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Talk to your pharmacist!

The Script

CALIFORNIA BOARD OF PHARMACY JANUARY 2008

SB 472: Standardization of Labeling Requirements of Prescription Drugs

Senate Bill 472, recently signed by Governor Schwarzenegger, requires the Board of Pharmacy to establish parameters that will standardize prescription container labels into a patient-centered format. The Board will do this over a phased-in, three-year project. The first year, the Board will hold a series of public meetings throughout California, gathering information and input from consumers and the health professions for adopting regulations to standardize prescription labels. In the second year, the Board will adopt regulations to standardize prescription labels. In year three, all pharmacies dispensing drugs to California patients must convert their labels to this new format by January 1, 2011.

The Board feels very strongly that creating a standardized prescription label that is patient-centered will increase patient compliance when taking medications and improve medication outcomes and patient safety.

The Board successfully advocated amendments to strengthen this bill to create legislation that addresses some of the findings in the Senate Concurrent Resolution 49 Report. The SCR report was the result of a panel that studied the causes

of medication errors and recommended changes to reduce errors associated with the delivery of prescription and over-the-counter medication to consumers and promote better patient medication outcomes. The panel included representatives from a school of pharmacy, the California Pharmacists Association, the California Association of Health Plans,

the Pharmaceutical Research and Manufacturers of America, the California Medical Association, the Assembly Democratic Caucus, the Assembly Republican Caucus, and a consumer.

This bill mandates that the Board develop regulations standardizing the prescription label

by first holding a series of public meetings to elicit comments and suggestions about how to standardize the prescription label and make it patient-centered. Taking into account that these meetings will occur throughout 2008 and that the Board will promulgate regulations at the conclusion of these public meetings, the Board ideally will complete the rulemaking process in 2009. The legislation requires that the standardized labels be in place no later than January 1, 2011, giving the profession time to comply with the new requirements.

President Powers appointed the following Board members to the subcommittee who will work on this project: Ken Schell, Chair, Bill Powers, Rob Swart, Ruth Conroy and Susan Ravnan. Meetings will be held statewide in locations that are easily accessible to the public, i.e. community centers, senior centers, etc. Notices of these meetings will be placed on the Board's Web site.

Good Drugs Inc. Refill: (555) 555-5555
000 West Ave
Sacramento, CA 95834
Rx# 000 1234567 Dr. Smith, J

DOE, JANE
IBUPROFEN 800MG TABLETS
For: MOTRIN Qty: 100 TABS

Take 1 tablet orally every 8 hours when needed for pain

Refills Left: 3 Please call 24 hours in advance
Mfg: PHARMFARM Discard After: 12/09

By January 1, 2011 such non-standardized prescription labels will be a thing of the past.

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President's Message

By William Powers,
Public Member,
President, Board of Pharmacy

presence of such products has negative effects on aquatic species and may also affect human health. To reduce the likelihood of improper disposal of drugs into waterways and to provide safe drug disposal, under SB 966, the Board will be assisting the California Department of Waste Management in developing requirements for drug "take back" programs. The intent of these programs is to provide the public with a means to dispose of unwanted drugs in ways that are environmentally friendly. The Board will work in concert with other agencies to complete the models no later than December 1, 2008.

Projects for the coming year also include continuing efforts by the Board to complete implementation of the e-Pedigree requirements by January 1, 2009. By that date, all dangerous drugs must have an electronic pedigree that details all ownership transactions of the drugs, from the original sale by the manufacturer, through the wholesaler, to the final sale to a pharmacy or person who furnishes, administers or dispenses the drug.

At the beginning of 2008, many of the Board's fees will increase. I note that most of our licensees and applicants haven't seen an increase in fees in almost 20 years, except for the period between 1995 and 1999 when fees were increased and then subsequently returned to pre-increase levels. Over the years, the Board has been able to function without increasing fees. However, the Board no longer can continue its operations at current levels without a fee increase, which for pharmacists will go from \$115 to \$150 for biennial renewal and for pharmacies, from \$175 to \$250 annually.

For more than a year, the Board has been promoting pharmacy readiness to respond to emergencies and disasters and now extends its gratitude to all those in the profession that used their skills and assets to help their communities during the devastating San Diego County fires. We are proud to be associated with you!

I look forward to seeing as many of our licensees and students as possible at future Board of Pharmacy meetings. You are also welcome to attend the various Board Committee meetings. Lists of the meetings are always posted on the Board's Web site.

As we move into a new year, the Board and the pharmacy profession are facing many challenges: implementation of AMP for reimbursement of MediCal prescriptions, a new law that will standardize prescription container labels by 2011 (SB 472), development of model programs for the collection and proper disposal of prescription drugs returned by patients (SB 966), implementation of e-Pedigree requirements for all prescription drugs dispensed or shipped through California, and increases in some Board licensing fees. These changes are set against a growing state deficit that could impact the Board's future operations and ongoing responsibilities such as inspections, staffing and travel.

Regarding new projects required by 2007 legislation: under SB 472, the Board will be developing regulations for prescription container labels that are more patient-friendly and more easily read and understood. The new labels must also address the needs of those with limited English skills. To develop these requirements, throughout 2008 the Board will be seeking input at public meetings and urging consumers, including seniors, pharmacists, other health care professionals, and all interested parties to attend and provide comments. The meetings should start in February 2008, and notices of the meetings will be posted on the Board's Web site.

In another area that will involve the Board, studies have shown that streams across the country have measurable concentrations of prescription and nonprescription drugs, steroids, and reproductive hormones. The

Changes in Pharmacy Law for 2008

The Assembly and Senate bills listed in this article were enacted in 2007, and unless otherwise specified, took effect January 1, 2008. The new and amended Business and Professions Code (B&PC) and Health and Safety Code (H&SC) statutes are paraphrased or summarized below, but you are urged to review the exact language of the statutes on the Board's Web site, www.pharmacy.ca.gov or at www.leginfo.ca.gov under Bill Information, Session 2006-2007.

SB 1048 (Committee on Business, Professions and Economic Development), Chapter 588, Statutes of 2007

Dispense Dangerous Drug or Controlled Substance to Emergency Room Patient; Requirements B&PC 4068 (Amended)—requires emergency room prescribers, in instances where the hospital pharmacy is closed and there is no pharmacist available, to report Schedule IV controlled substances, as well as Schedules II and III, to CURES, pursuant to H&SC 11165.

Adulterated or Counterfeit Dangerous Drug or Device

B&PC 4084 (Amended)—Under prior law, Board inspectors are required to affix a tag or other marking to identify adulterated or counterfeit drugs. That requirement is now extended to include “misbranded” drugs. Misbranded is defined as having labeling or packaging that contains false or misleading information about the contents of a container.

Pharmacist-in-Charge, Designated Representative-in-Charge: Termination of Employment; Notification to Board

B&PC 4101 (Amended)—updates pharmacy law by replacing the term “exemptee-in-charge” with “designated representative-in-charge,” as the individual who is responsible for drug wholesalers and veterinary food drug-animal retailers.

Wholesaler and Out-of-State Wholesaler: Temporary License

B&PC 4160 and 4161 (Amended)—specifically updates the law to designate the fee for a temporary wholesaler or nonresident wholesaler license to be either \$550 or an amount not to exceed the annual fee for renewal of a license to compound injectable sterile drug products.

Wholesaler / Nonresident Wholesaler License Surety Bond; Requirements

B&PC 4162 and 4162.5 (Amended)—extends the provision requiring wholesaler surety bonds from January 1, 2011, to January 1, 2015, for a wholesaler license or a nonresident wholesaler license. This



change matches the extension given to implement the e-pedigree requirements in 2006, that was inadvertently cancelled by another bill also enacted in 2006.

Pharmacist License Requirements

B&PC 4200, 4200.1 and 4200.2 (Amended)—changes the law examination name from “Multi-State Pharmacy Jurisprudence Examination for California” to the “California Practice Standards and Jurisprudence Examination for Pharmacists” to more accurately reflect the requirements for this examination contained in B&PC 4200.2.

Intern Pharmacist License

B&PC 4208 (Amended)—allows the Board discretion to extend duration of an intern license up to two years for those who are unable to complete the licensing requirements for experience during the initial license period.

Board May Issue Citations Containing Fines and Orders of Abatement

B&PC 4314 (Amended)—allows the Board to cite and fine licensees for violations of H&SC 150200 – 150206. These sections were enacted in 2005 to authorize counties to establish by local ordinance, a repository and distribution program for specified unused medications from skilled nursing homes to medically indigent patients served by government-owned pharmacies.

Changes in Pharmacy Law

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Letter of Admonishment: Issuance; Action by Licensee; Review

B&PC 4315 (Amended)— allows the Board to issue a letter of admonishment for violations of Division 116 (commencing with H&SC 150200).

SB 966 (Simitian), Chapter 542, Statutes of 2007

This bill pertains to a repository and distribution program from skilled nursing facilities to medically indigent patients served by government-owned pharmacies by requiring the California Integrated Waste Management Board, within the California Environmental Protection Agency, to develop model programs for the collection and proper disposal of prescription drugs returned by patients. The development of these models will be done in consultation with appropriate state, local, and federal agencies, including among others, the Board of Pharmacy, the Department of Toxic Substances Control, and the State Water Resources Control Board. The model programs would be required to include specific actions and informational elements and be available to eligible participants (governmental entities, pharmacies, veterinarians, clinics, and other medical settings) no sooner than July 1, 2008, and no later than December 1, 2008.

Background: A study of streams across the country by the United States Geological Survey found that 80 percent had measurable concentrations of prescription and nonprescription drugs, steroids, and reproductive hormones. Exposure to these products, even to low levels, has been shown to have negative effects on fish and other aquatic species and may have negative effects on human health.

To reduce the likelihood of improper disposal of drugs, a program must be established through which the public may return and ensure the safe and environmentally sound disposal of drugs in a way that is convenient for consumers. One model program should include at the minimum a means by which a pharmacy is required to provide, at no additional charge to the consumer, for the safe take back and proper disposal of the type or brand of drugs (excluding Schedules I – V) that the pharmacy sells or previously sold. The program would also provide a means by which a pharmacy would protect against the potential for the diversion of drug waste for unlawful use or sale.

SB 472 (Corbett), Chapter 470, Statutes of 2007

Standardized Prescription Drug Labeling

B&PC 4076.5 (New)—requires the Board to promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California. To ensure maximum public comment, the Board will seek information via public meetings from groups representing consumers, seniors, pharmacists or the practice of pharmacy, other health care professionals, and other interested parties.

The following factors shall be considered:

- Increased understandability of labels;
- Improved direction for use;
- Improved font types and sizes;
- Placement of information that is patient-centered;
- The needs of patients with limited English proficiency;
- The needs of senior citizens; and
- Technology requirements necessary to implement the standards.

Regulation Update Summary

This article contains a summary of changes to Division 17, Title 16 of the California Code of Regulations. The exact language of the amendment to CCR section 1707.2(g) is contained below:

1707.2(g) (Amended) Notice to Consumers

The Board has amended to the Notice to Consumers to include information about a patient's right to obtain lawfully prescribed medicine from a pharmacy. This information must be printed on the Notice to Consumers poster or alternatively printed on the back of receipts.

To accommodate the additional language, two posters are likely to be necessary. The Board is currently developing new posters to include this information and when available, will mail the posters to all pharmacies by June 2008. Until the posters are mailed, please continue to display the red and blue Notice to Consumer poster.

The following language was added:

Know your rights under California law concerning medicine and devices prescribed to you.

You have the right to receive medicine and devices legally prescribed to you, unless:

1. *The medicine or device is not in stock in the pharmacy,*
2. *The pharmacist, based upon his or her professional judgment determines providing the item:*
 - *is against the law,*
 - *could cause a harmful drug interaction, or*
 - *could have a harmful effect on your health*

This pharmacist may decline to fill your prescription for ethical, moral or religious reasons, but the pharmacy is required to help you get the prescription filled at this or another nearby pharmacy timely.

The pharmacy may decline to provide the medicine or device if it is not covered by your insurance or if you are unable to pay for the item or any copayment you owe.

If the pharmacy is unable to fill your prescription, you are entitled to have the prescription returned to you or transferred to another nearby pharmacy. Ask about our procedure to help you get an item that we don't have in stock.

Any questions? Ask the pharmacist!

1749 (Amended) Fee Schedule

For more than four years the Board's expenses have exceeded revenues. However, money in the Board's reserve fund has allowed operations to continue. Applicants and licensees have not experienced a fee increase since 1988 except for a four-year period between 1995 and 1999 (when fees were increased then reduced). While the Consumer Price Index reveals that the cost of consumer goods has risen steadily since 1988 (approximately 73%), Board fees have remained unchanged.

However, effective January 1, 2008, all Board fees will be raised to their statutory maximum. Affected licensees will be notified of their fee increase as part of their license renewal process, and exact language of the regulation can be found at www.pharmacy.ca.gov/laws_regs/1749_exact_language.pdf.

Please note: Pharmacy Technician fees remain unchanged.

FDA cracks down on firms marketing unapproved Hydrocodone products

The FDA announced on September 28, 2007, that the agency will take enforcement action against companies marketing unapproved prescription drug products containing hydrocodone. The action does not affect other hydrocodone formulations that have FDA approval.

The FDA told companies marketing unapproved hydrocodone products labeled for use in children younger than six years of age to cease manufacture and distribution

of the products by October 31, 2007. Those marketing any other unapproved hydrocodone drug products must stop manufacturing such products by December 31, 2007, and must cease further shipment in interstate commerce by March 31, 2008. The FDA warns that failure to meet these deadlines could subject violators to legal action.

More information is available on the FDA Web site at www.fda.gov/cder/drug/unapproved_drugs/default.htm.

Background and Summary of the e-Pedigree Law

Problem: there is an increasing prevalence of counterfeit prescription drugs showing up in the U.S., intermingled with the legitimate drug supply. Counterfeit prescription drugs are a worldwide problem, reaching as high as 30 percent or more of the supply in some countries. The World Health Organization estimates that in developed countries, counterfeit drugs are less than one percent of the market.

To put this in perspective: 3.4 billion prescriptions were dispensed in the U.S. in 2006. If one percent of this supply is counterfeit, this would mean that perhaps 34 million of these U.S. prescriptions were filled with counterfeit medicine. In California, we have roughly 10 percent of the U.S. prescription drug market, so this would indicate that perhaps 3.4 million prescriptions were filled and dispensed in California with adulterated medicine in 2006.

In an attempt to prevent counterfeit medicine from entering the legitimate supply chain in California, in 2004 the state legislature passed anti-counterfeiting and anti-diversion legislation (SB 1307), including provisions pertaining to the licensure and qualifications of wholesalers, restrictions on furnishing, and the requirement of an electronic pedigree to accompany/validate drug distributions. Portions of the legislation were implemented in 2005 and 2006. In 2006, subsequent legislation (SB 1476) sponsored by the Board moved the implementation date for the electronic pedigree component until 2009, and the same legislation also augmented and clarified portions of the electronic pedigree requirements.

Under current law, as of 1/1/2009, no wholesaler or pharmacy may sell, trade or transfer a prescription drug at wholesale without providing, and no wholesaler or pharmacy may acquire any prescription drug without receiving, a pedigree. The pedigree is a record in electronic form containing information regarding each transaction resulting in a change of ownership of the given prescription drug, including returns. The law specifies the particular data elements pertaining to the drug and to each of the ownership links in the chain of distribution that must be included in this record, and requires that the pedigree track each drug at the smallest package or immediate container (saleable unit). To implement this unit-level tracking requirement in an interoperable electronic system, requirements include a unique identifier (serialization number) placed on the smallest container saleable to a pharmacy, by the pharmaceutical manufacturer. Likewise, the manufacturer will also initiate the pedigree and pass that pedigree with the initial distribution; thereafter, the electronic pedigree will at all times accompany that particular container, appended by each successive owner to document each change of ownership of that particular container.

Simply put, the goal is for any owner/possessor of a prescription drug located at a licensed wholesaler, repackager, reverse distributor, or pharmacy in California, upon request, to have and keep electronic records that show the lineage of the drug from the manufacturer through to the current point in the

drug distribution channel (wholesaler, repackager, pharmacy). The electronic pedigree must contain specific information required by statute, and must be made and passed in an “interoperable electronic system,” an electronic track and trace system based on unique identification numbers (serialization) affixed at the point of manufacture.

The unique identifier or unique serialized number on each saleable container of prescription drugs will most likely be carried on either on a 2-D bar code or an RFID chip placed on the saleable unit by the manufacturer. The California Legislature has not mandated these specific technologies, but they are the



two methods that have been identified that could meet the requirements of the legislation. The number on the serialized container could then be utilized to access the specific electronic pedigree for that individual container of prescription drug.

Industry participants have engaged in standards-setting work to develop industry standards necessary to interoperability and sharing of pedigree data and records. The primary standards-setting body for the industry that has been engaged in this work with industry participants has been EPCglobal, the same entity that developed the standards for the UPC bar code.

Requirements:

- **Pedigree:** “*means a record, in electronic form containing information regarding each transaction resulting in a change of ownership of a given dangerous 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 drugs. The pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution.*” (California Business and Professions Code section 4034(a)).
- **Interoperability:** this is one of the augmentations to the legislation in 2006. With input from industry, we determined for this pedigree concept to work effectively, all parties at all levels of the supply chain needed to be able to access the pedigree information without having to purchase numerous types of hardware, software and middleware to be able to read whatever format a particular manufacturer chooses for their electronic pedigree. This will discourage

e-Pedigree Law

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companies from developing their own incompatible proprietary systems of electronic pedigrees, preventing a proliferation of systems and making it complex to read the pedigree by entities downstream (e.g., wholesalers and pharmacies). In January 2007, EPCglobal ratified a document-based pedigree-messaging standard. Nearing finalization is a second EPCglobal standard, the EPCIS standard. The EPCIS standard would also allow the creation or appending of a pedigree, combined with a data storage and management system. This should be completed in several months.

“Interoperable electronic system” as used in this chapter means an electronic track and trace system for dangerous drugs that uses a unique identification number, established at the point of manufacture, contained within a standardized nonproprietary data format and architecture, that is uniformly used by manufacturers, wholesalers and pharmacies for the pedigree of a dangerous drug. (California Business and Professions Code section 4034(i))

- **Serialization** at the unit level: this is the key to being able to enter, for instance, a pharmacy or wholesaler, to distinguish one container of prescription drugs from another, and to access the pedigree for each individual container. In addition, as long as the original container is available, the entire history of ownership for that specific container may be accessed. Specifically: **“The pedigree shall track each dangerous drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler and received by the pharmacy or another person furnishing, administering, or dispensing the dangerous drug”** (California Business and Professions Code section 4034(d)).

With the California system, two containers of the same drug, same strength, same lot number and same expiration date, can be differentiated from each other. They each may have traveled very different supply chain routes to arrive at the same location. Only with the California serialized product can you tell each change of ownership for each container. The California process allows regulators to determine the origin of a container and be much more likely to identify when or if a product has been tampered with or if a counterfeit product has entered the supply chain.

- **Repackaging**: must be tracked on a single pedigree tracing back to the original manufacturer. Specifically: **“a single pedigree shall include every change of ownership of a given dangerous drug from its initial manufacture through to its final transactions**

to a pharmacy or other person for furnishing, administering, or dispensing the drug, regardless of repackaging or assignment of another National Drug Code (NDC) Directory number” (California Business and Professions Code section 4034(c)).

- **Returns**: must also be tracked on a single pedigree. **“Any return of a dangerous drug to a wholesaler or manufacturer shall be documented on the same pedigree as the transaction that resulted in the receipt of the drug by the party returning it.”** (California Business and Professions Code section 4034(e)).

The pedigree must contain (data elements):

1. The source of the dangerous drug, including the name, federal manufacturer’s registration number or a state license number as determined by the Board, and principal address of the source.
2. The trade or generic name of the drug, the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number, the container size, and the number of containers, the expiration dates, and the lot numbers.
3. The business name, address and the federal manufacturer’s registration number or a state license number as determined by the Board, of each owner of the dangerous drug, and the dangerous drug shipping information including the name and address of each person certifying delivery or receipt of the dangerous drug.
4. A certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate.

California law also prohibits pharmacies from acting as wholesalers, and

“A pharmacy may furnish dangerous drugs only to the following:

- (1) **A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.**
- (2) **The pharmaceutical manufacturer from whom the dangerous drug was acquired.**
- (3) **A licensed wholesaler acting as a reverse distributor.**
- (4) **Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.**
- (5) **A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.**

e-Pedigree Law

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- (6) *A health care provider that is not a pharmacy, but that is authorized to purchase dangerous drugs.*
- (7) *To another pharmacy under common control.* “ (California Business and Professions Code section 4126.5)
- **Sanctions:** in addition to other possible sanctions for non-compliance with pedigree requirements up to and including civil or criminal prosecutions, the Board may cite and fine \$5,000 per occurrence (each saleable unit) or take formal discipline. Wholesalers must post a \$100,000 bond with the Board as a condition of licensure, which provides a source to pay any fines assessed.
- **Reporting to the Board:** a manufacturer, wholesaler or pharmacy with reasonable cause to believe a prescription medicine in or having been in its possession is counterfeit or subject of a fraudulent transaction shall notify the California Board of Pharmacy in writing within 72 hours of obtaining knowledge (only for drugs sold or distributed through California).
- **Implementation Delay:** the Board can delay these requirements until 1/1/2011 if it determines, consistent with its public protection mandate, that manufacturers or wholesalers require additional time to implement electronic technologies to track the distribution of dangerous drugs within the state.

Board responds to medical needs of California wildfire victims

The Board of Pharmacy rushed to support the efforts of our licensees to care for patients impacted by the Southern California wildfires in October 2007. Once an emergency was declared, the Board immediately activated its disaster response provisions under the authority granted by Business and Professions Code section 4062, allowing pharmacists to, in good faith, furnish dangerous drugs or devices in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public.



Licensees who needed to evacuate or relocate their facilities were encouraged to contact the Board for assistance in maintaining care services to the public and the health community once the imminent danger had passed. However, the Board did not receive any requests

for assistance because of the fire. The Board issued three subscriber alerts advising licensees what to do. The Board received offers of assistance from the NABP and several non-California licensed companies who submitted basic paperwork to receive temporary permits. All this is a tribute to the disaster planning that has been ongoing in California since Hurricane Katrina.

In catastrophic events or disasters, please refer to Business & Professions Code section 4062 and to the Board's disaster response policy online at <http://www.pharmacy.ca.gov/publications/>

disaster_policy.pdf. Also, those who wish to join a Disaster Medical Assistance Team may apply by contacting the California Emergency Medical Services Authority at (916) 322-4336 or e-mail www.emsa.ca.gov.

Coumadin labeling updated to explain genetic considerations

The FDA recently approved updated labeling for Coumadin® and the generic warfarin to explain that patients' genetic makeup may influence how they respond to the medication. The labeling change highlights the opportunity for health care providers to use genetic tests to improve their initial estimate of what is a reasonable warfarin dose for individual patients.

Testing may help optimize the use of warfarin and lower the risk of bleeding complications. Warfarin is the second most common drug—after insulin—implicated in emergency room visits for adverse drug events.

The FDA's "personalized medicine" initiative makes use of pharmacogenomics—the science that predicts a response to drugs based upon a person's genetic makeup.

More information is available on the FDA Web site at www.fda.gov/cder/drug/infopage/warfarin/default.htm.

Changes in the Board

New Members

Governor Arnold Schwarzenegger appointed **Stanley C. Weisser, R.Ph.**, of Redlands, to the Board of Pharmacy on November 1, 2007. Mr. Weisser graduated from the University of Connecticut School of Pharmacy in 1963 and became licensed in California that same year. He opened his first pharmacy in 1969 and retired in 2000 as CEO and president of the chain, which had grown to a 30-store group of pharmacies located in Southern California and Las Vegas, NV. One of his pharmacies dispensed prescriptions to over 1,000 patients in convalescent homes and over 8,000 inmates in correctional facilities in San Bernardino and Riverside counties.



*Stan Weisser, Member,
Board of Pharmacy*

Mr. Weisser is presently an associate clinical professor at the Loma Linda University School of Pharmacy and is a member of the California Pharmacists Association. He also serves on the Redlands Community Hospital Board of Trustees and the University of Redlands Board of Trustees.

Governor Schwarzenegger additionally appointed **Shirley Wheat**, of Irvine, to the Board as a public member. Since 2006, she has served as a small business consultant in private practice. From 2004 to 2005, Ms. Wheat served as chief financial officer for Capital Campaigns. Prior to that, she served as deputy campaign manager for Rosario Marin for U.S. Senate from 2003 to 2004 and special assistant for the Office of the U.S. Treasurer from 2001 to 2003. She also served as senior analyst at the Republican National Committee from 1999 to 2001 in Washington, D.C. Ms. Wheat worked for the Committee on Budget in the U.S. House of Representatives and held the positions of director of coalitions in 1999 and a budget analyst from 1994 to 1999.

James Burgard, of Monte Sereno, was also appointed to participate as a public member on the Board by Governor Schwarzenegger. Since 1990, Mr. Burgard has served as president of Environetics Engineering Incorporated. Previously, he was director of plant operations for Seagate Technology from 1987 to 1990. Prior to that, he was director of corporate facilities for Synertek Corporation, which was later acquired by Honeywell, from 1978 to 1980.

The Board welcomes Mr. Weisser, Ms. Wheat and Mr. Burgard. Their extensive and varied experiences will be assets to the functioning of the Board.

Departing Member



*Clarence K. Hiura,
Former Member,
Board of Pharmacy*

After completing four terms as a member over the last three decades, **Clarence K. Hiura, Pharm.D.**, is leaving the Board of Pharmacy. Dr. Hiura was first appointed to the Board by Governor Jerry Brown in 1979, serving until 1986. More recently, he was appointed to the Board by Governor Gray Davis in 2001 and served two more terms.

Of the memories that Dr. Hiura will take with him, the one of which he is most fond is that of working with the Board staff, whom he felt was so supportive. His accomplishment on the Board included working to eliminate the “credited” and “unaccredited” continuing education categories for pharmacist license renewal, bringing on new rules and regulations for the burgeoning computer technology, working to require graduation from an ACPE accredited school of pharmacy for pharmacist licensure, and most recently urging use of the NAPLEX. Dr. Hiura also worked on establishing the e-Pedigree system to fight the proliferation of counterfeit drugs. We wish him the very best and acknowledge his many contributions to the Board of Pharmacy. He will truly be missed.

50-Year Pharmacist Pin



Earlier this year, the Board of Pharmacy designed and produced pins recognizing pharmacists who have been registered for at least 50 years in California. The Board is very proud of the pins and equally proud of the pharmacists who have earned them.

Upon reaching the 50-year mark, each pharmacist is mailed a commemorative certificate and invitation to attend a future Board Meeting in his or her area. The pharmacist will then be honored at the meeting and presented with the pin. The Board strongly encourages your participation in celebrating a lifetime spent in your chosen career.

Board honors pharmacists registered for at least 50 years

In an ongoing feature of *The Script*, the Board pays tribute to those who have been registered California pharmacists on active status for at least 50 years. The Board of Pharmacy 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.

Pharmacists who recently were awarded certificates commemorating 50 years of service and invited to attend Board meetings where they could be publicly honored are:

<i>Lloyd G. Chelli</i>	<i>Fulton, CA</i>
<i>Alexander Dorevitch</i>	<i>Chicago, IL</i>
<i>David Gary Foster</i>	<i>Van Nuys, CA</i>

Irving Gerber
Gloria Euleen Germo
Calvin D. Gilliam
Michael W. Kowgios
Paul F. Maurer
Noel F. McCarthy
Gordon M. Nagata
James B. Nickell
Melvin Orchen
Herman Sabsay
Robert D. Satterthwaite
Jules Schechner
David Sliptzin
Arthur B. Walton
Phyllis W. Wells

Fair Lawn, NJ
Los Altos, CA
Sylmar, CA
Yonkers, NY
Upland, CA
San Rafael, CA
Cutler, CA
Lakewood, CA
Carlsbad, CA
Lancaster, CA
Gig Harbor, WA
San Rafael, CA
San Francisco, CA
Signal Hill, CA
Phoenix, AZ

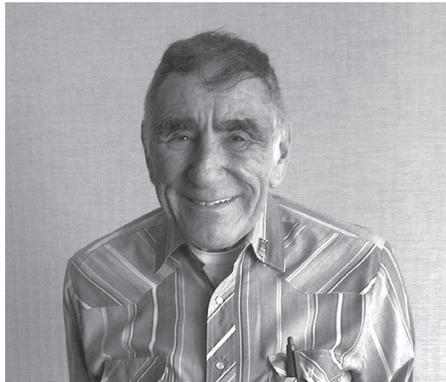
The following previously listed honorees attended the October 2007 Board meeting:



Milt Levinson

Milt Levinson was honored at the meeting by the reading of a personal letter written for the occasion by former Pharmacy Board president, Robert Elsner. Mr. Elsner wrote, in part, that Mr. Levinson epitomized the ideals of professionalism for pharmacies and pharmacists and that he considered Mr. Levinson an asset not only to the profession of pharmacy but also to the community.

Mr. Levinson noted that he enjoyed meeting and serving the families in his community, including many children and grandchildren and was the first to receive the Board's newly designed 50-year service pin.



Arthur Davis

Mr. Davis thanked the Board for its recognition of his work and added that this was the first Pharmacy Board meeting that he had had the opportunity to attend. He graduated from the University of Colorado and went on to become licensed in California in 1953. Mr. Davis has worked for Thrifty Drugs for 35 years and is a member of both CPhA and ACPhA.



John Kurilich with Robert Swart, Member Board of Pharmacy

After graduating from the University of New Mexico, Mr. Kurilich became licensed in California in 1952. He has owned an independent pharmacy and served as pharmacist in other independent and chain pharmacies.

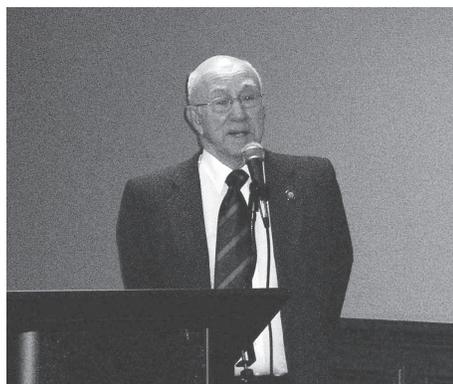
Mr. Kurilich thanked the Board for this recognition and mentioned that he was honored to attend and able to see what the Board accomplishes during its meetings.

See *Honored 50-year pharmacists*, Page 11

Honored 50-year pharmacists

Continued from Page 10

The following previously listed honorees attended the July 2007 Board meeting:



Eugene Elkin

Eugene Elkin, who graduated from pharmacy school in Canada, has been active in CPhA throughout his career and was elected past president in 1980 and “Pharmacist of the Year” by that association. Mr. Elkin operated Kustner’s Pharmacy for almost 40 years and worked the last 10 years in long-term care.



*Emil Marcarian with Stanley Goldenberg
Member, Board of Pharmacy*

Emil S. Marcarian, Pharm.D., another USC graduate, served as manager and director of hospital pharmacies, infusion companies, and in the retail environment. He described it all as a “great experience.”



*James Hoppe with Clarence Hiura,
Member, Board of Pharmacy*

James Hoppe, a USC graduate, began his practice with Malloy Prescription Pharmacy and is presently employed at Gemmel Pharmacy of Ontario, where he has been since 1957. Mr. Hoppe noted, “It’s been a wonderful 55 years!”



Ronald Marantz

Ronald Marantz, Pharm.D., graduated from USC and since then has been employed at Thrifty Drug Store, Payless Drug Store, and Rite Aid. Dr. Marantz remembered graduating from college and beginning his career when a woman came in to the store and said, “A punk like you? A doctor?” He always remembered that, and learned to have a lot of patience with the public. Dr. Marantz has been married for 50 years, has two sons, and is still saving lives!



*Joseph Hirt with Robert Swart, Member
Board of Pharmacy*

Joseph Hirt, a graduate of Arnold & Marie Schwartz College of Pharmacy, Long Island University in New York, first practiced in rural Virginia. He subsequently worked as a research pharmacist at the Harbor-UCLA Medical Center where he developed non-commercial items such as nitroglycerin IV and hyperalimentation nutritional products. Mr. Hirt commented that the thing he was most proud of during his years as a pharmacist was the positive impact of his influence on fellow employees to change their lives regarding alcohol, drug and tobacco addiction.



*Milton Bardovi with Susan Ravnan,
Member, Board of Pharmacy,*

Milton Bardovi, a USC graduate, was employed for 31 years at Sav-On Drugs and four years at Whelan Drug Co. He chose to work in chain stores where there was much less pressure than working for an independent and remarked that those 50 years as a pharmacist went by very fast. Mr. Bardovi recommended to the audience to just have integrity and do a good job.

Frequently Asked Questions

Q. Does each practitioner in a facility have to have his or her own DEA number?

A. Section 1301.22 of the Code of Federal Regulations allows an individual practitioner who is an agent or employee of a hospital or other institution to administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution which is registered, in lieu of being registered him/herself, provided the individual is authorized to do so by the facility. The hospital assigns a three-letter suffix to the facility's registration number to indicate that the practitioners listed are authorized to function under the facility's registration number.



Q. I received a letter saying that pharmacists shouldn't refill fluoride prescriptions as of December 3, 2007. Am I breaking pharmacy law if I refill such a prescription?

A. No. There is no statute or regulation prohibiting the refilling of a fluoride prescription during the following year. However, Dave Nelson, D.D.S., of the Department of Public Health Office of Oral Health related that a notice was sent to all California pharmacists, physicians and dentists advising that for one year, optimum amounts of fluoride are being added to the water supplied to Los Angeles, Orange, Riverside, Ventura, and San Diego Counties by the Metropolitan Water District of Southern California. The fluoride-treated water may also be blended with water supplies of other areas. The advisory was to alert licensees that in light of the added fluoride in the water, refill prescriptions for a fluoride supplement might result in dental or enamel fluorosis (a mottling discoloration of tooth enamel). If you are a pharmacist, particularly in one of the above named counties, and you are presented with a fluoride prescription, before filling the prescription, you might advise the patient to consult with the prescriber before continuing.

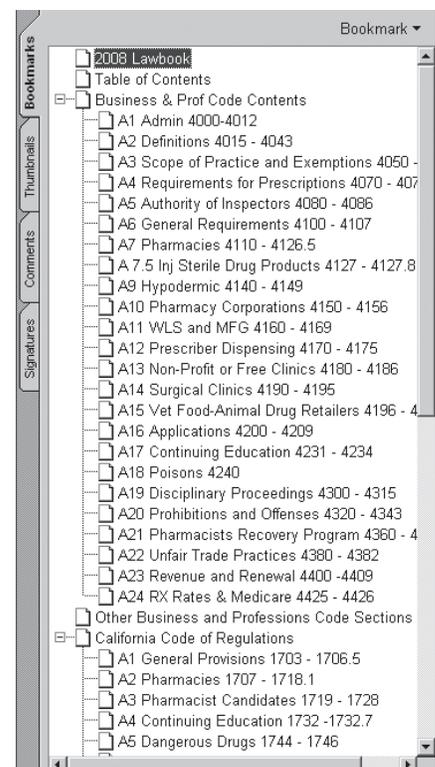
Questions About Pharmacy Law? You can find the answers!

The Board is pleased to announce that a new and improved Pharmacy Lawbook index can now be found online. This online version is more reader-friendly and contains additional entries to make your search for information easier. You will find that this index is substantially more detailed than the index published in the Pharmacy Lawbook itself.

Accessing www.pharmacy.ca.gov/laws_regs/lawbook.pdf takes you to the Pharmacy Lawbook Table of Contents. Then, to reach the new index and locate the section in which you are interested, click on the Bookmark tab/icon on the left of the screen.

Another important source for answers to law questions is the Pharmacy Self-Assessment that must be completed every two years, whenever there is a change of pharmacist-in-charge, or when a new owner takes over the pharmacy.

Also, information for ordering the 2008 Pharmacy Law with Rules & Regulations can be found on the back page of this issue.



I mailed my renewal fee — Where is my license?

Near the end of every month, the Board receives many such calls from individuals whose licenses expire on the last day of that month, and although they mailed their renewal application and fee, they have not yet received their renewed license. The following questions and answers may clarify the reasons for renewal license issuance delays and explain the need for prompt remittance of the renewal fee with a properly completed application.

Q. How far in advance does the Board send out license renewal notices?

A. Currently, license renewal notices are mailed out eight weeks before the license expiration date.

Q. Once the Board receives the renewal application and fee, how long does it take to post the payment and issue the renewal license?

A. Renewal applications that are mailed to the post office box address on the renewal application go directly to the Department of Consumer Affairs, not the Board of Pharmacy. The DCA also processes renewal payments for more than 20 other regulatory agencies (e.g., Barbering and Cosmetology Board, Board of Registered Nursing, Medical Board of California, etc.). It is presently taking DCA three weeks to cashier and post the payments. During this three-week interval, it may not be possible to ascertain whether an individual's payment has been received. Even if your bank verifies that your check has been cashiered by the DCA, your license record with DCA may not yet be updated to generate a renewal license. This is why articles in *The Script* encourage licensees to submit their renewal application as soon as they receive it.

Q. If there is an address or name change on the renewal application received by the Board, does it affect the amount of time required for issuing the renewal license?

A. Yes. Address and name changes submitted on renewal applications cause significant delays (three to four weeks) in the renewal of licenses. Section 1704 of the California Code of Regulations requires licensees to notify the Board of any change of address within 30 days. For these reasons, your address of record must be kept current with the Board.

To change your address, you may download and complete the Board's Change of Address form at www.pharmacy.ca.gov/forms/change_of_addr.pdf and fax it to the Board at (916) 574-8618.

Note: When notifying the Board of a name change, you must also enclose a copy of your Social Security card (redacting the first five digits) **and** a copy of your driver's license, both reflecting your new name. (The Board does not recommend faxing such documents, as fax lines are not secure for personal information.)

OR

You may submit a copy of your marriage certificate or other official name change document.

Q. Are there other things that might cause a delay in renewing a license?

A. **For pharmacist license:** Failure to enter the number of continuing education hours completed or a signature on the CE certification under penalty of perjury will cause delay.

For pharmacy or wholesaler license: If the corporate officer **and** the pharmacist-in-charge or designated representative-in-charge fail to sign the renewal application, or if an unknown corporate officer or an unknown PIC or DRIC signs the renewal, a change of permit must be submitted before renewal can be completed. These instances can result in the renewal application being returned to the licensee for completion and the license expiring before the renewal is completed.

Again, the Board urges its licensees to submit their payments as soon as they receive the renewal notice, and be sure all required information is entered. Any delay in submitting the payments and necessary information adds that much more time to whatever delay is encountered after reaching the Board.

www.pharmacy.ca.gov

Answers to Estate Planning Questions Related to Pharmacy

Pharmacy inheritance questions may arise occasionally, and the following is offered as an example.

Smith's Pharmacy has been family owned for 40 years and is currently owned by the surviving wife, Mary, who is 83 years old. The family wants to assure that they can maintain control of the pharmacy when Mary dies. The family does not intend to sell the pharmacy, nor do they wish to acquire partners. Two sons, John (a licensed pharmacist) and Tom, currently operate the pharmacy and will continue to maintain control.

Q. If no further estate planning is done, upon Mary's death all her shares of Smith's Pharmacy, Inc. will pass to the Smith Family Trust, with beneficiaries John and Tom. Will the Board of Pharmacy conclude that a transfer of ownership has occurred?

A. Yes. The Smith Family Trust is a new entity in the Board's records. This change needs to be reported as soon as possible when the change occurs, because the Trust is not able to operate the pharmacy as the new owner until the new owner is approved (California Code of Regulations section 1709[c]). It may be possible to obtain a temporary permit for the new owner. Again, this must be done before the pharmacy continues operation.

Q. Additional estate planning may include the gifting of fractional shares and possibly the sale of additional shares to family members. At what point, if any, will the Board of Pharmacy conclude that a transfer of

ownership has occurred? The pharmacy wants to avoid any possibility of losing the current pharmacy permit, thereby causing a disruption of billing with Medi-Cal.

A. In all likelihood, small changes in ownership may be covered as a change of permit where the ownership changes less than 10 percent. Any new owners added on would also trigger a change of permit notification (CCR section 1709[b]), until a change of 50 percent in ownership occurs, at which point a change of ownership application must be submitted.

Specifically:

California Code of Regulations section 1709(a) requires that any changes in a pharmacy's owner(s) must be reported to the Board within 30 days. Section 1709(b) states: "Any transfer, in a single transaction or in a series of transactions, of 10 percent or more of the beneficial interest in a business entity licensed by the board to a person or entity who did not hold a beneficial interest at the time the original permit was issued, shall require written notification to the board within 30 days." Section 1709(c) states: "The following shall constitute a transfer of permit and require application for a change of ownership: 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."

DEA regulation authorizes issuance of multiple prescriptions for Schedule II controlled substances

The Drug Enforcement Administration finalized a Notice of Proposed Rulemaking that, effective December 19, 2007, allows practitioners to provide individual patients with multiple prescriptions for the same Schedule II controlled substance. The prescriptions must be filled sequentially, and have the combined effect of allowing a patient to receive over time up to a 90-day supply of that controlled substance (21 Code of Federal Regulations Part 1306).

Prescribers can now issue multiple orders for the same Schedule II controlled substance on the same date, with the second, third, etc., prescription marked "Do not fill before _____," as long as the total amount of the prescriptions does not exceed a 90-day supply. For example: A physician might issue an order for OxyContin 80mg, #30, take one every 12 hours, and issue up to five more prescriptions, all dated January 1. The second prescription would be marked, "Do not fill before January 15," the third "Do not fill before February 1," the fourth "Do not fill before February 15," and the fifth "Do not fill before March 1."

However, the new rule does not limit the amount of any single prescription or for what period of time a single order may be written. A prescriber can still legally (under both federal and California law) issue an order such as: OxyContin 80mg #240, take one every 12 hours—a 120 day supply. It's only when the prescriber employs the serial Schedule II process that the supply is limited to 90 days.

Prevent tragedies caused by syringe tip caps



The death of a 5-month-old infant and near-death of a 9-month-old child resulted after liquid medication was drawn into a hypodermic syringe (without a needle) and the syringe's protective cap was ejected into the children's mouth and lodged in the trachea, blocking their air supply.

Syringes are often used to deliver oral medication, particularly to infants, young children and ailing older adults. They're easy to use and come in various sizes. But there are two types: an oral syringe that is specially designed for this purpose and the standard hypodermic syringe without the needle. It is the hypodermic syringes that have been involved in the reported accidents, and although parenteral hypodermic syringes without needles are not designed for oral administration, health care practitioners may provide them to patients or caregivers to measure oral liquids, without realizing how dangerous this practice may be.

Some syringe manufacturers place small, translucent caps as a protective cover on such syringes. However, practitioners may not realize the cap is there or may not inform patients or caregivers of the need for its removal prior to use. The danger arises due to the fact that the cap does not provide a good seal and can allow medications to be drawn into the syringe without removing the cap. If the cap is not removed before administration, the force of pushing the plunger can forcefully eject the cap and cause it to lodge in a child's throat.

The Institute for Safe Medication Practices (ISMP) recommends the following precautions for practitioners:

- Share this information with staff to illustrate why parenteral syringes should never be used for oral liquid medications.
- Ensure that **oral** syringes (without caps) or other appropriate measuring devices are readily available. Verify that the dosage can be accurately measured using the oral syringe. It may be necessary to keep different sizes on hand to ensure proper measurement of smaller doses.
- If parenteral syringes must be stocked for use with injectable products, purchase syringes that are not packaged with the translucent caps to minimize the likelihood of an accident.
- Add warning labels that state, "not for use with oral liquids" to boxes or storage bins containing parenteral syringes.
- Educate patients and caregivers regarding proper use of an oral syringe (or other measuring device).

New Notice to Consumers coming

Section 1707.2 of the California Code of Regulations was recently amended to require changes to the Notice to Consumer poster that urges consumers to talk to their pharmacist about their medication. The changes include information regarding the consumer's right to obtain lawfully prescribed medicine from pharmacies.

To accommodate the additional language, there will likely be two posters. The Board is in the process of designing and producing the two notices and will be mailing them to all pharmacies by mid-year 2008.

Notice to Consumers

Before taking any prescription medicine, talk to your pharmacist; be sure you know:

- 1** What is the name of the medicine and what does it do?
- 2** How and when do I take it – and for how long? What if I miss a dose?
- 3** What are the possible side effects and what should I do if they occur?
- 4** Will the new medicine work safely with other medicines and herbal supplements I am taking?
- 5** What foods, drinks or activities should I avoid while taking this medicine?

Ask your pharmacist if you have additional questions.

At your request, this pharmacy will provide its current retail price of any prescription without obligation. You may request price information in person or by telephone. Ask your pharmacist if a lower cost generic drug is available to fill your prescription. Prescription prices for the same drug vary from pharmacy to pharmacy. One reason for differences in price is differences in services provided.



California State Board of Pharmacy
(916) 574-7900 • www.pharmacy.ca.gov
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834



Until the new notices are distributed to all California pharmacies, pharmacies need take no action, but must continue to post the existing Notice to Consumers, or provide the notice information by printing it on the back of receipts.

The new notice language can be found in "Regulation Update Summary" on page 5 and will be included in the 2008 pharmacy law book.

Current Notice to Consumers will be replaced.

Medical Waste Transfer Station permit required for registered wholesalers who function as Reverse Distributors

A licensed wholesaler in California is permitted to act as a “reverse distributor” as part of the wholesale function. A reverse distributor is defined as a person who acts as an agent for pharmacies, drug wholesalers, manufacturers, and other entities by receiving, inventorying, and managing the disposition of outdated or nonsalable dangerous drugs. However, operating as a reverse distributor requires the storing (whether temporary or long-term) of nonsalable drugs, and this necessitates oversight by the California Department of Public Health—pursuant to the Medical Waste Management Act (Health and Safety Code sections 117600-118360). Consequently, wholesalers who wish to function as reverse distributors must be concurrently licensed by the Board of Pharmacy and must have a “medical waste transfer station” permit from the DPH.

Instructions and an application for the permit can be obtained from www.cdph.ca.gov/certlic/medicalwaste and clicking on “Medical Waste Facility Permit Application” (DHS form #8667). The permit cost is \$2,000 annually, and the applicant will be billed \$100 per hour for reviewing and processing the application.

Please direct any questions relating to transfer station permits to the DPH at (916) 449-5671 or to the Southern California Regional Office at (213) 977-7379 or (213) 977-6877. Mail all correspondence to:

California Department of Public Health
Medical Waste Management Program
P. O. Box 997377 (MS 7405)
Sacramento, CA 95899-7377

Medical Safety: Use of Medications with “Boxed Warnings”

The U.S. Food and Drug Administration is responsible for protecting the public health and carefully controls the content of prescription drug labeling. One of the ways of protecting the public health is by ordering pharmaceutical manufacturers to include boxed warnings with those medications where medical studies indicate that the medication carries a significant risk of serious or even life-threatening adverse effects. These boxed warnings are the strongest that FDA requires.

The California Department of Public Health, Center for Healthcare Quality, recently sent a letter to general acute care hospitals addressing concerns pertaining to the safe use of medication whose labeling contains boxed or

black box warnings. (The letter can be found at www.pharmacy.ca.gov/publications/boxed_warnings.pdf). Based on the requirements and interpretative guidelines of the California Code of Regulations, Title 22, Section 70263(c) (1) and 42 Code of Federal Regulations, Section 482.25, it is the Department’s expectation that appropriate safeguards for all medications are in place that acknowledge and manage each of the medication’s inherent risks with its benefits. Medications that have a boxed warning pose an additional challenge to promote safe use in light of their potential for serious adverse consequences.

If a hospital has the need to use medications in a manner that is not consistent with the manufacturer’s

specifications, including those with boxed warnings, documented evidence should be present of a deliberative, evidence-based process by your medical and pharmacy staff and appropriate hospital committees that support such use while ensuring patient safety.

To identify and improve processes for the use of all medications and especially those of high-risk, hospitals are urged to carefully review their current policies and procedures, including pre-printed orders, to ensure their adequacy.

Please direct any questions to Dr. Loriann De Martini, Chief Pharmaceutical Consultant, Center for Healthcare Quality, at (916) 552-8645.

CURES Reminder and Update

Assembly Bill 2986 (Mullin), Statutes of 2006, made changes to the electronic reporting of specific scheduled drugs to the CURES program. The Bureau of Narcotic Enforcement in the California Department of Justice has required the changes since July 1, 2007. To assist compliance by all pharmacies, here are the requirements:

- **Schedule IV** controlled substances must be reported in addition to Schedule II and III substances. This requires modifications to pharmacy software to incorporate Schedule IV with the Schedules II and III information already being collected.
- Pharmacies must submit this data to CURES on a **weekly** instead of monthly basis.
- Pharmacies must update their data reporting system from ASAP (American Society for Automation in Pharmacy) 1997 to **ASAP 2005**.
- Information about refills is required. A **Refill** code is now required. Pharmacies must now report the number of refills requested and whether a dispensed drug is a first time fill or a refill. (Schedule II drugs cannot be refilled.)

- The **number of refills authorized** is now required.
- Both the pharmacy **DEA number** AND the **pharmacy license number** are required.
- The **phone number of the ultimate user (patient) or researcher subject** is required. If the patient's phone number is not available, use the pharmacy's telephone area code followed by seven zeroes or seven ones.

Compounded Medications—The ASAP 2005 data specifications allow for reporting individual scheduled ingredients contained in a compounded drug. Instructions supplied by Atlantic Associates, Inc. (AAI), indicate that pharmacists should enter eleven 9s for the NDC number in the DSP segment. Please see the ASAP 2005 specifications for more information.

Direct all data transmission questions to AAI at (800) 539-3370 or fax to (877) 508-6704. All other reporting concerns should be addressed to BNE at (916) 319-9062.

Thanks to Those Who Helped

The California State Board of Pharmacy thanks its licensees and members of the pharmaceutical supply chain who provided assistance to Southern California during October's wildfire emergencies. As always, the profession continued its tradition of helping the community in time of crisis.

One of at least three pharmacies that were evacuated during the San Diego County fires was the Rancho Santa Fe Health Mart Pharmacy. Until they were ordered to evacuate, Bob Graul, R.Ph., owner, Jason Kim, Pharm.D., PIC and business partner, and Tiffany Clarke, Pharm.D., were able to serve evacuees who needed their medications. Although the pharmacy's electrical system had been shut down, their phone system was still operational, and they were able to retrieve voice mail messages from evacuees who had left their medications behind or were running out. After the pharmacy computers were restarted the



next day, they were able to transfer prescriptions via remote access from home. With the help of other independent and chain pharmacies (Longs Drug Stores, CVS Pharmacies, Walgreens, and Ralphs), they were successful in obtaining emergency meds for the evacuees. Dieter Steinmetz, R.Ph., owner of Coast Compounding Pharmacy in Oceanside, immediately contacted the pharmacy and offered to accommodate the needs of the pharmacy's patients.

Dr. Kim and Dr. Clarke also volunteered at the Del Mar evacuation center under the auspices of RxERT (San Diego County Pharmacy Emergency Response Team). They worked with volunteer physicians and nurses to take histories, make rounds, advise on appropriate therapy and dispense meds that had been donated by local pharmacies and hospitals, and brought in by CALMAT (California Medical Assistance Team). The RxERT and John Johnson, Pharm.D., worked at three evacuation sites: Qualcomm Stadium, Del Mar Fairgrounds, and San Diego High School.

Thanks also to CPhA for providing information and updates to its membership, and our gratitude to the following for their medical assistance:

Third drug category being explored

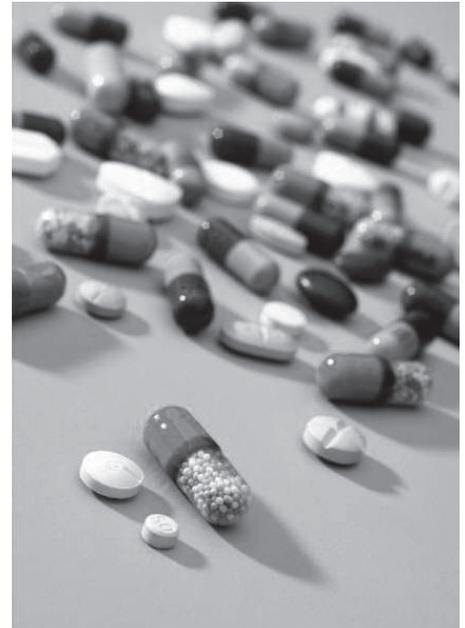
Presently, there are two categories of drugs: drugs requiring prescriptions from a prescriber and over-the-counter (OTC) medication. The Food and Drug Administration is exploring the possibility of a third category which the FDA calls "behind the counter" (BTC) drugs. These drugs would be available without a prescription only after intervention by a pharmacist. The availability of BTC medications would increase patient access to medications they previously may not have been able to use, particularly because they had no health insurance.

Variations of a BTC status are already in effect in other countries. In general, foreign countries have used the following criteria for switching a drug from prescription class to BTC class: (1) Indications suitable for self-medication, including self-diagnosis,

with the intervention of a pharmacist, and (2) the medicine has a low potential for side effects or overdose, and intervention by a pharmacist could minimize these risks. Other considerations include: Abuse potential, patient choice and accessibility, and public health issues. These BTC drugs would typically require the pharmacist to ensure the patient meets certain criteria prior to dispensing, as well as to provide education on proper use and monitoring.

The FDA has gathered comments from interested parties and held a public meeting in Washington, DC, to discuss the issue on November 14, 2007.

To date, no decision has been announced.



Thanks

Continued from Page 17

San Diego Medical Reserve Corps
UC San Diego Medical Center
Sharp Hospital
Scripps Hospital
San Diego Veterans Hospital

Our thanks to McKesson Corporation, who provided non-prescription meds and supplies to the San Diego Health Mart Pharmacies and also offered financial aid to help impacted pharmacies recover.

CVS/pharmacy, the retail division of CVS Caremark Corporation, donated more than \$350,000 in supplies to assist California fire relief efforts during the week of October 22nd. A truckload of healthcare and personal care items was delivered to Qualcomm Stadium in San Diego for evacuees sheltered there. Additionally, CVS Caremark donated \$25,000 to the American Red Cross California Wildfire Relief Fund to provide emergency shelter, food, clothing and medical supplies to victims of the fires.

During the evacuations, CVS/pharmacy established an emergency prescription delivery service to Qualcomm Stadium and delivered a 7-day supply of prescription medication to approximately 300 evacuees identified by on-site medical personnel. Shelters in the Temecula and Del Mar areas received

much needed emergency inhaler medicines and maintenance medications for those who were there. Shelters in Silverado received an emergency shipment of critical OTC items to assist over 1,000 people there. Several CVS/pharmacy staff members volunteered their time to provide assistance at the shelters during this critical time of need.

CVS/pharmacy provided more than 9,200 ExtraCare Relief Kits, which contain almost two dozen personal care items, to the Red Cross for distribution to shelters that were established in the areas affected by the fires. To assist the firefighting efforts, CVS/pharmacy donated several pallets of water to firefighter command posts, along with healthy snacks, masks, eye drops saline spray and lip balm.

Thanks also to Walgreens District 193 pharmacy supervisor, Tina Tarsitano, R.Ph., and store manager Daniel Arvizu of Saugus Walgreens #7556, who delivered many cases of bottled water and dried fruits to firefighters in the Santa Clarita area.

Rite Aid in Fallbrook kept their doors open, providing medication and other merchandise and answered an unusual request for help by housing and feeding evacuated llamas and goats in the pharmacy's enclosed outside areas.

See Thanks, Page 19

Innovative Programs for Serving the Underserved

The NABP 2007 District 7 & 8 Meeting was held in Ashland, OR, in October. The meeting's theme was "Access to Healthcare," and during the meeting, seminar speakers described groundbreaking programs involving the use of student/interns to address the overall public health issues created by the level of education, language barriers and often the total lack of health education, of the severely underserved and rural communities. Health education in these areas requires reevaluation and rethinking of approaches for significant change, and the following outlines the result of such reevaluation and rethinking.

Pharmacy schools in several states have come together to determine what would be a more appropriate and uniform preceptor/intern learning experience while focusing on today's health problems of obesity and diabetes. They subsequently found not only a more comprehensive way of preparing students to deal with leading health problems, but also another resource for areas where there are not enough pharmacists—student/interns.

For example, Colorado and Arizona have established Hispanic and Indian health programs that include a diabetes clinic, into which student/interns focusing on diabetes problems are brought to augment the understaffed clinics.

The University of Oregon School of Pharmacy faced the same challenges of trying to provide more health care to underserved populations who also faced obesity and diabetes problems and had not even the most basic understanding of good health. The school's outreach program sends first-year pharmacy students into local primary grade schools to present the basic aspects of good health habits in terms that match the children's level of comprehension. The student/interns return to the classrooms several times throughout the year to build the children's trust and establish ongoing relationships. Second year pharmacy students visit middle schools, and third year students visit high school classrooms. Fourth-year students go out into underserved areas to talk to everyone about basic good health, literally reminding them that they really are what they eat.



Kathleen Johnson, Pharm.D., MPH, Ph.D., of the University of Southern California School of Pharmacy, presented a program entitled, "Opportunities for Colleges of Pharmacy to Address Health Disparities," the goal of which

is to develop and implement a student volunteer program to assist in delivery of patient consultation and clinical pharmacy services in Latino communities and safety-net clinics. The subsequent execution of these goals has shown positive results in hypertension and diabetes outcomes. Another program has students working out of the Children's Hospital of Orange County Asthma Van that monthly visits 23 elementary schools with primarily Spanish and Vietnamese speaking populations. A network of both independent and chain pharmacies follow up with the patients.

Nancy Vorhees, Inland Northwest Health Services, presented "Reaching Out Through Distance Technologies," detailing how only two pharmacists at a remote location can, through computer scanning and transmitting, review prescriptions for consultation, adverse actions, etc., for a hospital that serves 2,000 inpatients. By implementing such a program, they are able to provide pharmacist service where it is not economically or geographically feasible to have a pharmacist on site. That is really "telemedicine" in action!

Meetings with such innovative ideas provoke us all to look for ways to further improve our pharmacy students' healthcare education and the health outcome of ALL California consumers.

Thanks

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Thanks not only to those mentioned but also to all the pharmacists, interns (particularly the students from UC San Diego and other schools as well), and pharmacy technicians who volunteered to help their community. The public was very well served by your efforts. Thank you.

The Board is interested in receiving information about and recognizing those who assisted in this effort. If you know of others who provided assistance in this regard, please e-mail these reports to Hope_Tamraz@dca.ca.gov.

We are also interested in learning if additional statutory law or regulations need amendment to permit better/stronger/faster response to the public during emergencies. Please provide any such proposals also to Hope Tamraz.

Don't forget your DEA inventory and recordkeeping procedures

The Drug Enforcement Administration requires every pharmacy to inventory all controlled substances upon opening of the business and every two years following the date of the initial inventory. The DEA also requires specific recordkeeping forms and procedures. For the exact language and specific requirements of the inventory, please refer to the Title 21, Code of Federal Regulations, section 1304.11.

The inventory must be written, typewritten or printed and maintained at the licensed location. If the pharmacy wishes to take the biennial inventory on a more convenient date, the inventory may be taken any time within two years of the previous biennial inventory date, with subsequent inventory to be done two years from the new date.

The importance of accuracy and completeness of this inventory and other recordkeeping procedures cannot be stressed enough. In addition to citations and fines that could be issued by the Board of Pharmacy, the DEA can impose substantial fines for each violation of the recordkeeping requirements. For example, the DEA maximum fine assessed for an incomplete or missing Form 222, invoice, or prescription is \$10,000 *per incident*.

In July 2007, the DEA announced that Broadway Pharmacy in Sacramento agreed to pay \$325,000 in a civil settlement

(without admission of liability, wrongdoing, or guilt on the part of the pharmacy or its owners) related to an accountability audit that revealed among other things, more than 2,800 recordkeeping deficiencies. Some of the deficiencies included:

- Failure to indicate what time of day inventory was taken—at beginning or end of business day;
- Failure to accurately complete DEA 222 Order Forms;
- Failure to account for returned medications as they were put back into inventory.

Another pharmacy, the North Highlands Pharmacy in North Highlands, agreed in a civil settlement to pay a fine of \$150,000 to the United States government for alleged violations of the Controlled Substances Act.

Between September 2002 and July 2005, the pharmacy purchased nearly two million tablets of Aprodine and failed to maintain proper records and report suspicious transactions concerning the sales of the drug. Aprodine, a List 1 drug whose active ingredient is pseudoephedrine, is a vital precursor chemical used in the illegal production of methamphetamine.

The DEA is dedicated to holding pharmacies, and the individuals who operate them, accountable for the regulated products they dispense.

In Memoriam: William (Bill) Marcus, J.D.

On December 4, 2007, the Board of Pharmacy lost a longtime friend and advocate, William Marcus. From 1976 through 2001, he was a deputy attorney general in the Licensing Section of the California Department of Justice where he represented professional and licensing boards and bureaus in the Department of Consumer Affairs. From 1982-2001, he was the Liaison Counsel from the Attorney General's Office to the Board of Pharmacy. His interest and passion for pharmacy law and dedication to the Board continued right up to November 20, when at 1:20 AM, he e-mailed the Board his summary of the DEA's regulation allowing serial Schedule II prescriptions.

Dr. Marcus was very instrumental in a multitude of ways during his years working with the Board—he was a great drafter of legislation and regulation proposals, was vigorous as an anti-drug diverter and pain management advocate. His advice and assistance to the Board had a profound effect on pharmacy law and consequently on pharmacy practice in California. In addition to his association with the Board, Dr. Marcus taught pharmacy law at the Skaggs School of Pharmacy and Pharmaceutical Sciences and at the University of California, San Francisco, School of Pharmacy.

Bill will be missed by those of us who had the opportunity to know and work with him.



CE hours are awarded for attending one full day of a Pharmacy Board or Committee meeting or for becoming a Certified Geriatric Pharmacist

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 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 meetings are held four times per year: 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 pharmacy activities for the improvement of consumer protection.
- Licensing Committee—Ensures 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, 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 eligible for CE; this is designated on the agenda. Attendees at the committee meetings must arrive at the designated meeting time. 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 will be 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 for 2008 are:

January 23 – 24

**Town & Country Hotel
500 Hotel Circle North
San Diego, CA 92108
(619) 291-7131**

April 23 - 24

July 23 - 24

October 29 - 30

Sacramento

Orange County

San Francisco

The committee meeting dates for 2008 are not yet available, but will be on the Board's Web site when the sites and dates are determined.

Explanation of Disciplinary Terms

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

Revocation or Revoked—The license is revoked, and the licensee's right to practice or operate a Board-licensed entity is ended.

Revoked, Stayed—The license is revoked, the revocation is put on hold, and the license is subject to probationary conditions, which may include suspension of the licensee's right to practice.

Stayed—The revocation of suspension 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.

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 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 licensee.

Reinstatement of License—A previously revoked license is reinstated with specified terms and conditions.

Disciplinary Actions

From June 1, 2007, through November 1, 2007, the following licenses were disciplined through action taken by the Board:

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.

Arias, Sallyann Marie, TCH 39619, Modesto, CA – Case 3032

Decision effective 10/05/07

Blackwell, Ronald Andre, TCH 50387, San Francisco, CA – Case 3051

Decision effective 06/20/07

Castro, Yolanda S., TCH 30657, San Bernardino, CA – Case 2958

Decision effective 10/05/07

Dominguez, Adolfo, TCH 30828, Lancaster, CA – Case 2909

Decision effective 06/20/07

Evans, Tanisha Julie, TCH 54003, Compton, CA – Case 3016

Decision effective 08/08/07

Gomez, Rodolfo, TCH 52062, National City, CA – Case 3037

Decision effective 06/20/07

Jackson, Duwana Janise, TCH 54470, Los Angeles, CA – Case 3083

Decision effective 10/05/07

Johnson, Roxana M., TCH 30754, Citrus Heights, CA – Case 2990

Decision effective 06/14/07

Kono, Charlene Ann, RPH 37551, Sacramento, CA – Case 2966

Decision effective 06/20/07

Leon, Monica Iris, TCH 58541, La Puente, CA – Case 3013

Decision effective 08/08/07

Ofstedahl, David J., RPH 26029, Rancho Mirage, CA – Case 2960

Decision effective 07/11/07

Rodick, Erin Kathleen, RPH 46916, La Crescenta, CA – Case 2873

Decision effective 08/22/07

Revoked Pharmacy Licenses

The following pharmacy is no longer licensed and may not operate.

Fireside Pharmacy, PHY 33827, Palm Desert, CA – Case 2960

Decision effective 07/11/07

Pharmacist Licenses Revoked, Stayed, Three Years' Probation

The following licenses were revoked, revocations placed on hold, and the licenses placed on probation. If the terms or conditions of probation are not followed, the original revocations can be reinstated.

Cheung, Hoi Chi, RPH 35355, Diamond Bar, CA – Cases 2578 & 3106

Decision effective 06/06/07

Defay, Ralph Michael, RPH 31725, Poway, CA – Case 2944

Decision effective 08/08/07

Disciplinary Actions

Continued from Page 22

Flores, Michael, RPH 27129,
Visalia, CA – Case 3131

Decision effective 09/11/07

McConnell, Dewane, RPH 35655,
Oroville, CA – Cases 2237 & 3104

Decision effective 06/06/07

Pharmacy License Revoked, Stayed, Three Years' Probation

The following license was revoked, revocation placed on hold, and the license placed on probation. If the terms or conditions of probation are not followed, the original revocations can be reinstated

Community Medical Pharmacy,
PHY 44260, San Diego, CA – Case 2944
Decision effective 08/08/07

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

The following licenses were revoked, revocations placed on hold, and the licenses placed on probation. If the terms or conditions of probation are not followed, the original revocations can be reinstated.

Baker, Gerald Charles, RPH 30905,
Carmichael, CA – Case 3005

Terms of probation include suspension
from practicing pharmacy for 90 days.

Decision effective 06/14/07

Dadkho, Fariba, RPH 50036,
Venice, CA – Case 2997

Decision effective 10/05/07

Ducotey, Janice Renee, RPH 53575,
Chico, CA – Case 2946

Terms of probation include suspension
from practicing pharmacy for 30 days.

Decision effective 06/20/07

Guy, Mary Jane, TCH 44416,
Oceanside, CA – Case 3058

Probation includes suspension of
practicing as a pharmacy technician until
certified by the Pharmacy Technician
Certification Board.

Decision effective 10/24/07

Haslam, Ronald, RPH 43678,
La Mesa, CA – Case 2797

Terms of probation include suspension
from practicing pharmacy for 30 days.

Decision effective 08/31/07

Scaggs, Donald, RPH 26162,
Three Rivers, CA – Case 3061

Terms of probation include suspension
from practicing pharmacy for 60 days.

Decision effective 08/08/07

Toombs, Donald Franck, RPH 48396,
Hermosa Beach, CA – Case 2988

Decision effective 10/05/07

Vu, Chu Huu, RPH 39728,
Oroville, CA – Cases 2236 & 3105

Terms of probation include taking
and passing the California Pharmacy
Jurisprudence Examination

Decision effective 06/06/07

Warnecke, Gary, RPH 38265,
Yorba Linda, CA – Case 2851

Terms of probation include suspension
from practicing pharmacy for 90 days.

Decision effective 07/11/07

Voluntarily Surrendered Personal Licenses

*The licenses of the following individuals
were surrendered.*

Agent, Selwyn, RPH 33256,
Madison, MS – Case 2934

Decision effective 10/05/07

Olivares, Luis Eduardo, TCH 53234,
Manteca, CA – Case 3090

Decision effective 11/08/07

Parker, Jr., Jack Welby, RPH 24562,
Napa, CA – Case 3071

Decision effective 10/05/07

Zorola, Joanne G., TCH 34227,
San Marcos, CA – Case 2965

Decision effective 06/20/07

Voluntarily Surrendered Site Licenses

*The licenses of the following
businesses were surrendered.*

United Pharmacy, PHY 45289,
Berkeley, CA – Case 3064

Decision effective 07/11/07

Compromise of NAPLEX Resolved

On August 6, 2007, the NABP (National Association of Boards of Pharmacy) issued a notice to all state pharmacy boards and deans of schools and colleges of pharmacy, stating that U.S. Marshals had seized materials and computers from the University of Georgia College of Pharmacy after allegations of breaches of the NAPLEX (North American Pharmacy Licensure Examination). Consequently, NABP ceased administration of this exam nationally and the Georgia MPJE (Multistate Pharmacy Jurisprudence Examination) on August 25.

After fully investigating the matter and taking the necessary actions to secure its examination from future compromise, the NABP resumed national administration of the NAPLEX on October 5, 2007, a month sooner than projected.

Swift resolution of this issue was critical because California, and other states as well, must have complete trust in the licensing examinations. These examinations are the key process the Board uses to determine the minimal competency of applicants for pharmacist licenses. Cheating on such examinations is not just an issue of obtaining a passing score; it is a public safety issue if less than competent individuals are licensed as pharmacists.

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For 2008, 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 9 years, is making them available at a very affordable price.

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