

CALIFORNIA BOARD OFPHARMACY **MARCH 2012** 

# Patient-Centered Labeling Requirements in Effect

Pharmacies are required to use patient-centered prescription drug container labels pursuant to Title 16, California Code of Regulations (CCR) section 1707.5. Additionally, subsection (d) requires pharmacies to have policies and procedures in place to help patients with limited or no English proficiency understand the information on the prescription label. Also, the pharmacies must secure oral interpreters for those patients if the interpretive services in such language are available, during all hours that the pharmacy is open.

For easy reference, the regulation language with the detailed requirements is provided here.

?OMG CAP CALP 'SULA ORALMENTE CADA DIA SAN DIEGO, CA 92128 LISINOPRIL 5MG TAB MYLAN PATIENT NAME TAKE 1 TABLET EVERY DAY Dr NAME, DOCTORS
tablet round scored peach (M L23)
"Discard this medication after:
"Discard this medication of the peace of Disp." 03 Jan 12 2 Refills Left

See Patient-Centered Labeling, Page 6

# Carisoprodol is Now Schedule IV

The Drug Enforcement Administration (DEA) issued a final rule, placing carisoprodol into Schedule IV of the Controlled Substances Act, effective January 11, 2012. The most widely known product impacted by this change is Soma, but this decision impacts any generic or brand name drug that contains carisoprodol.

The DEA <u>notice</u> regarding the final rule includes a summary of the background and procedural history of the final rule and a detailed review of the data considered in determining whether the drug should be scheduled. The notice was published in the Federal Register on December 12, 2011.

Any questions should be directed to:

Rhea D. Moore **Drug Enforcement Administration** 8701 Morrissette Drive Springfield, VA 22152 (202) 307-5266

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

Title 16, California Code of Regulations section 1707.5, requiring a patient-centered label on prescription drug containers, went into effect January 1, 2011. California is the first state to implement this requirement, which will help patients better understand their drug regimens. Many pharmacies have modified their labels to conform to the easy-to-read label requirement. Use of patientcentered labels has been added to pharmacy self-assessments, and to assure that the pharmacy labels meet the regulated requirements, container labels will be reviewed as part of any Board inspection. One year after implementation, the Board expects that pharmacies will have modified their labels. Failure to have the modified label system in place will be a violation of pharmacy law.

The regulation also has a provision that requires pharmacies to have interpreters available for patients with limited English skills. If such interpreter services are not available in the pharmacy from staff, they can be secured via telephone service. Part of the patient-centered labeling requirements also includes standardized directions for use—that are to be used "when appropriate." The Board has added to its Web site translations in Russian, Chinese, Vietnamese, Spanish, and Korean of these standardized directions for use.

The Board has amended the text of the current Notice to Consumers posters to add advisements about interpreters, the availability of a larger font (12 point) on the container label, and the requirement for patient consultation. New posters will be available sometime in mid-2012 and will be mailed to pharmacies when available.

Another aspect of educating consumers about their medications is the primary one of patient consultation. As a pharmacist, I feel that patient consultation gives me one more way to help prevent medication errors that can occur because of the wrong drug being dispensed or a prescription dispensed to the wrong patient. Medication errors may also be due to patients' failure to understand the importance of being made aware of contraindications, missed doses, possible side effects, and the opportunity to ask any questions they might have about their therapy. And remember, consultation does not begin with "Do you want to

talk with the pharmacist?" It begins with the patient being advised that the pharmacist will be providing consultation. The patient can agree to or refuse consultation directly with the pharmacist. Don't miss these opportunities to protect consumers from the consequences of being unaware of potential problems with their medications.

Because the destruction of unused or unwanted medication is a troubling problem, due to the endangerment of the environment and to drug diversion, drug take-back programs continue to be a growing consumer demand. To provide permanent places for consumers to dispose of their unused or expired medications, the California Integrated Waste Management Board (now CalRecycle) has developed guidelines for the establishment of home-generated pharmaceutical waste collection and disposal program models. We are including in this issue an article outlining those guidelines on Page 23.

Drug diversion and controlled substances thefts from pharmacies are increasingly the subject of Board investigations and are a growing concern of the Board. Related to this issue, the Board has cosponsored a day-long presentation with the DEA on "Diversion of Controlled Substances: What every pharmacist should know to prevent diversion." Two meetings have been held in the past year in Los Angeles and were successfully received. We hope to provide more such presentations in the future. Watch for the agenda via our subscription alert system.

# Reappointments to the Board

Board members Stanley C. Weisser and Randy B. Kajioka, Pharm.D. were recently reappointed to the Board by Governor Brown. Their terms will expire June 1, 2016.

# **Changes in Pharmacy Law for 2012**



The Senate and Assembly bills listed in this article were enacted in 2011, and unless otherwise specified, will take effect January 1, 2012. The new and amended Business and Professions Code (B&PC), Health and Safety Code (H&SC), and Civil Code laws are paraphrased or summarized below, but for pertinent information that is not included in the summaries, you are strongly urged to review the exact language at www. pharmacy.ca.gov/laws\_regs/new\_laws.pdf.

## SB 24 (Simitian), Chapter 197, Statutes of 2011

#### **Civil Code section**

1798.29—Amended the current law that requires the persons or entities conducting business in California and who own computerized data that includes personal information, to report any security breach to each California resident involved. This amendment adds new content requirements for the security breach notice sent to each resident affected by the breach.

Civil Code section
1798.82—Amended to require
a copy of the security breach
notification to be electronically
submitted to the Attorney General if
the security breach notification is sent
to more than 500 California residents.

### SB 41 (Yee) Chapter 738, Statutes of 2011

**B&PC** sections 4144, 4145, and

4148 were amended; section 4149.5 was added; sections 4144.5, 4145.5 and 4148.5 were added and repealed; section 4140 was **repealed.** These sections allow, until January 1, 2015, a physician or pharmacist to furnish 30 or fewer hypodermic needles and syringes solely for personal use to a person 18 years of age or older. These sections also address the storage of products to ensure they are available only to authorized personnel, require that disposal options are provided to consumers, and require pharmacies to provide written information or verbal counseling about how to access drug treatment, at the time of furnishing.

**H&SC section 11364—Amended** to provide that this section is inoperative until January 1, 2015.

H&SC section 11364.1—Added to allow possession of 30 or fewer hypodermic needles or syringes if acquired from a source that is authorized by law to provide them without a prescription until January 1, 2015, on which date the section is repealed, unless a later enacted statute that is enacted before January 1, 2015, deletes or extends that date.

# H&SC section 121281—Added to assist pharmacists and pharmacy personnel by requiring the Office of AIDS to provide on its Web site, "Access to Sterile Syringes-California Department of Public Health/Office of AIDS," the following information:

- How consumers can access testing and treatment for HIV and viral hepatitis;
- How consumers can safely dispose of syringes and hypodermic needles or other sharps waste; and
- How consumers can access drug treatment.

As additionally required by this regulation, the Board of Pharmacy posts and maintains on its Web site, the Office of AIDS Internet link for accessing the above information.

## SB 360 (DeSaulnier), Chapter 418, Statutes of 2011

# H&SC sections 11161.5, 11162.1, 11165 and 11165.1—Amended to require:

- All prescriptions for Schedule II, III, or IV controlled substances, defined under federal law in Title 21 of the Code of Federal Regulations, sections 1308.12, 1308.13, and 1308.14, must be reported to CURES;
- Security printer applicants to provide the location, names, and titles of anyone who has access to or management of controlled substance prescription forms;
- A signed statement from applicant indicating whether those who have access to or management of controlled substance prescription forms have ever been convicted of a law violation:
- The preprinted address of the prescriber. Prescription forms not in compliance will not be accepted after July 1, 2012; and
- Establishment of the process by which health care providers may obtain approval to access information stored on the Internet regarding the controlled substance history of a patient.

H&SC sections 11165.2 and 11165.3—Added to detail the establishment of the CURES Prescription Drug Monitoring Program (PDMP) for monitoring and assessing fines for violations. Additionally, the theft or loss of prescription forms must be reported immediately (no later than three days) to the CURES/PDMP.

#### SB 431 (Emmerson), Chapter 646, Statutes of 2011 (Board Sponsored)

**B&PC section 4104—Amended** to clarify that a pharmacy must provide to the Board, within 14 days, evidence of theft by or impairment

See Changes in Pharmacy Law, Page 4

#### **Changes in Pharmacy Law**

Continued from Page 3

of a licensee. This section requires a pharmacy, when directed by the Board, to conduct an audit to determine the scope of the drug loss and provide the Board with a certified copy of the audit results within 30 days.

**B&PC** section 4105—Amended to specify the time period (within three business days) for which records shall be provided to the Board when requested by an inspector or other authorized representative of the Board. An extension of time may be requested, but is not to exceed 14 calendar days from the requested date.

**B&PC section 4112—Amended** to prohibit a nonresident pharmacy from allowing a pharmacist, whose license has been revoked in California, to provide pharmacist-related services to Californians.

### SB 514 (Simitian), Chapter 199, Statutes of 2011

H&SC section 11110—Added to make it a violation and infraction, punishable by a fine, to willfully and knowingly provide any drug or compounded mixture that contains dextromethorphan to anyone under 18 years of age in an over-the-counter sale without a prescription. A retail clerk who fails to request age-verification documentation will not be held accountable unless the clerk is a willful participant in an ongoing criminal conspiracy to violate this section.

#### to require entities that sell overthe-counter products containing dextromethorphan to use a cash register with an age-verification feature that directs the retail clerk to request "bona fide evidence of majority and identity," including driver's license or State I.D. card, for

such sales.

**H&SC** section 11111—Added

### SB 850 (Leno) Chapter 714, Statutes of 2011

Civil Code section
56.101—Amended to require an electronic health or medical record system to automatically record and preserve any change or deletion of electronically stored medical information and would require the record to include, among other things, the identity of the person who accessed and changed the medical information and the change that was

SB 943 (Committee on Business, Professions and Economic Development) Chapter 350, Statutes of 2011 (Board Sponsored)

made to the medical information.

B&PC section 4200—Amended to change examination requirements for pharmacist licensure by no longer offering the applicant the option of having passed a written and practical examination given by the Board before December 31, 2003, as a qualifying method. Now the applicant must have passed only the North American Pharmacist Licensure Examination for Pharmacists and the California Practice Standards and Jurisprudence Examination for Pharmacists on or after January 1, 2004.

# AB 507 (Hayashi) Chapter 396, Statutes of 2011

H&SC section 11453—Repealed, relating to employment of a physician by the Department of Justice to interview and examine any patient prescribed controlled substances and to testify at administrative hearings...

H&SC section 124960—Amended to make technical and conforming changes to existing law related to severe chronic intractable pain and to the California Intractable Pain Treatment Act.

**H&SC section 124961—Amended** to revise the Pain Patient's Bill of Rights.

### AB 604 (Skinner) Chapter 744, Statutes of 2011

H&SC sections 121349, 121349.1, 121349.2, and 121349.3—Amended to allow the State Department of Health to authorize certain entities to provide hypodermic needle and syringe exchange services in any location where the department determines that the conditions exist for the rapid spread of HIV, viral hepatitis, or any other potentially deadly or disabling infections that are spread through the sharing of used hypodermic needles and syringes. Such authorization will be for a two-year period unless reauthorized.

**H&SC 121349.3—Added** to require an annual report detailing the status of clean needle and syringe exchange programs of the involved jurisdiction.

### AB 1424 (Perea), Chapter 455, Statutes of 2011

**B&PC** sections 31 and 476—Amended and 494.5—Added to direct state governmental licensing entities (including the Board of Pharmacy) to refuse to issue, reactivate, reinstate, or renew a license and suspend the license if the licensee's name is included on lists, prepared by the State Board of Equalization and/or the State Franchise Board, of the 500 largest tax delinquencies. The complete text of these related sections can be found in the "Other Important Sections of the Business and Professions Code" of the Pharmacy Law 2012. The online pharmacy law book is under "Laws and Regulations" on the Board's Web site, www.pharmacy. ca.gov.

## **Regulation Update**

The following regulation changes to Division 17, Title 16 of the California Code of Regulations are in effect.

### Notice to Consumers and Duty to Consult

**1707.2—Amended** and renamed Duty to Consult. All references to Notice to Consumers was moved to new section 1707.6.

#### **Notice to Consumers**

**1707.6 (New)** [the text of which follows for your convenience]

- (a) In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by a prescription drug consumer, a notice containing the text in subdivision (b). Each pharmacy shall use the standardized poster-sized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval. As an alternative to a printed notice, the pharmacy may also or instead display the notice on a video screen located in a place conspicuous to and readable by prescription drug consumers, so long as: (1) The video screen is at least 24 inches, measured diagonally; (2) The pharmacy utilizes the video image notice provided by the board; (3) The text of the notice remains on the screen for a minimum of 60 seconds; and (4) No more than five minutes elapses between displays of any notice on the screen, as measured between the time that a one-screen notice or the final screen of a multiscreen notice ceases to display and the time that the first or only page of that notice re-displays. The pharmacy may seek approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.
- (b) The notice shall contain the following text:

#### NOTICE TO CONSUMERS

California law requires a pharmacist to speak with you every time you get a new prescription.

**You** have the right to ask for and receive from any pharmacy prescription drug labels in 12-point font.

**Interpreter** services are available to you upon request at no cost.

Before taking your medicine, be sure you know: the name of the medicine and what it does; how and when to take it, for how long, and what to do if you miss a dose; possible side effects and what you should do if they occur; whether the new medicine will work safely with other medicines or supplements; and what foods, drinks, or activities should be avoided while taking the medicine. Ask the pharmacist if you have any questions.

This pharmacy must provide any medicine or device legally prescribed for you, unless it is not covered by your insurance; you are unable to pay the cost of a copayment; or the pharmacist determines doing so would be against the law or potentially harmful to health. If a medicine or device is not immediately available, the pharmacy will work with you to help you get your medicine or device in a timely manner.

**You** may ask this pharmacy for information on drug pricing and use of generic drugs.

(c) Every pharmacy, in a place conspicuous to and readable by a prescription drug consumer, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, shall post or provide a notice containing the following text:

**Point** to your language. Interpreter services will be provided to you upon request at no cost.

This text shall be repeated in at least the following languages: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong,

Korean, Mandarin, Russian, Spanish, Tagalog, and Vietnamese.

Each pharmacy shall use the standardized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

The pharmacy may post this notice in paper form or on a video screen if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she requests assistance. Otherwise, the notice shall be made available on a flyer or handout clearly visible from and kept within easy reach of each counter in the pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the pharmacy is open. The flyer or handout shall be at least 8 1/2 inches by 11 inches.

**Note:** Authority cited: Sections 4005 and 4122, Business and Professions Code. Reference: Sections 733, 4005, 4076.5 and 4122, Business and Professions Code.

## Self-Assessment of a Pharmacy by the Pharmacist-in-Charge

1715 was amended to also require a pharmacy self-assessment be completed within 30 days of a change in the licensed location of a pharmacy to a new address. This section was also amended to modify the name of Form 17M-13 to "Community Pharmacy Self-Assessment / Hospital Outpatient Pharmacy Self-Assessment," to clearly state that the self-assessment applies to both community and hospital outpatient pharmacies, and to note the latest revision date. This component also applies to Form 17M-14, "Hospital Pharmacy Self-Assessment."

#### **Patient-Centered Labeling**

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### 1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements

- (a) Labels on drug containers dispensed to patients in California shall conform to the following format:
  - (1) 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-pooint 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 of the drug, or the generic name and the name of the manufacturer.
    - (C) The directions for the use of the drug.
    - (D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.
  - (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) of 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

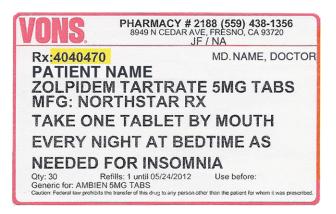
- morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening
- (L) Take 3 [insert appropriate dosage form] in the morning, 3 insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening
- (M) Take 1 [insert appropriate 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. The pharmacy shall, at minimum, 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.

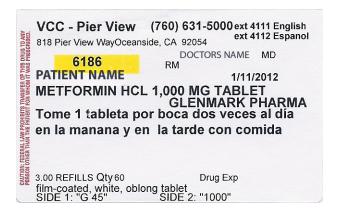
#### **Patient-Centered Labeling**

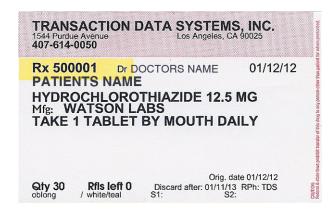
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(f) As used in this section, "appropriate dosage form" includes pill, caplet, capsule or tablet.

Label samples follow:









### **Advisement to Pharmacies:**

#### Translations of Patient-Centered Labeling Directions for Use Available Online

Section 1707.5(a)(4) of the California Code of Regulations lists standardized directions for use when appropriate on prescription container labels. Translations of these directions are available in five other languages and are now online at <a href="http://www.pharmacy.ca.gov/publications/labels\_info.shtml">http://www.pharmacy.ca.gov/publications/labels\_info.shtml</a>.

Also, pharmacies should be aware that during board inspections, prescription labels will be reviewed to ensure their compliance with the new label specifications which took effect January 1, 2011.

#### **Regulation Update**

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Self-Assessment of a Wholesaler by the Designated Representative-in-Charge

1784 was amended to reflect the most recent revision date of Form 17M-26 "Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment" and to update references within the self-assessment form itself.

**Pharmacy Technician Application** 

1793.5 was amended to add a requirement that, as a condition of licensure, a Pharmacy Technician applicant must submit to the Board with his or her application a sealed, original "Self-Query Report" from the National Practitioner Data Bank-Healthcare Integrity and

Protection Data Bank, dated no earlier than 60 days of the date an application is submitted to the Board. The Pharmacy Technician Application instructions provide guidance on how to acquire the required Self-Query Report.

Reference to a requirement to sign a statement relating to whether the applicant has ever been convicted of or pled no contest to a violation of any law of a foreign country, the United States, any state, or local ordinance was removed, as this statement is incorporated in the Pharmacy Technician Application (Form 17M-15).

Additionally, once the application is complete and upon completion of any investigation conducted pursuant to section 4207 of the Business and Professions Code (B&PC), the Board will notify the applicant within 60 days of a license decision.

The application fee is now listed in subdivision (r) of section 4400 of the B&PC.

The complete text of these regulation changes can be viewed on the Board's Web site under Pharmacy Law Book.

# The Pharmacist Scholarship and Loan Repayment Program needs your help

In September 2002, the California Pharmacist Scholarship and Loan Repayment Program (Business and Professions Code section 4409 and Health and Safety Code sections 128198 and 128198.5) was established to provide scholarships to pay for the educational expenses of pharmacy students and to repay qualifying loans of pharmacists who agree to serve in medically underserved areas of the state. Money for the program comes from donations, but appropriations for the program by the Legislature can be implemented only to the extent that sufficient money is available in the fund.

The fund is administered by the Office of Statewide Health Planning and Development, which directs that \$200,000 must be available before scholarship can be provided. Currently there is only \$104,357.06 in the fund, which does not yet accommodate administration of the program. Once the \$200,000 threshold is reached, application forms for scholarship or loan repayment assistance will be available on the Board's Web site.

#### **How Can You Donate?**

Voluntary donations of \$25 to \$35 can be made on pharmacist or pharmacy license renewal applications at the time

of renewal and include that amount in the payment check. When making a donation on a renewal application, it is extremely important to make a check mark in the appropriate box because if the check is written for more than the renewal amount and the box is NOT checked, the excess will be refunded to you.

For donations exceeding \$25, you must <u>indicate in writing</u> somewhere on the renewal form that the excess is intended for the Pharmacist Scholarship and Loan Repayment program, even if the donation box is checked.

Donations for more than \$35 also may be mailed separately (with a note indicating that the money is for the Pharmacist Scholarship and Loan Repayment program) to:

Accounting Department
Office of Statewide Health Planning and Development
(OSHPD)
400 R Street, Suite 359
Sacramento, CA 95811

Your donations are the basis of and critical to this program.

# Failure to Report Change of PIC within 30 days is a Violation of Pharmacy Law

The pharmacist-in-charge (PIC) is the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. That is why it is extremely important to the pharmacy, the PIC, and the Board to have complete information regarding the exact dates that each pharmacy's PIC held the position.

Consequently, failure of any <u>pharmacist</u> to notify the Board in writing that he or she has ceased to act as the PIC of a pharmacy, <u>AND</u> of any <u>pharmacy</u> to notify the Board in writing that a PIC is no longer acting in that capacity, within the 30-day period specified in the Business and Professions Code (B&PC) sections 4101 and 4113, is a violation of the Pharmacy Law (B&PC section 4305).

#### **Pharmacy Notification to the Board:**

Section 4113 of the Business and Professions Code requires every pharmacy to notify the Board in writing of all required information, a fee of \$100 (excluding clinics and government-owned facilities), and a "Certification of Personnel" form for the newly appointed PIC, within 30 days of the date when the current PIC ceases to act in that capacity. The Board provides a form (17A-14), "Change of Pharmacist-in-Charge," for that notification and it is available at <a href="https://www.pharmacy.ca.gov/forms/change\_of\_pic.pdf">www.pharmacy.ca.gov/forms/change\_of\_pic.pdf</a>.

Note: The associating date of the new PIC must not overlap the disassociation date of the former PIC: Two pharmacists cannot be listed as PIC at the same time at the same pharmacy.

#### **Pharmacist:**

A pharmacist who ceases to act as PIC of a pharmacy must notify the Board in writing—there is no form for this—within 30 days of the date of changing status. The notification should include necessary information, such as the:

- pharmacist's name and license number for identification purposes,
- name, license number, and address of the pharmacy from which the pharmacist is disassociating; and
- disassociation date.

Another method of notification allows the pharmacist to report his or her disassociation as PIC by completing the "... pharmacist-in-charge being replaced" section of the same Change of Pharmacist-in-Charge form (Form 17A-14) that the pharmacy has completed for submission to the Board. However, if this method is used, the departing pharmacist must ensure that the pharmacy mails the form in a timely manner—within 30 days of the change of PIC.

# E-Mail Alert Notification Subscribing for Owners/ Companies with Multiple Facilities

Section 4013 of the Business and Professions Code requires any Boardlicensed facility to join the Board's e-mail notification list within 60 days of obtaining a license or at the time of license renewal. This section also allows an owner of two or more facilities to provide only one e-mail address—instead of an address for each individual facility—if the owner maintains an electronic notice system within all of its licensed facilities that, upon receipt of an e-mail notification from the Board, immediately transmits electronic notice of the same information to all of its licensed facilities. The owner of such notification systems must register the electronic notice system with the Board by July 1, 2011, or within 60 days of initial license,



whichever is later. Additionally, the owner is responsible for making changes in any facility's e-mail address on the Board's e-mail notification list within 30 days of the change.

To register a single e-mail address for an owner or company of two or more facilities, go to the Board's Web site, www.pharmacy.ca.gov and:

• Click on the "Sign up to Receive E-Mail Alerts" from the menu on the left side of the page;

- Upon reaching the Board's E-mail notification page, click on "E-Mail Notification from Centralized Owner/Company Form:"
- Download the form, and complete the information, including description of the electronic notice system being used, and license numbers of facilities who will be notified through your electronic notice system; and
- Submit the completed form to the Board as an <u>e-mail attachment</u> to <u>pharmacy.subscriberlist@dca.</u> <u>ca.gov</u>

Do not postal mail the completed form or a copy to the Board.

# Security Breach Notification Requirement

On August 31, 2011, Governor Brown approved Senate Bill 24 (Simitian, Chapter 197), which amends sections 1798.29 and 1798.82 of the Civil Code, relating to personal information breaches. These sections require any person or entity, who conducts business in California and who owns or licenses computerized data that includes personal information, to disclose security breaches to all California residents whose unencrypted personal information has been or reasonably believed to have been acquired by an unauthorized person.

The new law will also require specified content for such security breach notices that are sent to each California resident affected by the breach. One of the amendments to these sections

requires additional action regarding the security breach notification: If the security breach notification is sent to more than 500 California residents, a copy of the notification must be electronically submitted to the Attorney General.

These sections include all security breach notification requirements and can be reviewed at www.pharmacy.ca.gov/laws regs/new laws.pdf.

# **Informational Videos Online**

The Board of Pharmacy Web site now has two Informational Videos for Consumers and a DEA presentation:

- Avoiding Medication Errors—Reminds consumers to consult with their pharmacists and cautions them to be sure they have the right drug, the right drug strength and dosage, and the right name on the medication container.
- 2. Purchasing Drugs from the Internet—Advises consumers that 95 percent of online pharmacies are not operating within the law and provides information for verifying the legitimacy of any pharmacy advertising online
- 3. Issues and Trends Involving Controlled Substances and Prescription Drug Abuse—Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control of the US Drug Enforcement Administration discusses the skyrocketing use of prescription medication as the most abused substances.

By making your patients aware of these educational videos, you can help them to protect themselves from medication



errors and from unlicensed and illegal pharmacies that sell medication that has not been obtained from licensed distributors.

The Board also encourages everyone to also review the DEA presentation that details the rise of

prescription medications to number 1 of the most abused drugs in the US, following marijuana.

# **Changes to Notice to Consumers**

To ensure that patients are aware that they can obtain a prescription label printed in 12 point font, rather than the minimum requirement of 10 point font, changes are required to be made to the Notice to Consumers posters that must be posted in pharmacies. The new posters will inform consumers that their pharmacy will provide, upon request and at no cost to the consumer, interpreter services for those with limited English skills.

It is not the Board's intent to add another poster to the existing two, but to integrate the additional information into one new poster. The new posters should be available sometime in 2012.

The Notice to Consumer requirements and additional methods for displaying the notice are detailed in the California Code of Regulations, section 1707.6, which is included in the "Regulation Update" on Page 5.

# Importance of Your Address of Record

All licensees of Board of Pharmacy are required to provi a proper and current residence address to the Board and to notify the Board within 30



days of changing that address by giving both the old and new address (Title 16 California Code of Regulations section 1704 and Business & Professions Code section 4100). Licensees must designate an "Address of Record" which is the address to which all licenses, license and permit renewals, and correspondence from the Board are mailed. It is also listed on the Board's Web site where it is available to the public.

Because addresses of record are public record by law, those licensees who wish to withhold their residence address from the public may provide a post office box, a personal mailbox number, place of employment, etc. as the address of record as long as the residence address (which would then not be available to the public) is also provided.

Please note that relying on your business address as your address of record has proven problematic in some cases. For example, if you are employed in a large hospital complex with several pharmacies, opportunities for lost personal mail could exist. Also, using a business address as the address of record would require you to change your address with the Board every time you change your place of employment. And which address do you use when you work in more than one pharmacy?

Failing to provide a reliable address does not comply with Pharmacy Law and can result in the renewal notice not being received by the licensee. Failure to renew timely may result in loss of licensure due to nonrenewal and subsequent cancellation of the license.

# **Counterfeit Drug Reporting**

Manufacturers, wholesalers, and pharmacies are reminded that if they have reasonable cause to believe that a counterfeit dangerous drug or a drug that is the subject of a fraudulent transaction is in, or has been in, their possession, they must report to the executive officer of the Board of Pharmacy within 72 hours of obtaining that knowledge (Business and Professions Code section 4034[h]).

# E-Pedigree Requirement Discussions

The Board has resumed quarterly meetings where implementation of

California's e-pedigree requirements will be discussed with pharmacies, wholesalers, manufacturers and others. These discussions will normally take place at Enforcement

Committee Meetings statewide.

The next Enforcement Committee

Meeting will be held on March 21 at the:

Hilton San Francisco Airport

600 Airport Blvd.
Burlingame, CA 94010

Meeting materials will be available at <a href="https://www.pharmacy.ca.gov/about/meetings">www.pharmacy.ca.gov/about/meetings</a>.

shml#enforce 10 days before the meeting. The remaining dates for 2012 are June 12, September 11, and December 4



# Beware of drug transfer dealers that are not California-licensed Wholesalers

Frequently, pharmacies find themselves with near-expired drugs, partially full containers of drugs, and drugs that are rarely dispensed and unlikely to be dispensed in the near future. The pharmacies may return such drugs to the wholesaler they purchased them from or to a reverse distributor, and less frequently to the manufacturer itself. Sometimes a pharmacy may be partially reimbursed for the cost of the drugs or charged a fee for destroying the drugs.

Some California pharmacies, seeking to reduce their inventory of such drugs have become involved with out-of-state companies who solicit membership in their online business, which allows members to post their requests to buy, sell, bid on, or trade unwanted drugs to other members. One such company assures that becoming a member and using their services will increase the pharmacies' profits by 50 percent. However, all

the parties to such transactions may be violating California law if they are not Californialicensed wholesalers and pharmacies. Section 4043 of the Business and Professions Code (B&PC) defines wholesaler as a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler who sells for resale, or negotiates for distribution, or takes possession of any drug requiring a prescription, pursuant to B&PC section 4022. While the online company may not be selling for resale, negotiating for distribution, or taking possession of the drugs being transferred, the company is acting as an agent and is the means by which the transfers occur.

Section 4169 prohibits the purchase, trade, sale, or transfer of dangerous drugs at wholesale to a person or entity that is not licensed by the California Board of Pharmacy as a wholesaler or pharmacy. Section 4119.5(a) allows a pharmacy to transfer a reasonable supply of dangerous drugs to another pharmacy and section 4126.5(a) specifies to whom a pharmacy may furnish dangerous drugs. This includes provision to another pharmacy pursuant to a prescription; to another pharmacy under common control; or to another pharmacy for alleviation of a temporary shortage of a dangerous drug that could result in the denial of health care; and then the pharmacy can transfer only enough to alleviate the temporary shortage.

A transaction example: A California pharmacy buys a quantity of unwanted drugs, through Cheap Drugs (the online membership company) from a Kansas pharmacy:

- The California pharmacy is in violation if the Kansas pharmacy is not licensed as a nonresident pharmacy in California (B&PC sections 4161 and 4169[a][1]).
- Cheap Drugs, who is acting as wholesaler (agent), is in violation if not a California-licensed wholesaler or nonresident wholesaler (B&PC 4043, 4160, 4161).
- The Kansas pharmacy that sends the drugs into California is in violation if not a California-licensed nonresident pharmacy B&PC 4112(b).

Pharmacies that transfer dangerous drugs to other pharmacies outside California shall not transfer, sell or deliver to any person outside this state, unless they are in compliance with California laws, United States laws, and the laws of the state or country to which the dangerous drugs are to be delivered (B&PC 4059.5[e]).

If the lures of greater profits are tempting, before taking action on the temptation, always research pharmacy law to insure the compliance of everyone involved. Disciplinary action may be taken and fines of up to \$5,000 can be assessed for each violation occurrence (e.g., invoice) (B&PC sections 4301[j] and 4126.5[b]).



Do you have a question or an issue that you would like to see addressed in the newsletter? If so, please e-mail them to <a href="https://docs.press.org/">Hope\_Tamraz@dca.ca.gov</a>.

For this issue, the Board seemed to accumulate more inquiries than usual about controlled substance dispensing and refilling dates. Several of the following questions are related to the same issue, but are slightly different.

- Q. For a prescription for Ambien, 10mg @ 30 per month with five refills, is the patient entitled to five refills within 6 months or for only four refills, which would be 120 days?
- A. That prescription cannot be refilled five times. The number of refills allowed is determined by the 120-day supply amount. Section 11200(b) of the Health and Safety Code (H&SC) states, "No prescription for a Schedule III or IV substance may be refilled more than five times and in an amount, for all refills of that prescription taken together, exceeding a 120-day supply."

To determine how many refills can be dispensed, calculate one day's supply for the 30 tablets prescribed—one tablet per day. A prescription for 30 tablets for a 30-day supply can be "refilled" only four times. Four months or 120 days' supply of Ambien at 30 tablets per month allows a total of 120 tablets to be dispensed as refills. The pharmacy cannot dispense the fifth refill because it would exceed the 120 day's supply (5 X 30 =150) for all refills of that prescription. The initial dispensing is not counted as one of the refills.

- Q. Can we dispense five refills of a controlled substance prescription within six months from the original prescription date or only up to 120 days of refills?
- A. The answer to this question is related to the question above. Section 11200(a) of the H&SC provides that (a) controlled substances prescriptions cannot be dispensed or refilled more than six months after the prescription date; and (b) a Schedule III or IV substance may not be refilled more than five times and in an amount, for all refills taken together, not to exceed a 120-day supply. If a Schedule III or IV controlled substance prescription is written with five refills, the number of refills allowed depends on the per day supply of the prescription.

Example 1. A prescription for Vicodin 5mg/500mg for a quantity of 30 is written as a 10-day supply with five refills. The pharmacy may refill all five refills within six months because each refill will be a 10-day supply. Five refills would be a total of 150 tablets or a 50-day supply. Filling all five refills will not exceed the 120-day supply limit. Again, the initial dispensing is not counted as one of the refills.

Example 2. A prescription for Norco 10mg/325mg for a quantity of 120 is written as a 30-day supply with five refills. The pharmacy may dispense only four refills within six months from the date written because each refill will be a 30-day supply. Four refills would be 480 tablets or a 120-day supply. Dispensing the fifth refill would exceed the 120-day supply limit, and the pharmacy would be in violation of H&SC section 11200(b).

Q. What is the time limit on filling Schedule
II prescriptions? One statement in section
1745 of the California Code of Regulations
(CCR) says 60 days, but another section
says six months. Which is correct?

A. Section 1745, of Title 16 of the CCR refers to the partial filling of Schedule II prescriptions when a pharmacist is unable to supply the full quantity ordered by the prescriber for patients who are NOT skilled nursing or terminally ill patients. If the pharmacy

is unable to dispense the full quantity prescribed, a partial amount may be dispensed, and the remaining portion may be filled within 72 hours of the first partial filling. If the remaining portion is not filled within the 72-hour period, the remaining portion can NOT be dispensed, the prescriber must be notified, and a new prescription will be required.

Sections 11200(a) and 11166 of the H&SC prohibit a person from filling a prescription for a controlled substance after six months have elapsed from the date written on the prescription by the prescriber.

- Q. A two-part question regarding errors and omissions in Schedule II prescriptions: 1) What does the pharmacist do if there is no prescriber signature, and 2) What if the date on the prescription has been altered or is missing?
- A. Part 1: Section 11164(a)(1) of the H&SC requires each prescription for controlled substances classified in Schedule II, III, IV, or V to be signed and dated in ink by the prescriber. If the pharmacy receives a Schedule II prescription that is not signed and/or dated by the prescriber,

#### **Rx for Good Practice**

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the prescription must be returned to the prescriber for correction or a new prescription. However, Schedule III, IV, and V controlled substances prescriptions with omissions or errors can be changed after contacting the prescriber. When failure to dispense a prescription for a controlled substance may result in loss of life or intense suffering, a pharmacist may dispense an emergency prescription pursuant to H&SC section 11167 on an oral order, an electronic transmission order, or a written order not made on a controlled substance form, provided that all requirements are followed.

Part 2: If the date on the prescription is missing, refer to the answer in Part 1. If the date is altered, H&SC section 11166 states that no person shall knowingly fill a mutilated or forged or altered prescription for a controlled substance except for the addition of the address of the person for whom the controlled substance prescription is prescribed. Title 16, CCR section 1761 also states that no pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. To determine whether or not to fill a prescription with an altered date, the pharmacist should confer with the prescriber prior to dispensing. The other solution is to have the patient return to the prescriber for a new prescription with a date handwritten by the prescriber or dispense an emergency prescription pursuant to H&SC section 11167 when denial of the controlled substance may result in loss of life or intense suffering.

- Q. I received an electronically printed Schedule II prescription from a hospital, and the date was not handwritten, it was printed electronically. If the issue date is not handwritten, does the patient have to obtain a new prescription, or are we allowed to call the doctor to verify the date?
- A. The date does not have to be handwritten when the prescription forms are generated by a computerized prescription generation system from a hospital or other licensed health care facility (H&SC section 11162.1 [c][4] [B]). Forms for licensed health care facilities, "...that are printed by a computerized prescription generation system may contain the prescriber's name, category of professional licensure, license number, federal controlled registration number, and the date of the prescription."

Additionally, institutional style forms do not require the quantity check-off boxes. If boxes are present on a prescription form, the boxes may be checked off or not, as long as the quantity is entered elsewhere on the form (H&SC section 11162.1[c][4][B]).

- Q. I am confused about the medication description required on labels by section 4076(a)(11)(A) of the Business and Professions Code. Should all labels have color AND shape AND any identification, or is it OK to just have the imprint OR just color and shape? What about OTC containers that don't always have descriptions of the drug?
- A. The prescription label must contain all three: color, shape, and imprint of the drug being dispensed. Please refer to the September 2010 issue of *The Script*, Pages 4, 5, and 6. These pages contain the exact language of section 1707.5, Title 16, of the CCR that details what is required of patient-centered prescription drug container labels. It also displays several label examples that are acceptable. Go to <a href="https://www.pharmacy.ca.gov">www.pharmacy.ca.gov</a> and select "Publications." Then scroll down to where all issues of *The Script* are located.

As for OTCs, your computer system may not have the physical description of the pill, tablet, etc., but the label of any drug dispensed pursuant to a prescription must include a description of the drug. The regulation does not tell you what to do if the computer doesn't include a description, but you are not prohibited from hand writing it or adding an auxiliary label with the description.

- Q. As PIC at my pharmacy, am I responsible for mailing the self-assessment form to the Board?
- A. No. Do NOT mail the pharmacy self-assessment or copies to the Board. You are responsible to ensure that each completed self-assessment form is kept on file at the pharmacy for three years after it is performed (Title 16, CCR 1715[d]).
- Q. What is the Board's policy regarding a pharmacy that forces a pharmacist to give immunization shots? Can a pharmacist be fired if he or she refuses to give immunization shots?
- A. The Board has no policy regarding this subject. Although B&PC section 4052(a)(9) allows pharmacists to administer immunizations pursuant to a protocol with a prescriber, there is no law requiring pharmacists to do so. This is an issue to be addressed with your employer or union advisor.
- Q. If a physician writes a prescription for Dilaudid 8mg qty 20: 1 tab po q6h prn severe pain, can we change it to Dilaudid or Hydromorphone 4mg qty 40: 2 tablets (8mg) po q6h prn severe pain without requesting a revised prescription? We currently have 4mg, not 8mg, in stock. Can we legally change the strength to what we have in stock as well as the quantity so that the dose and total number of doses match with those in the original prescription?

#### **Rx for Good Practice**

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- A. The use of Dilaudid/hydromorphone 4mg in place of Dilaudid 8mg is allowed under B&PC 4052.5. If the change does take place, the patient must be advised. Also, if the generic hydromorphone is used, the patient must be advised of this as well (B&PC 4073[e]).
- Q. If a fax is received for a controlled substance, is an electronic or digital signature of the prescriber sufficient, or do I need to call the prescriber to verify and then treat it as a verbal prescription?
- A. If an image of the prescription is faxed from the prescriber's fax machine to the pharmacy's fax machine, the prescriber's written signature is required. Controlled substances prescriptions cannot be transmitted from a computer to a pharmacy fax or to a pharmacy computer.
- Q. Can a pharmacist dispense a Schedule II prescription written by a physician known by both the pharmacist and the patient to be deceased?
- A. Yes. Since there was a valid physician/patient relationship when the prescription was written, the pharmacist may fill the prescription.
- Q. Is a prescription for Cipro ear drops valid when prescribed by a dentist?
- A. When uncertain about the validity of a prescription, Title 16, CCR section 1761(a) prohibits a pharmacist from compounding or dispensing "...any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration." This law further directs the pharmacist to contact the prescriber to obtain the information needed to validate the prescription.

If after consulting with the prescriber, the pharmacist is still concerned about whether the prescription is written for a drug that appears to be outside the prescriber's scope of practice, he or she should address those concerns with the prescriber's regulatory board.

- Q. What are the rules regarding who needs preprinted prescription blanks to write controlled substance prescriptions? When is it OK to write in or stamp the prescriber's name?
- A. All controlled substance prescriptions must be on tamperproof security prescription blanks (H&SC sections 11162.1 et seq. and 11164), all of which contain preprinted information.

For licensed health care facilities (e.g., hospitals, skilled nursing facility, intermediate care facility), a designated prescriber's name is preprinted, and additional space is provided for the actual prescriber within the facility to write or stamp the required prescriber information.

The rules are too lengthy to include here, but they can be found in the October 2005 issue of *The Script* on Page 13, and samples of tamper-proof prescription blanks can be seen in the January 2005 issue on Pages 16 and 17.

- Q. I have heard other pharmacists declare that without the prescriber's authorization, they would partially refill controlled substance prescriptions only for "heart medications." Is this the law?
- A. No. Section 11201 of the H&SC states that *except for Schedule II*, a prescription for a controlled substance <u>may</u> be refilled by the pharmacist without the prescriber's authorization if the prescriber is unavailable for authorization and if, in the pharmacist's professional judgment, failure to refill the prescription might present an immediate hazard to the patient's health and welfare or might result in intense suffering. The pharmacist is allowed to refill only a reasonable amount sufficient to maintain the patient until the prescriber can be contacted.

# **Identification of APAP and NSAIDs on Container Labels**

This article republishes information from a letter sent to State Boards of Pharmacy by the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research in January 2004 and is intended to raise the awareness of pharmacists about the important educational role that they can play in preventing acetaminophen induced hepatotoxicity and nonsteroidal antiinflammatory drug-related gastrointestinal bleeding and renal toxicity in consumers using these medicines.

The FDA recognizes the pharmacist's important role in educating patients about acetaminophen and nonsteroidal anti-inflammatory drug induced unintentional overdoses, and believes that some of the reasons for such overdoses include the failure of consumers to recognize that various prescription and over-the-counter (OTC) drugs contain the same active ingredients and can be toxic when taken at the same time. Another contributing factor may be that prescription labeling may not clearly identify APAP as acetaminophen and NSAID as containing the same-acting active ingredients, and that the same ingredients are widely available in OTC products.

Some of the reasons for unintentional overdoses include:

- The lack of consumer understanding of the potential adverse consequences of simultaneously taking two different products containing acetaminophen or two different products containing an NSAID.
- Failure of consumers to recognize the potential harm from exceeding the recommended dose of such medications.
- The wide variety of products available both OTC and by prescription that contain acetaminophen or NSAIDs (e.g., combinations, single ingredient, multiple formulations).
- Failure of consumers to recognize the active ingredients in various combination prescription and OTC drug products.
- Container labeling for pharmacy-dispensed prescription products that may not clearly identify acetaminophen or NSAID as one of the active ingredients and the maximum daily dose limit of these products.

These unintentional overdoses remain a serious public health problem, and because the FDA believes that pharmacists are vital in any adverse event prevention effort, the agency encourages them to provide information that ensures that patients and consumers use prescription and OTC pain relievers correctly.

FDA acetaminophen recommendations for pharmacists to consider:

- All prescription drugs containing acetaminophen should be adequately labeled on the container, so that all active ingredients and strengths appear on the prescription label
- Spell out "acetaminophen." Do not use drug name abbreviations, such as APAP for acetaminophen, to avoid consumer confusion.
- Include a statement instructing the patient to avoid concurrent use of any other acetaminophen containing products.
- Include a statement instructing the patient not to exceed the maximum daily recommended dose of acetaminophen.
- Include a statement instructing the patient to avoid alcoholic drinks while using the drug product.

The use of NSAIDs, while taking other drugs that contain ingredients that have the same effect, is the other concern addressed here. Multiple NSAIDs are available OTC (e.g., aspirin, ibuprofen, naproxen) and by prescription (ibuprofen, indomethacin, etc.) Attributable adverse events such as GI bleeding and renal toxicity associated with the use of these drugs are well known. The FDA recommends that pharmacists consider that the labeling for all prescription drug products containing NSAIDs:

- Clearly identify that one of the ingredients in the product is an NSAID.
- Include a statement instructing the patient not to exceed the recommended single and/or daily dose.
- Include a statement instructing the patient to avoid taking any other NSAID containing products (OTC or prescription), or with products containing anticoagulants, corticosteroids, or diuretics.
- Include a statement instructing the patient to avoid alcoholic drinks while using the drug product.

Pharmacists are the first line of defense in educating patients to the dangers of overdoses caused by taking prescription and OTC drugs with the same active ingredients at the same time, and easily understood prescription container labels can be the first step in reducing those overdoses. Pharmacists are encouraged to consider the FDA's recommendations and implement new procedures to accomplish that goal.

### 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.

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

Abramson, Lewis W. Abramson, Robert M. Alfheim, Vernon C. Angres, Fred Applebaum, Paul C. Au, Kenneth B. Beard, Rolland J. Becker, Donald E. Betti, Robert E. Brown, Alan D. Brown, Elwin L. Brown, Julia M. Bukovsky, Joseph F., Jr. Caruso, Robert G. Chan, Edward T. Chung, William Cohen, Sanford Davis, Gerald E. Drum, John S. Faus, Ola B. Fishell, Gerald S. Fishman, Charles B. Frew, Patricia G. Fujita, Barbara Wong Goldstein, Donald B. Govatos, Anthony M Havens, Sarah Catherine Hejlik, Richard R. Hernandez, Albert E. Hill, Bruce J. Hoffman, Joel Honeychurch, Dennis J. Hurych, Richard H. Inouve, Tom Iwamoto, Henry T. Johnson, Michael L.

Jordan, Linda

Sherman Oaks, CA Oxnard, CA Clovis, CA San Diego, CA Whittier, CA Millbrae, CA Delhi, CA Goleta, CA Santa Cruz, CA Los Angeles, CA South Pasadena, CA Bullhead City, AZ St. Charles, IL San Diego, CA Arcata, CA Upland, CA Woodland Hills, CA Los Osos, CA Corona, CA Aptos, CA Yuba City, CA Jackson Heights, NY Sacramento, CA Rancho Palos Verdes, CA Dana Point, CA Nipomo, CA West Covina, CA Modesto, CA Redwood City, CA Antioch, CA Valencia, CA Twain Harte, CA Woodbridge, CA Whittier, CA Los Angeles, CA Fort Lauderdale, FL

Soquel, CA

Juchau, Larry K. Garden Grove, CA Jurach, Anthony M. Karabensh, Jerold K. Kawakami, Menlo Leach, David P. Lee, John Lewis, Stanly M. Long, Harvey G. Longeway, Carole A. Magaudda, John R. Markley, M. C. McDonald, Donald E. Mead, William B. Meier, Steve A. Meshel, Herbert P. Momita, Milton S. Moore, Sylvia A. Newton, Gaylord W. Rappaport, Melvin Reifman, Kenneth S. Reinhardt, Robert W. Roberts, Charles V. Rogers, Rodney J. Schalo, Larry B. Scheid, Douglas T. Schneider, Joseph Seifert, Alex Eugene Shmaeff, Robert T. Shore, Benson R. Sogliuzzo, John Sorrentino, Elettra Spanos, Nickolas, Jr. Stephens, David D. Strear, Irwin Stuart, Jav L. Sugino, Kenneth K. Sullivan, William J. Turley, Micheline Valente, Rudy P. Van Vleck, Forest A., Jr. Vogel, Ralph Walters, Charles Thomas Weiss, Irwin S. Wheeler, William J. Wilkin, Daniel P. Woon, West Zandberg, Charles M.

Sacramento, CA Mendocino, CA San Jose, CA Three Rivers, CA Bakersfield, CA Palos Verdes Estates, CA Riverside, CA Groveland, CA El Cajon, CA Redland, CA Claremont, CA Oak View, CA Long Beach, CA Tucson, AZ Clayton, CA Laguna Beach, CA Temecula, CA Santa Monica, CA San Diego, CA Salinas, CA Minneapolis, MN Sacramento, CA Chico, CA Fresno, CA Los Angeles, CA Stockton, CA Tarzana, CA Indian Wells, CA San Pedro, CA Palm Desert, CA Loci, CA Coachella, CA Rancho Cordova, CA Gridlev, CA Thousand Oaks, CA Piedmont, CA Canoga Park, CA Aptos, CA Novato, CA Woodland Hills, CA Shell Beach, CA Danville, CA Carmel, CA Beverly Hills, CA San Francisco, CA Granada Hills, CA

See Honored 50-year pharmacists, Page 18

#### **Honored 50-year pharmacists**

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Two 50-year pharmacist honorees were welcomed to the July 2011 Board meeting in Sacramento. President Weisser recognized Wayne D. Mallouf, a graduate



Wayne D. Mallouf

of the University of Oklahoma and registered pharmacist since February 10, 1961, and Thomas E. Barnett, who graduated from

the University of Utah and became a registered pharmacist November 1, 1958.

President Weisser presented the 50-year California pharmacist pin to Mr. Barnett, and Mr. Mallouf was presented with the pin by his wife, Jacqueline.



Thomas E. Barnett



John R. Magaudda

At the October 2011 meeting, John R. Magaudda, a graduate of the New England College of Pharmacy in

Boston, MA, was honored and presented with the 50-year pharmacist pin by President Weisser. Mr. Maguadda began his California pharmacy career in 1962 and was employed by Thrifty Drugs for 37 years. Currently, he works part-time at Sharp Hospital and Costco. John added that he had worked in a Massachusetts pharmacy that sold leeches!

At the January 2012 meeting, President Weisser recognized Forest Van Vleck from Novato,



Forest Van Vleck

and Dr. Kajioka presented Mr. Vleck with a 50-year pin. Mr. Van Vleck shared that he began his practice as a pharmacist in Mill Valley, worked with Long's for six years, and was employed as a pharmacy manager for Safeway in Santa Rosa until his retirement.

Bob Betti of Santa Cruz was recognized by President Weisser and presented with the 50-year pin by Dr. Kajioka.



Bob Betti

Mr. Betti, a graduate of the University of Pacific, School of Pharmacy in 1961, was the owner of Escalon Drug in Escalon from 1969 to 2002 and is currently employed as the pharmacy manager at Rite Aid Pharmacy in Santa Cruz.

# **License Renewal Processing Delayed**

A special alert was recently forwarded to all Board E-mail Notification Subscribers advising that the renewal operations of the Department of Consumer Affairs (DCA) had announced a delay of approximately four weeks in the renewal of Board licenses—both individual and site licenses—that expired on January 31 or February 1, 2012. Such delays postpone the issuance of renewal licenses and affect license statuses that can't be updated on the Board's Web site until the renewal application has been processed.

License renewal applications are mailed to licensees approximately ten weeks before the license expiration date. The Board urges licensees to always submit their renewal application, fee, and all required information to the Board as soon as they are received. Any delay in submitting the renewal application or submitting an incomplete or improperly completed renewal application can add significant time to the processing time.

Due to uncertainties in Departmental staffing that can affect renewal of your license, early renewal is the surest way to prevent being caught in a processing delay.

# **Top Four CURES Reporting Errors**

Atlantic Associates, Inc., the CURES data collection vendor, has identified to the Board the four most often occurring reporting errors. Pharmacies are entering:

- 1. Invalid NDC numbers;
- 2. Incorrect NDC codes for compounded formulations: They should be entering the NDC code for the main active ingredient and identifying the prescription as a compounded drug; and
- 3. Invalid prescriber DEA numbers.
- 4. Pharmacies are also failing to enter the Method of Payment: Cash, Medicaid/Medi-Cal, Medicare, Commercial Insurance, Major Medical, or Workman's Compensation.

To ensure proper data collection, those who are responsible for making CURES entries must make every effort to enter valid and accurate information.

# **Reporting Dispensed Federal Schedule Drugs to CURES**

All prescriptions for California Schedule II, III, or IV controlled substances and those defined II, III, or IV under **federal law** in Title 21 of the Code of Federal Regulations, sections 1308.12, 1308.13, and 1308.14, must be reported to CURES weekly to the data collection vendor, Atlantic Associates, Inc. (AAI), using the American Society for Automation in Pharmacy (ASAP) 2009 version 4.1 format. If you are not already registered with AAI, you must do so for

instructions on how to submit data and receive confirmation of the submission.

For information regarding data transmission and/or format, please contact:

Atlantic Associates, Inc. Phone: (800) 539-3370 9:00a.m. to 8:00 p.m. EST E-mail: data@aainh.com

If you have additional questions regarding the CURES program, please visit the Department of Justice Web site at <a href="http://www.ag.ca.gov/bne/cures.php">http://www.ag.ca.gov/bne/cures.php</a>, call the new phone number, (916) 227-3843, or e-mail <a href="mailto:pmp@doj.ca.gov">pmp@doj.ca.gov</a>.

# www.pharmacy.ca.gov

# Real-Time Access to Patients' Controlled Substance Prescription History

The California Department of Justice's Controlled Substance Utilization Review and Evaluation System (CURES) now has a prescription drug monitoring program (PDMP) system which allows pre-registered users to access real-time patient controlled substance history information. Such users include licensed healthcare prescribers eligible to prescribe controlled substances, pharmacists authorized to dispense controlled substances, law enforcement, and regulatory boards.

The CURES database contains over 100 million entries of controlled substance drugs that were dispensed in California. Each year the CURES program responds to more than 60,000 requests from practitioners and pharmacists. The online PDMP system will make it much easier for authorized prescribers and pharmacists to review controlled substances information via the automated patient activity report (PAR) in an effort to identify and deter drug abuse and diversion of California state and federal Schedule II, III, and IV controlled substances. Note: Faxed PARs are no longer accepted.

To obtain access to the PDMP system, prescribers and pharmacists must **first register with PDMP** by clicking on the following link: <u>Department of Justice website</u>.

In addition, your registration must be followed up with a signed copy of your application and notarized copies of your validating documentation which includes: Drug Enforcement

Administration Registration, State Medical License or State Pharmacy License, and a government issued identification. You can mail your application and notarized documents to:

> Bureau of Narcotic Enforcement (BNE) Attn: PDMP Registration P.O. Box 160447 Sacramento, CA 95816

Another option would be to forgo the notary and present your documents in person at any one of the Department of Justice's regional office locations and sworn personnel will validate and collect your supporting documentation.

Dissemination or distribution of PDMP information to anyone other than the registered user is strictly prohibited. Disciplinary, civil or criminal actions may be taken by the Department of Justice and/or appropriate regulatory board for any misuse or inappropriate accessing of patient data.

The Health Insurance Portability and Accountability Act (HIPAA) and all confidentiality and disclosure provisions of California law cover the information contained in this database. All users must comply with HIPAA Privacy Rule Requirements when using the PDMP system. US Department of Health and Human Services, HIPAA guidelines are located at <a href="http://www.hhs.gov/ocr/privacy/index.html">http://www.hhs.gov/ocr/privacy/index.html</a>.

# Another TEAspoon – mL Mix-Up

This article was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyses medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/ Ambulatory Care Edition by visiting www.ismp.org. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at www.ismp. org. ISMP address: 200 Lakeside Dr., Suite 200, Horsham, PA 19044. Phone 215/947-7797. E-mail: ismpinfo@ismp.

A few weeks ago ISMP heard from a mother whose child was accidentally given an overdose of an antibiotic. A pharmacist accidentally provided instructions on the prescription label for the child to receive 3.5 TEAspoonfuls of a liquid antibiotic for 10 days instead of 3.5 mL. The medication was dispensed in a 60 mL bottle. The child was given 3.5 TEAspoonfuls each day for three days. By the fourth day only one TEAspoonful (5 mL) was left in the bottle, so the mother called the pharmacy and learned that the dosage amount on the label was incorrect. The child experienced bouts of diarrhea and a yeast and fungal infection in the vaginal area.

[From the Editor: Another recent TEAspoon - mL mix-up involved a California pharmacist who received an antibiotic suspension prescription with no directions for use. He called the prescriber to obtain the dosing directions which were "4.5 mL twice daily," and he consulted with the father on the directions. A pharmacy clerk subsequently scanned the prescription and produced a drug container label that read "4.5 teaspoonfuls twice daily." A second pharmacist approved the label and furnished the medication to the father. Fortunately, the patient's mother recognized that the dose was too high and contacted the pharmacy—thereby avoiding possibly serious consequences.]

Mix-ups between teaspoons and mL are common and have been happening for many years. ISMP first mentioned the problem in its June 28, 2000, newsletter article, "Oral liquid medications may be more vulnerable to errors than previously recognized"(www.ismp.org/Newsletters/ acutecare/articles/20000628\_2.asp). ISMP has received more than 50 similar errors in recent years, most resulting in patient harm. It is time to standardize to a single way of measuring liquid medications, using the metric system with volumes expressed in mL. If we all used the metric measurement when prescribing, dispensing, and administering medications, these types of mix-ups would no longer happen.

In response to ongoing errors, in June 2009, ISMP called for elimination of

TEAspoonful and other nonmetric measurements

to prevent errors (www.ismp. org/pressroom/PR20090603.pdf). In May 2011, FDA published a guidance suggesting ways for manufacturers to improve the labeling of over-the-counter (OTC) liquid drug products to minimize the risk of accidental overdoses (www.fda. gov/Drugs/DrugSafety/MedicationErrors/ UCM253715.htm). Unfortunately, the guidance still mentions both TEAspoon and TABLEspoon. The Consumer Healthcare Products Association has also published guidelines (www.chpa-info. org/scienceregulatory/Voluntary Codes. aspx#volumetricmeasure) to improve the format for volume measures within the dosing directions for OTC products. The abbreviation "mL" is recommended for use on accompanying dosing devices that measure OTC oral liquid drug products so they match the dosing directions in labeling for children. The group has also told companies to avoid directions that mention tablespoon, cubic centimeters (cc), dram, fluid ounce (Fl Oz), and dropper(ful), and to use mL as the sole unit of measure in the dosing directions or, alternatively, mL and the "TEAspoonful" equivalent (eg, 5 mL (1 TEAspoon)).

While these are excellent moves to improve safety, ISMP would like to see the complete elimination of **TEA**spoonful amounts and the abbreviation "tsp." Doses expressed using mL alone would be the best way to eliminate the risk of mixups. The ISMP board fully supports this initiative and is currently in the process of approving a formal ISMP position on this issue. ISMP hopes the health care industry will also support this initiative.

# Medication Safety Committee releases guidelines on FentaNYL Transdermal Patches and Anticoagulants

The core of the following article was originally printed on August 18, 2011, by the California Society of Health-System Pharmacists. It is re-printed here with permission.

In 2009, the California Hospital Association, in collaboration with the California Society of Health-System Pharmacists (CSHP), the Board of Pharmacy, the California Department of Public Health, and multiple other health care organizations within California, developed a statewide, multi-disciplinary, Medication Safety Committee.

This Committee was formed to provide a forum for diverse health care organizations, which includes health care delivery organizations, patient safety organizations, discipline-specific professional associations/organizations and regulatory agencies, to promote safe medication practices in the state of California. The Committee has focused on acting as a source of medication safety expertise, providing a venue for the coordination of medication safety activities and making recommendations related to medication safety legislation and regulations.

The mission of the Committee is to provide leadership within the health care community to promote the highest standards related to the safe and effective use of medications. To help accomplish the Committee's mission, a Committee workgroup, the High Risk/High Alert (HR/HA) Medication Workgroup, was formed to address different aspects where medication safety is critically needed. The group subsequently created recommendations to increase the safe use of high alert medication, the first product being the FentaNYL patch, the second being anticoagulants.

After reviewing other health care institutions' related policies on FentaNYL patches and subsequent deliberation, the Committee has completed "Best Practice Guideline on FentaNYL Transdermal Patches." These recommendations suggest that the FentaNYL patch should not be used on opiate-naïve patients. More recently the Committee also produced "High Alert Medication Guidelines for Select Anticoagulants."

[Editor: To help reduce FentaNYL patch and anticoagulant-related medication errors in California, and for your convenience, the Medication Safety Committee requests readers to please review the guideline attached above, and provide any feedback by e-mailing medsafety@cshp.org.]

# 2011 Self Assessment Forms Available Online

Pharmacy and wholesaler self-assessment forms have been amended to update citations and references, and make formatting and other changes.

Some of the more substantial changes include:

- Requiring completion of a pharmacy assessment within 30 days whenever there is a change in the licensed location of the pharmacy;
- Modifying the name of Form 17M-13 to "Community Pharmacy Self-Assessment" "Hospital Outpatient Pharmacy Self-Assessment." This change would clearly state that the self-assessment applies to both community and hospital outpatient pharmacies.
- Modifying the signature block for each self-assessment form by adding a place for acknowledgement by the holder of the pharmacy license. This will ensure that the pharmacy license holder has read and reviewed the completed form and acknowledged that failure to correct any deficiency identified in the form(s) could result in the revocation of the license.

The amended forms are available on the Board's Web site under "Publications" and "Applications and Forms."

# New Requirement for Printed Security Prescription Forms



Effective January 1, 2012, security prescription forms for controlled substances must include the preprinted address of the prescriber (Health & Safety Code section 11162.1). Security prescription forms that do not have the preprinted address of the prescriber can be dispensed by the pharmacist until July 1, 2012,

after which date the forms without the prescriber's address will not be valid and cannot be accepted by the pharmacist.

Additionally, licensed health care facilities or clinics exempt under Section 1206 (those having 25 or more licensed physicians or surgeons preprinted on the form) are not required to preprint the category of licensure and license number of their facility or clinic (Health & Safety Code 11162.1[c][2]).

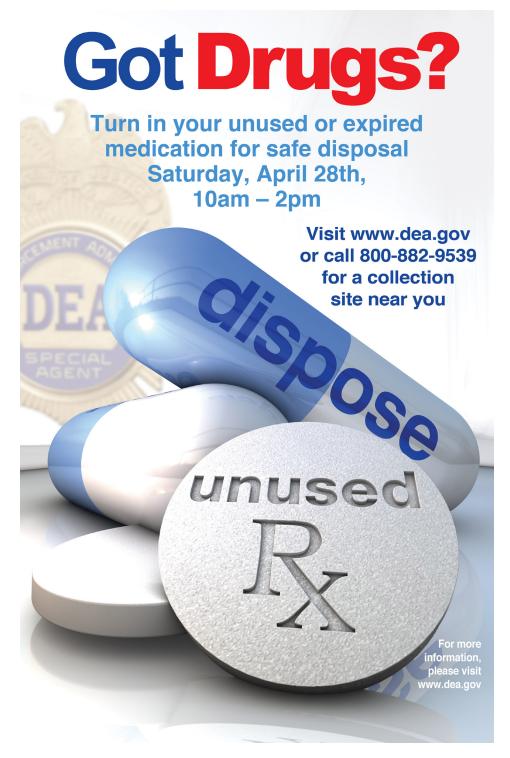
# National Prescription Drug Take-Back Day

The Drug Enforcement Administration (DEA) has scheduled another National Prescription Drug Take-Back Day on Saturday, April 28, 2012, from 10:00 a.m. to 2:00 p.m. This is a great opportunity for consumers to safely dispose of unwanted, unused or expired prescription drugs.

Americans that participated in the DEA's previous prescription take-back event on October 29, 2011, turned in more than 377,086 pounds (188.5 tons) of unwanted or expired medications for safe disposal. When the results of the three prior Take-Back Days are combined, the DEA and its state, local, and tribal lawenforcement, and community partners have removed 995,185 pounds (498.5 tons) of medication in the past 13 months.

It is very important to make consumers aware of this coming event, and for use in your pharmacy, the DEA offers posters, pamphlets, and other items, all in several languages. These can be downloaded by clicking on "Take-Back Day Partnership Toolbox" at <a href="http://www.deadiversion.usdoj.gov/drug\_disposal/takeback/index.html">http://www.deadiversion.usdoj.gov/drug\_disposal/takeback/index.html</a>. (See sample.)

A list of collection site locations will not be available until March, and public inquiries can be directed to 1-800-882-9539 at that time.



### **Verification of Out-of-State Intern Hours**

The California Board of Pharmacy will no longer accept intern hours verifications transferred from other states. Applicants for the California pharmacist licensure examination will now be required to submit proof of their 1,500 hours of intern experience

on the California "Pharmacy Intern Hours Affidavit" (form 17A-29) as part of their licensure examination application. Form 17A-29 can be downloaded at: www.pharmacy.ca.gov/forms/intern\_hours\_affidavit.pdf.

# **Guidelines for Drug Take-Back Programs**

Prescription drug abuse is soaring. Today more people die from prescription drug overdoses than from automobile accidents. Part of the problem may be the availability of unwanted pharmaceuticals in homes and other locations, drugs that need to be discarded and destroyed.

But law has not kept up with the issue nor with consumer demand to provide environmentally appropriate ways to dispose of the medication. Much work remains to be done to develop a strong take-back program for consumers that will protect the environment and not contribute to drug diversion for collection sites.

For the last two years, the federal Drug Enforcement Administration has held twice annual drug take-back days so consumers can dispose of their unwanted medication in environmentally safe ways. The next of these days is April 28 (see article on Page 22), and the collection of controlled substances will be accepted at these specific events.

In 2008, the Board of Pharmacy worked with the then California Integrated Waste Management Board (now CALRecycle) and several other public agencies to develop guidelines for take-back programs for the disposal of prescription drugs that have been dispensed to patients. The guidelines address parameters for both permanent and occasional take-back event collection sites. There is also a mailback component, where the patient can purchase or obtain a preaddressed, postage paid mailer to send unwanted medication through the mail to a licensed waste hauler

A copy of the full approved guidelines can be obtained from the board's Web site at: <a href="www.pharmacy.ca.gov">www.pharmacy.ca.gov</a>. (Note, there are other prior versions of the guidelines available on the CalRecycle Web site—the final version adopted by the Integrated Waste Management Board was approved on February 24, 2009. To get the approved version of the guidelines, make certain you use the link above, and not a search function on the CalRecycle Website.

These guidelines are complex and must be read carefully.)

#### What Can and Cannot Be Collected

- a. Home-generated prescription drugs dispensed to a consumer, or a non-prescription item in the possession of a consumer, such as over-the-counter drugs, vitamins and supplements, and veterinary pharmaceutical waste, may be accepted.
- Sharps in containers approved
   by the local enforcement agency may be accepted at collection sites, but shall <u>NOT</u> be placed in the same containers as the homegenerated pharmaceutical waste.
- c. Medical waste such as human surgery specimens, blood samples, vaccines and serum, trauma scene waste, human surgery specimens, cultures from pathology laboratories, items containing human fluid blood vaccines, and serum shall <u>NOT</u> be accepted.
- d Controlled Substances -Controlled substances cannot be collected by these programs unless a sworn law enforcement officer is onsite to take custody of, document, and dispose of these controlled substances. Controlled substances are a specific category of prescription drugs and are defined as any substance listed in Sections 11053-11058 of the California Health and Safety Code. Some examples of controlled substances include opiates (morphine and codeine), painkillers, muscle relaxants, depressants and stimulants (amphetamines).

#### Signage

Signage must be provided regarding what is acceptable for collection and what is not acceptable (controlled substances,

sharps, garbage, etc.), as well as the hours during which collection is permitted.

Home-generated pharmaceutical wastes are generally classified as household waste and as such can be commingled in containers with other household waste or hazardous waste. However, if home-generated pharmaceutical wastes are mixed with other medical waste or managed as medical waste, the waste shall be segregated for storage in a separate container or secondary container, and that container shall be labeled with the words "INCINERATION ONLY" or other label approved by the California Department of Public Health on the lid and sides, so as to be visible from any lateral direction.

### **How Home-Generated Pharmaceuticals Shall Be Collected**

The consumer, not the pharmacy staff, should empty home-generated pharmaceuticals from their original prescription containers into the secured container at the collection location. Then the consumer will place the empty container into a separate collection bin for proper management.

The pharmacy must ensure that the home-generated pharmaceutical licensed waste hauler or handler transports the home-generated pharmaceuticals for proper destruction. Collected home-generated pharmaceuticals shall not be resold or reused. No individual or collection site shall purchase or offer to purchase home-generated pharmaceutical waste from consumers, nor shall such returned waste be sold, donated, or provided to anyone other than a registered medical or hazardous waste hauler as specified in these procedures.

#### **Storage**

In accordance with Board of Pharmacy specifications, collection sites located in pharmacies shall not commingle pharmaceutical waste with expired, recalled or other quarantined drugs that

See Drug Take-Back Programs, Page 24

#### **Drug Take-Back Programs**

Continued from Page 23

have never been dispensed. Collected home-generated pharmaceuticals may only be stored in the secure sealed containers or in the custody of law enforcement. Once collected, home-generated pharmaceutical waste may be stored at an onsite location for not longer than 90 days when the container is ready for disposal. In certain circumstances, additional storage time may be obtained with prior written approval from the enforcement agency or the California Department of Public Health.

#### **Container Security**

It is the responsibility of the pharmacy overseeing the collection location to provide for the security of the collected home-generated pharmaceuticals. The home-generated pharmaceutical waste must be deposited into secured containers to prevent diversion and theft opportunities and not allow staff at the pharmacy overseeing the program from having access to the contents. Containers at permanent locations such as pharmacies shall be locked and stored in an area that is either locked or under direct supervision or surveillance. The collection device must be within the physical plant of a pharmacy, so that it can only be accessed during operating hours.

Bins located at pharmacies shall have a two-key security system—one in the possession of the pharmacy's designated responsible person and the other in the possession of the licensed waste hauler who will pick up the contents for appropriate destruction. Containers may be stored in the following manner—a lockable cage on the container, lockable collection bins or kiosks, or lockable closets. Intermediate storage areas shall be marked with the international biohazardous symbol. These warning signs shall be readily legible from a distance of five feet.

Home-generated pharmaceutical waste may not be removed from a collection device and stored in a pharmacy, medical office or any other location. Instead, once the

pharmaceuticals are removed by the waste hauler, they must be taken by the hauler. When a collection device becomes full, no more pharmaceutical waste can be accepted from consumers at the collection site until a waste hauler has removed the pharmaceutical waste and re-stocked the collection device with an empty container. Any theft of or loss from the collected home-generated pharmaceutical shall be reported within 24 hours to the local police department, California Department of Public Health, California State Board of Pharmacy, and other agencies that have authorized the collection program.

#### Record Keeping

Detailed information and invoices about each pick up from a home-generated pharmaceutical collection site shall be retained in a log by the collection site for three years after the life of the collection device and readily retrievable at the request of a government enforcement agency. Each collection location must keep a log specific to that collection device and contain:

- The name, address, phone number, and title of the collection site person authorized for the collection device;
- The address, phone number, and location number where device is located:
- The date the collection device was installed at the location;
- The dates for every opening of the device and purpose of opening;
- The names of the two persons that accessed the device (one column for collection site's personnel and one column for the medical or hazardous waste hauler;
- The weight of home-generated pharmaceutical waste removed from the device:
- Additional columns for the final disposition of the drugs and other security measures implemented to prevent unauthorized removals from the device; and
- The name, address, and

registration number of the waste hauler taking the drugs.

In late 2009, the Board of Pharmacy adopted the policy that if a pharmacy wishes to establish a prescription drug take back program, the collection should comply with the guidelines excerpted below. Before instituting a homegenerated take-back program, be familiar with all the components in the guidelines above.

# CE hours are awarded for attending one day of a Pharmacy Board or Board Committee meeting

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).

**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. Recertification is NOT a requirement of the California State Board of Pharmacy for pharmacy technician license renewal.

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 to strengthen 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 information to improve 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, and sign out when they leave.

The remaining Board meeting dates and locations for 2012 are:

May 1-2 Loma Linda

July 17-18 Sacramento

October 24-25 San Diego

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, 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.

# Letter from a Disciplined PIC

As part of the probation terms and conditions of his stipulated disciplinary settlement, PIC Robert John Payne submitted to the Board for publication a cautionary letter addressing the actions for which he was disciplined: (1) Allowing the illegal furnishing of bulk dangerous drugs and controlled substances without a required Board of Pharmacy wholesaler license; (2) allowing the furnishing of dangerous drugs to non-Board approved entities; and (3) failing to maintain appropriate security against the theft or diversion of dangerous drugs.

For space and clarity considerations, RPH Payne has given the Board of Pharmacy permission to publish an edited version of his original letter. Omissions from the original are shown with asterisks (\*) or ellipses (...) Additions or alterations to the original text are surrounded by [brackets].

#### To Whom It May Concern:

I am writing this letter with the hope that pharmacists accepting Pharmacist-in-Charge positions can learn from my experience and avoid potential disciplinary action by the board and avoid negatively impacting the pharmacy profession. From 12/2004 through 3/2007 I was the Pharmacy Director and the Pharmacist in Charge (PIC) for Sacramento County and the Primary Care Center Pharmacy. We provided controlled substances and dangerous drugs to county correctional facilities and multiple clinics. During that time I placed at risk patient care, community safety, and trust in and reputation of the pharmacy profession and all pharmacists.

\* \* \*

The pharmacy [that I oversaw] furnished "floor stock" medications to clinics and correctional facilities without a prescription. ...
The pharmacy sold, transferred and delivered dangerous drugs to clinics and correctional facilities not licensed by the board. ...
[thereby also] acting as a wholesaler without a license. ... During my term as PIC I failed to use appropriate judgment by allowing illegal selling of bulk controlled drugs and dangerous drugs to continue. ... I failed to maintain appropriate security against theft or diversion of dangerous drugs. During the time period March 2005 through February 2008 there was theft of approximately 216,000 hydrocodone/acetaminophen 10/325 tablets from the pharmacy. ... My unprofessional conduct created real and potential negative impacts on patient care, pharmacy operations, community safety, the pharmacy profession and pharmacists.

Provision of floor stock medications to clinics bypasses a very important pharmacist review of drug therapy prior to start of a new therapy. This is a patient safety issue and should be mandatory in any pharmaceutical system. Even though we were providing "starter packs" for patients that could not get to the pharmacy, this is not acceptable without pharmacist review prior to initiating new therapy. Additionally we could not assure that communication to the pharmacy would be complete and all prescriptions dispensed at the clinic would be communicated to the pharmacy. Missing medications in the prescription record is very dangerous for the patient.

Pharmacy operations were negatively impacted by retroactive entry into the prescription record, and retrospective review of prescription records. Our patient population was difficult and time-consuming to contact or locate if a pharmacist needed to contact about medications they had already received. Inventory control in the pharmacy was difficult to manage and automated inventory was not possible because of the floor stock being taken out of the warehouse and delivered to clinics without notification of the dispensing personnel. The lack of security and the diversion of large quantities of controlled substances placed the local community at risk as a contributory drug abuse source, in addition the risk of violence that accompanies these activities.

Pharmacy has been one of the most trusted professions and the publicity around this board action definitely has the possibility of reducing the trust in the profession. Trust is the foundation necessary for the provision of optimum pharmaceutical care. As trust declines in the profession, a pharmacist's capability to provide maximum care may be hampered.

There has been negative impact on my license. My Pharmacist license was revoked, stayed, suspended for 60 days and placed on probation for 5 years. My flexibility in employment is somewhat restricted. My conduct also placed the County' pharmacy license in jeopardy. I am thankful that I continue to practice pharmacy and will use this experience in a positive manner. I will explain below in PIC Roles and Duties how I could have avoided this whole situation.

#### **PIC Roles and Duties**

Section 4113(b) of the Code states the **Pharmacist-In-Charge shall be responsible** for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. At the county I concentrated my energies on what I considered

#### **Letter from a Disciplined PIC**

Continued from Page 26

to be "patient care issues". I chose to let other processes continue on as they were. What I've discovered is that for the PIC, patient care issues have to take in consideration laws and regulations of pharmacy. I also learned that letting old processes continue hampered patient care. And it would have been so easy to fix this system when I first began.

First, licensing all the clinics with the board would have allowed delivery of medications to automated dispensing machines, which would utilize a pharmacist's review of prescription and authorization before release to the patient at the clinic. It would also have allowed legal delivery of prescriptions to the clinics for patient pickup.

To maintain centralized purchasing for the clinics, I could have pursued a wholesaler permit allowing shipment of non-prescribed medications to the clinics. This might have been necessary for provision of floor stock medications to the public health clinics where patients walk in and may be given a one-time medication treatment.

Dangerous drugs and controlled substance use in the correctional facilities would have been best handled by creating space for a pharmacy in the jails, with all drug distribution being managed by that pharmacy. I should have insisted on this change. Controlled substance floor stock with appropriate security and accountability could have been pursued with the board. Second option would have been to pursue licensing options with board allowing their own purchasing of drugs without having a pharmacy.

Security of the pharmacy was by electronic monitoring. Pharmacists had an alarm pass code, which they had to use to open the pharmacy. After there was a pharmacist signed to the pharmacy, swipe cards would open the doors for access by other pharmacy staff. Tightening of the authorizations and installation of a video surveillance system in a pharmacy this size would have been appropriate and should have been done. For controlled substances control systems need to be in place. I have used perpetual inventories in facilities before, but in this case comparing controlled prescription log to purchases weekly would have identified drug theft and lead to early resolution.

#### Summary

I have learned a great deal from this unfortunate and completely avoidable mishap. A PIC has a huge responsibility. Providing appropriate patient care includes setting your patient care within the parameters of pharmacy law and regulations. I am being disciplined for unprofessional conduct, using poor professional judgment. Let my story be a learning experience for PICs or those that may become a PIC in the future. When becoming a PIC and during periodic review, make sure that you not only complete your self-assessment, but also evaluate your pharmacy for special services rendered, customers served, and laws and regulations relative to those services. If you discover problem areas, fix them. Ignoring a problem does not fix it, it only makes it worse. Pharmacy is a great profession, but always remember you are not in it alone. Your actions, and inactions, reflect on pharmacy and your fellow pharmacists. I am very disappointed in myself for the negative impacts of my poor judgment. I apologize to my fellow pharmacists and I will work hard to build and maintain trust in the profession.

Professionally,

Robert John Payne, R.Ph. RPH 26146

[Edit: The PIC is charged with the responsibility of ensuring that his or her pharmacy is in compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.]

www.pharmacy.ca.gov

## **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 or Reproval**—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**

The following licenses were disciplined through actions taken by the Board and previously unpublished from June 22, 2011, to 12/23/2011. 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."

Information on a specific licensee can be obtained by selecting "Verify a License" from the Quick Hits menu. After entering the licensee name or license number and the licensee information appears, click on the red underlined licensee name to search for any disciplinary actions against the license.

#### **Pharmacist Licenses**

**Al'Ghabra, Maher I.,** RPH 44421, San Diego, CA—Case 3433

By Stipulated Settlement, license subject to Public Reproval and licensee must successfully complete an approved ethics course and complete 15 hours of remedial pharmacist education before next license renewal.

Decision effective 12/21/2011 **Bereliani, Tooraj**, RPH 51817, Encino, CA—Case 3251

By Stipulated Settlement, license was revoked, stayed and placed on five years' probation, subject to terms and conditions that include but not limited to: 100 days' suspension from practicing; cannot supervise any intern pharmacist or perform preceptor duties; cannot be pharmacist-in-charge; no new ownership of any Board-licensed entity; and must successfully complete an approved ethics course. Decision effective 12/21/2011

**Beswick, Jack Keates**, RPH 27135, Visalia, CA—Case 3420

By Stipulated Settlement, license was revoked, stayed and placed on five years' probation, subject to terms and conditions that include but not limited to: no additional ownership of any Board-licensed entity; and may act as pharmacist-in-charge with a consultant.

Decision effective 08/19/2011

Dore, John Paul, RPH 51348,

San Francisco, CA—Case 3879
By Default Decision, license was revoked.

Decision effective 11/23/2011

**Edginton, Michael Thomas,** RPH 27137, Napa, CA—Case 3604

By Default Decision, license was revoked, revocation stayed, and

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license placed on three years' probation, which includes being prohibited from supervising any intern pharmacist or functioning as pharmacist-in-charge for two years. Decision effective 10/27/2011

Ha, Giang L., RPH 57897,

Upland, CA—Case 3593

By Stipulated Settlement, license was revoked, stayed and placed on five years' probation, subject to terms and conditions that include but not limited to: 60 days' suspension from practicing; no ownership of any Board-licensed entity; cannot supervise any intern or perform preceptor duties; cannot act as pharmacist-in-charge; and must successfully complete an approved ethics course.

Decision effective 08/19/2011

Harwood, Megan Brigid, RPH 60791, Hollywood, CA—Case 3526

> By Stipulated Settlement, license revoked, revocation stayed, and license placed on three years' probation subject to terms and conditions that include but not limited to: cannot supervise any intern pharmacist; perform preceptor duties; or be pharmacist-in-charge.

Decision effective 11/23/2011

Kerley, Robert Garlin, RPH 26099,

Porterville, CA—Case 3841

By Default Decision, license was revoked.

Decision effective 06/22/2011

Kim, Yeon Hyang, RPH 44940,

Cupertino, CA—Case 3853

By Stipulated Settlement, license was revoked, stayed and placed on three years' probation, subject to terms and conditions that include but not limited to: may be pharmacist-in-charge with consultant; and must successfully complete an approved ethics course. Decision effective 11/23/2011

Lee, Daniel Inbong, RPH 42633,

Poway, CA—Case 3761

By Stipulated Surrender, license was voluntarily surrendered.

Decision effective 10/19/2100

Mantese, Gary Victor, RPH 47841,

Coalinga, CA—Case 3890

By Stipulated Settlement, license

was revoked, stayed and placed on three years' probation, subject to terms and conditions that include but not limited to: cannot supervise any intern pharmacist; perform preceptor duties or be pharmacist-incharge; no ownership of any Boardlicensed entity; and practice must be supervised.

Decision effective 09/05/2011

McKillip, Brian, RPH 32896,

San Diego, CA—Case 3423

By Stipulated Settlement, license was revoked, stayed and placed on five years' probation, subject to terms and conditions that include but not limited to: 90 days' suspension from practicing; may be pharmacist-incharge with a consultant; and must successfully complete an approved ethics course.

Decision effective 06/22/2011

Montag, Steven R., RPH 59622,

San Diego, CA—Case 3803

By Stipulated Settlement, license was revoked, stayed and placed on four years' probation, subject to terms and conditions that include but not limited to: practice must be supervised; and cannot own any Board-licensed

Decision effective 08/19/2011

Nguyen, Nga Tan, RPH 43814,

South Gate, CA—Case 3335

By Stipulated Settlement, license was revoked, stayed and placed on five years' probation, subject to terms and conditions that include but not limited to: no additional ownership of any Board-licensed entity; and may be pharmacist-in-charge with a consultant.

Decision effective 08/19/2011

Nguyen, Nguyen Khoi, RPH 57940,

Placentia, CA—Case 3714

By Stipulated Settlement, license was revoked, stayed and placed on two years' probation, subject to terms and conditions that include but not limited to: cannot supervise any intern pharmacist or perform preceptor duties or be pharmacist-in-charge; and no ownership of any Boardlicensed entity.

Decision effective 11/17/2011

Otis, Stephen Mason, RPH 62442,

Frisco, CO—Case 3536

By Decision after a hearing before an Administrative Law Judge, license was revoked.

Decision effective 09/15/2011

Raber, Stephen, RPH 39275,

Saginaw, MI—Case 3968

By Default Decision, license was revoked.

Decision effective 09/15/2011

Reel, Richard Allyn, RPH 37626,

Chula Vista, CA—Case 3885

By Default Decision, license was revoked.

Decision effective 06/22/2011

Reynolds, Linda Marie, RPH 37729,

West Sacramento, CA—Case 3716

By Stipulated Settlement, license was revoked.

Decision effective 12/21/2011

Rozema, Brian Thomas, RPH 43402,

Salinas, CA—Case 3751

By Stipulated Settlement, license was revoked, stayed and placed on five years' probation, subject to terms and conditions that include but not limited to: practice must be supervised; cannot supervise any intern pharmacist or perform preceptor duties; cannot act as pharmacist-incharge; no ownership of any Boardlicensed entity; and must successfully complete an approved ethics course.

Decision effective 10/27/2011

Sabastina, Gary, RPH 36143,

Kings Beach, CA—Case 3767

By Stipulated Settlement, license was revoked, stayed and placed on five years' probation, subject to terms and conditions that include but not limited to: cannot supervise any intern pharmacist or perform preceptor duties; cannot act as pharmacist-incharge; practice must be supervised; no ownership of any Board-licensed entity; and must successfully complete an approved ethics course. Decision effective 06/22/2011

Sawyer, Charles Arthur, RPH 26997,

Fresno, CA—Case 4027

By Stipulated Settlement, license was voluntarily surrendered.

Decision effective 12/21/2011

Continued from Page 29

Schaefer, Mark Allen, RPH 32265,

Los Angeles, CA—Case 3645

By Stipulated Settlement, license was revoked, stayed and placed on three years' probation, subject to terms and conditions that include but not limited to: cannot supervise any intern or perform preceptor duties; cannot act as pharmacist-in-charge; practice must be supervised; no ownership of any Board-licensed entity; and must successfully complete an approved ethics course.

Decision effective 06/22/2011

Stocker, John, RPH 46011,

Cabazon, CA—Case 3753

By Default Decision, license was revoked.

Decision effective 10/27/2011

**Toney, Dennis Steven**, RPH 35784, Eureka, CA—Case 3206

By Stipulated Settlement, license was revoked, stayed and placed on four years' probation, subject to terms and conditions that include but not limited to: cannot supervise any intern or perform preceptor duties; cannot act as pharmacist-in-charge; practice must be supervised; no ownership of any Board-licensed entity; and must successfully complete an approved ethics course.

Decision effective 06/22/2011

**Tran, Elizabeth Duc**, RPH 48237, Fountain Valley, CA—Case 3125

By Stipulated Surrender of License, license was voluntarily surrendered. Decision effective 12/21/2011

Willey, Grant Arthur, RPH 38872,

Rancho Cucamonga, CA—Case 3888

By Stipulated Settlement, license was revoked, stayed and placed on four years' probation, subject to terms and conditions that include but not limited to: cannot supervise any intern pharmacist, perform preceptor duties or act as pharmacist-in-charge; practice must be supervised; and no ownership of any Board-licensed entity.

Decision effective 11/23/2011

**Yered, Louis Joseph Jr.**, RPH 37006, Camarillo, CA—Case 3506

By Stipulated Settlement, license was revoked, stayed and placed on

three years' probation, subject to terms and conditions that include but not limited to: cannot supervise any intern pharmacist, perform preceptor duties or act as pharmacist-in-charge; practice must be supervised; and must successfully complete an approved ethics course.

Decision effective 12/21/2011

Zenuni, Jemal, RPH 57261,

San Diego, CA—Case 3749

By Default Decision, license was revoked.

Decision effective 11/17/2011

#### **Pharmacist Technicians and Intern**

Acosta, Patricia Estella, TCH 4497,

Gardena, CA—Case 3578

By Stipulated Surrender of License, license was surrendered.

Decision effective 10/19/2011

Aispuro, Nestor Sicaibos, TCH 90528,

Los Angeles, CA—Case 3514

By Default Decision, license was revoked.

Decision effective 06/22/2011

Aldana, Claudia, TCH 75109,

San Fernando, CA—Case 3354

By Default Decision, license was revoked.

Decision effective 09/15/2011

Alipio, Jojo Rosario, TCH 72334,

Brentwood, CA—Case 3835

By Default Decision, license was revoked

Decision effective 07/27/2011

Allen, Holly Lynn, TCH 15233,

Joshua Tree, CA—Case 3586

By Stipulated Settlement, license was revoked, stayed and placed on four years' probation, subject to but not limited to: must pass the Pharmacy Technician Certification Board Exam; no ownership of any Board licensed entity; needs a worksite monitor, and no ownership of a Board-licensed premises..

Decision effective 09/15/2011

Allen, Karen, TCH 28779,

Winnetka, CA—Case 3831

By Default Decision, license was revoked.

Decision effective 12/02/2011

Alonzo, Sebastion,

Pharmacy Technician applicant,

Mentone, CA—Case SI 3726

By Decision after a hearing before an Administrative Law Judge, license was denied.

Decision effective 10/27/2011

Astorga, Rachel, TCH 69636,

San Diego, CA—Case 3993

By Stipulated Settlement, license was voluntarily surrendered.

Decision effective 12/21/2011

Anckle, Jennifer, TCH 64312,

Compton, CA—Case 3702

By Default Decision, license was revoked.

Decision effective 06/22/2011

Anderson, John, TCH 37186,

Paramount, CA—Case 3848

By Default Decision, license was revoked.

Decision effective 09/23/2011

Anderson, Kerstin Lynn, TCH 2327,

La Quinta, CA—Case 3766

By Decision after a hearing before an Administrative Law Judge, license revoked, stayed, and placed on three years' probation, subject to but not limited to: no ownership of a Board-licensed entity and must have worksite monitor.

Decision effective 10/19/2011

Anselmo, Azul M., TCH 75317,

Daly City, CA—Case 3720

By Default Decision, license was revoked.

Decision effective 06/22/2011

Armenta, Lorena, TCH 106294,

Escondido, CA—Case 4006

By Default Decision, license was revoked.

Decision effective 09/21/2011

Baker, Andrew, TCH 67940,

Riverside, CA—Case 4066

By Default Decision, license was revoked.

Decision effective 11/23/2011

Basallo, Marc Anthony, TCH 46875,

San Dimas, CA—Case 3259

By Decision after a hearing before an Administrative Law Judge, license was revoked.

Decision effective 10/27/2011

Blakeman, Debra, TCH 1184,

Bloomington, CA—Case 3916

Continued from Page 30

By Stipulated Surrender, license was surrendered.

Decision effective 11/23/2011

Briceno, Juan Carlos, TCH 68987,

Los Angeles, CA—Case 3701

By Default Decision, license was revoked.

Decision effective 10/12/2011

Brooks, Maurice Andre, TCH 93197,

Stockton, CA—Case 3814

By Default Decision, license was revoked.

Decision effective 10/19/2011

Carpio, Patricia Ann, TCH 3520,

Lancaster, CA—Case 3933

By Default Decision, license was revoked.

Decision effective 06/22/2011

#### Castiel, Michael,

Pharmacy Technician applicant,

Thousand Oaks, CA—Case SI 3719

By Decision after a hearing before an Administrative Law Judge, license was denied.

Decision effective 10/27/2011

#### Cessna, Mark, TCH 57069,

Alhambra, CA—Case 3591

By Stipulated Surrender, license was voluntarily surrendered.

Decision effective 08/19/2011

#### Cetrone, Amy Marie, TCH 54565,

San Diego, CA-Case 3511

By Default Decision, license was revoked.

Decision effective 12/21/2011

#### Chavez, Miguel A., TCH 65899,

Orange, CA—Case 3788

By Default Decision, license was revoked.

Decision effective 06/22/2011

#### Cruz, Carlos, TCH 93734,

Indio, CA—Case 3938

By Default Decision, license was revoked.

Decision effective 09/15/2011

#### Delacruz, Raquel, TCH 62221,

Anaheim, CA—Case 3563

By Default Decision, license was revoked.

Decision effective 11/23/2011

#### DeLeon, Allan Diaz, TCH 94059,

San Diego, CA—Case SI 3995
By Stipulated Settlement, license
was issued, immediately revoked,
revocation stayed and placed on five

years' probation, which includes but is not limited to passing the Pharmacy Technician Certification Examination and no ownership of a Board-licensed entity.

Decision effective 10/19/2011

#### Dember, Susan K., TCH 93567,

Fullerton, CA—Case SI 3842

By Stipulated Settlement, application for license was granted. Upon satisfaction of all statutory and regulatory requirements, a license was issued, immediately revoked, stayed and placed on two years' probation, subject to terms and conditions that include but not limited to: passing the Pharmacy Technician Certification Board exam; and no ownership of any Board-licensed entity.

Decision effective 11/23/2011

#### Deollas, Wilfredo, TCH 63786,

Sacramento, CA—Case 3674

By Decision after a hearing before an Administrative Law Judge, license was revoked.

Decision effective 06/22/2011

#### Dianand, Johann Regindin,

Pharmacy Technician applicant,

Santa Clara, CA—Case SI 3772

By Decision after a hearing before an Administrative Law Judge, license was denied.

Decision effective 06/22/2011

#### Digardi, Jenny, TCH 44640,

Kelseyville, CA—Case 3759

By Default Decision, license was revoked.

Decision effective 11/23/2011

#### Elix, Mark Jon, TCH 71805,

Temecula, CA—Case 3935

By Default Decision, license was revoked.

Decision effective 06/22/2011

#### Faraj, Christopher, TCH 51762,

Pasadena, CA—Case 3812

By Default Decision, license was revoked.

Decision effective 09/15/2011

#### Flores, Juan, TCH 62816,

Pacoima, CA—Case 3668

By Default Decision, license was revoked.

Decision effective 11/23/2011

Folmar, Kenneth Roger, TCH 8785,

Spring Valley, CA—Case 3693

By Decision after a hearing before an Administrative Law Judge, accusation was dismissed.

Decision effective 11/17/2011

#### Forrest, Krista Lynn, TCH 12072,

Oceano, CA—Case 3676

By Stipulated Surrender, license was voluntarily surrendered.

Decision effective 07/27/2011

#### Garcia, Wendy, TCH 91004,

Los Angeles, CA—Case 4004

By Default Decision, license w

By Default Decision, license was revoked.

Decision effective 12/21/2011

#### Gutierrez, Osvaldo, TCH 97983,

East Palo Alto, CA—Case 4061

By Default Decision, license was revoked.

Decision effective 11/23/2011

#### Ghazarian, Sevak, TCH 76239,

Glendale, CA—Case 3852

By Stipulated Surrender, license was voluntarily surrendered.

Decision effective 09/15/2011

#### Gonzalez, Marty Joseph, TCH 23010,

Wildomar, CA—Case 3508

By Stipulated Surrender, license was voluntarily surrendered.

Decision effective 08/19/2011

#### Grundy, Jennifer Robin, TCH 13364,

Corning, CA—Case 3525

By Stipulated Settlement, license was revoked, stayed and placed on five years' probation, subject to but not limited to: must pass the Pharmacy Technician Certification Board Exam; no ownership of any Board licensed entity; and needs a worksite monitor. Decision effective 07/27/2011

#### Harry, Mark Jason, TCH 84312,

Riverside, CA—Case 3978

By Default Decision, license was revoked.

Decision effective 09/23/2011

#### Highsmith, Brian D., TCH 64644,

El Sobrante, CA—Case 3871

By Decision after a hearing before an Administrative Law Judge, license was revoked.

Decision effective 10/27/2011

#### Ide, Sarah Jean, TCH 66657,

Murrieta, CA—Case 3692

By Board Decision, license was

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revoked, stayed and placed on five years' probation, subject to terms and conditions that include but not limited to passing the Pharmacy Technician Certification Board Exam.

Decision effective 09/07/2011

Jackson, Joannea, TCH 54730,

San Diego, CA—Case 3711

By Decision after a hearing before an Administrative Law Judge, license was revoked.

Decision effective 07/27/2011

Jones, Cedric Gerard, II, TCH 70464, Vallejo, CA—Case 3610

By Stipulated Settlement, license was revoked, stayed and placed on four years' probation, subject to terms and conditions that include but not limited to: must have worksite monitor; no ownership of any Board-licensed entity; and must pass the Pharmacy Technician Certification Board Exam. Decision effective 06/22/2011

Jumper, Kikilynn, TCH 68444,

Chula Vista, CA—Case 3899

By Default Decision, license was revoked.

Decision effective 06/22/2011

#### Khan, Mohammad A.,

Pharmacy Technician applicant, Live Oak, CA—Case SI 3622

By Decision after a hearing before an Administrative Law Judge, license was denied.

Decision effective 07/27/2011

Kim, Carolyn J., TCH 98945,

Buena Park, CA—Case 3957

By Stipulated Settlement, license was revoked.

Decision effective 11/17/2011

#### Kim, Silvia Soo, TCH 77294,

Irvine, CA—Case 3951

By Stipulated Settlement, license revoked, stayed and placed on four years' probation, subject to terms and conditions that include but not limited to: must have worksite monitor; no ownership of any Board-licensed entity; and must pass the Pharmacy Technician Certification Board Exam. Decision effective 10/19/2011

#### Koutroulis, Anthony Adani, TCH 90111,

Aliso Viejo, CA—Case 3907

By Stipulated Surrender, license was voluntarily surrendered.

Decision effective 11/23/2011

**La Mott, Rosanne Marie**, TCH 33869, Pomona, CA—Case 3552

By Decision after a hearing before an Administrative Law Judge, license was revoked.

Decision effective 11/17/2011

#### Lee, Bryan, TCH 44694,

Madera, CA—Case 3648

By Decision after a hearing before an Administrative Law Judge, license was revoked, stayed and placed on three years' probation, subject to terms and conditions that include but not limited to passing the Pharmacy Technician Certification Board Exam. Decision effective 06/22/2011

#### Likens, Dustin Matthew, TCH 83670,

Oceanside, CA—Case 3855

By Default Decision, license was revoked.

Decision effective 11/30/2011

#### Lomeli, Eulalio J., TCH 94369,

Ontario, CA—Case SI 3739

By Stipulated Settlement, application for license was granted. Upon satisfaction of all statutory and regulatory requirements, a license was issued, immediately revoked, stayed and placed on four years' probation, subject to terms and conditions that include but not limited to: passing the Pharmacy Technician Certification Board Examination; no ownership of any Board-licensed entity; and needs a worksite monitor. Decision effective 10/19/2011

#### MacDonald, Alex, TCH 86095,

Oceanside, CA—Case 3832

By Stipulated Surrender, license was voluntarily surrendered.

Decision effective 06/22/2011

#### Malekshoar, Amir John, TCH 88255,

Cupertino, CA—Case 3881

By Default Decision, license was revoked.

Decision effective 11/23/2011

#### Mares, Andrew, TCH 72300,

Ontario, CA—Case 4024

By Default Decision, license was revoked

Decision effective 10/12/2011

#### Martinez, Laura, TCH 2516,

Lakewood, CA—Case 3851

By Decision after a hearing before an

Administrative Law Judge, license was revoked.

Decision effective 10/27/2011

#### Masushige, Jeffrey Kazuo,

Pharmacy Technician applicant,

Monterey Park, CA—Case SI 3450

By Default Decision, license was denied.

Decision effective 11/30/2011

#### Masih, Sohail, TCH 43261,

Loma Linda, CA—Case 3787

By Default Decision, license was revoked.

Decision effective 06/22/2011

#### McGee, Simone Gizelle, TCH 70844,

Stockton, CA—Case 3705

By Decision after a hearing before an Administrative Law Judge, license was revoked.

Decision effective 10/27/2011

#### Mendoza, Jose, TCH 70114,

Santa Rosa, CA—Case 3846

By Decision after a hearing before an Administrative Law Judge, license was revoked.

Decision effective 10/27/2011

#### Molina, Alvaro, TCH 66419,

North Hollywood, CA—Case 3925

By Default Decision, license was revoked.

Decision effective 12/21/2011

#### Navarrette, Greta, TCH 49773,

San Jose, CA—Case 3965

By Default Decision, license was revoked.

Decision effective 11/23/2011

#### Navasardyan, Edgar. TCH 60051,

North Hills, CA—Case 3728

By Stipulated Surrender, license was voluntarily surrendered.

Decision effective 11/23/2011

#### Niktalean, Asefeh, TCH 74975,

Thousand Oaks, CA—Case 3543

By Stipulated Settlement, license was revoked, stayed and placed on three years' probation, subject to terms and conditions that include but not limited to: must have worksite monitor; no ownership of any Board-licensed entity; and must pass the Pharmacy Technician Certification Board Exam. Decision effective 08/19/2011

#### Nguyen, Khanh Phi,

Pharmacy Technician applicant,

Continued from Page 32

Fountain Valley, CA—SI 3997

By applicant's withdrawal of the appeal, the Statement of Issues was withdrawn.

Decision effective 11/10/2011

#### Ochoa, Dennis,

Pharmacy Technician applicant, Newark, CA—Case SI 3856

By Decision after a hearing before an Administrative Law Judge, license was denied.

Decision effective 11/17/2011

#### Panek, Tanna Lee, TCH 47032,

Thermal, CA—Case 3887

By Stipulated Surrender, license was voluntarily surrendered.

Decision effective 09/15/2011

#### Pereda, Genoveva, TCH 30005,

Sun City, CA—Case 3836

By Default Decision, license was revoked.

Decision effective 07/27/2011

#### Perez, Martin Omar, TCH 50207,

Pomona, CA—Case 3509

By Decision after a hearing before an Administrative Law Judge, license was revoked.

Decision effective 10/19/2011

#### Perrotti, Anthony, TCH 102203,

El Cajon, CA—Case 3983

By Default Decision, license was revoked.

Decision effective 09/15/2011

#### Phillips, Shawna Lynn, TCH 56911,

Pittsburg, CA—Case 3930

By Stipulated Settlement, license was revoked, stayed and placed on four years' probation, subject to terms and conditions that include but not limited to: must have worksite monitor; no ownership of any Board-licensed entity; and must pass the Pharmacy Technician Certification Board Exam. Decision effective 10/27/2011

#### Pokorny, Brian James, TCH 11175,

Woodland Hills, CA—Case 3663

By Stipulated Surrender, license was voluntarily surrendered.

Decision effective 11/23/2011

#### Poon, James, INT 27733,

Vallejo, CA—Case SI 3843

By Stipulated Settlement, application for license was granted. Upon satisfaction of all statutory and regulatory requirements, a license was issued, immediately revoked, stayed and placed on four years' probation, subject to terms and conditions that include but not limited to: cannot supervise any intern or perform preceptor duties; cannot be pharmacist-in-charge or serve as consultant; and no ownership of any Board-licensed entity.

Decision effective 06/01/2011

#### Quinn, Cammie Lee, TCH 98152,

Newport Beach, CA—Case 3991

By Stipulated Surrender, license was voluntarily surrendered.

Decision effective 11/23/2011

#### Ramirez, Marlene, TCH 52404,

Riverside, CA—Case 3612

By Stipulated Settlement, license was revoked, stayed and placed on three years' probation, subject to terms and conditions that include but not limited to: no ownership of any Boardlicensed entity; and must pass the Pharmacy Technician Certification Board Exam.

Decision effective 09/15/2011

#### Ramirez, Stevi Elizabeth, TCH 51354

Sacramento, CA—Case 3828

By Stipulated Surrender, license was voluntarily surrendered.

Decision effective 06/22/2011

#### Rapue, Tracy M., TCH 30030,

Yucaipa. CA—Case 3745

By Stipulated Settlement, license was revoked, stayed and placed on four years' probation, subject to terms and conditions that include but not limited to: no ownership of any Board-licensed entity and passing the Pharmacy Technician Certification Board Exam.

Decision effective 06/22/2011

#### Rivera, Eduardo, TCH 70498,

Bakersfield, CA—Case 3780

By Default Decision, license was revoked.

Decision effective 09/15/2011

#### Robinson, Andre Carl, TCH 70130,

La Jolla, CA—Case 3502

By Decision after a hearing before an Administrative Law Judge, license was revoked.

Decision effective 07/27/2011

Rock, Colin Kelly, TCH 51857, Los Angeles, CA—Case 3582 By Default Decision, license was revoked.

Decision effective 07/27/2011

#### Ryden, Max August, INT 18460,

Big Bear Lake, CA—Case 3408

By Stipulated Settlement, license was revoked.

Decision effective 12/21/2011

#### Sandoval, Samantha Selene,

TCH 87471, Norwalk, CA—Case 3521 By Default Decision, license was

revoked.

Decision effective 11/23/2011

#### Schilling, Lisa Marie,

Pharmacy Technician applicant,

Tustin, CA—Case SI 3872

By applicant's withdrawal of appeal, the filed Statement of Issues was withdrawn.

Decision effective 11/10/2011

#### Singh, Aminish, TCH 80448,

Chowchilla, CA—Case 4087

By Default Decision, license was revoked.

Decision effective 11/23/2011

#### Smith, Lisa M., TCH 79731,

Morgan Hill, CA—Case 3585

By Stipulated Settlement, license was revoked, stayed and placed on three years' probation, subject to terms and conditions that include but not limited to: passing the Pharmacy Technician Certification Board Exam, and must have worksite monitor.

Decision effective 11/17/2011

#### Sundquist, Trevor, TCH 53676,

Eureka, CA—Case 3844

By Stipulated Surrender of License, license was surrendered.

Decision effective 10/19/2011

#### Terrazas, Yamina Gissel, TCH 83775,

Pomona, CA—Case 3820

By Default Decision, license was revoked.

Decision effective 12/21/2011

#### Thao, Nou Chai, TCH 78290,

Sacramento, CA—Case 3786

By Stipulated Settlement, license was revoked, stayed and placed on four years' probation, subject to terms and conditions that include but not limited to: no ownership of any Boardlicensed entity, passing the Pharmacy Technician Certification Board Exam,

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and needs worksite monitor. Decision effective 07/27/2011

#### Thompson, Shannon Michele,

TCH 47914, Wheatland, CA—Case 3708
By Default Decision, license was
revoked.

Decision effective 07/27/2011

#### Thweatt, Anthony, TCH 49549,

West Covina, CA—Case 3777

By Default Decision, license was revoked.

Decision effective 09/15/2011

#### Tidwell, Terrie Lynnette, TCH 956,

Covina, CA—Case 3839

By Default Decision, license was revoked.

Decision effective 06/22/2011

#### Trieu, Calvinnghia Hoang, TCH 45518,

Santa Ana, CA—Case 3911

By Default Decision, license was revoked.

Decision effective 10/19/2011

#### Tufo, Michael, TCH 33538,

Daly City, CA—Case 3850

By Stipulated Surrender, license was voluntarily surrendered.

Decision effective 08/19/2011

### Valadez, Jorge Saldana, TCH 87769,

Hayward, CA—Case 3941

By Stipulated Settlement, license was revoked, stayed and placed on four years' probation, subject to terms and conditions that include but not limited to: no ownership of any Board-licensed entity, and passing the Pharmacy Technician Certification Board Exam.

Decision effective 11/17/2011

#### Villagomez, Raymond, TCH 85162,

Indio, CA—Case 3966

By Default Decision, license was revoked.

Decision effective 09/15/2011

#### Walker, Rosalie Katherine, TCH 78028,

Fullerton, CA—Case 3973

By Default Decision, license was revoked.

Decision effective 12/21/2011

#### **Pharmacies**

#### Carequest Pharmacy, PHY 50419,

Reseda, CA—Case SI 3921

By Stipulated Settlement, application for license was granted. Upon

satisfaction of all statutory and regulatory requirements, a license was issued, immediately revoked, stayed and placed on three years' probation, subject to terms and conditions of probation.

Decision effective 11/17/2011

#### CVS Pharmacy #9849, PHY 47923,

Riverside, CA—Case 3714

By Stipulated Settlement, license was revoked, revocation stayed, and placed on two years' probation, subject to terms and conditions of probation.

Decision effective 11/17/2011

#### Fed-RX Pharmacy, PHY 39339,

Poway, CA—Case 3761

By Stipulated Surrender of License, license was surrendered.

Decision effective 10/19/2011

#### Holt Pharmacy, PHY 49084,

Pomona, CA—Case 3593

By Stipulated Settlement, license was revoked, stayed, and placed on five years' probation and subject to terms and conditions of probation.

Decision effective 08/19/2011

#### Tahoe City Plaza Pharmacy, Inc.,

PHY 43340, Tahoe City, CA—Case 3767 By Stipulated Surrender, license was voluntarily surrendered.

Decision effective 06/22/2011

#### Top Care Pharmacy, PHY 44224,

South Gate, CA—Case 3335

By Stipulated Settlement, license was revoked, stayed, and placed on five years' probation and subject to terms and conditions of probation.

Decision effective 08/19/2011

#### **UPAS Pharmacy**, PHY 36112,

San Diego, CA—Case 3423

By Stipulated Settlement, license was revoked, stayed and placed on five years' probation during which time, pharmacy must post probation notice to be seen by the public. Other terms and conditions of probation apply.

Decision effective 06/22/2011

#### Valley Pharmacy, PHY 43889,

Sunnyvale, CA—Case 3853

By Stipulated Settlement, license was revoked, stayed, and placed on three years' probation and subject to terms and conditions of probation Decision effective 11/23/2011 This newsletter is published by the

#### California State Board of Pharmacy Department of Consumer Affairs

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