroll/05enrollment_DHCS6205.pdf.

Step 5.

The National Council for Prescription Drug Programs (NCPDP) Provider ID assists pharmacies with 3rd party reimbursement. To obtain the NCPDP Provider ID information and/or application, call **(480) 477-1000**.

Step 6.

Check with the city or county of your area to determine whether a business license is required for your operation.

I'm closing my Pharmacy—What do I do?

A very large part of closing a pharmacy, whether due to retirement, sale, or bankruptcy, is determining what to do with the inventory and hard copy and electronic records. Section 1708.2 of Title 16 of the California Code of Regulations (16 CCR) directs pharmacies to contact the Board prior to transferring or selling any dangerous drugs, devices or hypodermics inventory as a result of termination of business or bankruptcy proceedings and to follow all other instructions provided in this section. You must also contact the DEA for their instructions regarding your registration.

In the cases where a pharmacy files a bankruptcy petition or enters into a liquidation arrangement that would result in the sale or transfer of inventory, the Board must be notified in writing of the following, if known:

- Date of sale or transfer of drugs, poisons, devices or appliances;
- Name and address of purchaser;
- Inventory of dangerous drugs and devices showing their disposition; and

- Location of records of acquisition and disposition of dangerous drugs and devices (16 CCR section 1705).

Additionally upon closing a pharmacy, the pharmacist-in-charge and pharmacy owner must complete, sign, and submit to the Board a Discontinuance of Business (DOB) form. The form can be downloaded at www.pharmacy.ca.gov/forms/17m8.pdf. The large wall license, current pharmacy license renewal certificate, and an inventory of dangerous drugs and devices must be submitted to the Board with the DOB form.

When a pharmacy discontinues business, all prescription records, electronic files (patient profiles, invoices and prescriptions), a current inventory of dangerous drugs and devices, and acquisition and disposition records must be maintained in a board-licensed facility for at least three years (Business & Professions Code sections 4081, 4105 and 4333). Again, this information is required on the DOB form.

Real Time Access to CURES Data

For several years, Robert Pack (co-founder of NetZero and founder of the Alana and Troy Pack Foundation) has worked with several state agencies, including this board, spearheading an effort to secure online, real time reports for practitioners via a secured Internet system operated by the DOJ. Such a system would allow significantly faster access to a patient's controlled substance history, drawn from CURES data, which provides information about dispensed controlled substances, the specific drug, strength, and quantity dispensed by a pharmacy or practitioner. It also contains information as to the prescriber, the dispenser, and the patient.

Real time access to CURES data would allow practitioners to determine quickly whether a patient is a "doctor shopper" for controlled drugs and thereby prevent the prescribing and dispensing of controlled drugs to that patient. Currently,

prescribers and dispensers must obtain a controlled substance history of a particular patient by submitting a "Patient Activity Report" (PAR) to the DOJ, who retrieves the information from CURES data. The PAR form can be downloaded from the Board's Web site, www.pharmacy.ca.gov, (under "Publications," then "Applications and Forms"), and mailed or faxed to the DOJ.

Although CURES data is reported weekly by practitioners into the system, by the time processing occurs and a PAR report is obtained (it can be weeks), there is usually insufficient time for the practitioner to prevent subsequent prescribing or dispensing of controlled drugs. That is why the need for real time access is critical.

The cost to support the real time access software system for the DOJ is approximately \$1.5 million. Along with

the Alana and Troy Pack Foundation, Kaiser Permanente has committed to this cause, but additional private funding is still needed to implement the program.

To receive additional information about the Foundation, you may e-mail troyandalana@sbcglobal.net or contact:

Troy and Alana Pack Foundation
9000 Crow Canyon Road
Danville, CA 94506
Telephone: (925) 918-0843

The California Board of Pharmacy was the initial funder of the CURES program and fully supports the implementation of a secured Internet system for real time access to controlled substance patient histories. A feasibility report has been completed, and both the Legislature and the Attorney General's Office have approved use of this program.

Important Information for Applicants *LiveScan Fingerprint Errors*

During this past year, applicants for licensure with the Board of Pharmacy have reported that processing of their LiveScan fingerprints was delayed because information, such as social security numbers, birth dates, etc., was incorrectly entered into the computer by the LiveScan technicians. These errors impact both the applicants' ability to complete their applications and the Board's ability to review applications and issue licenses in a timely manner.

The three LiveScan fields required to verify the applicant's identity are the applicant's:

- Name,
- Birthdate, and
- Social security number.

If any of the above fields contains erroneous information, the applicant is required to be fingerprinted again.

[It is also important to insure that the LiveScan technician submits the fingerprints to both the FBI and DOJ for criminal background checks](#), as both are required before licensure can be completed. Be sure that the fingerprint technician checks both boxes when entering the information into the computer.

Example:

Level of Service DOJ FBI

To be sure that the correct information has been entered by the fingerprinting technician, applicants should ask the fingerprint technician to read back the information for verification.



Board honors pharmacists registered for at least 50 years

In an ongoing feature of *The Script*, the Board of Pharmacy pays tribute to those who have been registered California pharmacists on active status for at least 50 years. The Board recognizes these individuals and gratefully acknowledges their years of contribution to the pharmacy profession. These pharmacists may take great pride in being part of such an ancient and honorable profession for so long.

At the November 2008 E-Prescribing Forum, RPh Melvin G. Snidman of Los Angeles attended and was presented with a 50-year California pharmacist pin by Vice President Tim Dazé. Honored at the January 2009 Board Meeting, RPh William B. Ratzlaff of Santa Rosa and RPh Harry C. Pfeifer, Jr., of La Mesa, were presented with 50-year California pharmacist pins.

Mr. Ratzlaff noted that his career in pharmacy began when he was a teen-ager, washing a drug store's windows, sweeping floors and delivering prescriptions. After graduating from USC, he became licensed in 1949 and moved to Santa Rosa in 1951 where he still works at the Sonoma Development Center.



William B. Ratzlaff with Robert E. Swart, Member; Board of Pharmacy

Mr. Pfeifer related that he graduated from Ferris State College in Michigan in 1952. After a tour in the Navy, he returned to California where he became licensed in 1958. Most of his career has been with Long's, which is now CVS/Caremark and he is still working two days a week.



Harry C. Pfeifer, Jr. with D. Timothy Dazé, Vice President, Board of Pharmacy

Pharmacists who recently received a certificate commemorating 50 years of service and were invited to attend future Board meetings to be publicly honored are:

Astor, Eugene Y.	Palm Desert, CA
Baneth, Philip	Menlo Park, CA
Barnett, Thomas E.	Ahwahnee, CA
Becker, William W.	Daly City, CA
Davison, James Arch	Colusa, CA
Dembski, Thomas F.	Kailua Kona, HI
Fiderlick, George A., Jr.	Reno, NV
Francis, Robert Munk	Santa Monica, CA
Greendofer, Hannah P.	Daly City, CA
Heller, Irwin	Woodland Hills, CA
Lubick, Morris	Winnetka, CA
Maringer, John P., Jr.	San Diego, CA
Martin, Lillian E.	Camarillo, CA
Pfeifer, Harry C., Jr.	La Mesa, CA
Sand, Richard F.	Whittier, CA
Schmad, Wayne A.	Windsor, CO
Starkman, Bernard S.	Whittier, CA
Stasiak, Thomas W.	Belmont, CA
Turk, Naim S.	Foster City, CA
Weiner, Wilbert M.	Laguna Woods, CA

Electronic Prescribing in California

Since at least 1994, California has allowed e-prescribing for dangerous drugs and controlled substances, but the Drug Enforcement Administration does not permit DEA registrants to e-prescribe controlled substances. However, prescribers and payers are turning to e-prescribing technology to increase efficiency and reduce expenses. Recognizing that matching technology with pharmacy laws and regulations creates questions for pharmacists and prescribers, the Board of Pharmacy held a forum on November 20, 2008, to review e-prescribing guidelines and discuss future legislation. The Board was joined in the forum by the Medical Board of California and the California Dental Bureau, and the following pertinent elements of electronically transmitted prescriptions were reviewed:

Electronically Transmitted Prescriptions Defined

Section 4040 of the Business & Professions Code (B&PC) and section 11027 of the Health & Safety Code (H&SC) include “electronic transmission order” in the definition of a prescription and adds that electronic transmission prescriptions include both image and data prescriptions:

- **Electronic image transmission prescription** means any prescription for which a facsimile of the order is received by a pharmacy from a licensed prescriber.
- **Electronic data transmission prescription** means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

Requirements of a Prescription

Title 16 of the California Code of Regulations section 1717.4 states that e-prescriptions must include:

- Name and address of the prescriber (prescriber’s address, license classification and federal registry number may be omitted if they are on file and readily retrievable in the receiving pharmacy.);
- Telephone number for oral confirmation;
- Date of transmission; and
- Identity of the recipient, as well as any other information required by federal or state law or regulations.

Remember, the above requirements are general and not technology-specific. This permits the use of different formats and technologies.

Reducing Electronic Data Transmissions to Writing

B&PC section 4070 specifies that an oral or electronic data transmission prescription must be reduced to writing by the pharmacist, but the pharmacist is **not** required to write the address, telephone number, license classification, federal registry number of the prescriber or address of the patient if the information is readily retrievable in the pharmacy.

Altering Electronically Stored E-Prescriptions

B&PC section 4070 states that e-prescription and dispensing records cannot be altered or destroyed. However, if after a dangerous devise or drug has been dispensed and the previously created record is found to be incorrect, a correcting addition can be made by or with the approval of the pharmacist. The resulting record must contain:

- The correcting addition and the date it was made to the record;
- Identity of the person or pharmacist making the correction; and
- The identity of the pharmacist approving the correction.

Authorized to Transmit Prescriptions (Excluding Schedule II Controlled Substances)

B&PC section 4071 allows a prescriber to authorize an agent, on the prescriber’s behalf, to orally or electronically transmit a prescription (no Schedule IIs) to the furnisher. The pharmacy must make a reasonable effort to determine that the person who transmits the prescription is authorized to do so and record the name of the authorized agent who transmits the order.

Electronic Prescription into Pharmacy or Hospital Computer

B&PC section 4071.1 permits a prescriber, a prescriber’s authorized agent, or a pharmacist to electronically enter a prescription or order into a pharmacy’s or hospital’s computer from a remote location, with the permission of the pharmacy or hospital.

Electronic Transmission of Prescription—Health Care Facility

B&PC section 4072 allows certain licensees (pharmacists, registered nurses, licensed vocational nurses, licensed psychiatric technicians, or other healing arts licentiates) if authorized by regulation to do so and if employed by or serving as consultant for a licensed skilled nursing, intermediate care, or other health care facility, to electronically transmit a prescription (excluding Schedule II) to the furnisher. Again, the authorization of the transmitter must be confirmed and his or her name recorded.

Generic Substitution on Electronic Prescription

B&PC section 4073 permits a prescriber to indicate “Do not substitute” on an electronically transmitted prescription. The prescriber’s manual signature or initials are not required.

See ePrescribing in CA, Page 18

ePrescribing in CA

Continued from Page 17

Electronic Schedule III-V Prescriptions

H&SC section 11164 requires that written Schedule II, III, IV, and V prescriptions be written on controlled substance prescription forms. However, prescribers or their agents may electronically transmit Schedule III-V (no Schedule II) prescriptions, which must be produced in hard copy form, signed, and dated by the dispensing pharmacist. Additionally, any person who transmits, maintains, or receives any electronically transmitted prescription shall ensure the security, integrity, authority, and confidentiality of the prescription.

Electronic Prescriptions or Orders to Pharmacies and Hospitals

H&SC 11164.5(a) states that **only** with the approval of the Board of Pharmacy and the Department of Justice, and **only** if authorized by federal law and DEA regulations, may a hospital or pharmacy receive electronic data transmission prescriptions or computer entry prescriptions or orders for any Schedule II-V controlled substance. More simply put: **E-prescriptions for controlled substances cannot be received or dispensed until permitted by federal law and the DEA.** If a controlled substance e-prescription is received for Schedule III-V, it must be treated as an oral prescription. No oral prescriptions for Schedule II are permitted.

DEA Approval Pending

The DEA published on June 27, 2008, a proposed rule to permit e-prescribing of controlled substances under specific, fairly detailed requirements. Comment period on the rulemaking closed in September 2008, but a date for finalization of the rule is unknown.

Download Board of Pharmacy Fact Sheet for your patients

Public education is an essential element of the Board's mission to protect California consumers. Pharmacy practice shares that mission by educating patients about their medication and health. To that end, the Board's Communication and Public Education Committee's public outreach program is dedicated to providing educational material, some in several languages, directly to the public and also making it available to pharmacies for downloading and disseminating free to their customers.

Fact Sheets were developed through the Committee, some in collaboration with the UCSF School of Pharmacy and the UCSF Center for Consumer Self Care, to address current health issues faced by consumers. A sample, *Diabetes—Engage Your Health Team*, is on the opposite page and may be downloaded for distribution to patients.

Those planning to copy and distribute Fact Sheets may do so if the information is downloaded and unaltered. If information is taken from the Fact Sheets to be used for other purposes, the meaning of the copied text may not be changed or misrepresented; the Board and other collaborators must be given credit; and all copies must be distributed free of charge. In other situations, express written authorization is required.

Below is the list of Fact Sheets, some of which are also in Spanish, Chinese and Vietnamese, that are available at www.pharmacy.ca.gov under "Publications" and "Consumer Fact Sheet Series."

- *Diabetes—Engage Your Health Team*
- *Did You Know? Good Oral Health Means Good Overall Health*
- *Do you understand the directions on your Rx medicine label?*
- *Drug Discount Programs*
- *Ever Miss a Dose of Your Medicine? Here are Some Tips*
- *Generic Drugs—Real Medicines at High Quality, Low Cost*
- *Is Your Medicine in the News?*
- *Lower Your Drug Costs so You can Keep on Taking Your Medicines*
- *Measuring Liquid Medicine*
- *Pill Splitting...not for every person, and not for every pill*
- *Thinking of Herbals? Check Carefully Before You Take Them with Medicines*
- *Traveling Medicine Chest*
- *Vaccinations and Travel Outside the U.S.*
- *What's the Deal with Double Dosing? Too Much Acetaminophen, That's What*

To order copies online of the following brochures that cannot be downloaded, go to "Publications," then select "Request a Publication."

- *Prescription Drug Discount Program for Medicare Recipients*
- *Healthy Californians Through Quality Pharmacists Care*
- *Do You Have a concern or Complaint About a Pharmacy or Pharmacist?*
- *Children and Their Medicines*
- *How to Take Your Pain Medications Effectively and Safely*
- *Get the Answers! Talk to a Pharmacist*
- *Personal Medical Information Cards (English and Spanish)*

Pharmacists are urged to familiarize themselves with the consumer information available on the Board's Web site, and use it freely for their patients.



Diabetes

Engage your health team!

FACT: Diabetes can cause serious health complications including heart disease, blindness, kidney failure, and lower-extremity amputations. Diabetes is the sixth leading cause of death in the United States.

If you think you might have diabetes, visit a physician for a diagnosis. You might have SOME or NONE of the following symptoms:

- Frequent urination
- Excessive thirst
- Unexplained weight loss
- Extreme hunger
- Sudden vision changes
- Tingling or numbness in hands or feet
- Feeling very tired much of the time
- Very dry skin
- Sores that are slow to heal
- More infections than usual.

You can help prevent or postpone type 2 diabetes by taking a central role in your own self care:

- Don't smoke.
- Achieve a healthy weight and maintain it.
- Be physically active.
- Limit your intake of fat and sugar.
- Eat regular, balanced meals that include the four food groups.
- Keep your cholesterol and other blood fats within the target level.
- Maintain a normal blood pressure.

Engage your health team!

- Monitor your blood glucose regularly, as recommended by your **doctor**.
- Take your medication as prescribed. Ask your **pharmacist** about questions you may have on the use of your medicines, their safety or possible drug interactions.
- Take care of your feet by examining the skin for redness and sores. Ask your **pharmacist** for suggestions on products that can help improve your foot care.
- Make a date to visit your **doctor, dentist, and eye specialist** for regular check ups. Your role in making these visits is key to preventing problems.
- Consult a **dietitian** about creating balanced meals.
- If you drink alcohol, be moderate in how much you drink. Avoid drinking on an empty stomach as this can cause hypoglycemia (low blood glucose).
- If you are pregnant, ask your **doctor** about using artificial sweeteners.

University of California
San Francisco



School of Pharmacy

California State Board of Pharmacy
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CALIFORNIA STATE
BOARD OF PHARMACY



CE hours are awarded for attending one day of a Pharmacy Board or Committee meeting, for becoming a Certified Geriatric Pharmacist, or completing the PSAM

Continuing education (CE) hours are being awarded to encourage pharmacists and pharmacy technicians to learn more about the issues and operation of the Board by:

- Attending one full day of a Board meeting annually (six hours of CE); only one Board meeting per year
 - Attending a one-day committee meeting (two hours of CE for each of two different committee meetings); only four units annually
 - Completing the Pharmacist Self-Assessment Mechanism (PSAM) program through the NABP (six hours of CE)
 - Upon becoming certified by the Commission for Certification in Geriatric Pharmacy (three hours of CE)

Note: It is the pharmacy technician's responsibility to determine from the Pharmacy Technician Certification Board how many, if any, of the above hours are acceptable for recertification with that board.

Board of Pharmacy meetings are held at least four times per year: typically January, April, July and October. There are four committees that usually hold public meetings prior to each Board meeting:

- Enforcement Committee—Exercises oversight over all regulatory and enforcement activities for the improvement of consumer protection.
 - Licensing Committee—Exercises oversight of the development of minimum standards for the professional qualifications of licensees.
 - Legislation and Regulation Committee—Advocates legislation and promulgates regulations that advance the vision and mission of the Board to improve the health and safety of Californians.
 - Communication and Public Education Committee—Prepares relevant information to consumers and licensees for the improvement of consumer awareness and licensee knowledge.



Attendance at these meetings provides an opportunity to participate in the development of policies that will guide the Board in its decision-making. Frequently, both statutory and regulatory text are formulated at such meetings, modifications to current programs are developed, and evidence-based decisions are made.

Board or committee meetings are held in various locations throughout California to give the public and licensees the opportunity to attend. No reservations are needed: you simply arrive at the meeting location at the start of the meeting. For Board meetings, only one day is designated as eligible for CE; this is specified on the agenda. To obtain CE credit for attending committee meetings, attendees must arrive at the designated start of the meeting, and there will be a sign-in sheet for those interested in obtaining CE.

Additional information regarding the dates, locations and agendas for board and committee meetings are posted on the Board's Web site, www.pharmacy.ca.gov/about/meetings.htm, at least 10 days prior to each meeting. Also, you may download meeting information packets that contain action items and background information that will be discussed during the meeting. This material is placed on the Board's Web site about five days before each meeting.

The Board meeting dates and locations for 2009 are:

April 29-30	Sacramento
July 22-23	Los Angeles
October 21-22	San Francisco/Bay Area

Explanation of Disciplinary Terms

Effective Date of Action—the date the disciplinary action goes into operation.

Revocation or Revoked—the license is revoked as a result of disciplinary action by the Board, and the licensee's right to practice or operate a Board-licensed entity is ended.

Revoked, Stayed—the license is revoked, but the revocation is postponed until the Board determines whether the licensee has failed to comply with specific probationary conditions, which may include suspension of the licensee's right to practice.

Stayed—the revocation or suspension action is postponed, and the licensee is put on probation.

Probation—the licensee may continue to practice or operate a Board-licensed entity under specific terms and conditions for a specific period of time.

Voluntary Surrender—the licensee has agreed to surrender his or her license, and the right to practice or operate Board-licensed entity is ended.

Suspension—the licensee is prohibited from practicing or operating a Board-licensed entity for a specific period of time.

Suspension/Probation—the licensee is prohibited from practicing or operating a Board-licensed entity for a specific period of time, and the right to practice or operate is contingent upon meeting specific terms and conditions during the probationary period.

PC 23 Order Issued—the licensee is restricted from practicing or operating a Board-licensed entity by a court order that is issued under the provisions of Penal Code section 23.

Public Reprimand—resulting from a disciplinary action, the licensee is issued a letter of public reprimand.

Accusation Filed—an accusation is the document containing the charges and allegations filed when an agency is seeking to discipline a license.

Reinstatement of License—a previously revoked or suspended license is reinstated with specified terms and conditions.

Statement of Issues—a legal document that details the factual or legal bases for refusing to grant or issue a license.

Disciplinary Actions

From May 10, through November 5, 2008, the following licenses were disciplined through actions taken by the Board. To view details of the probation terms and conditions of each case, go to the Board's Web site, www.pharmacy.ca.gov, and from the "Quick Hits" menu, select "Verify a License," and select license type. After pulling up the licensee's name, click on the name.

Revoked Pharmacist and Pharmacy Technician Licenses

The following individuals are no longer licensed, and the right to practice as a pharmacist or pharmacy technician has been terminated.

Brock, Teresa M., TCH 18119, Armona, CA—Case 3147

Decision effective 09/17/08.

Burgos, Christina D., TCH 36042, North Hills, CA—Case 2926

Decision effective 05/21/08.

Castaneda, Richard O., TCH 51709, Los Angeles, CA—Case 3121

Decision effective 11/05/08.

Chanthavong, Clint, TCH 46977, Fresno, CA—Case 3114

Decision effective 05/21/08.

Crowley, Kenton Lance, RPH 38214, Temecula, CA—Case 3107

Decision effective 10/31/08.

Garcia, Michelle, TCH 36159, Sacramento, CA—Case 3026

Decision effective 08/08/08.

Johnson, Rashandra D., TCH 28563, Long Beach, CA—Case 3060

Decision effective 10/23/08.

Martinez, Anthony G., TCH 30168, Indio, CA—Case 3148

Decision effective 10/03/08.

McKenzie, Larry D., TCH 56107, El Cajon, CA—Case 3133

Decision effective 05/28/08.

Owenby-Collins, Melissa D., TCH 44342, Artesia, CA—Case 3079

Decision effective 08/08/08.

Varderesyan, Yervand, TCH 30864, Van Nuys, CA—Case 3102

Decision effective 12/03/08

York, Jennifer J., TCH 43949, Corona, CA—Case 3129

Decision effective 12/03/08.

Zalez-Simon, Carol, RPH 41523, Encino, CA—Case 2683

Decision effective 08/18/08.

Revoked Pharmacy License

The following pharmacy is no longer licensed and the right to operate a pharmacy has been terminated.

Life Wellness Pharmacy, PHY 45971, Carlsbad, CA—Case 3000

Decision effective 10/03/2008.

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Disciplinary Actions

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Pharmacist and Pharmacy Technician Licenses Revoked, Stayed, Three Years' Probation

The following licenses were revoked, revocations stayed, and the licensees placed on three years' probation. If the terms and conditions of probation are not followed, the original revocations can be reinstated.

Fenix, Lori Ann, RPH 51014,
Santa Rosa, CA—Case 3141

Decision effective 11/05/08.

Goodman, Fred, RPH 37591,
West Hollywood, CA—Case 3055

The terms of probation also suspend practicing as a pharmacist for ten days.
Decision effective 08/08/08.

Pharmacist License Revoked, Stayed, Four Years' Probation

The following license was revoked, revocation stayed, and the licensee placed on four years' probation. If the terms or conditions of probation are not followed, the original revocation can be reinstated.

Canales, Amanda L., RPH 44504,
San Juan Capistrano, CA—Case 3000

The terms of probation also suspend practicing as a pharmacist for 60 days.
Decision effective 10/03/08.

Pharmacist, Pharmacist Intern, and Pharmacy Technician Licenses Revoked, Stayed, Five Years' Probation

The following licenses were revoked, revocations stayed, and the licensees placed on five years' probation. If the terms and conditions of probation are not followed, the original revocations can be reinstated.

Bennett, William L., RPH 28245,
Stockton, CA—Case 3103

The terms of probation also suspend practicing as a pharmacist for six months.
Decision effective 08/08/08.

Cheng, Donna, RPH 33071,
Alhambra, CA—Case 2963

The terms of probation also suspend practicing as a pharmacist for six months.

Decision effective 06/27/08.

Lenzner, Michael, RPH 33245,
Carlsbad, CA—Case 3000

The terms of probation also suspend practicing as a pharmacist for one year.
Decision effective 10/03/08.

Panab, Lisa Anne, RPH 47276,
Fremont, CA—Case 3050

The terms of probation also suspend practicing as a pharmacist for 12 months.
Decision effective 06/27/08.

Ryden, Max A., INT 18460,
Los Angeles, CA—Case 3048

Decision effective 08/08/08.

Saadeh, Dennis E., RPH 41232,
San Clemente, CA—Case 2924

The terms of probation also suspend practicing as a pharmacist for 30 days.
Decision effective 08/13/08.

Tidwell, Terrie L., TCH 956,
Lawndale, CA—Case 3020

Decision effective 10/23/08.

Pharmacy Licenses Revoked, Stayed, Five Years' Probation

The following licenses were revoked, revocation stayed, and placed on five years' probation. If the terms and conditions of probation are not followed, the original revocations can be reinstated.

Park Pharmacy, PHY 41748,
Irvine, CA—Case 2924

Decision effective 08/13/08.

PMC Pharmacy, PHY 48762,
Daly City, CA—Case 3025

Decision effective 05/21/08.

TOT Pharmacy dba All Med Drugs,
PHY 45269, Thousand Oaks, CA—
Case 2683

Decision effective 08/18/08.

Pharmacist License Revoked, Stayed, Seven Years' Probation

The following license was revoked, revocation stayed, and the licensee placed on seven years' probation. If the terms and conditions of probation are not followed, the original revocation can be reinstated.

Ririe, Loren C., RPH 40583,
Novato, CA—Case 3116

Decision effective 10/03/08.

Voluntarily Surrendered Pharmacist and Pharmacy Technician Licenses

Through disciplinary actions of the Board, the following licenses were voluntarily surrendered.

Allen, Shevaila L., TCH 34912,
Los Angeles, CA—Case 3087

Decision effective 05/21/08.

Edington, John C., RPH 20579,
Sun City West, AZ—Case 3123

Decision effective 09/17/08.

Fisichella, Nicholas, TCH 64354,
Ramona, CA—Case 3054

Decision effective 09/10/08.

Gutierrez, Sean A., TCH 36449,
Bonita, CA—Case 3062

Decision effective 08/27/08.

Kanouse, Craig Murray, RPH 38910,
Visalia, CA—Case 3127

Decision effective 08/27/08.

Quinn, David M., TCH 31573,
Costa Mesa, CA—Case 3031

Decision effective 10/23/08.

Quintanilla, Mayra A., TCH 49672,
Los Angeles, CA—Case 3077

Decision effective 10/03/08.

Wong, Nolan, RPH 31808,
San Francisco, CA—Case 3025

Decision effective 05/21/08.

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Disciplinary Actions

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Voluntarily Surrendered Pharmacy Licenses

Through disciplinary actions of the Board, the following licenses were voluntarily surrendered.

Family Pharmacy, PHY 36795, Pasadena, CA—Case 2963

Decision effective 06/27/08.

PMC Pharmacy, PHY 36005, San Francisco, CA—Case 3025

Decision effective 05/21/08.

Statement of Issues

The following individuals were initially denied ability to register or take examination for licensure, but were subsequently licensed, revoked, revocation stayed and licensee placed on probation.

Haas, Gregory, RPH 61951, Petaluma, CA—Case 3134

License issued, immediately revoked, revocation stayed, and licensee placed on three years' probation.

Decision effective 11/03/08

Horwitz, Robert Eugene, TCH 77802, Walnut Creek, CA—Case 3163

License issued, immediately revoked, revocation stayed, and licensee placed on ten years' probation.

Decision effective 11/14/08

Medi-Cal Tamper-Resistant Prescription Requirements

Federal legislation, which was signed into law on May 25, 2007, states that in order for Medi-Cal or Medicaid outpatient drug costs to be reimbursed by the federal government, all written, non-electronic prescriptions must be executed on tamper-resistant pads. This requirement applies to all outpatient drugs, including over-the-counter drugs. The Center for Medicaid and State Operations issued guidelines stating that prescription pads for Medicaid or Medi-Cal patients must contain all of the following elements, effective October 1, 2008:



1. One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription;
2. One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber; and
3. One or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

For several years California has had tamper-resistant prescription forms with specific security features for prescribing controlled substances, and the California-required tamper-resistant prescription pads for controlled drugs fully meet the federal Medi-Cal requirements.

However, pharmacists must be aware that controlled substance prescriptions written on Medi-Cal prescription pads containing only the three requirements above, are in violation of Health & Safety Code section 11162.1, which has additional requirements.

Updated DEA Form-106

The Drug Enforcement Administration, Office of Diversion Control, has updated its electronic version of the DEA Form-106 (Report of Theft or Loss of Controlled Substances). The new format is available for DEA registrants at www.deadiversion.usdoj.gov. The form may be completed online and electronically submitted via the Internet to DEA Headquarters.

In an effort to streamline data collection, promote the accuracy of information, and to better track lost or stolen controlled substances, the DEA now requires entry of the National Drug Code (NDC) number on the Form-106. The NDC number identifies the manufacturer, product, dosage form, and package size.

For registrants who submit the DEA Form-106 electronically, entry of the NDC number will prompt the system to auto-populate additional fields such as the name of the product, dosage form, dosage strength, and quantity per container. This new requirement ultimately reduces the registrant's burden by saving time and facilitates the submission of error-free reports.

Questions regarding the electronic submission of the DEA Form-106 should be directed to DEA's Registration and Program Support Section at (202) 307-4925.

This newsletter is published by the

California State Board of Pharmacy
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2009 PHARMACY LAW with RULES & REGULATIONS

For 2009, the California Board of Pharmacy is unable to provide free copies of the Pharmacy Law book due to financial constraints. However, *LawTech*, the publisher of the Pharmacy Law book for the past 10 years, is making them available at a very affordable price.

Order now to keep you and your staff up-to-date with the new law changes for 2009!

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