

CALIFORNIA BOARD OF PHARMACY SEPTEMBER 2010

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Board honors 2010 Remington Honor Medalist, Mary Anne Koda-Kimble, Pharm.D.



Mary Anne Koda-Kimble, Kenneth Schell, and Stanley Weisser, President, Board of Pharmacy

On March 13 of this year, Dr. Mary Anne Koda-Kimble was awarded the pharmacy profession's highest honor, the 2010 Remington Honor Medal, at the annual meeting of the American Pharmacists Association in Washington, DC. The award, named for eminent community pharmacist, manufacturer, and educator Joseph P. Remington, recognizes distinguished service and/or outstanding achievement on behalf of American pharmacy.

The 2006 Remington Medalist, Robert D. Gibson, nominated Koda-Kimble for the award for, "... not only the sheer quality and quantity of her accomplishments, but also her leadership, her steadfast dedication, and her sustained commitment to education, the public good, and the advancement of the profession that make her a more-thandeserving nominee." Another nomination discipline in which pharmacists directly care for patients in all settings to ensure optimal and safe use of medications.

Realizing that student pharmacists and practitioners needed a textbook uniquely designed for their emerging clinical roles, Dr. Koda-Kimble and colleague Lloyd Young, Pharm.D., led the 1975 publication of Applied Therapeutics for Clinical Pharmacists, the first textbook of its kind. The book, recognized as the standard at pharmacy schools here and abroad, has had eight additional editions and a change of title, Applied Therapeutics: The Clinical Use of *Drugs*. In between accepting incalculable awards and delivering more than 200 lectures, Koda-Kimble has published 36 articles, 16 books and contributed 31 book chapters. Few names in clinical pharmacy worldwide are as recognizable as hers.

At the July 2010 meeting, the Board of Pharmacy recognized Koda-Kimble's many, many accomplishments, and honored her as one of our own. In 1976, she was appointed to the Board, where she served almost eight years as a professional member and functioned as president for two years. Further, she served as chair of the Board's Competency Committee, participating in the development of pharmacy board examination questions for approximately 18 years.

Dr. Koda-Kimble's leadership, recognized locally, nationally, and beyond for advancing the profession as an integral part of the healthcare process, has been unparalleled. The Board hereby expresses its appreciation and gratitude for her tireless efforts that produced a positive and lasting impact worldwide in the education and training of pharmacists.

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President's Message By Stanley C. Weisser, R.Ph. President, Board of Pharmacy

In June 2010, I became the Board's President, succeeding the two-year term of prior president, Ken Schell. This is my first President's Message, and since the Board's paramount statutory mandate is consumer protection, I am pleased to report that we have a number of activities underway to expand the Board's consumer protection efforts. During the past year, the Board has partnered with other healing arts boards and the Department of Consumer Affairs to examine the current enforcement process and make improvements to reduce the investigation and resolution times of formal discipline (where the Board seeks to restrict or remove a license). These discussions produced the

Consumer Protection Enforcement Initiative (CPEI), which resulted in a three-pronged solution to improve enforcement efforts: (1) A new computer system, (2) Additional enforcement staff, and (3) Statutory and regulatory changes.

Over the coming months, the Board will proceed with changes to strengthen its enforcement. One new change is a regulation (detailed in this newsletter on Page 3) that requires certain pharmacists to submit new fingerprints if they do not have <u>electronic</u> fingerprints on file with the California Department of Justice. All pharmacists will also need to certify at time of renewal that they have not been convicted of a crime. In the future, similar requirements will be pursued for pharmacy technicians and designated representatives.

Additionally, the Board has worked for the past two and one half years on requirements for a "patientcentered" prescription container label (see Page 4). These requirements should go into effect on January 1, 2011, and represent a major effort to highlight the information most important to patients (patient name, drug name and directions for use and purpose, if entered on the prescription) on their drug container's label. This is an important change to improve patient access to information on container labels. The requirements also specify that the services of an oral interpreter need to be provided for those with limited English skills.

The Board has also produced a three-minute video for consumers on how to help prevent receiving the wrong medication. See this video at *www.pharmacy.ca.gov.*

I wish to remind all licensees that California law requires all Board-licensed facilities to become subscribers to the Board's e-mail notification system. Individuals who are licensed by the Board can also join, as can any interested party. By joining the subscriber alert, you will receive notices of new online newsletters—newsletters are no longer mailed—drug recalls, public meetings of the Board, and new laws and regulations. There is no charge to become a subscriber (see Page 7).

As president, I am looking forward to the coming year, recognizing the many challenges and opportunities we will have to address, such issues as the Health Care Reform Act, e-prescribing, e-prescribing of controlled substances, increasing reports of prescription drug abuse, drug take-back programs, all in a deficit economy.

Further, I encourage you to come to a Board or Committee Meeting and participate in the Board's deliberations on these and other issues. Information about the meetings is available online at *www.pharmacy.ca.gov/about/ meetings.shtml*. Agendas are posted at least 10 days before a meeting and meeting materials are posted about four days before a meeting.

Friday Furloughs Reinstated with Changes

Pursuant to Governor Schwarzenegger's Executive Order S-12-09, which was issued due to continuing budget restraints, employees of the Department of Consumer Affairs and other State government offices will now be closed on the second, third and fourth Friday of every month until the 2010/11 budget is in place.

Please be assured that Board employees will continue to be as responsive as possible to the needs of the public and the pharmacy profession.

New Refingerprinting Requirements for Some Pharmacist License Renewals

Two important changes related to pharmacist license renewals begin in December 2010. These changes are required by new regulation, section 1702, of the California Code of Regulations.

First: Pharmacists must disclose on the license renewal form whether they have been convicted of any violation of law in this or another state, omitting traffic infractions under \$300 that do not involve alcohol, dangerous drugs, or controlled substances.

Second: Designated pharmacists who were licensed before 2001 will be notified that they need to resubmit fingerprints to the Board <u>before</u> their license renewal date. This change is required to ensure that the Board receives timely notice of arrests and convictions.

There are 38,000 California-licensed pharmacists, of which more than 15,000 must be refingerprinted because their prints are not stored in the California Department of Justice (DOJ)'s electronic system. Of these pharmacists, those who reside in California must submit fingerprints via Live Scan. Those whose address of record is outside California must resubmit to the Board their fingerprints on cards that will be electronically entered into the DOJ's system. Detailed directions will be mailed to the affected pharmacists six weeks before expiration of their licenses.

Failure to comply with all the above requirements will result in the renewal application being considered incomplete, and prevent renewal of the license until the Board has confirmation of compliance.

In the future, pharmacy technicians and designated representatives also will be required to comply with the same requirements. However, the Board will phase in these requirements in the next two to three years.

Background for the New Requirements

The Board of Pharmacy is mandated by Business and Professions Code section 4001.1 to protect the public from incompetent, unethical and unprofessional practitioners. To do this, it is necessary for the Board to be informed of past and current criminal convictions that are substantially related to the qualifications, functions or duties of the profession for which they are licensed. This information is acquired in part by submitting the licensee's fingerprints to both the DOJ and the Federal Bureau of Investigation (FBI) for criminal background checks. Arrest(s) and conviction(s) of licensees are then reported electronically to the Board for investigation and action.

Electronic fingerprinting for the Board's applicants went into effect around January 1, 2001, with the use of "Live Scan," a system used in California for submitting fingerprints electronically to the DOJ. Before that date, applicants submitted inked fingerprints on cards that were not entered into the DOJ electronic database. As a result, the Board does not receive timely notices of arrest and convictions of these licensees.

Additionally, prior to January 1, 2001, background checks for applicants were done by the DOJ, and applicants were not routinely required to submit fingerprints for a background check by the FBI. Since FBI checks are now required, Live Scan electronic fingerprints are transmitted to both the DOJ and the FBI. The complete text of section 1702 can be viewed at *www.pharmacy.ca.gov/ laws_regs/1702_adopted.pdf*.

Improved prescription drug container labels coming in January

By January 2011, pharmacies and others dispensing medication to patients in California will be required to modify their prescription container labels to conform to regulations adopted by the California State Board of Pharmacy to produce a "patient-centered" label. The Board strongly encourages pharmacies to begin development of the regulation-conforming labels now, so that patients will receive the benefits of these new labels as soon as possible.

Note: The regulation is still being reviewed by the required Administration agencies and is not yet final. However, California Business and Professions Code section 4076.5 mandates the requirements to be in effect on or before January 2011. The Board will release periodic updates through its subscriber alert system (see Page 7) about the status of the regulation, and the implementation date.

A patient-centered label identifies, standardizes, clusters and makes most prominent on prescription drug container labels, information of greatest importance to patients (specifically and in this order: patient name, name of the drug and strength, directions for use, and purpose, if entered onto the prescription document by the prescriber). Fifty percent of the label must be dedicated solely to these elements, and they must be printed in at least 10 point sans serif font, and if requested by the patient, in 12-point sans serif font. All other information required to be on the label is to be placed in the remaining portion of the label. The ultimate goal is to make the labels easier for patients to read, easier for patients to locate key information, and to improve patient understanding of how to take their medicines.

Although not part of the label, the Board of Pharmacy has also adopted requirements that interpretive services in patient languages be available through pharmacies so that patients can learn how to take their medicines properly via an interpreter. The interpreter may be available on the phone or in-person.

The specific requirements for these labels are provided in section 1707.5 of the California Code of Regulations, the text of which is located on Page 6.

The changes are the result of a two-year effort by the California State Board of Pharmacy to establish state standards for a patient-centered prescription label called for under Senate Bill 472 (Corbett, Chapter 470, Statues of 2007), also known as the California Patient Medication Safety Act. A patient-centered label is designed to help reduce medication errors, which harm more than 1.5 million U.S. residents a year, according to the Institute of Medicine, who also reports that just under half of American adults cannot understand the label on their prescription medication.

The redesigned labels will emphasize consumer information first, and minimize all other required information, making the key consumer items about use of the medication easier to read. Highlighting in color, using bolder or larger type, enclosing in white box, and clustering of patient information in specific order are ways to make the key information easier to locate, no matter what pharmacy dispenses the medicine. See samples below.

Why emphasize certain items?

The goal is improved patient health. Patients can quickly distinguish their medicine from other family members if the name is prominently displayed. The name of the medicine and strength aids patients in remembering and identifying what medicine they are taking. The directions for use remind patients about how to take the medicine, and the purpose of the prescribed medicine helps patients to know what the medicine is for and helps them to prevent errors.

The Board of Pharmacy spent over two years studying ways to improve the labels, including conducting consumer surveys from patients about what does and does not work on prescription labels. They reviewed research results in the area of label design, and heard from experts and others about how labels can be improved for "readability." California is the first state to develop such standards for improved labels for patients, and because California dispenses about 10 percent of all prescription drugs in the U.S. each year, these requirements will likely be used in other states as well.

1625 N. Market Blvd. Sacramento, CA 95834 (555) 555-9810 Rx [#] 06197 1234567	DATE FILLED: 10/31/20 ORIG RX DATE: 02/24/2009 RPH: KPT Store DEA# B	1 09 15841867
JOHNSON, JUDY	5873 EVERGREEN AVE DAVIS, CA 95615 (555) 555-7889	ΟE
VERAPAMIL ER 240 MG TABLET		COD
Take 1 tablet in the morning, and take 1 tablet in the evening Treats high blood pressure		BAR
Prescriber: Roger Brown MD Quantity: 60 Expires: 05/30/2011 Oblong ivory tablet 73 00 logo Generic for: ISOPTIN SR Refills remaining: 02/23/2010 ^{CAUTON: Federal law PROHIBITS the transfer of this drug to} any person other than the patient for whom it was prescribed.		

Patient information in 10 point typeface, Tahoma

See more sample labels and Title 16, California Code of Regulations on the following two pages.

See Improved Labels, Page 5

Improved labels

Continued from Page 4



Patient information in 12 point typeface, Myriad



AMOXICILLIN 125/5ML Sandoz

Take 1/2 teaspoon in the morning, 1/2 teaspoon at noon, and 1/2 teaspoon in the evening for 10 days to treat infection

Prescriber: Roger Brown MD Pink liquid Quantity: 80 Refills: 0 Dispensed: 03/08/07 NDC: 00789-1234-55 CAUTIONS IMPORTANT: Finish All Of This Medicine Unless Otherwise Directed By Your Doctor. Refridgerate, Shake Well Before Each Use. Discared The Unused Portion Of This Medicine After (555) 555-9810 §1234567-06197 VICTOR'S PHARMACY 1625 N. Market Blvd. Sacramento, CA 95834

Patient information in 12 point typeface, Tahoma



Patient information in 10 point typeface, Franklin Gothic Book



Patient information in both 10 & 12 point typeface, Tahoma



Patient information in 12 point typeface, Franklin Gothic Book

Title 16, California Code of Regulations

Section 1707.5. Patient-Centered Labels on Medication Containers

(a) Labels on drug containers dispensed to patients in California shall conform to the following format to ensure patient-centeredness.

- Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 10-point sans serif typeface or, if requested by the consumer, at least a 12-point typeface, and listed in the following order:
 - (A) Name of the patient
 - (B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name, or the generic name and the name of the manufacturer.
 - (C) Directions for use.
 - (D) Purpose or condition. If entered onto the prescription by the prescriber.
- (2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).
- (3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) or subdivision (a). These additional elements may appear in any style, font, and size typeface.
- (4) When applicable, directions for use shall use one of the following phrases:
 - (A) Take 1 [insert appropriate dosage form] at bedtime
 - (B) Take 2 [insert appropriate dosage form] at bedtime
 - (C) Take 3 [insert appropriate dosage form] at bedtime
 - (D) Take 1 [insert appropriate dosage form] in the morning
 - (E) Take 2 [insert appropriate dosage form] in the morning
 - (F) Take 3 [insert appropriate dosage form] in the morning
 - (G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime
 - (H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime
 - (I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime
 - (J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and 1 [insert appropriate dosage form] in the evening

- (K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening
- (L) Take 3 [insert appropriate dosage form] in the morning, 3 insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening
- (M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime
- (N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime
- (O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime
- (P) If you have pain, take __ [insert appropriate dosage form] at a time. Wait at least __ hours before taking again. Do not take more than __ [appropriate dosage form] in one day

(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies. (c) Beginning in October 2011the board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance. (d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services in the patient's language. If interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with

Business and Professions Code section 4076.5.

(f) As used in this section, "appropriate dosage form" includes pill, caplet, capsule or tablet.

Authority cited: Sections 4005 and 4076.5, Business and Professions Code. Reference: Sections 4005, 4076, and 4076.5, Business and Professions Code.

Reminder to All Board-Licensed Facilities to Join the Board's E-Mail Notification List–It's Mandatory

If your facility is not yet on the Board's e-mail notification list, this is a reminder that beginning July 1, 2010, Business and Professions Code section 4013 requires all Board-licensed <u>facilities</u> to join the Board's e-mail notification list. New facilities must join within 60 days of obtaining a license or at the time of license renewal. Facilities are also required to update their e-mail address with the Board within 30 days of any e-mail address change.

Additionally, the Board strongly encourages <u>individual</u> <u>licensees</u> to join the list, since it is now the primary means for disseminating important information from the Board. To join the list:

- Go to the Board's Web site, *www.pharmacy.ca.gov*;
- Click on "sign up to receive e-mail alerts" on the left side of the page;
- Click on the "Board of Pharmacy E-mail Notification List" box;
- Scroll down the page and select "Subscribe;"
- Enter your e-mail address and we'll do the rest!

Note: If you or your facility joined the e-mail notification list prior to November 17, 2009, you will need to join again, due to the Board's upgrading of the software for collecting e-mail addresses.

Expedited Partner Therapy (EPT) Electronic Prescriptions

To reduce the spread of sexually transmitted diseases (STDs), the U.S. Centers for Disease Control and Prevention and the California Department of Public Health recommend expedited partner therapy (EPT) to treat partners (exposed contacts) of persons with chlamydia or gonorrhea without waiting for a clinical evaluation. Section 120582 of the Health and Safety Code allows physicians who diagnose STDs to "... prescribe, dispense, furnish, or otherwise provide prescription antibiotic drugs to that patient's sexual partner or partners without examination of the patient's partner or partners."

An organization assisting in reducing the spread of STDs is the Internet Sexuality Information Services, Inc. (I.S.I.S., Inc.), a nonprofit organization dedicated to developing and using Internet technologies to prevent disease transmission and enhance the sexual well-being of individuals and communities. By going to *www.inspot.org*, it is possible for an individual who is infected with chlamydia or gonorrhea to anonymously, or openly, e-mail any recent partner(s) and let them know that they may be infected and need clinical evaluation and therapy.

Individuals in many other cities in the U.S., and even worldwide, can use the InSpot notification capabilities. Additionally, under authorization of the San Francisco STD Controller at the San Francisco Department of Public Health, Dr. Susan Philip, San Francisco InSpot users can obtain an electronic prescription (example: two tablets of azithromycin 500 mg with no refills), for the treatment of chlamydia and gonorrhea.



It is important for pharmacists to recognize such prescriptions, so please see the sample above. For further information, please contact:

Dr. Susan Philip STD Prevention and Control Services San Francisco, CA 94103 (415) 487-5509

Inactive and Retired Pharmacist License Differences

Holders of an "inactive" or a "retired" pharmacist license are prohibited from practicing pharmacy: Pharmacy law requires an "active" license for practicing. The similarities end there. The following information relates to the differences between how "inactive" licenses are obtained and the methods for restoring them to "active" status and for acquiring a "retired" license.

An *inactive license* is acquired in several ways, the most common being when a pharmacist requests the Board to change an active license to inactive because he or she wants to retain the license but no longer wishes to practice pharmacy. The inactive license can then be renewed every two years by paying the renewal fee but without fulfilling the continuing education (CE) requirement. However, no licensee whose license has been revoked, suspended, placed on probation, or otherwise punitively restricted by the Board can obtain an inactive license (Business and Professions Code [B&PC] section 701).

An inactive license can be restored to active status on the license renewal application by submitting the renewal fee, checking the Active box, and attaching copies of certificates reflecting completion of 30 hours of CE earned within the previous two years. If the pharmacist chooses to return to active status before the renewal period, he or she may send a written request to the Board and copies of certificates reflecting completion of 30 hours of CE earned within the previous two years. Additionally, pursuant to B&PC section 4231(c) of the Business and Professions Code (B&PC), conversion of an inactive pharmacist license to an active license requires the payment of a new renewal fee.

Inactive status is assigned to the license of a pharmacist who fails to sign the renewal application or certify completion of the required CE hours. The Board notifies the licensee of this deficiency, and if the deficiency is not corrected within 15 days of the date of the Board's notification letter, the license is placed on inactive status, and no license is issued. Pharmacists whose licenses are in this inactive status are prohibited from practicing pharmacy until the renewal application is corrected and an active license is issued.

Inactive status is also assigned to a pharmacist who is non-responsive to the Board's notification that a deficiency was noted during a CE audit by the Board (B&PC section 4231[d]).

A <u>retired license</u> is issued to a pharmacist who notifies the Board that he or she wishes to retire from the practice of pharmacy, voluntarily surrenders his or her license, and submits a fee of \$35. However, to regain an active pharmacist license in the future, the retired pharmacist is required to fulfill all the requirements of a new application for licensure. This includes taking both the NAPLEX and the CPJE (B&PC section 4200.5).

A pharmacist who does not renew his or her license, whether active or inactive, within three years of the license expiration date will have the pharmacist license cancelled by operation of law (B&PC section 4402[a][b][1]).

Changes in the Board

New officers, whose terms began June 1, 2010, were elected at the April Board Meeting in Loma Linda:

President: Stanley C. Weisser, R.Ph.

Vice President: Randy B. Kajioka, Pharm.D. (Reelected)

Treasurer: Gregory N. Lippe, Public Member

Departing Member

Robert Swart, Pharm.D., left the Board on December 31, 2009. During his tenure on the Board, he served as chairperson of the Board's Enforcement Committee and served on the Legislation and Regulation Committee and the Communication and Public Education Committee. Dr. Swart also participated in the Public Forum on Medicare Part D Plans and the Senate Bill 472 Medication Label Subcommittee.

The Board recognizes and extends its appreciation to Dr. Swart for his contributions to California's pharmacy profession.

Issues and Trends Involving Controlled Substances



Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control of the US Drug Enforcement Administration Presentation at the Board of Pharmacy meeting, July 28, 2010

Nationwide there is growing concern about the high rates of prescription drug abuse and the diversion of prescription drugs, including controlled substances. On July 28, 2010, Joseph Rannazzisi, Deputy Assistant Administrator. Office of Diversion Control of the US Drug Enforcement Administration provided a presentation at the Board's July public meeting about issues and trends involving controlled substances. The

video of the presentation is available on the Board's Web site at *www.pharmacy.ca.gov*. This presentation is riveting and the Board recommends its viewing.

www.pharmacy.ca.gov

Google requires VIPPS-Accreditation for Internet Pharmacy Advertisers



On February 9, 2010, Google announced that its company will accept advertisements only from Internet pharmacies in the U.S. that are accredited through the Verified Internet Pharmacy Practice Sites (VIPPS[®]) and pharmacies in Canada that are accredited by the Canadian International Pharmacy Association (CIPA).

Google will not accept ads from Internet pharmacies who pose as legitimate pharmacies and dispense dangerous prescription drugs to patients without a valid prescription or medical oversight. Additionally, the drugs dispensed are often unapproved for sale in the U.S. and are often substandard, contaminated, or counterfeit.

VIPPS-accredited pharmacies must successfully complete the National Association of Boards of Pharmacy accreditation process, which includes a thorough review of all policies and procedures regarding the practice of pharmacy and dispensing of medicine over the Internet, as well as an on-site inspection of all facilities used by the site to receive, review, and dispense medicine.

Ads for Internet drug outlets that are not accredited by VIPPS or CIPA will no longer appear in Google's sponsored search results.

Power of Attorney for Ordering Schedule I and II Controlled Substances

There is confusion among some hospital pharmacists as to whom and how a power of attorney (POA) may be granted for ordering Schedule I and II controlled substances and signing DEA 222 forms. A POA is granted to the DEA registrant of the hospital, usually the CEO or corporate officer who signed the application for DEA registration. <u>Only the registrant</u> can then assign (or revoke) the POA to another person to act on the registrant's behalf for ordering Schedule I and II drugs and signing DEA 222 forms. Pharmacists with assigned POA have mistakenly reassigned that POA to other pharmacists, resulting in Schedule II orders being placed that are based on invalid POAs.

The DEA encourages pharmacists to review the POA document, 21 CFR 1305.05, *http://www.deadiversion.usdoj. gov/21cfr/cfr/1305/1305_05.htm* and especially note the use of the word "registrant." Unless the pharmacist is the registrant on the DEA license, he or she cannot grant or revoke a POA for anyone else.

Reporting Controlled Substances Drug Theft and Loss to DEA

Section 1301.74(c) of the Code of Federal Regulations requires a Drug Enforcement Administration (DEA) registrant to ... "notify the Field Division Office of the Administration in his area, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of such theft or loss. ... Thefts and significant losses must be reported whether or not the controlled substances are subsequently recovered or the responsible parties are identified and action taken against them." Additionally, section 1715.6 of Title 16 of the California Code of Regulations requires the owner to report to the Board of Pharmacy within thirty (30) days of discovery of any loss of controlled substances, including their amounts and strengths.

In a recent disciplinary case, a pharmacy employee had removed vials of hydrocodone from a patient's prescription bags, poured the contents into her pocket, destroyed the vials and threw the register receipts away. Further investigation disclosed that the employee also had taken drugs prescribed for other patients, and had made partial payments for some of them. She agreed to make restitution of approximately \$250 to the pharmacy for the drugs, and her employment was terminated. Although the pharmacy reported the drug theft/loss to the Board of Pharmacy within 30 days, there was no



DEA Form 106 (Report of Theft or Loss of Controlled Substances) on file at the pharmacy.

Perhaps the pharmacy did not consider the monetary loss significant or consider that a theft had occurred and for those reasons failed to file the DEA form. However, whenever theft of a controlled substance occurs, it must be reported. In addition, "significant loss" does not necessarily refer to monetary loss. When determining whether a loss is significant, other factors should be considered, including the following:

- The actual quantity of controlled substances lost in relation to the type of business;
- The specific controlled substances lost;
- A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and if known,
- Whether the specific controlled substances are likely candidates for diversion.

Whether the drug loss is accomplished through false prescriptions, removed by subterfuge or whatever other means, theft or loss of all controlled substances must be reported to the DEA. To report online, go to *www.deadiversion.usdoj.gov* and click on "DEA Form 106: Report of Theft or Loss

of Controlled Substances."





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. I have heard that the Board will be inspecting sterile injectable compounding pharmacies regarding their accreditation. What does this mean?
- The Business and Professions Code (B&PC) sections Α. 4127.1(d) and 4127.2 require sterile injectable pharmacies to be licensed by either the Board or accredited by JCAHO (Joint Commission on Accreditation of Healthcare Organizations) or other accreditation agencies approved by the Board-CHAP (Community Health Accreditation Program) and ACHC (Accreditation Commission for Health Care) have current approval by the Board until April 2011. DNV (Det Norske Veritas) was recently approved by the Board at its July board meeting. During Board inspections, attention will be given to whether accredited pharmacies are in compliance with the new compounding regulations at Title 16, Code of California Regulations (CCR) sections 1735 - 1735.8 and 1751 - 1751.8, that became effective July 6, 2010. A pharmacy that is accredited must be in compliance with the new compounding regulations, whether the pharmacies were accredited prior to or after July 6, 2010.

Q Are nonresident pharmacies (NRPs) required to report to CURES all Schedule II – IV prescriptions dispensed to patients in California?

A. Yes. An NRP functions under the same definition of "pharmacy" as a California pharmacy (B&PC section 4037). Section 11165(d) of the Health and Safety Code (H&SC) directs all pharmacies or clinics that dispense prescriptions for Schedule II - IV controlled substances to report that information to the Department of Justice (CURES) on a weekly basis. Further, because B&PC section 4112(e) requires all nonresident pharmacies to maintain records of controlled substances dispensed to patients in this state (emphasis added), it follows that the reporting procedures to CURES refers only to controlled substances dispensed to patients in California. For further reporting information, please contact http:// www.4infinitesolutions.com/cures/.

Q. Who can sell Plan B, the "morning-after pill?" Must it be sold only by a pharmacist?

A. Plan B and Plan B One-Step emergency contraceptives (EC) are sold over-the-counter to purchasers 17 years or older and can be sold by ANY pharmacy employee (pharmacist, intern pharmacist, pharmacy technician, clerk, or cashier). However, EC products are stored behind the pharmacy counter, so the products cannot be sold—by anyone—if the pharmacy area is closed. Purchasers under the age of 17 require a prescription, which can be issued and/or dispensed only by a pharmacist.

Q. Can Plan B be sold OTC to men?

A. Yes. The FDA specifies that both Plan B and Plan B One-Step can be sold to men or women who present proof that they are age 17 years or older.

Q. If a man can obtain Plan B products OTC for a female 17 years or older, can he also obtain a prescription for those products from the pharmacist for a female who is 16 years or younger but not present?

A. No. The prescription is written for the ultimate user of the product—the patient—and the protocol for dispensing emergency contraceptives requires the prescribing pharmacist to ask, "Are you allergic to any medication?"

The required question to be asked and directions to be given by the pharmacist to the ultimate user indicate the patient is a woman. Also, the required actions represent a good-faith, face-to-face examination of the patient.

[Edit. Emergency contraception laws can be reviewed at B&PC section 4052.3 and CCR section 1746. The Protocol for Pharmacists Furnishing Emergency Contraception can be viewed at *http://www.pharmacy.ca.gov/licensing/ec_protocol.pdf*.]

Q. Can a prescriber in a clinic dispense a 72-hour supply of Schedule II drugs?

- A. No. The dispensing of Schedule II controlled substances in a clinic is prohibited by B&PC sections 4184 and 4194.
- Q. A physician insisted that a pharmacy can refill Schedule II prescriptions. Is that true?

Rx for Good Practice

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- A. No. No prescription for a Schedule II substance may be refilled (H&SC section 11200[c]).
- Q. Can I fill a controlled substance prescription written by a prescriber in another state if it is written on a California security prescription form? Can I fill it if it is not written on a California security prescription form?
- A. The answer to the first question is yes, but the answer to the second question is not so simple. If it is <u>not</u> written on a California security prescription form, H&SC section 11164.1 directs that the prescription must conform to the laws of the state where the prescription was written. California pharmacists may dispense Schedule III-V controlled substances pursuant to a prescription issued by a prescriber in another state, but prescriptions for Schedule II medications may be dispensed only <u>for delivery to a</u> <u>patient in another state</u>. In other words, the pharmacist cannot dispense a Schedule II controlled substance directly to the patient in California if the prescription is not on a California security prescription form.
- Q. Can I fill a controlled substance prescription written by a prescriber on a military base in California if it is not written on a California security prescription form?
- A. No. Again, the same answer applies to this question as the one given for the previous question.
- Q. What expiration date do you put on a repackaged item that you pour from a manufacturer's container into a smaller container? I've heard two answers to this question, but which is correct, (1) the exact manufacturer's date or (2) up to one year of the dispensing date.
- A. Actually, both answers are correct, as long as the one-year of the dispensing date does not exceed the manufacturer's expiration date. The United States Pharmacopeia, 24th Rev. and The National Formulary, 19th Ed. guidelines for beyond-use dates for multiple-unit containers are "not later than (a) the expiration date on the manufacturer's label or (b) one year from the date the drug is dispensed, whichever is earlier." [Edit. The Board's primary concern is that no drugs are dispensed with expiration dates beyond that on the manufacturer's label.]
- Q. Pharmacists are supposed to sign for all drug deliveries to their pharmacy, but who signs for deliveries that arrive when the pharmacy is closed and there is no pharmacist present?
- A. When there is no pharmacist present to sign for a drug delivery, B&PC section 4059.5(f) allows the delivery to be accepted if all the following requirements are met:

- The drugs are placed and locked in a secure storage area in the same building as the pharmacy;
- Only the PIC or a pharmacist designated by the PIC has access to the secure storage area where the delivered drugs are stored;
- The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or devices have been delivered;
- The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and devices to a secure storage facility [Edit. The policies and procedures would likely include information about who can accept and sign for secure storage when there is no pharmacist.]; and
- The delivering agent leaves documents indicating the name and amount of each dangerous drug or device delivered in the secure storage facility.
- Q. Often, patients bring in hand-written prescriptions that have stamped/electronic signatures that look like they might have been made or created by the patients. Can written prescriptions have stamped prescriber signatures?
- A. In describing a prescription, B&PC section 4040(a)(1)(F) states that if the prescription is in writing, it must be signed by the prescriber. [Edit. No signature stamp.] Electronic signatures are allowed on electronic prescriptions—computer-to-computer or computer-to-fax.

Q. Can physicians prescribe drugs, including controlled substances, for themselves or their family members?

A physician **cannot** write a controlled substance prescription for himself (H&SC 11170). He or she must refer to another physician for controlled substance or dangerous drug prescriptions. The prescribing physician would then be responsible for the prescription record keeping.

A physician can write prescriptions for family members **only** if there is a physician/patient relationship, if the prescriptions are for a legitimate medical purpose, if a good-faith examination is performed, and if appropriate records are kept.

However, in an emergency situation, a physician can prescribe a controlled substance for a family member, but the prescription should be for no more than just enough to last until the family member is able to see his or her regular physician for subsequent care.

Always refer to the Standard of Practice, and your own professional judgment.

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Rx for Good Practice

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- Q. On a prescription form for controlled substances, is it true that if the number of drugs (tablets, capsules, etc.) is not noted at the bottom, the prescription is void and invalid?
- A. Yes. It even states on the bottom of prescription blanks for controlled substances (H&SC section 11162.1[a][8]) that the "Prescription is void if the number of drugs prescribed is not noted." If the prescriber has failed to check one of the drug quantity boxes, the pharmacist must contact the prescriber for the number of drugs to be dispensed.
- Q. If a fax is received for a non-controlled substance, is an electronic signature of the prescriber sufficient, or must I call the prescriber for confirmation?
- A. If the prescription was transmitted via computer from the prescriber to the pharmacy fax machine, it is considered an "electronic <u>data</u> prescription," and a digital signature may be used (B&PC section 4040[c]).

If the prescriber faxes a prescription to a pharmacy fax machine, it is considered to be an "electronic <u>image</u> prescription"—an originally written prescription—and pursuant to B&PC section 4040(a)(1)(F), the prescriber's written signature is required on the prescription to be faxed.

- Q. Is a pharmacist allowed to dispense, pursuant to a verbal order from a physician who announces that the prescription is a "terminal code 11159.2," a Schedule II medication without a faxed or written back-up prescription?
- A. No. A H&SC "11159.2 exemption" prescription can be dispensed pursuant only to an original written prescription, which does not have to be written on a tamper-proof, security prescription pad. It cannot be dispensed if the prescription is faxed or orally transmitted.

- Q. If a patient, who is in a methadone treatment program as well, is being discharged from the hospital, can a pharmacist fill the doctor's prescription for a two-day supply of methadone to help the patient through the weekend while the methadone clinic is closed?
- A. Yes, a prescription for methadone can be filled if the patient is being treated in the hospital for a non-addiction condition such as illness, surgery, or injury (B&PC section 2241[c] [1] and H&SC section 11217.5). Professional judgment should dictate and consideration should be given to the consequences of forcing an addict who is suffering from a non-addiction illness or injury to endure two days of addiction while the methadone clinic is closed.

Correction: This column in the February 2010 issue of *The Script* omitted pertinent information related to the following question—One of the items on the Hospital Pharmacy Self-Assessment form asks if "Patient package inserts [Edit. PPIs] are dispensed with all estrogen and progesterone medications (21 CFR 310.515). Are acute-care and long term care facilities required to distribute PPIs for such products? The response was yes, such PPIs are required, but the response failed to add that Title 21 Code of Federal Regulations Part 310.516, requiring patient labeling for progestational products information, has been revoked and deleted.

When the Hospital Pharmacy Self-Assessment form is next revised, the requirement to include progestational information on PPIs will be deleted.

Reporting Financial Settlements to the Board



The Board recently learned that there are licensees and insurance companies that are unaware of their responsibilities to report to the Board pursuant to sections 801 to 804 of the Business and Professions Code. These provisions require the following reporting, by professional liability insurers and by licensees without professional liability insurance:

- Any settlement or arbitration award over \$3,000.00 of any claim or action for damages or death or personal injury caused by a licensee's negligence, error, or omission in practice, or by his or her rendering of unauthorized professional services, shall be reported to the Board by the insurer within 30 days after the settlement agreement has been reduced to writing and signed by all parties or within 30 days after service of the arbitration award on the parties (section 801);
- Any settlement or arbitration award over \$3,000.00 of any claim or action for damages or death or personal injury caused by a licensee's negligence, error, or omission in practice, or by his or her rendering of unauthorized professional services, shall be reported to the Board by a licensee who does not possess professional liability insurance within 30 days after the settlement agreement has been reduced to writing and signed by all parties or within 30 days after service of the arbitration award on the parties (section 802);

In addition, section 803 requires that the clerk of a court that renders a judgment that a licensee has committed a crime, or is liable for any death or personal injury resulting in a judgment for an amount over \$30,000.00 caused by the licensee's negligence, error or omission in practice, or his or her rendering of unauthorized professional services, report that judgment to the Board within 10 days after the judgment is entered.

Lastly, any required report is complete only if it includes all of the following:

- 1. The name and last known business and residential addresses of every plaintiff or claimant involved in the matter;
- 2. The name and last known business and residential addresses of every provider who was claimed or alleged to have acted improperly, whether or not that person was a named defendant and whether or not any recovery or judgment was had against that person;
- 3. The name, address, and principal place of business of every insurer providing professional liability insurance to any of the providers identified in (2);
- 4. The name of the court in which the action or any part of the action was filed along with the date of filing and docket number of each action;
- 5. A brief description or summary of the facts upon which each claim, charge or judgment rested including the date of occurrence; (6) the names and last known business and residential addresses of every person who acted as counsel for any party in the litigation or negotiations, along with identification of the party whom said person represented;
- 6. The date and amount of final judgment and/or settlement; and
- 7. Any other information Board regulations may require (section 804). If any person named in the report is notified by the Board of this obligation within 60 days of the filing of the report, he or she must maintain any records he or she has as to the matter in question and shall make those available to the Board upon request.

The Board subsequently enters the reported information into a licensee's central file (section 800). That central file provides an individual historical record for each licensee. The contents of the file that are not public records are kept confidential. The licensee or his or her attorney or representative may inspect the file and have copies made except any materials disclosing the identity of an information source. The Board may also permit a law enforcement or regulatory agency to inspect and copy the file when required for an investigation of unlawful activity or for licensing, certification, or regulatory purposes.

Failure(s) to report such financial settlements may result in action by the Board.

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.

April 2010 Board Meeting Honoree



At the April 2010 meeting, Dr. Kajioka recognized Donald J. Sabol, R.Ph., a graduate of Drake University. Mr. Sabol spent five years in the U.S. Air Force and began his civilian pharmacy career at Horton and Converse. He later became the pharmacy director at Conejo

Donald J. Sabol

Valley Hospital, subsequently opened three pharmacies, and is currently with CVS Pharmacy. Public Member Ryan Brooks presented Mr. Sabol with a pharmacy 50-year pin.

July 2010 Board Meeting Honorees

The July 2010 meeting welcomed at least eight 50-year honorees—the most honorees ever attending for recognition by the Board. All of the honorees were introduced by Board President Stanley Weisser and Dr. Kajioka presented them with 50-year pharmacist pins.



After graduating from University of the Pacific in 1959, Mr. George W. Mac Murphey operated independent pharmacies for nearly 30 years.

George W. MacMurphy

Don Rey Myers graduated from the University of Utah in 1960 and worked as a community pharmacist for 14 years, a hospital pharmacist for 25 years, and is still working in community pharmacy.



Don Rey Myers

The owner of three pharmacies during his career, Dr. Willard B. Henry graduated from UCSF in 1961. Donald F. Lee owned his own pharmacy for 30 years and also became a hospital pharmacist. In 1980, he was recognized as the Orange County Pharmacist of the Year.



Donald F. Lee and Mrs. Lee



Howard L. Strause, owner and operator of Neighborhood Pharmacy, also worked in assisted living and skilled nursing pharmacies, and is still practicing today.

Howard L. Strause with family and Randy Kajioka, Vice President, Board of Pharmacy

Upon graduating from the University of Utah, Harvey K. Swenson worked in a variety of pharmacy settings that included retail, hospital, long term care, and the Department of Health.



Harvey K. Swenson

After graduating from the University of Colorado, Charles A. Beazell worked as a pharmacist at

Thrifty Drug and Corner Drug in

Woodland, California.



Charles A. Beazell and Mrs. Beazell

George H. Pennebaker was the first pharmacy consultant for the Medi-Cal program and served as president of the California Pharmacists Association. Pennebaker recognized fellow pharmacist and son, Tim Cutler.



George H. Pennebaker and son Tim Cutler

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

Abbanat, Jerry Abramson, Morton I. Stephen Monterey, CA Williamsville, NY

Willard B. Henry and Mrs. Henry

Honored 50-year pharmacists

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Allsman, Ronald L. Andrade, Richard F. Aubert, Richard L. Bailiss, Elton L. Barnum, Karl R., Jr. Baron, Frederick N. Beazell, Charles A. Blomquist, James S. Boring, Edwin K. Bunkin, Michael Byrd, Monte D. Calagna, Joseph V. Chan, Wilev L. Christ, Alexander Churness, David A. Claydon, James T. De Herrera, Joseph A. De Wilde, Jerald Dreyfus, Gary A. Earner, Kathleen A. Etherton, Lawrence N. Farris, Walton H. Florman, Jerald J. Frank, Clarence E. Frankel, Lane Goodfriend, Bovd J. Henry, Willard B. Himelfarb, Jerrold Holland, Sheldon D. Howells, George F., Jr. Johnson, Richard D. Kaufman, Leonard B. Kawasaki, Kiyoshi Kentera, Milosh K. Kligman, Leonard Koenig, Lawrence Korn, Carl S. Kramer, Dale L. Kramer, Howard K. Krinsky, Oscar J. Kruger, Louis H. La Mattino, Joseph Latour, John Paul Lea, Jed K. Lee, Donald F. Lehine, Alfred Lewis, Donald B. Marcalus, Frederick C. Marshall, Leonard A. Marshall, Monte W. Mc Gown, Gary R. Mc Gown, Jovce T. Mc Intosh, Edward A. Mendlovits, Alvin Miyade, Akira

Bakersfield, CA Redding, CA St. Helena, CA Culver City, CA Sequim, WA Garberville, CA Woodland, CA Riverbank, CA San Clemente, CA Thousand Oaks, CA Fresno, CA Claremont, CA San Francisco, CA San Francisco, CA San Pedro, CA Jackson, CA Santa Barbara, CA Los Angeles, CA Corona Del Mar, CA Corona Del Mar, CA Gallup, NM Rolling Hills Estates, CA Santa Ana, CA Red Bluff, CA Beverly Hills, CA Denton, TX Chester, CA Northridge, CA Placerville, CA Aptos, CA Kansas Citv, MO Glendale, CA Hollister, CA San Jose, CA Northridge, CA Cathedral City, CA Charleston, SC Danville, CA Calabasas, CA Long Beach, CA Chico, CA Carlsbad, CA Roseville, CA San Carlos, CA Anaheim, CA Arcadia, CA Soquel, CA Jewel, IA Moraga, CA Delano, CA Modesto, CA Modesto, CA Belmont, CA San Diego, CA Huntington Beach, CA

Miyamoto, Michio Mori, Richard T. Mortensen, Charles F. Moyer, Rodney G. Myers, Don Rey Nishi, Alice F. Nishkian, Vahan, Jr. Norrby, Dennis G. Padlipsky, Joel Pennebaker, George H. Pickens, W. Eugene Pierce, Thomas R. Pierick, Thomas L. Poage, Jan Poerio, Vincent J. Ravnik, Alex J. Reavlin, Bernard Leon Redlich, Lila J. Reinhart, Richard E. Ricci, Louis F., Jr. Rohnow, Rollie E. Rosenbaum, Jerrold L. Ross, Kenneth W. Roulette, Amos W. Sanders, Phillip R. Schick, John R. Schroeder, Gail Ellen Scott, Phil G. Siegel, Alan N. Silicato, Carmen G. Smith, Roger D. Sorenson L. Wayne Spellman, Arnold Stephens, Alvin Strause, Howard L. Sunshine, Gerald Swenson, Harvev K. Swire, John A. Talley, Gary M. Tedeschi, Richard P. Tonnemacher, Donald A. Toso, Gilbert G. Trachtman, Lawrence Tsutsui, Kenneth F. Turiace, William P. Uveda, Chivoko Van Le, Thuy Tien Weyand, Garry L. Whitney, B. H., Jr. Wise, Robert A., Jr. Woo, Wilson B. Yamada, Minoru

Sanger, CA Rancho Palos Verdes, CA Concord, CA Provo. UT Lincoln, CA Huntington Beach, CA El Granada, CA Carmel Vallev, CA Pasadena, CA Rancho Cordova, CA Anaheim, CA San Gabriel, CA Canvon Lake, CA Santa Cruz, CA El Dorado Hills, CA Hayward, CA Bakersfield, CA Tustin, CA Huntington Beach, CA San Rafael, CA Zephyr, NV Long Beach, CA North Hollywood, CA Palm Desert, CA Carson City, NV Garden Grove, CA Calabasas, CA Palm Desert, CA Simi Valley, CA Tujunga, CA Sequim, WA Barstow, CA Tarzana, CA Riverside, CA Lafavette, CA Panorama City, CA Sacramento, CA Santa Rosa, CA San Diego, CA Granada Hills, CA Red Bluff, CA Modesto, CA Manhasset, NY Fresno, CA Auburn, CA Arcadia, CA Los Angeles, CA Bakersfield, CA Santa Ana, CA Novato, CA Sunnyvale, CA San Francisco, CA

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 awarded to encourage pharmacists and pharmacy technicians to learn more about the issues and operation of the Board. These hours can be earned by:

- Attending one full day of a Board meeting per year (maximum of six hours of CE per year); or
- Attending a one-day committee meeting (two hours of CE for each of two different committee meetings—maximum of four hours per year); or
- Completing the Pharmacist Self-Assessment Mechanism (PSAM) program through the NABP (six hours of CE); or
- 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—Makes recommendations to the Board regarding oversight of all regulatory and enforcement activities for the improvement of consumer protection.
- Licensing Committee—Makes recommendations to the Board regarding the development of standards for the professional qualifications of licensees.
- Legislation and Regulation Committee—Advocates legislation and recommends 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 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 texts 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 register on the CE sign-in sheet.

The remaining Board meeting date and location for 2010 are:

October 20-21	University of California, San Diego
	School of Pharmacy
	Health Sciences Educational Auditorium
	9500 Gilman Dr.
	La Jolla, CA 92093-0657

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

Guidelines for Improving Procedures for Handling Recalled Drugs in Hospital

The July 2008 issue of *The Script* included an article that discussed the problems associated with recalled drugs being found in California hospitals. The article detailed the recall of specific heparin products that had been linked to more than 80 deaths in the U.S. and an oversized Digitek tablet that contained more than the required amount of the active ingredient.

Although five separate heparin recall notices were issued during early 2008 to pharmacies by specific manufacturers, and three "subscriber alerts" about the recall were e-mailed by the Board of Pharmacy, focused pharmacy inspections of hospitals found recalled heparin in 94 California hospitals. Additionally, recalled Digitek was found in pharmacies after the manufacturer's recall notice and after a notice mailed by the Board to 6,000 pharmacies, followed by a separate subscriber alert by the Board. Faced with these apparent failures in communication or proper response to drug recalls, the Board determined that it was important to convene the Subcommittee to Evaluate Drug Distribution in Hospitals to identify ways to improve the safety of drug distribution in hospitals and strengthen procedures for drug and device recalls.

Three subcommittee meetings were convened in 2009. During these meetings, information about how recalls are initiated and communicated was provided by the U. S. Department of Food and Drug, the Food and Drug Branch of California Department of Public Health (CDPH), and the Chief Pharmaceutical Consultant of the Licensing and Certification Unit of CDPH. Also participating in the meeting were more than 100 pharmacists, pharmacy administrators, wholesalers and others who described workplace issues that interfered with proper adherence to recall directives.

After information gathering and discussion, the subcommittee ultimately developed guidelines (not laws, statutes, or regulations) that include a list of possible actions to take to remove recalled drugs or devices from all patient care and in hospitals. These practices can be summarized as:

- 1. Pre-position the facility to receive notice of recalls from multiple sources;
- 2. Identify whether the facility has the recalled product;
- 3. If so, quickly remove the product from all patient care areas;
- 4. Identify, assess, notify and treat patients who may have received the product;
- 5. Identify alternative products to maintain therapy;
- 6. Return the quarantined product; and
- 7. Document and evaluate the process.

Pre-recall planning steps include the hospital pharmacy department's development and implementation of written policies and procedures for the effective removal of recalled products from all patient care areas (inpatient and outpatient) and storage areas. Representatives from nursing, medicine, pharmacy services, and administration should be involved in development of the policies and procedures.

The written procedures should also include information related to the identification of all locations where drugs are stored throughout the hospital, actions to take once a recall has been initiated, quality assurance and improvement processes, ways to improve recalls with drug wholesalers, and the use of technology-based solutions.

For more accurate and timely recall systems, hospitals also should have an effective recall notification system that originates in one place, listing the issue, what should be done, what steps to be taken, etc. Instituting a bar code system to better track drugs throughout the facility should also be considered.

The July 2008 issue of *The Script* (*www.pharmacy.ca.gov/publications/08_ jul_script.pdf*) contains a full description of the heparin and Digitek recall problems that were encountered.

Unlicensed Distribution of Dangerous Devices to Hospitals

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals. Such drugs or devices have cautionary statements advising that federal law prohibits dispensing without a prescription (Business & Professions Code section 4022). Further, section 4169 prohibits the purchase, trade, sale, or transfer of dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy.

Dangerous device manufacturers, who are not licensed as wholesalers, are not authorized to sell or broker sales of dangerous devices to hospitals or other authorized entities from locations that are not licensed as a manufacturing plant or as a wholesaler.

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.

Stipulated Settlement—the board and a licensee mutually agree to settle a disciplinary case brought by the board by way of a settlement agreement.

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. The board may agree to accept the surrender of a license through a "stipulation" or agreement. **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 January 6 to May 25, 2010, 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 "Enforcement Actions."

Revoked Pharmacist Licenses The following individuals are no longer licensed, and the right to practice has been terminated.

Falemi, Oladimeji, RPH 36945, Carson, CA—Case 3158 By Default, license revoked. Decision effective 01/06/2010 Lang, Johnny, RPH 50571, Bakersfield, CA—Case 3242 Decision effective 04/21/2010 Mai, Michelle, RPH 58012, Fountain Hills, AZ—Case 3234 Decision effective 01/28/2010
Moon, Michael, RPH 42325,
Santa Maria, CA—Case 3262 Decision effective 06/09/2010
Muraoka, Kris, RPH 38703,
Laguna Niguel, CA—Case 3374 Decision effective 04/21/2010
Nisonoff, Keith, RPH 43677,
Englewood, CO—Case 3209 By Stipulation, license revoked. Decision effective 04/29/2010

> Pharmacist Licenses Revoked, Stayed, Probation

The following licenses were revoked, revocations stayed, and placed on probation. If the terms and conditions of probation are not followed, the original revocations can be reinstated. Chu, Peter, RPH 48836, Irvine, CA—Case 3431 Three years' probation; cannot supervise any intern pharmacist and cannot act as preceptor or PIC. Decision effective 04/21/2010 Eng, Ken, RPH 35351, Canyon Country, CA-Case 3222 Five years' probation; cannot supervise any intern pharmacist and cannot act as preceptor or PIC. Decision effective 04/21/2010 Fujitaki, Wayne, RPH 31483, Marina Del Rey, CA-Case 3161 By Stipulation, five years' probation, license suspended for 120 days, no ownership of Board-licensed entity, cannot act as preceptor or PIC. Decision effective 05/26/2010

Gibson, Marvin, RPH 27732, Folsom, CA—Case 3291 Five years' probation; cannot **Disciplinary Actions**

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supervise any intern pharmacist; cannot act as preceptor or PIC; and no ownership of Board-licensed entity.

Decision effective 04/21/2010 **Kim, Gene**, RPH 43406,

La Canada, CA—Case 3161 By Stipulation, three years' probation, must complete an approved ethics course, cannot act as preceptor or PIC; and no ownership of Board-licensed entity. Decision effective 05/26/2010

Koerpel, Philip, RPH 39167,

San Francisco, CA—Case 3367 Five years' probation; cannot supervise any intern pharmacist; and cannot act as PIC. Decision effective 02/18/2010

Lee, Brian, RPH 51443, Bakersfield, CA—Case 3243 Three years' probation; cannot supervise any intern pharmacist; cannot act as preceptor or PIC; and no ownership of Board-licensed entity.

Decision effective 04/21/10 Lok, Terence, RPH 48193,

Thousand Oaks, CA—Case 3139 Three years' probation; cannot supervise any intern pharmacist; cannot act as PIC; and no ownership of Board-licensed entity. Decision effective 01/06/2010

Park, Jae Young, RPH 44773,

Diamond Bar, CA—Case 3084 By Stipulation, after one year's suspension, five years' probation; practice must be supervised; cannot act as preceptor or PIC; no ownership of Board-licensed entity; and must successfully pass an approved ethics course.

Decision effective 05/26/2010 **Patterson, Annette**, RPH 42732,

Ventura, CA—Case 3185 By Stipulation, three years' probation; practice must be supervised; cannot act as preceptor or PIC; and no ownership of Boardlicensed entity.

Decision effective 05/26/2010 **Rosenzweig, Judith**, RPH 47399, San Diego, CA—Case 3343

Three years' probation; cannot

supervise any intern pharmacist; and cannot act as PIC. Decision effective 01/08/2010 **Weaver, Shauna**, RPH 49557, Pebble Beach, CA—Case 3225 By Stipulation, five years' probation; cannot supervise any intern pharmacist; cannot act as PIC; and no ownership of Board-licensed entity. Decision effective 04/21/2010

Revoked Pharmacy Technician and Exemptee Licenses The following individuals are no longer licensed, and the right to practice has been terminated.

Ali, Rihaad, TCH 38102, San Jose, CA-Case 3221 By Default, license revoked. Decision effective 04/08/2010 Balian, Andre, TCH 35894, Pasadena, CA-Case 3232 By Default, license revoked. Decision effective 04/29/2010 Barton-Tylij, Carolyn, TCH 33671, Tracy, CA-Case 3382 By Default, license revoked. Decision effective 05/26/2010 Beavers, Christopher, TCH 40420, Ridgecrest, CA-Case 3273 By Default, license revoked. Decision effective 04/29/2010 Boyd, Mindy, TCH 34012, Santa Cruz, CA-Case 3346 Decision effective 02/10/2010 Calderon, John, TCH 63110, Santa Ana, CA-Case 3396 By Default, license revoked. Decision effective 04/08/2010 Castaneda, Robert, TCH 74030, Woodlake, CA-Case 3520 By Default, license revoked Decision effective 05/26/2010 Chantry, Christy, TCH 50438, Moreno Valley, CA-Case 3340 By Default, license revoked. Decision effective 04/08/2010 Cooper, Wendy, TCH 8392, Alta Loma, CA-Case 3272 By Default, license revoked. Decision effective 02/18/2010 Dague, Luke, TCH 53510, Ontario, CA-Case 3287 Decision effective 01/28/2010 Dixon, Flora, TCH 64779,

Los Angeles, CA-Case 3207 Decision effective 04/04/2010 Dyer, Tanya, TCH 25254, Chico, CA-Case 3339 By Default, license revoked. Decision effective 04/08/2010 Edge, Jaime, TCH 78753, Huntington Beach, CA-Case 3323 Decision effective 04/03/2010 Elreda, Mohamad, TCH 68570, Bell, CA-Case 3322 Decision effective 01/28/2010 Freitas, Michael, TCH 59123, Newark, CA-Case 3381 By Default, license revoked. Decision effective 04/29/2010 Gamboa, Nancy, TCH 82115, San Diego, CA-Case 3403 By Default, license revoked Decision effective 05/26/2030 Garcia (AKA Hernandez), Sara, TCH 46353, Colton, CA-Case 3276 By Stipulation, license revoked. Decision effective 04/29/10 Garay, Raquel, TCH 53038, Van Nuys, CA-Case 3164 Decision effective 01/06/2010 Garlipp, Caleb, TCH 74999, Berkeley, CA-Case 3252 By Default, license revoked. Decision effective 02/18/2010 Gill, Jennifer, TCH 36591, El Cajon, CA-Case 3398 By Default, license revoked. Decision effective 04/08/2010 Gonzalez, Joseph, TCH 55572, Anaheim, CA-Case 3320 Decision effective 01/28/2010 Guy, Mary Jane, TCH 44416, Oceanside, CA-Case 3458 By Default, license revoked. Decision effective 05/28/2010 Habig, Frances, TCH 45006, Modesto, CA-Case 3373 By Default, license revoked. Decision effective 02/18/2010 Harness, Anthony, TCH 16136, Palm Springs, CA-Case 3235 By Default, license revoked. Decision effective 02/18/2010 Hart, Kimberly, TCH 76431, Valley Springs, CA-Case 3313 By Default, license revoked. Decision effective 02/24/2010 Hegeman, Kimberly, TCH 69009, Montclair, CA-Case 3307

Disciplinary Actions

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By Default, license revoked. Decision effective 02/18/2010 Hernandez (AKA Garcia), Sara, TCH 46353, Colton, CA-Case 3276 Decision effective 04/29/10 Holloway, Joanna, TCH 39797, Redding, CA-Case 3361 By Default, license revoked. Decision effective 02/24/2010 Hussein, Shreen, TCH 50453, Mt. Eden, CA-Case 3395 By Default, license revoked. Decision effective 04/08/2010 Ibarra, Angelina, TCH 18088, East Palo Alto, CA-Case 3333 By Default, license revoked. Decision effective 05/26/2010 James, Arlitha, TCH 35116, Los Angeles, CA-Case 3326 Decision effective 01/29/2010 Jimenez, Thelma, TCH 50178, Sun City, CA-Case 3350 Decision effective 02/10/2010 Lawrence, Jessica, TCH 49013, Upland, CA—Case 3319 By default, license revoked. Decision effective 04/29/2010 Madruga, Jr., Jerry, TCH 19498, Hanford, CA-Case 3315 Decision effective 01/06/2010 Manto, Jayna, TCH 73450, Richmond, CA-Case 3357 Decision effective 02/10/2010 Paguirigan, Melinda, TCH 51809, Antioch, CA-Case 3348 By Default, license revoked. Decision effective 04/08/2010 Palomera, Alejandra, TCH 61961, Sylmar, CA—Case 3227 By Default, license revoked. Parks, Jennifer, TCH 57498, Walnut Creek, CA-Case 3409 Decision effective 02/10/2010 Parret, Britton, TCH 61069, Nipoma, CA-Case 3569 By Default, license revoked. Decision effective 05/26/2010 Pasache, Waldo, TCH 79340, San Francisco, CA-Case 3345 Decision effective 02/10/2010 Phan, Taylor, TCH 62860, Pomona, CA-Case 3281 By Default, license revoked. Decision effective 04/29/2010

Pitts, Priscilla, TCH 77544,

Anaheim, CA-Case 3250 By Default, license revoked. Decision effective 02/18/2010 Plascencia, Benito, TCH 13530, Whittier, CA-Case 3229 Decision effective 01/29/2010 Rafael, Claudia, TCH 46934, Los Angeles, CA-Case 3267 By Default, license revoked. Decision effective 05/26/2010 Renderos, Juan, EXC 16578, Santa Ana, CA-Case 3208 Decision effective 04/03/2010 Riaski, Aimee, TCH 41180, Hollister, CA-Case 3499 By Default, license revoked. Decision effective 04/29/2010 Romero, Emmanuel, TCH 51614, Riverside, CA-Case 3295 By Default, license revoked. Decision effective 04/08/2010 Salas, Joseph, TCH 41759, Fontana, CA-Case 3325 By Default, license revoked. Decision effective 04/08/2010 Simmons, Angela, TCH 59251, Carlsbad, CA-Case 3461 By Default, license revoked. Decision effective 04/29/2010 Storms, Tracy Lynn, TCH 76085, Pebble Beach, CA-Case 3302 By Default, license revoked. Decision effective 05/26/2010 Tolosa, Tristan, TCH 50743, Foster City, CA-Case 3280 Decision effective 02/10/2010 Vanderwiel, Chelsea, TCH 25777, Sonora, CA-Case 3245 By Default, license revoked. Decision effective 03/02/2010 Vargas, Christopher, TCH 31717, Chula Vista, CA-Case 3359 Decision effective 02/10/2010 Williford, Cortney, TCH 63070, Woodside, CA-Case 3311 By Default, license revoked. Decision effective 02/24/2010 Wood, Earl, TCH 6721, Pomona, CA-Case 3220 Decision effective 01/29/2010

Pharmacy Technician Licenses Revoked, Stayed, Probation

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

Crist, Cynthia, TCH 20695, Suisun, CA-Case 3304 Four years' probation; suspended from working as a pharmacy technician until certified by the Pharmacy Technician Certification Board; and no ownership of any Board-licensed entity. Decision effective 01/28/2010 Komirenko, Tatyana, TCH 65494, Cupertino, CA-Case 3389 By Stipulation, three years' probation; must pass the Pharmacy Technician Certification Exam; must have worksite monitor; and no ownership of any Board-licensed entity. Decision effective 05/26/2010 Krull, Amanda, TCH 60171, Palm Desert, CA-Case 3240 Two years' probation; suspended from working as a pharmacy technician until certified by the Pharmacy Technician Certification Board; and no ownership of any Board-licensed entity. Decision effective 01/28/2010 Pereda, Genoveva, TCH 30005, Sun City, CA-Case 3309 By Stipulation, five years' probation; no ownership of any Board-licensed entity; and no tech-check-tech. Decision effective 04/29/2010 Saucedo, Margarie, TCH 40762, Buena Park, CA-Case 3265 Three years' probation and must have worksite monitor. Decision effective 02/18/2010

Revoked Pharmacy License The following pharmacy is no longer licensed and the right to operate a pharmacy has been terminated. Fornoles, Elias, TCH 79276,

Disciplinary Actions

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City of Angels Medical Center

Pharmacy, HSP 43766,
Rosemead, CA—Case 3139 Decision effective 01/06/2010
Forum Drug, PHY 44525,
Diamond Bar, CA—Case 3084 By Stipulation, license revoked. Decision effective 05/26/2010

Pharmacy License Revoked, Stayed, Probation

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

Bluepoint Pharmacy, PHY 43188,

Stockton, CA—Case 3219 Three years' probation and pharmacy must post a notice of probation. Decision effective 02/10/2010

Voluntarily Surrendered Individual Licenses

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

Abad, Jennifer, TCH 39013,

Winnetka, CA-Case 3170 By Stipulation, license surrendered. Decision effective 02/18/2010 Buu, Que, RPH 45364, Westminster, CA-Case 3221 By Stipulation, license surrendered. Decision effective 04/08/2010 Chin, Darryl, RPH 28889, San Leandro, CA-Case 3289 By Stipulation, license surrendered. Decision effective 04/08/2010 Costere, Randy, TCH 44904, Aptos, CA-Case 3228 Decision effective 01/28/2010 Cummings, Vanessa, TCH 34068, Fontana, CA-Case 3471 By Stipulation, license surrendered. Decision effective 05/26/2010 Fernandez, Patricia, TCH 79276, East Palo Alto, CA-Case 3407 Decision effective 01/28/2010

Mission Viejo, CA-Case 3300 By Stipulation, license surrendered Decision effective 02/18/2010 Gurrola, Ramon, TCH 63846, Fillmore, CA-Case 3256 By Stipulation, license surrendered. Decision effective 04/08/2010 Husak, Thomas, RPH 23267, Auburn, CA-Case 3282 By Stipulation, license surrendered. Decision effective 04/29/2010 Laguna, Ramon, TCH 44921, Irvine, CA-Case 3224 Decision effective 01/28/2010 Lopez, Robert M., RPH 37861, Los Banos, CA-Case 3199 By Stipulation, license surrendered. Decision effective 04/08/2010 Lum, Sherman, RPH 21342. San Francisco, CA-Case 3297 By Stipulation, license surrendered. Decision effective 04/08/2010 Michmali, Michael, TCH 61671, Ceres, CA-Case 3144 Decision effective 01/28/2010 Nasser, Reem, TCH 69031, La Jolla, CA—Case 3312 By Stipulation, license surrendered. Decision effective 04/29/2010 Relingo, Romy, TCH 46262, Daly City, CA-Case 3238 By Stipulation, license surrendered. Decision effective 04/08/2010 Salazar, Brandee, TCH 28683, Modesto, CA-Case 3347 By Stipulation, license surrendered. Decision effective 04/08/2010 Sawyer, Sylvia, TCH 27671, Huntington Beach, CA-Case 3275 By Stipulation, license surrendered. Decision effective 04/08/2010 Sherman, Jr., Joseph, EXC 16823, Atascadero, CA-Case 3271 Decision effective 01/28/2010 Simmons, Angela, TCH 59251, Carlsbad, CA-Case 3461 By Default, license surrendered Decision effective 04/29/2010 Soares, Brittney, TCH 80292, Hanford, CA-Case 3406 By Stipulation, license surrendered. Decision effective 04/29/2010 Yuen, Patrick, RPH 33210, Fremont, CA-Case 3388

Decision 01/28/2010

Voluntarily Surrendered Pharmacy Licenses

Through disciplinary actions of the Board, the following license was voluntarily surrendered.

Pacific Pharmacy, PHY40567, Westminster, CA—Case 3101 By Stipulation, license surrendered. Decision effective 04/08/2010 Skyridge Pharmacy, PHY 21812, Auburn, CA—Case 3282 By Stipulation, license surrendered. Decision effective 04/29/2010

Statement of Issues

Through disciplinary action of the Board, applications for license granted, licenses issued, revoked, stayed and placed on probation.

Crosby, Anthony, TCH 80457, Richmond, CA-Case SI 3383 License issued; four years' probation; and may not work as Pharmacy Technician until certified by the Pharmacy Technician Certification Board. Decision effective 04/21/2010 Miller, Justin, TCH 86960, Sacramento, CA-Case SI 3285 License issued; no probation. Decision effective 04/21/2010 Nguyen, Mimi, INT 25738, Elk Grove, CA-Case SI 3369 By Stipulation, license issued; five years' probation.

Decision effective 04/19/2010

Accusation Dismissed

By hearing decision, the actions against these licenses were dismissed.

Adibi, Afshin, RPH 44301,

San Mateo, CA—Case 2347 Decision effective 12/26/2008 International Pharmaceutical Services, WLS 2955,

San Francisco, CA—Case 2347 Decision effective 12/26/2008

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