

### CALIFORNIA BOARD OF PHARMACY 📕 FEBRUARY 2010

### Joining the Board's E-Mail List to be Mandatory for Facilities

Beginning July 1, 2010, Senate Bill 821, Chapter 307, Statutes of 2009, will enact Business and Professions Code section 4013 which will require all Boardlicensed <u>facilities</u> to join the Board's e-mail notification list within 60 days of obtaining a license or at the time of license renewal. Facilities will also be required to update their e-mail address with the Board within 30 days of any e-mail address change.

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

- Go to the Board's Web site, www. pharmacy.ca.gov;
- Select "Subscribe to Our E-Mail Notification List" from the Quick Hits menu on the left side of the page;
- Click on the "Board of Pharmacy – E-mail Notification List" box;
- Scroll down the page and select "Subscribe;"
- Enter your e-mail address and we'll do the rest!

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

# Future Issues of *The Script* to be **Published Online Only**

The Board of Pharmacy has mailed newsletters to its licensees since January 1971. However, this issue of *The Script* is the last to be mailed. Future issues can be viewed at and downloaded from the Board's

Web site. By joining the Board's e-mail notification list, you will be electronically notified and provided with a direct online link to the document.

To join the list, go to the Board's Web site, *www.pharmacy. ca.gov*, and select "Subscribe to Our E-Mail Notification List" from the Quick Hits menu on the left side of the page.

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**President's Message** By Kenneth Schell, Pharm. D., President, Board of Pharmacy

There is a line in the story of the *Man of La Mancha* that reads, "to run where the brave dare not go." This is the direction I would like to take as President of the Board. I was honored by my colleagues on the Board and re-elected President.

One of our key efforts last year was to not only give voice to consumers, licensees and others, but to listen. I feel we did. We are now working with dedicated hospital and health system practitioners to evaluate and optimize the safety of medication delivery in hospitals. While this is a daunting task and far from completed, we are working together to address the challenges. The Board has brought together other State and Federal agencies to participate so that the full scope of the situation can be addressed.

In other areas, the Board continues to move forward with SB 472 (Corbett) to address the legislative mandate to enact regulations that will result in a standardized prescription label. We have held public meetings over the past two years, and we are confident that all parties have been given a voice and have been heard. It is our goal to have regulations in place so that the 2011 deadline for achieving a standardized prescription label is met.

There are many other issues facing the state and the pharmacy profession in the coming years. One issue I would like to begin addressing is that of impaired pharmacists. We all know that pharmacists play a key role in the medication use process, and as more responsibilities are placed on pharmacists, the stress of doing this job becomes more difficult. Some succumb to that stress by abusing alcohol and drugs. But what happens after those pharmacists recover? Are they embraced by the public and profession, or are they unable to return to the profession they cherished? It is a challenging issue and one that must be considered. While some may say there are more challenging issues

facing the Board, my feeling is that we must not forget our human side and support those who have given so much to the profession but may have strayed. During this year, I will determine what might be a good way to address this issue.

Finally, I want to speak briefly about the future of pharmacy. The role of the pharmacist has changed dramatically in my 25 years as a pharmacist. What pharmacists in training are taught today is very different from when I was in school. While pharmacists are being trained to be valuable in many areas in health care, the issue becomes whether there are enough pharmacists to perform all the roles the public expects. The Board has already begun evaluating requirements for becoming licensed, including those activities that are appropriate for satisfying the intern hours requirement. In addition, the Board has looked into the hours requirement itself. While there are no guarantees for change, it is my hope that we evaluate what we are doing so that California has the finest trained pharmacists in the world.

All these challenges may seem unattainable. I don't see it that way. We can attain excellence in delivering pharmaceutical care by listening and working with each other. We will run where the brave dare not go. I wish for everyone a successful, healthy and productive year.

## **Board of Pharmacy to be closed three Fridays of every month**

Pursuant to Governor Schwarzenegger's Executive Order S-13-09, which was issued due to budget restraints, employees of the Department of Consumer Affairs and other State government offices will continue to be closed the first, second and third Friday of every month through June 2010.

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

### **Changes in Pharmacy Law for 2010**

The Senate and Assembly bills listed in this article were enacted in 2009, and unless otherwise specified, took effect January 1, 2010. The new and amended Business and Professions Code (B&PC), Health and Safety Code (H&SC), Insurance Code, and Welfare and Institutions Code laws are paraphrased or summarized below, but you are urged to review the exact language at *www. pharmacy.ca.gov/laws\_regs/new\_laws. pdf.* 

### SB 470 (Corbett), Chapter 590, Statutes of 2009

#### Prescriptions

**B&PC** §4040 (Amended)—adds to the requirements of a prescription, the purpose for which a prescription is written if requested by the patient.

Prescription Container/ Requirements for Labeling B&PC §4076 (Amended)—adds to the requirements of a prescription container label, the purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

#### SB 762 (Aanestad), Chapter 16, Statutes of 2009

### Licensed Department of Consumer Affairs Businesses

**B&PC §460 (Amended)**—does not allow cities and/or counties to prohibit a professional who is licensed by an agency of Department of Consumer Affairs from practicing or engaging in a business that falls within the licensee's scope of practice, but does not prevent enforcement of local ordinances governing zoning, business licensing, or reasonable health and safety requirements in effect prior to January 1, 2010.

### SB 819 (Yee), Chapter 308, Statutes of 2009

Dispensing Legally Prescribed Drugs or Devices B&PC §733(d) (Amended)— changes section number referenced for drug therapy.

### Designated Representative: Designated Representative-in-Charge

**B&PC** §4022.5 (Amended)—does not require a designated representative license for a licensed pharmacist fulfilling a designated representative's duties. A designated representative-in-charge or a pharmacist must be proposed by a wholesaler or veterinary foodanimal drug retailer and approved by the Board to be the supervisor or manager for ensuring the business's compliance with laws and regulations pertaining to the licensed practice.

Skilled Nursing Facility/ Intermediate Care Facility/ Other Health Care Facilities B&PC §4027 (Amended)—changes section numbers referenced for "licensed health care facility" and for "health care facility."

### Pharmacist-in-Charge

**B&PC** §4036.5 (New)—defines a "pharmacist-in-charge" as a pharmacist proposed by a pharmacy and approved by the Board to be the supervisor or manager responsible for ensuring the pharmacy's compliance with pharmacy laws and regulations.

**Conduct Limited to Pharmacist: Conduct Authorized by Pharmacist B&PC §4051 (Amended)**—changes section numbers referenced for allowing a pharmacist to authorize the initiation of a prescription.

### Who May Order Dangerous Drugs or Devices

**B&PC §4059.5 (Amended)** specifies that where a licensee is permitted to operate through a designated representative, the designated representative shall sign for and receive deliveries from a wholesaler.

### Controlled Substance –

**Prescription Required: Exceptions B&PC §4060 (Amended)**—changes section reference that allows the possession of controlled substances by a person upon a prescription by a pharmacist.

### Furnishing Dangerous Drugs and Dangerous Devices during Emergency

**B&PC** §4062 (Amended)—adds conditions for allowing the employment of a mobile pharmacy during a declared emergency in impacted areas.

Records of Dangerous Drugs and Dangerous Devices Kept Open for Inspection; Maintenance of Records, Current Inventory B&PC §4081 (Amended)—clarifies that the designated representativein-charge is also responsible for maintaining records and inventory and shall not be criminally responsible for acts of the owner, officer, partner, or employee who violates this section if the DRIC had neither knowledge of nor participation in the acts.

### License Required; Temporary Permit upon Transfer of Ownership

**B&PC §4110 (Amended)** authorizes use of a mobile pharmacy when the pharmacy is destroyed or damaged and sets fee for temporary pharmacy permit for transfer of ownership.

### Restrictions on Prescriber Ownership

**B&PC** §4111 (Amended)—changes section reference related to the issuance of a new or renewal pharmacy license for a pharmacy owned and/or operated by a pharmacist authorized to issue a drug order.

#### Furnishing Dangerous Drugs by Pharmacy B&PC §4126.5 (Amended)—clarifies who in the supply chain may receive dangerous

# **Reporting and Reducing Theft in the Pharmacy**

Section 4104 of the Business & Professions Code directs pharmacies to have written policies and procedures for addressing chemical impairment as well as theft, diversion or self-use of dangerous drugs by licensed individuals employed by the pharmacy. That section also directs that any theft, diversion, review acquisition and disposition records carefully, frequently, and regularly. If the purchasing of dangerous drugs has been delegated to a clerk or pharmacy technician, the pharmacistin-charge is held responsible for those activities. Compare the drug wholesaler's billing reports with the pharmacy's invoice

or self-use of dangerous drugs where there is an admission, video, or documentary evidence of such use or theft by an employee must be reported to the Board within 30 days of receipt or development of such information. Additionally, Health & Safety Code section 11103 requires losses or theft be reported to the Department of Justice on a Form 106 (*www. deadiversion.usdoj.gov/21cfr\_ reports/theft/*) within three days of discovery. Often, when theft by an

employee is suspected, by the time conclusive evidence is obtained,

the amount of stolen drugs has multiplied substantially, so early reporting is critical for early investigation.

Additionally, section 1715.6 of the California Code of Regulations requires pharmacy owners to report to the Board <u>within thirty (30) days of discovery</u> of any loss of the controlled substances, including their amounts and strengths.

A review of ways to prevent theft in the first place might be helpful here, and one of the first ways to become quickly alerted and to head off possible theft is for the pharmacist-in-charge to



records to ensure that no pharmacy invoices are missing. Be sure that "returned to stock" drugs are truly returned to stock and noted in pharmacy records. Be alert to who puts what in the pharmacy trash, and check indoor trash containers before they are emptied into the outside trash bins. And don't wait until theft is suspected to install security cameras in the pharmacy.

As well as discovering theft and reporting it, the Board believes it is important public policy for the pharmacy to actively assist

enforcement in prosecuting those who are stealing drugs. Simply giving a warning or terminating the thief's employment could subject a future pharmacy employer to also suffer such losses and adversely impact the public that we serve.

It is not easy to ascertain whether an employee is stealing drugs, even with security cameras. That's why it is so important to "think out of the box," because if there is a way to steal, an unscrupulous person will find it. Managers and pharmacists-incharge must be as inventive in watching for theft as the thieves are in devising ways to steal.

### Pharmacists must comply with FDA Side Effect Statement labeling requirement

The Federal Food and Drug Administration (FDA) published its final rule regarding adverse event reporting, which became law on January 1, 2008. The rule, which the FDA began enforcing January 1, 2009, requires the addition of a statement on the labeling of certain human drug products for which an application is approved under the federal Food, Drug and Cosmetic Act (Act) (21 Code of Federal Regulations § 209.10). The statement must read:

"Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088." Each authorized dispenser or pharmacy must choose one or more of the following options for delivering the clear, easy-to-read statement with the drugs:

- On a sticker attached to the unit package, vial, or container of the drug product (font size no smaller than 6 pts.);
- On a preprinted pharmacy prescription vial cap (font size no smaller than 6 pts.);
- On a separate sheet of paper (font size no smaller than 10 pts.);

- In consumer medication information (font size no smaller than 10 pts.); or
- In the appropriate FDAapproved Medication Guide that contains the side effects statement (font size no smaller than 10 pts.).

This requirement does not apply to over-the-counter drug products approved as new drugs under the Act if the product packaging includes a manufacturer's or distributor's toll-free number for reporting complaints.

### **Development of Model Guidelines for "Take Back" Programs for Unwanted Drug Disposal by Patients**

For a number of years, patients have asked how they should dispose of their unwanted medication. Regulatory agencies, including the Board of Pharmacy, sometimes advised making the medicine unpalatable (e.g., mixing with kitty litter) and disposing of it in the trash. Some patients were advised to flush it down the toilet. Other patients were advised to ask pharmacies to take the drugs back for disposal. Controlled drugs always had to be returned only to law enforcement agencies.

However, today patients are increasingly seeking an environmentally friendly alternative to tossing drugs in the trash or flushing down the toilet.

Two years ago, Senate Bill 966 (Simitian, Chapter 542, Statutes of 2007) directed the California Integrated Waste Management Board (CIWMB) to develop guidelines for model programs for the collection from consumers and proper disposal of unused or expired home-generated pharmaceuticals. Homegenerated pharmaceuticals. Homegenerated pharmaceuticals in this context refer to prescription and over-the-counter pills, liquids, and inhalers that are no longer wanted or needed by the consumer. It does not include "sharps" (e.g., hypodermic needles and syringes).

The guidelines subsequently were developed by CIWMB in consultation with a pharmaceutical working group (staff from CIWMB, Board of Pharmacy, California Department of Public Health, Department of Toxic Substances Control, and the State Water Resources Board) that provided parameters for the model programs through which the public may return unused or expired drugs. The model programs include parameters for both permanent and occasional take-back event collection sites, and there is a "mail back" component as an alternative to onsite collection.

In February 2009, the CIWMB adopted the required model programs' guidelines for providing consumers with the ability to dispose of unwanted prescription and over-the-counter drugs—but NOT controlled substances, which must be returned only to law enforcement—without flushing them down the toilet or tossing them in the garbage.

The Board expects all pharmacies to use the CIWMB guidelines for any "Take Back" program they offer the public.

The model guidelines identify pharmacies as one of the authorized permanent collection sites. The general concept is that pharmacies can (1) use postage pre-paid envelopes so that consumers can return unwanted drugs to licensed waste disposal facilities, away from pharmacies where health care is provided, or (2) establish a collection bin for ongoing collection at pharmacies.

The model guidelines, "Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs," can be viewed at: www.ciwmb.ca.gov/hhw/pharmwaste/ modelprogram/criteria.pdf.

Offering a "Take Back" program is voluntary, not mandatory. However, CIWMB's guidelines are those that the Board expects pharmacists to use if they choose to offer options to the public for the return of drugs. In particular, the following guidelines should be observed:

> • Drugs should not be reviewed personally by staff at a collection site (whether a pharmacy or community event) before being deposited into a secured collection bin. The patient or patient's agent should deposit the drugs themselves, thereby preventing staff from knowing what is being returned.

- Drugs that are collected should be separated from their containers by patients or their agents before being placed in the collection bin, reducing the disposal costs because the containers will not be part of the pharmaceutical waste.
- There should be two separate locks on the secured collection bin: one key should be in the possession of the pharmacy, the other key in the possession of the licensed integrated waste hauler who will pick up what is now classified as "hazardous household waste." This dual lock ensures that the pharmacy cannot open the collection bin without the presence of the integrated waste hauler, and vice versa.

It is also important to note that on January 21, 2009, the Drug Enforcement Administration published its intent to examine consumer disposal options for controlled substances (Federal Register/ Vol. 74, No. 12/ Wednesday, January 21, 2009, Proposed Rules). However, at the current time, there is no new policy from the DEA.

The Board of Pharmacy looks forward to continuing to work on developing these programs so that they provide the public with the options they seek and the safety and accountability needed to protect our prescription drug supply.

# Pharmacists and Physicians have Corresponding Responsibility when Writing and Dispensing Controlled Substance Prescriptions

If a physician writes a controlled substance prescription that is not for a legitimate medical purpose, the pharmacist who fills the prescription shares a corresponding responsibility or liability

with that physician if he or she fills that prescription while knowing or having objective reason to know that the prescription was not issued for a legitimate medical purpose.



A pharmacist's "objective reason to know" includes, but is not limited to, warnings, cautions, or other suspicious information from a Board inspector, Board publications,

the media, other pharmacy personnel, or personnel of other drug entities. These are all ways of putting a pharmacist on notice to be cautious and to use that information and his or her professional judgment to determine whether a prescription should be filled *before* filling it. The more the pharmacist is already on notice to be cautious, the less additional information or factors it should take to establish that he or she failed to properly consider prescriptions before filling them.

That said, how does a pharmacist evaluate a controlled substance prescription that appears—at least on its face—to have all the elements of a valid prescription? To make it easier to evaluate questionable prescriptions, the Board has developed a set of questions which pharmacists may ask themselves as guidelines. However, it's important to remember that these guidelines do not cover every possibility; nor will every question listed apply in every case.

### **Questions Relating to the Patient**

- Are you able to verify the true name and identity of the patient?
- Does the patient live within or outside the normal trading area of the pharmacy?
- How far is the patient's residence from the prescriber's office? Is the distance so great that it is unlikely the patient would travel so far to fill a legitimate prescription?
- What do you know about the drug use history of the patient?
- What is the patient's physical appearance and demeanor, in relation to the drug being prescribed?
- When a third party picks up the prescription, what is his or her relationship to the patient? What is his or her physical appearance or demeanor?

### Questions Relating to the Prescribing Physician

- Is information present in the pharmacy regarding the prescribing patterns of the physician, including the type of drugs, their frequency and volume? If not, is that information readily available to you?
- Of the physician's total prescriptions filled at your pharmacy, does there appear to be an excessive percentage of prescriptions written for controlled substances and other potentially abusable drugs? Is that information readily available to you?
- What is the nature of the physician's practice, including any recognized area of specialty?
- Are you aware of any prior criminal or disciplinary action taken against the prescriber?

### Questions Relating to the Therapeutic Appropriateness of the Prescription

- What are the abuse history and current patterns of abuse of the drug prescribed?
- Is the prescribed drug therapeutically appropriate for the diagnosis, if given?
- Is the frequency of refills or new prescriptions for the same drug the same as in the directions for use given by the physician?
- How do the length and quantity of the prescribed drug therapy compare to recognized and accepted prescribing practices?
- Is the physician prescribing unusual combinations of drugs or antagonistic or contraindicated drugs?

### **Regulatory References**:

Under federal law and regulations (21 United States Code section 841, taken together with 21 Code of Federal Regulations section 1306.04[a]), a pharmacist is criminally liable for knowingly filling prescriptions for controlled substances for other than a legitimate medical purpose. State law, Health & Safety Code (H&SC) section 11153(a) is similar.

For disciplinary liability, the standard is repeated acts of clearly excessive furnishing for other than a legitimate medical purpose (Business & Professions Code section 4301[o], taken together with H&SC section 11153[a]) or dispensing a controlled substance prescription when the pharmacist knows or has objective reason to know that the prescription was not issued for a legitimate medical purpose (Title 16 California Code of Regulations section 1761[b]).

# **Keeping Required Documents Handy**

Have you ever been at work in the pharmacy, the pharmacist-in-charge (PIC) is not present, a Board of Pharmacy Inspector arrives asking to see all kinds of documentation, and you don't know where anything is located? Inspectors have reported that this happens frequently, so the Board is encouraging (<u>not</u> <u>requiring</u>) pharmacies to have their PIC prepare a binder—a "Pharmacy Compliance Manual," in which relevant documentation is kept in an easy-to-find location in the pharmacy. Short of preparing a binder, at least have instructions readily available noting the location of the required documents.

To assist with organization of the binder, suggested headings for the binder dividers are listed below. If any of the sections have too much documentation to include in the binder, provide a notation where the separately filed documentation is located.

- 1. Past Inspection Reports
- 2. Pharmacy Self-Assessments (Note: Maintain for three years.)
- 3. Copies of Employee Licenses
- 4. Master List of Pharmacist and Technician Initials
- 5. DEA 222 Forms/ Power of Attorney (to purchase Schedule II controlled substances.)
- 6. DEA 222 Forms, Executed
- 7. DEA 106 Form, Theft and Loss (Note: Include policies and procedures and maintain for three years.)
- 8. DEA Inventory (Note: Maintain for three years.)
- 9. Policies and Procedures/ Pharmacy Technicians
- 10. Policies and Procedures/ Quality Assurance Program for Medication Errors (Note: Include incident reports.)
- 11. Policies and Procedures/ Deliveries when Pharmacy is Closed
- 12. Policies and Procedures / Immunization (Note: Review annually to assure policies and procedures are still valid with physician.)
- 13. Policies and Procedures/Absence of the Pharmacist
- 14. Protocol/ Licensee refuses to dispense, based on ethical, moral and/or religious grounds (Note: List of pharmacists' names and reason for refusal should be on file.)
- 15. Procedures for Emergency Contraceptives (Note: Plan B as OTC, copy of "*Pharmacists Protocol for Dispensing Emergency Contraception,*" *www.pharmacy.ca.gov/licensing/ ec\_protocol.pdf*, documentation of EC training, and a list of area pharmacies offering EC)
- 16. Purchase Invoices (Notation of the location, including but not limited to controlled substances)

#### Headings for Licensed Sterile Compounding Binder

- 1. Sterile Compounding Self-Assessments (Note: Maintain for three years.)
- 2. Policies and Procedures\*
- 3. Master Formulas\*
- 4. Compounding Worksheets\*
- 5. End Product Testing Results\*
- 6. Competency Training and Quality Assurance Records\*
- 7. Hood Certification Records
- 8. Cleaning and Equipment Maintenance Records\*
- 9. Drug Disposal Records

\* May want to keep in a separate binders due to large volume of paperwork.

Again, maintaining such a binder is not required by law, but it will greatly reduce confusion for pharmacy employees and help the inspection go smoothly with less disruption in the pharmacy.

### **Changes in the Board**

The Board welcomes four new public members, Gregory N. Lippe, Ramón Castellblanch, Rosalyn Hackworth, and Tappan Zee and one professional member, Deborah Veale, to the Board of Pharmacy. The Board also extends its best wishes and appreciation to departing professional members, Robert Graul and Susan Ravnan, and public members, James Burgard, D. Timothy Dazé, and Andrea Zinder.

New officers were elected at the April 2009 Board meeting, with terms that will end June 1, 2010. Congratulations to Ken Schell, who was reelected president, James Burgard, vice president, and Stanley C. Weisser, treasurer. However, Mr. Burgard's appointment to the Board expired shortly thereafter, and Randy Kajioka was subsequently elected vice president at the July 2009 Board Meeting.

#### **New Members**

On February 26, 2009, Governor Schwarzenegger appointed **Gregory N. Lippe**, CPA, to the Board of Pharmacy. Mr. Lippe, a resident of Woodland Hills, holds a B.S. in Business Administration (Accounting major) from Woodbury University in Los



Gregory N. Lippe, CPA

Angeles and became a Certified Public Accountant in 1970. Since that time, his accounting experience has included that of managing partner of his own CPA firm and chief financial officer and manager of other companies. Mr. Lippe's employment also includes auditing and reviewing the financial statements of corporations with revenues ranging from \$5-200 million dollars. An ever-active participant in civic and business affairs, Mr. Lippe has served on the boards of multiple community organizations and has authored many newspaper articles.

Mr. Lippe's term will expire June 1, 2012.



Ramón Castellblanch,

Ph.D., was appointed to the Board by the Senate Committee on Rules on April 22, 2009. Dr. Castellblanch, an associate professor at San Francisco State University, was one of the advocates of SB 472 (Corbett, Chapter 470, Statutes

*Ramón Castellblanch, Ph.D.* of 2008), which addresses the development of patient-centered prescription labels and was a member of the precursor SCR 49 Panel on Medication Errors. Among Dr. Castellblanch's academic achievements are a Ph.D. in Health Policy and Management, Johns Hopkins University, and a Master of Public Policy, Harvard University. His writings have been widely published and included in the Journal of Health Policy, Politics and Law and the Journal of Healthcare

Administration Education.

Dr. Castellblanch's term will expire on June 1, 2012.



Rosalyn Hackworth

Former Speaker of the Assembly Karen Bass appointed **Rosalyn Hackworth**, of San Marcos, to the Board on July 15, 2009. Ms. Hackworth has spent the majority of her life in the San Diego area, where she is the secretary-treasurer of United Food & Commercial Workers Union, Local 135. She represents pharmacists who are employed in major grocery stores and chains

in San Diego county and other individuals—15,000 members employed in various industries in the area. She also serves as a trustee for multiple benefit and pension trust funds in Southern California and is currently the Labor & Industry Chair for the North San Diego County NAACP; a proud wish granter for the Make A Wish Foundation for the last few years; a member of the UFCW Minority Coalition; a member of the UFCW Women's Network and a member of the North County African American Women's Association. In her "spare time", Ms. Hackworth loves to travel, garden and engage in various forms of art.

Her term will expire June 1, 2012.

**Deborah Veale**, R.Ph., of Palos Verdes Estate, was appointed to the Board by Governor Schwarzenegger on January 19, 2010. Since 2008, she has been director of managed care for CVS Pharmacy. Previously, Ms. Veale worked for Albertsons/Sav-On as regional manager of managed care from 1996 to 2006; division pharmacy manager from



Deborah Veale, R.Ph.

1994 to1996; regional pharmacy trainer from 1993 to 1994; regional pharmacy recruiter from 1989 to 1991; and pharmacy manager from 1983 to 1989. She is a member of the California Pharmacist Association, National Council of Prescription Drug Programs and California Retailers Association.

Her term will expire June 1, 2013.

**Tappan Zee**, Esq., (no photograph available) was also appointed to the Board by Governor Schwarzenegger on January 19, 2010. Since 2001, Mr. Zee, of South Pasadena, has served as managing attorney for Zee Law Group, and since 2003, has served as reserve deputy sheriff for the Los Angeles County Sheriff's Department. He previously served as an elected representative of the American Bar Association from 1999 to 2000 and a municipal commissioner for South Pasadena from 1989 to 1994. Mr. Zee is a member of the board of directors for the Los Angeles Chinese Chamber of Commerce and the Sheriff's Support Council.

His term will expire June 1, 2013.

#### **Departing Members**

**James Burgard** was appointed to the Board on January 2, 2008, by Governor Schwarzenegger. As a public member Mr. Burgard served on both the Licensing and the Enforcement Committees. He was very interested in technology's role in improving patient care.

**RPh Graul** was appointed to the Board February 1, 2007, by Governor Schwarzenegger. Mr. Graul served on the Licensing Committee from March 2007 to June 2008. He was the chair of the Legislation/Regulation Committee, and he served on the Subcommittee to Evaluate Drug Distribution within Hospitals.

**D. Timothy Dazé**, Esq., was appointed to the Board by Governor Schwarzenegger on August 17, 2006. Mr. Dazé was elected treasurer of the Board in April 2007 and later became vice president in April 2008. Looking back over his two and a half years with the Board, he stated that working on the e-pedigree issue was by far the most important to the health and safety of the public. He also stressed the importance of ensuring that California's pharmacists and pharmacy technicians are of the highest caliber. Mr. Dazé added that his fellow board members and staff were bright, energetic people and that working with them was a great experience that he will truly miss.

Susan Ravnan, Pharm.D., was appointed to the Board on June 30, 2006, and her term expired June 1, 2009. Dr. Ravnan's many contributions to the pharmacy profession included her involvement with Senate Concurrent Resolution 49 that created a panel to study the causes of medication errors in the outpatient setting and recommend changes to the healthcare system that would reduce errors associated with prescription and overthe-counter medication use. She also worked on the SB 472 Implementation Subcommittee, that produced a law that requires the Board to promulgate regulations for a standardized, patient centered prescription drug label for all prescription medication dispensed to California patients. Additionally, Dr. Ravnan served on several other Board committees: Competency, Licensing, Enforcement, and Public Education. She further worked to establish a course in ethics as one of the optimal requirements for licensees on disciplinary probation.

In May 1999, **Andrea Zinder** was appointed to the Board by Speaker of the Assembly Antonio R. Villaraigosa, reappointed by Speaker Robert Hertzberg in June 2000, and reappointed again in December 2004 by Speaker Fabian Nừñez. Ms. Zinder was a member of the Communication and Public Education Committee and served as chairperson of the Legislation/Regulation Committee. In her 'good-byes' to the Board and the profession she served, Ms. Zinder wished to include the following:

In my 10 years with the Board, I was a part of determining the role ever advancing technology plays in consumer health. I have learned some of the benefits and some of the risks and I believe that balancing these will continue to challenge the minds of the Board Members appointed to serve the public's interest well into the future. Personally, I have been excited about the Board's ongoing work to assure that the professional integrity of the pharmacists has been upheld, and not undermined by these technological advances or by other business efforts to reduce costs in difficult times. At the same time, I am encouraged by the tremendous work the Board has done on issues like e-pedigree to make sure that the industry embraces the opportunities of technology as a means of protecting public health.

Early on in my tenure with the Board, we supported and helped pass laws and regulations which made it possible for pharmacists to take lunch and rest breaks even when they are the only pharmacist on duty. We also worked diligently to make sure the ratio of pharmacists to support staff was appropriate, balancing a pharmacist's need for adequate help while at the same time, not overly burdening pharmacists with too many supervisory responsibilities. These will always be ongoing and evolving issues, and I look forward to remaining involved as a member of the public.

Development and distribution of consumer fact sheets to the public has been another highlight of my time with the Board. I am grateful for the opportunity to have worked with UCSF staff and students to identify issues of critical importance and to help oversee the production of a series of public hand outs which will allow consumers to access timely health and safety information.

My involvement in critical decision of ongoing issues such as e prescribing, e-pedigree and safe disposal of unused medications has provided me with the opportunity to understand the issues of the next generation of Board Members and the role the public must play to assure that these proceed smoothly and quickly through the legislative and regulatory process.

Mostly, I am thankful to have worked with the dedicated staff of the Board of Pharmacy. Through some very difficult times with inadequate resources and budget cuts, the Board's personnel have demonstrated the meaning of public service.

# **Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008**

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Act) amended the Controlled Substances Act (CSA) and Controlled Substances Import and Export Act by adding several new provisions to prevent the illegal distribution and dispensing of controlled substances via the Internet. The DEA issued an interim rule, effective April 13, 2009, that added two new criminal offenses to the CSA: to "deliver, distribute, or dispense a controlled substance by means of the Internet, except as authorized by [the CSA]" or to aid or abet such activity. one in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine, within the previous 24 months; and is temporarily unavailable to conduct the evaluation of the patient (21 U.S.C. 829[e][2][C]; 21 CFR section 1300.04[b]).

A most important provision of the Act mandates that anyone operating an "online pharmacy" must obtain a

### To all California pharmacists

If you are approached by telephone, fax or in person by anyone representing an online drug sales entity and soliciting your participation, educate yourself before making a decision. Review California laws, particularly Business & Professions Code sections 4067, 4059.5 and 4105. Additionally, refer to October 2003 and July 2008 issues of *The Script* that contain information about disciplined pharmacists and pharmacies who were substantially fined for dispensing illegal Internet prescriptions.

The Act was named for an 18-yearold who died in 2001 by ingesting Vicodin that he purchased on the Internet without a legitimate prescription. To prevent such illicit online sales, one of the major new provisions of the Act reinforces two of the fundamental prerequisites of a prescription:

- A prescription must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice; and
- The prescriber must either:
  - 1. have conducted at least one in-person medical evaluation of the patient, or
  - 2. meet the definition of a "covering practitioner." The Act defines covering practitioner as a practitioner who conducts a medical evaluation (other than an in-person medical evaluation) at the request of a practitioner who has conducted at least

DEA registration modification that expressly authorizes such online activity, and only DEA registrants can obtain the modification. Engaging in online pharmacy activity without the modified DEA registration is a potentially criminal violation.

### **Online Pharmacy Defined**

- Any Web site that sells or offers to sell any controlled substance or a prescription therefore to a person in the United States;
- Any person ("person" includes "corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals" [1 U.S.C. Section 7]) who operates such a Web site;
- Any person who pays a practitioner to write prescriptions for controlled substances for customers of such a Web site;

- Any person who pays a pharmacy to fill prescriptions for controlled substances that were issued to customers of such a Web site;
- Any pharmacy that knowingly or intentionally fills prescriptions for controlled substances that were issued to customers of such a Web site; and
- Any person who sends e-mail that:
  - 1. Offers to sell a controlled substance or a prescription for a controlled substance in a manner not authorized by the Act;
  - 2. Directs buyers to a Web site operating in violation of the Act; or
  - 3. Otherwise causes or facilitates the delivery, distribution, or dispensing of a controlled substance in a manner not authorized by the Act.

### **Online Pharmacy Requirements**

- Obtain DEA registration modification allowing online pharmacy activities;
- Report monthly to DEA the dispensing of 100 or more prescriptions or 5,000 or more dosage units of all controlled substances combined; and
- Display on its Internet page:
   1. The name and address of the pharmacy;
  - The pharmacy's telephone number and e-mail address;
  - 3. The name, professional degree, and States of licensure, and telephone number of the pharmacist-in-charge;
  - 4. A list of the States in which the pharmacy is licensed to dispense controlled substances;

# **Illegal Internet Dispensing can Cost You Million\$**

Although the Board of Pharmacy has sought to alert the profession to the penalties for illegal Internet controlled substances dispensing, some pharmacies and pharmacists continue to become involved with unscrupulous Internet prescribing individuals or entities who promise huge profits. These enticements, sometimes in e-mail broadcasts to pharmacists/pharmacies or advertisements in professional pharmacy publications, offer those profits in exchange for dispensing and shipping controlled substances pursuant to Internet prescriptions (written without a prior good faith health examination of the patient).

### Pharmacies and participating pharmacists can each be fined up to \$25,000 for each illegal Internet dispensing occurrence

The illegal Internet prescriptions are based on online questionnaires and written by a prescriber who has never seen the person for whom the drugs are intended. And often pharmacy owners and pharmacists-in-charge are unaware of or indifferent to the pharmacy law violation of dispensing prescriptions that have been written without a good faith prior examination of the patient or without a legitimate medical purpose.

Pharmacies and participating pharmacists can each be fined up to \$25,000 for each illegal Internet dispensing occurrence, plus additional fines for associated violations. That means that if on one hundred occasions the pharmacy participates in dispensing and delivering controlled substances pursuant to prescriptions written without a good faith prior health examination or a legitimate medical purpose, the pharmacy could be fined up to \$2.5 million. In the same case, the pharmacist-in-charge or the participating pharmacist could be fined the same amount.

In recent months, the Board has cited and fined three pharmacies and their pharmacists-in-charge millions of dollars for the following violations:

- Dispensing dangerous drugs pursuant to Internet prescriptions issued without good faith prior examinations—Business & Professions Code section 4067(a);
- Dispensing erroneous or uncertain prescriptions—Title 16 California Code of Regulations (16 CCR) section 1761(a);
- Failing to report Schedules II and III controlled substances to the Department of Justice—Health & Safety Code (H&SC) section 11165(d);
- Dispensing prescriptions where patient's name was changed to another name—16 CCR section 1716;
- Failing to report Schedule III controlled substances data to the Department of Justice—H&SC section 11165(d); and
- Failing to verify licensure of prescriber(s) licensed in another state—16 CCR section 1717(d).

Clearly, the consequences of huge fines and/or loss of license outweigh the short-term profits of illegal Internet dispensing.

### **Real Time Access to Patient Prescription History**

The California Department of Justice has launched the Prescription Drug Monitoring Program (PDMP) System which allows licensed healthcare practitioners eligible to prescribe controlled substances, pharmacists authorized to dispense controlled substances, law enforcement, and regulatory boards who are pre-registered, to access real time patient prescription history information to better identify and prevent the abuse of prescription drugs.

To access the PDMP system, prescribers and pharmacists must register themselves and submit their own application electronically at *https://pmp. doj.ca.gov/pmpreg/RegistrationType\_ input.action*. The practitioner must use his or her own e-mail address and not that of a group/community, as the system will only accept a unique e-mail address. After submission, you will need to print the application and verify your e-mail address via an e-mail confirmation within 72 hours. Please ensure that e-mails from *pmp\_registration@doj.ca.gov* are not directed to your spam folder. The registration help desk number is (916) 319-9274.

The Department of Justice requires a notarized (jurat) signature on all mailin applications and copies of validating documentation which include: Drug Enforcement Administration (DEA) Registration Certificate, State Medical License or State Pharmacist License, and government issued identification. Please mail your notarized (jurat) application and documents to the Bureau of Narcotic Enforcement (BNE), Attn: PDMP Registration, P.O. Box 160447, Sacramento, CA 95816.

To forgo the notary, you must make an appointment with one of the BNE Regional Office locations (*https://pmp. doj.ca.gov/pdmp/bne\_locations.html*) where BNE personnel will collect and validate your supporting documentation.

Important Note: The patient information contained in the PDMP is extremely confidential. Therefore, your login and password must not be shared with anyone.



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

- Q. Can our pharmacy technician or clerk call the doctor to request a refill on a controlled substance prescription that has already been refilled five times?
- A. No. If a Schedule III or IV prescription was issued more than six months ago (with no refills ordered), or if refills were ordered and already refilled a maximum of five times (whichever the case), the *pharmacist* must call the prescriber for authorization to dispense the prescription again. If authorization is received, the pharmacist must initiate a new prescription with a new prescription number, and if the prescriber authorizes further refills, enter on the prescription the number of refills that may be dispensed. 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. And no prescription for a Schedule II substance may be refilled. (Health & Safety Code [H&SC] section 11200 and 21 Code of Federal Regulations [CFR] section 1306.22)

- Q. What if the prescriber is unavailable to authorize a refill or a new Schedule III or IV controlled substance prescription?
- A. The prescription may be refilled if, in the pharmacist's professional judgment, failure to refill might present a hazard to the patient's health or result in intense suffering. However, the pharmacist may refill only enough to maintain the patient until the prescriber can be consulted. Other disclosures and recordkeeping requirements must also be met. The pharmacist must note on the reverse side of the prescription the date and quantity of the refill, the unavailability of the prescriber, and the basis for his or her judgment to refill the prescription. (See H&SC section 11201 and 21 CFR section 1306.22)
- Q. What is the Board's policy on Sudafed? I know that it has to be kept in a secure area, but does that area have to be in the pharmacy proper? Is it legal to sell those medications when there is no pharmacist on the premises?
- A. The Board's policy on Sudafed and other OTC ephedrine products can be found on page 9 of the September 2006 Board of Pharmacy newsletter, *The Script*. The article

states that "These products must be located behind the counter or in a locked cabinet." It is legal to sell OTC ephedrine products where there is no pharmacist present. The cashier or whoever completes the sale in such instances is responsible for adhering to ephedrine sales limitations and recordkeeping requirements. Thus, pharmacies and grocery stores are permitted to either keep the products locked away or stored behind the counter like cigarettes. Another article on ephedrine sales restrictions can be found in the January 2005 issue of *The Script*, page 21.

To view the articles referenced above, please visit *www. pharmacy.ca.gov*, select "Publications," and scroll down to the Board newsletters. Legal citations for the sale of ephedrine products are H&SC sections 11100-11106.

Q. One of the items on the Hospital Pharmacy Self-Assessment form asks if "Patient package inserts [Ed. PPIs] are dispensed with all estrogen and progesterone medications (21 CFR 310.515)." Are acute-care and long term care facilities required to distribute PPIs for such products?

> A. Yes. Section 310.515 of 21 CFR requires manufacturers and distributors to provide a PPI in or with each package of the drug product dispensed. In cases of multiple dispensing, and in the case of injectables in multiple-dose vials, a sufficient number of PPIs must be provided to the dispenser to allow each patient to receive it with

the product, and nothing prevents the manufacturer from providing additional PPIs to the dispenser. In acute care and long term facilities, the PPI must be provided to the patient before administration of the first estrogen and every 30 days thereafter, as long as therapy continues.

# Q. What do I do about a doctor that continues to write controlled substance prescriptions on non-secure prescription pads?

A. Health & Safety Code section 11161.5 requires controlled substance prescriptions to be written on forms obtained from security printers approved by the Department of Justice. Physicians who are non-compliant may be reported to:

Medical Board of California Central Complaint Unit 2005 Evergreen St., Suite 1200 Sacramento, CA 95815

### Want a job with great benefits? Be an inspector for the Board of Pharmacy

If you are an innovative, highly motivated individual who is looking for an exciting career that puts you on the front line of changes in pharmacy practice, the Board of Pharmacy is looking for you!

The Board has inspector vacancies statewide (not specific to a particular city or area) and is seeking self-starting pharmacists with experience in the new practice areas of pharmacy such as automated drug dispensing, clinical case management, specialty clinic management, and patient education.

Inspectors from all over California are assigned to work in teams, and each inspector's duties are divided between those performed in a home office environment (report writing, etc.) and those requiring travel. Travel, which includes local and statewide, is approximately 20-25 percent of the workweek.

Inspectors are provided the use of home office equipment: telephone, cell phone, computer, printer, and fax machine. They are also provided business and travel expense reimbursement, and all the health and retirement benefits of state civil service. The salary is approximately \$113,000 annually.

To be considered, you must be a California registered pharmacist with at least two years' experience practicing pharmacy and possess a valid California driver's license. To apply, you must first become ranked on a civil service examination. That process is now done online and applications will be accepted anytime. The examination results will determine your ranking on the civil service list. Based on your ranking and other qualifications, you may be called to appear for the Board's employment interview and writing skills evaluation.

Application information was provided to everyone on the Board's E-Mail Notification List. If you have not joined the list, you may view the Board of Pharmacy Inspector Examination Announcement at *www.dca.ca.gov/ about\_dca/jobs/inspector.pdf*.

# www.pharmacy.ca.gov

### **Importance of Your Address of Record**

All licensees of the Board of Pharmacy are required to provide 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 <u>as long</u> <u>as the residence address (which</u> <u>would then not be available to</u> <u>the public) is also provided.</u> 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.

### **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.



Thomas E. Barnett and family with Stanley Weisser, Treasure, Board of Pharmacy

Barnett was honored at the April 2009 Board meeting. Mr. Barnett noted that he has been involved with pharmacy most of his life, beginning with his father, who was a pharmacist. Then during his own long career, he worked for Drug Fair, Thrifty Drug, Von's Pharmacy and for ten years owned his

own pharmacy in Oakhurst. Mr. Barnett received his 50-year pharmacist pin from the Board treasurer, Stanley Weisser

At the July Board meeting, President Kenneth Schell recognized R.Ph. Vernon Mah, who was licensed in 1959 and has been a pharmacist with VM Pharmacy for over 40 years. Mr. Mah shared that he comes from a family of pharmacists. He highlighted some of the changes in pharmacy and stated that overall, the changes have been good.



Vernon Mah with Randy Kajioka, Vice President, Board of Pharmacy

Also honored at the

July meeting, was R.Ph.

her career, she has worked

at a variety of hospitals and was president of

the Southern California

Hospital Pharmacists in 1962. Ms. Nigro stated

that the profession has

been quite a journey and

Nelly Nigro, who was licensed in 1948. During

Mr. Mah encouraged the board to decrease regulations to allow pharmacists more time to work with the public. Dr. Kajioka presented Mr. Mah with the 50-year pharmacist pin.



Nelly Nigro with Shirley Wheat, Member, Board of Pharmacy

shared that she was one of only three women in her graduating class. Public Member Shirley Wheat presented Ms. Nigro with

the 50-year pharmacist pin.

During the October Board meeting, President Schell acknowledged R.Ph. Katherine Owyoung who was the only female in the first graduating class of the University of the Pacific in 1959. Ms. Owyoung was employed for 40 years at St. Joseph Hospital where she served as director of pharmacy. After recounting some of the many changes she has seen in pharmacy throughout her years as a pharmacist, she was given the 50-year pharmacist pin.



Danny Chan with Ramón Castellblanch, Member, Board of Pharmacy

R.Ph. Jimmie Choi was presented with the 50-year pharmacist pin by President Schell. Mr. Choi noted that he had graduated from the University of Washington in 1954, served two years in Korea, and owned his own pharmacy for 23 years.



Katherine Owyoung with Ken Schell, President, Board of Pharmacy

R.Ph. Danny Chan, a graduate of the University of Utah, was employed at Thrifty Drugstores for 34 years. The 50-year pharmacist pin was presented to Mr. Chan by Public Member Ramón Castellblanch.



Jimmie Choi

Public Member Greg Lippe presented the 50-year

pharmacist pin to Richard

D. Mortensen, a graduate of Idaho State University, who

reviewed the enjoyment he experienced throughout his years

as a pharmacist and commended

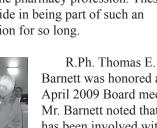
the new pharmacists who are

entering the practice.



Richard D. Mortensen

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



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Adams, Robert T. Adams, William L. Aldridge, James I., Jr. Anderson, Delward W. Bailey, Gary B. Barche, Lawrence J. Barker, Dale R. Barnard, Robert W. Barnett, Ruie D. Berland, Mavnard C. Bilodeaux, David F. Bogdan, M., Nan S. Booth, Tony B. Boring, Taylor I. Bradford, Gaines T., Jr. Brettell, Charles E. Bridger, Osgood C., Jr. Brown, David G. Butler, David James Carroll, Stuart Cernac, John J. Chan, Danny T. Chin, Robert Y. Chin, Warren S. Choi, Jimmie Chun, Wevman Cirino, Jesus P. Clavton, John M. Collins, John P., Jr. Connolly, Robert Lee Cossolias, James Cullipher, Roy Dale Dern, George Din, Henry Dokimos, Ernest J. Durlester, Wayne Eirew, Melvin Eisenberg, Harold J. Fitz, Lynn T. Frank, Donald A. Fuery, Victor L., Jr. Gady, Howard Geane, Nick A. Gishkin, Joel E. Glass, Earl L. Grainger, Vance L. Golbuff, Alex Hall, Jack W. Hamilton, Bill C. Hansen, Elden M. Harrison, Edward W., Jr. Hayata, Tami T. Hernandez, Alfred, L Herring, Clifford L. Hirscher, David A. Hoffmann, Donald A. Honig, Martin E. Horiuchi, Akira Huber, Ronald E.

Los Angeles, C. Apple Valley, CA San Diego, CA Eureka, CA Ridgecrest, CA Carmel, CA Roseville, CA Benicia, CA San Juan Capistrano, CA Wahkon, MN Chico, CA Tulalatin, OR Miami, OK Manhattan Beach, CA Los Angeles, CA Valley Center, CA Tehachapi, CA Buffalo, NY Bakersfield, CA Sacramento, CA Pueblo, CO Sacramento, CA San Francisco, CA Richmond, CA Elk Grove, CA El Sobrante, CA Oxnard, CA Meadow Vista, CA San Jose, CA Riverside, CA Ashland, OR San Ysidro, CA Northridge, CA Sacramento, CA Sacramento, CA Foster City, CA Hemet, CA Bakersfield, CA Calexico, CA Murrieta, CA Pasadena, CA Kaneohe, HI San Bernardino, CA San Francisco, CA Palm Desert, CA Madera, CA Ventura, CA Pasadena, CA Grants Pass, OR Fallbrook, CA Altadena, CA Los Angeles, CA Pleasanton, CA Costa Mesa, CA Los Angeles, CA Bakersfield, CA Palm Desert, CA Visalia, CA

Roseville, CA

Huster, William E. Ito, Yuichi Jacob, Joseph C. Jacomella, Charles P. Jara, Lionel F. Jeong, John J. Johansen, Donald E. Jone, Gilbert W. King, Richard M. Klein, Eva L. Kluge, Charles A. Kropidlowski, Edmond F. Laikind, Stanley Lane, Robert M. Lee, Calvin Chew Levine, Norman R. Lewinter, Robert A. Lewis, Richard E. Lindow, John R. Lindberg, Charles L. Low, Henry Mac Murphey, George W. Sacramento, CA Mah, Vernon Lee Manabe, Eugene Y. Martin, Janet G. Mercer, Herbert M. McCluskev, John S. Mc Conville, J. Lawrence Soulsbyville, CA Mc Donald, James D. McGehee, Mark R. Megredy, Robert F. Melia, Crandall N. Miller, Ronald J. Mitchell, Louis J. Mochidome, Iwao Mortensen, Richard D. Myers, John F. Nyman, Allan Ogata, Gerald Ouchida, Kenneth A. Owyoung, Katherine Pappas, Nick A. Park, Delbert A. Perlman, Gerald N. Pejsa, Joseph A. Pfitzer, Harvard F. Pilpel, Monio Piper, William C. Pori, Albert P. Jr. Rivenes, Ann O. Roberts, Thomas W. Rodriguez, David R. Rosenzweig, Herbert Rowan, Milo L., Jr. Sabol, Donald J. Samaniego, Eliseo M. Schenone, Angelo J.

Hemet, CA Gardena, CA Lake San Marcos, CA Carmel Valley, CA Cupertino, CA Sausalito, CA Eureka, CA Kensington, CA Redlands, CA San Francisco, CA Kelsevville, CA Santa Ana, CA N. Hollywood, CA Huntington Beach, CA Oakland, CA Los Angeles, CA Newport Beach, CA Camarillo, CA El Dorado Hills, CA Ben Lomond, CA Los Banos, CA Monterey Park, CA Calabasas, CA San Pedro, CA Thousand Oaks, CA Naches, WA Sacramento, CA Anderson, CA Los Angeles, CA Upland, CA Arcadia, CA Pasadena, CA Torrance, CA Walnut Creek, CA Yorba Linda, CA Rancho Mirage, CA Fresno, CA Sacramento, CA Stockton, CA Reno, NV Bountiful, UT Deerfield, IL Magalia, CA Modesto, CA San Francisco, CA Bend, OR Mountain View, CA Livermore, CA Santa Rosa, CA Walnut Creek, CA Irvine, CA Merced, CA Thousand Oaks, CA Elk Grove, CA Foster City, CA

See Honored 50-year pharmacists, Page 20

### Ryan Haight

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- A certification that the pharmacy is registered to deliver, distribute, or dispense controlled substances via the Internet;
- 6. The name, address, telephone number, professional degree, and States of licensure of any practitioner who has a contractual relationship to provide medical evaluations or issue prescriptions for controlled substances, through referrals from the Web site or at the request of the owner or operator of the Web site, or any employee or agent thereof; and
- 7. The following statement, "This online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at least one prior in-person medical evaluation or medical evaluation via telemedicine in accordance with applicable requirements of section 309."

#### Exceptions to Online Pharmacy Registration Requirement

The Act contains exceptions to the online pharmacy definition above, and those exceptions should be reviewed carefully before submitting an application for DEA registration modification. For example, excluded from the definition of an online pharmacy are DEAregistered pharmacies whose dispensing of controlled substances via the Internet consist solely of refilling Schedule III, IV, or V prescriptions or filling new prescriptions for controlled substances in Schedule III, IV, or V.

The Act specifies that a **refill** prescription includes **only** the refills actually authorized on the original

prescription. [In California, it has become somewhat common to refer to repeatedly re-issued prescriptions of the same medication (e.g., for pain management) as refills and even use the same prescription number, but the Act makes it clear that such repeat prescriptions are not refills.] Every prescription that is "written" anew (i.e., not a pre-authorized refill) is a new prescription.

**Example**: If a patient has previously had a non-Internet prescription for Hydrocodone, and is on a regular maintenance dose/schedule of prescriptions, the filling pharmacy may then contact the prescriber (at the patient's request/authorization) to seek new prescriptions for the drug, and it **may** fill those prescriptions via the Internet without being an "online pharmacy."

Filling new prescriptions means filling a (Schedule III-V) prescription only where:

- The pharmacy has previously dispensed that same drug to that same patient pursuant to a non-Internet prescription;
- The pharmacy contacts the original prescriber at the patient's request to seek authorization for a new prescription for that drug; and
- The prescriber determines there is still a legitimate medical purpose for the new prescription for the same drug.

**Example**: If a patient wants the doctor to write a prescription for Valium, and there has been no previous non-Internet-facilitated fill of a Valium prescription, the pharmacy may **not** fill that prescription via the Internet without being an "online pharmacy."

Additionally, there are exceptions for electronic prescribing (e-prescribing) of controlled substances and for communication of prescription or drug information via the Internet for purposes of operating a remote automated dispensing system. Thus, a pharmacy is not required to modify its registration to be an online pharmacy if its delivery, distribution, or dispensing of controlled substances (and/or facilitation of same) by means of the Internet consists solely of (a) filling prescriptions that were electronically prescribed\* or (b) the transmission of prescription information between a pharmacy and an automated dispensing system located in a long-term care facility when the registration of the automated dispensing system is held by that pharmacy, so long as the pharmacy does not by its other activities constitute an online pharmacy (i.e., e-prescribing does not prevent this status). \*Note: the e-prescribing exemption is not effective until such time as the DEA finalizes its separate rulemaking to permit electronic prescribing of controlled substances. This is presently prohibited, pending final publication of the final e-prescribing rule(s).

### **Telemedicine Defined**

An in-person evaluation is not required in the practice of "telemedicine," but the "legitimate medical purpose" of the prescription is still required. The interim rule developed by the DEA also includes a temporary definition relating to telemedicine, which is in effect now. A new definition will be adopted in final form, effective January 15, 2010. (21 U.S.C 841[h][1]); 21 Code of Federal Regulations [CFR] section 1300.04[i])

Under the interim rule, telemedicine means the practice of medicine by a "practitioner (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using ... an interactive telecommunications system..." that satisfies the requirements of Title 42, CFR section 410.78(a)(3). This definition is in place until January 15, 2010, unless prior to that date regulations are created for issuance of a special "telemedicine" registration. Beginning January 15, 2010, a new

### Always verify identity of Board of Pharmacy Inspectors

Recently an individual approached a hospital employee and falsely presented himself as a Board of Pharmacy inspector requesting to conduct an inspection of the pharmacy. His appearance and demeanor alerted pharmacy personnel, and he was prevented from entering the pharmacy area. No real harm was done, but in light of such activities, always verify the identity of inspectors by asking to see their photo-identification badge and/or by contacting the Board at (916) 574-7900.

### 2009-2010 Influenza Season: Information for Pharmacists

The Centers for Disease Control and Prevention provides important information for pharmacists to help fight both the

2009 H1N1 ("swine flu") and seasonal flu viruses at: *http://www.cdc.gov/H1N1flu/pharmacist/pharmacist\_info.htm.* 

### Ryan Haight

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telemedicine definition becomes law, and will include additional requirements that telemedicine practice fall within one of the following practice categories:

- While the patient is being treated by and is physically located in a registered hospital or clinic;
- While the patient is in the physical presence of another (treating) practitioner;
- By a practitioner who is an employee or contractor of the Indian Health Service, or is working for an Indian tribe or tribal organization;
- During a public health emergency as declared in the relevant area by the Secretary of Health and Human Services (HHS);
- By a practitioner who has obtained a special "telemedicine" registration;
- During a medical emergency in a VA facility; or
- Under any other circumstances set forth in regulations adopted by the Secretary of HHS.

### **Specific Information for Pharmacists**

If you are a pharmacist and your DEA-registered pharmacy falls within the definition of an "online pharmacy," your pharmacy must obtain a DEA registration modification authorizing it to engage in such activity. Any pharmacist who fails to obtain the modification and who knowingly engages in practices that fall within the definition of an online pharmacy is in violation of 21 U.S.C. 841(h)(1) and subject to potential criminal prosecution. To obtain registration modification, access *https:// www.deadiversion.usdoj.gov/webforms/ jsp/regapps/ipharms/ipharmsLogin.jsp.* 

Also, a pharmacist has corresponding responsibility, with respect to new requirements of the Act, to ensure that controlled substances are dispensed in accordance with the Act. For example, a pharmacist may not knowingly or intentionally fill a controlled substance prescription that was issued in violation of the in-person medical evaluation requirement or was issued without a legitimate medical purpose.

#### **Summary of Violations**

In addition to the new provisions, examples of other types of conduct which would violate the Act include:

- Delivering, distributing, or dispensing a controlled substance by means of the Internet by an online pharmacy that is not validly registered with a modification authorizing such activity;
- Writing a prescription for a

controlled substance for the purpose of delivery, distribution, or dispensation by means of the Internet in violation of 21 U.S.C. 829(e);

- Serving as an agent, intermediary, or other entity that causes the Internet to be used to bring together a buyer and seller to engage in the dispensing of a controlled substance not authorized by 21 U.S.C. 823(f) or 829(e);
- Offering to fill a prescription for a controlled substance based solely on a consumer's completion of an online medical questionnaire; and
- Making a material false, fictitious, or fraudulent statement or representation in a notification or declaration under 21 U.S.C. 831(d) or (e).

To view a copy of the federal register, which explains the DEA's implementation of the Act and accompanying regulations, go to *www.deadiversion.usdoj.gov/fed\_ regs/rules/2009/fr0406.pdf*.

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

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

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

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

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

- Enforcement Committee—Exercises oversight over all regulatory and enforcement activities for the improvement of consumer protection.
- Licensing Committee—Exercises oversight of the development of minimum standards for the professional qualifications of licensees.



• Communication and Public Education Committee—Prepares relevant information to consumers and licensees for the improvement of consumer awareness and licensee knowledge.

Attendance at these meetings provides an opportunity to participate in the development of policies that will guide the Board in its decision-making. Frequently, both statutory and regulatory 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 there will be a sign-in sheet for those interested in obtaining CE.

The Board remaining meeting dates and locations for 2010 are:

April 21-22	Loma Linda
July 28-29	San Francisco
October 20-21	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.



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### **Proper Drug Storage Temperatures are Critical**

Title 22, California Code of Regulations (CCR), section 702663(q) states that, "Drugs shall be stored at appropriate temperatures. Refrigerator temperature shall be between 2.2 degrees C (36 degrees F) and 7.7 degrees C (46 degrees F) and room temperature shall be between 15 degrees C (59 degrees F) and 30 degrees C (86 degrees F)." Additionally, CCR section 1714(b) requires that a pharmacy shall maintain its equipment so that drugs are safely and properly maintained.

Recently, it was learned that a hospital engineer failed to

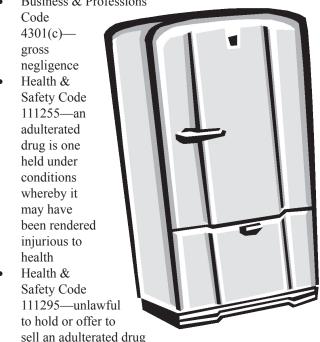
inspect a drug storage refrigerator every three months pursuant to hospital policy. Adding to that failure. the refrigerator, containing hepatitis B and

It is important that all staff be fully trained to recognize, document AND take corrective action when abnormal temperatures involving drug storage are detected.

tetanus toxoid vaccines, was documented daily by pharmacy staff for approximately seven months as having *below freezing* temperatures, with no corrective action being taken. Such non-action resulted in more than 1,600 newborn babies being inoculated with the temperature-damaged hepatitis B vaccine. More seriously, five of the babies had mothers who had positive surface antigens for hepatitis B and were inoculated with both the hepatitis B and the hepatitis immunoglobulin vaccines. All of the babies and the positive antigen mothers had to be identified and reinoculated.

Aside from potential injury to patients, several pharmacy laws were violated:

• **Business & Professions** 



To prevent such incidences, it is important that all staff be fully trained to recognize, document AND take corrective action when abnormal temperatures involving drug storage are detected.

### **Senate Bill 853: Interpreted and Translated Healthcare Services for Insured Californians**

Senate Bill 853 (Escutia) Chapter 713, Statutes of 2003, became effective January 1, 2004, with requirements that the Department of Managed Health Care (DMHC) and Department of Insurance (DOI) adopt regulations to implement its provisions by 2006. This bill requires all health care service plans, including dental and vision plans, (e.g., Blue Cross, Healthnet, PacifiCare, etc.) and specified health insurers to provide, free of charge, language assistance programs that give enrollees with limited English skills access to translated written material and oral interpreters. Regulations adopted by the DMHC and DOI require those language assistance programs to be in

place by January 1, 2009, and April 1, 2009, respectively.

Language assistance programs will include a survey by the insurer (health plan) to determine which of their enrollees have language assistance needs, and in what language, and subsequently provide them with appropriately translated documentation regarding their benefits. Additionally, the health plan must provide a system whereby an insured with limited English proficiency would have the services of an interpreter at every "point of contact," which is defined as "an instance in which an insured (or enrollee) accesses the

services covered under a health insurer's policy (or plan contract), including administrative and clinical services, telephonic and in-person contacts." (Title 28 California Code of Regulations [CCR] 1300.76.04 and Title 10 CCR 2538.2)

Pharmacy services, doctor and lab visits can be included among the insureds' points of contact, and it is important to understand that it is the responsibility of the insurer (health plan), not the pharmacy or the doctor, to develop and provide access to translators and interpreters for the insured patients at the points of contact.

### Join our Emergency **Compounding List**

The Board of Pharmacy and the California Department of Public Health are seeking to identify California pharmacies that can prepare pediatric and or other non-standard formulations of medications during declared emergencies. When emergencies arise, it is important for state and federal agencies to be able to quickly identify and contact those who can prepare compounded medication for children and others.

At this time, the H1N1 flu is commanding much attention. The Board is asking pharmacies that are interested in preparing liquid formulations of Tamiflu® from solid capsules, to join the emergency notification list by going to www.dca.ca.gov/webapps/pharmacy/ subscribe.php and registering your practice site. You will be asked to provide contact information, and in an emergency, an e-mail message asking for your assistance will be sent to you.

By signing up for these notifications, your pharmacy will be contacted by the Board if such services are needed. However, joining the e-mail list does not mean that pharmacies will be **required** to provide services. Nor does it mean that your pharmacy's information will be shared with any other agency. Other agencies will notify the Board of their need, and the Board will then contact you.

As a reminder to pharmacists, the CDC has a website that contains much information about the H1N1 pandemic. For example, instructions for compounding liquid formulations of 75 mg Tamiflu® can be found at www.cdc.gov/H1N1flu/pharmacist/pharmacist info.htm.

### Honored 50-year pharmacists

Continued from Page 14

Shapiro, Thomas R. Sherman, Edward Siemens, Theodore E. Silveria, Carol A. Sirard. Richard B. Smith, Fred N. Smith, H. G., Jr. Spitzer, Leonard H. Spriggs, Martha R. Stephenson, James W. Striplin, Warner M. Sugarman, Marvin R. Tadano, Ben Tanabe, Brian M. Terzian, Gregory A. Tidwell, Charles L. Tsukamoto, Nancy K. Tsuno, Hiroshi Tucker, Agnes M. Unruh, Harlan D. Van Walterop, Norman P. Modesto, CA Wasserman, Jacob L. Weaver. Ellerson F. Weinstein, Sheldon T. Weiss, Robert F. Weiss, Stanford L. Weybright, Arthur J. Whittemore, Jerry A. Wilcox, Quintin K. Williams, Robert G. Wong, Clifford A. Wong, Hank N. Wong, Wilton L. Wronker. Klaus Valceschini, Bud G. Yamamoto, Perry Yotsuya, Ernest M. Zanavich, Donald D. Zepkin, Marvin Zuckerman, Robert

Downey, CA Philadelphia, PA Klamath Falls, OR Las Vegas, NV Woodland, CA Goodyear, AZ Yreka, CA La Quinta, CA Sierra Madre, CA Upland, CA Oakdale, CA Santa Monica, CA Vacaville, CA San Jose, CA Newark, CA Lake Havasu City, AZ San Francisco, CA Anaheim, CA Sacramento, CA Chino. CA Los Angeles, CA Lafayette, CA Los Angeles, CA Paso Robles, CA Colorado Springs, CO Santa Cruz, CA Los Angeles, CA Clovis, CA Sonora, CA San Francisco, CA Monterey Park, CA San Francisco, CA Culver City, CA Susanville, CA Monterey Park, CA Turlock, CA Pismo Beach, CA Los Angeles, CA Encino, CA

### **Enforcement of FTC's Red Flags Rule has begun**

On November 1, 2008, the United State Federal Trade Commission (FTC) adopted the Red Flags Rule (Rule), an anti-fraud regulation requiring certain businesses and organizations-including many doctors' offices, hospitals, and other health care providers-to develop a written Identity Theft Prevention Program to detect, prevent, and minimize the damage that could result from identity theft. To provide time for affected practices to implement such programs, enforcement of the Rule was to have begun on May 1, 2009, was postponed to August 1, 2009, and postponed again to November 1, 2009.

Actual language of the Rule is found at: www.ftc.gov/ os/fedreg/2007/november/071109redflags.pdf. The FTC has published "Fighting Fraud with the Red Flags Rule: A How-To Guide for Business," a plain-language handbook on developing an Identity Theft Prevention Program. For a free copy of the Guide and step-by-step instructions for creating your own program that you can fill out online and print it, go to www.ftc.gov/redflagsrule.

If you have questions about the Rule, e-mail RedFlags@ftc.gov.

### **Exceptional Preceptor Awards**

After seeking nominations for preceptors who exemplify the highest standards of preceptorship, the Board of Pharmacy is pleased to present the Exceptional California Preceptor Award of 2009 to two pharmacist preceptors: Andrew Simental, Jr., Pharm.D., of Victorville and Mark D. Keever, Pharm.D., of Manhattan Beach.

Dr. Simental is currently employed at the Kaiser Permanente Fontana Medical Center where he functions as the Medication Safety Team Coordinator, Inpatient Pharmacy Supervisor, and Pharmacy Practice Residency Steering Committee. In those capacities, he has served as preceptor for innumerable pharmacy students.

It is common wisdom that there is often disparity between the wealth of one's knowledge and the ability to transfer that knowledge to others, but according to those who nominated him, Dr. Simental is known as one of the few innately talented individuals with the exceptional ability to transfer his knowledge to others.

Not only does he impart valuable, basic information, but his passion and dedication for the profession and his compassion for the patients excites and motivates those under his tutorship. His dedication often includes taking time out of his very busy day to have coffee and discussions with students about methods to help them determine what they could do to help nurses, doctors and patients work together for positive health outcomes. A former student, who because of his Internal Medicine rotation with Dr. Simental, changed his career path from retail pharmacy to work in the same hospital setting with Dr. Simental wrote:

"What distinguishes Dr. Simental from other preceptors is his unique style of teaching. The way he reasons and guides the student to arrive at an answer is done through a thought-provoking and logical manner. He encourages the student to critically evaluate a certain drug treatment allowing the student to decide, based on medical literature and didactic experience, what is best for that specific patient. Dr. Simental's patientspecific approach allows the student to be focused in his/her treatment plan, while considering other disease states. This method of teaching demonstrated, for example, that a disorder affecting one organ system could be caused by another, allowing the student to see the holistic nature of human physiology and the importance of patient-specific drug treatment. Because of Dr. Simental, I decided to come back to Fontana to practice what I learned and to impart to others the skills I learned from him."

Also to receive the Exceptional Preceptor Award is Dr. Mark D. Keever of Manhattan Beach. A letter submitted by a colleague states:

"Dr. Keever has been an employee in the Department of Pharmacy Services, Cedars-Sinai Medical Center since July 1989. He is a recognized expert in critical care medicine. Dr. Keever has instructed countless interns and residents in his specialty over the past 18 years. He received the "Preceptor of the Year" award for his Critical Care Clerkship from the UCSF School of Pharmacy in 1998. He also is the only non-physician to receive the Cedars-Sinai Medical Center's "House Staff Recognition Award" for excellence in education and patient care from the Department of Medicine in 2003. He also received the Cedars-Sinai "President's Award" in acknowledgement of his contributions to patient care and teaching of students and residents.

Mark's rotation is one of the most demanded rotations by students and residents alike. In addition, all new pharmacists who want to staff in the critical care units must be trained by Mark before they can solo. He is an excellent practitioner, preceptor, and outstanding role model. His dedication to patient care and his love of pharmacy serves our profession well."

The Board of Pharmacy is extremely gratified to acknowledge two such dedicated, talented and deserving pharmacists with the Exceptional Preceptor Award of 2009. Congratulations to you both and thank you.

To nominate an individual for this award, please send the nominee's name, a description of why his or her contributions are significant or worthy of Board recognition, and three letters of recommendation supporting the nomination to:

> Virginia Herold, Executive Officer California Board of Pharmacy 1625 N. Market Blvd., Suite N-219 Sacramento, CA 95834

# www.pharmacy.ca.gov

### **Changes in Pharmacy Law**

Continued from Page 3

drugs furnished by a pharmacy and deletes the definition of "long-term care facility."

#### Nonresident Wholesaler

**B&PC** §4161 (Amended)—clarifies the duties of a nonresident wholesaler.

### Dispensing by Pharmacist upon Order of Nurse Practitioner, et al.

**B&PC** §4174 (Amended)—changes section reference relating to pharmacists dispensing upon orders of a nurse practitioner, certified nurse-midwife, physician assistant or naturopathic doctor.

### Requirements for Renewal of Pharmacist License: CE Hours; Exemption

**B&PC** §4231 (Amended) authorizes the Board, as part of an audit or investigation by the Board, to inactivate a pharmacist license when a pharmacist certifies completion of the required CE as part of a renewal but fails to provide documentation substantiating completion of the CE.

#### Obtaining License by Fraud or Misrepresentation; Unprofessional Conduct

**B&PC** §4301 (Amended)—for purposes of this section, adds that the definition of "long term care facility" is the same as that in H&SC §1418.

**Disciplinary Grounds: Failure to** Notify Board of Termination of Pharmacist-in-Charge; Continuing to Operate without Pharmacist B&PC §4305 (Amended)-specifies that anyone licensed to conduct a pharmacy and who willfully fails to provide timely notification to the Board that the pharmacist-in-charge is no longer acting in that capacity, but continues to allow compounding or dispensing except by a pharmacist under the supervision of a pharmacist-in-charge, shall be subject to summary suspension or revocation of his or her license to conduct a pharmacy.

### Misdemeanor: Non-Pharmacist Acting as Manager

**B&PC** §4329 (Amended)—makes a non-pharmacist who performs as a manager, supervisor, or pharmacistin-charge of a pharmacy guilty of a misdemeanor.

**Misdemeanor: Pharmacy Owner B&PC** §4330 (Amended)—clarifies that any pharmacy owner that commits any act that subverts or tends to subvert the efforts of a pharmacist-in-charge to comply with the laws governing the operation of the pharmacy is guilty of a misdemeanor.

### Persons Authorized to Write or Issue a Prescription

**B&PC §11150 (Amended)**—Adds naturopathic doctor to the list of those who are authorized to write or issue a prescription within the scope of either Section 4052.1 or 4052.2.

Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature H&SC §11165 (Amended) requires a clinic that dispenses Schedules II, III or IV controlled substances to report the required information to CURES.

#### SB 821 (Committee on Business, Professions and Economic Development/ Consumer Affairs: Professions and Vocations), Chapter 307, Statutes of 2009

#### **E-Mail Notification List B&PC §4013 (New)**—requires any Board-licensed facility to join the Board's e-mail notification list within 60 days of obtaining a license or at the time of license renewal. Such facilities must update the Board's e-mail notification list within 30 days of any e-mail address change. Effective date is July 1, 2010.

Notification of Board: Pharmacistin-Charge; Designated Representative-in-Charge B&PC §4101 (Amended)—specifies that any pharmacist may act as pharmacist-in-charge upon the pharmacy's application to and approval by the Board. A designated representative or pharmacist may act as designated representative-incharge of a wholesaler or veterinary food-animal retailer upon the wholesaler's or veterinary foodanimal retailer's application to and approval by the Board. Any pharmacist-in-charge or designated representative-in-charge who ceases to act as such must notify the Board in writing within 30 days of his or her change in status.

### Nonresident Pharmacy Requirements

**B&PC §4112 (Amended)** explicitly states that a person cannot act as a nonresident pharmacy unless he or she has obtained a license from the Board and authorizes the Board to register a nonresident pharmacy organized as an LLC in the state in which it is licensed.

### Pharmacist-in-Charge: Notification to Board; Responsibilities

B&PC §4113 (Amended)—clarifies that a proposed pharmacist-in-charge must be approved by the Board, and a new or renewal license will not be issued without identification of an approved pharmacist-in-charge. Within 30 days of the date when a pharmacist-in-charge ceases to act in that capacity, his or her replacement shall be named on the same form and submitted to the Board for approval. If disapproved, the pharmacy must propose another replacement within 15 days of the disapproval. The Board will not issue or renew a pharmacy license without the identification of an approved pharmacist-in-charge. However, this section allows for the use of an interim pharmacist-incharge, for a period of not greater than 120 days, when a pharmacy is unable to identify a new permanent pharmacist-in-charge within 30 days as required.

#### Needle /Syringe Return in Sharps Container

**B&PC** §4146 (New)—authorizes pharmacies to accept the return of needles and syringes from the public if contained in a "sharps container," as specified in H&SC section 117750.

Wholesaler: License Required B&PC §4160 (Amended)—specifies that every wholesaler shall be supervised or managed by a designated representative-incharge who shall be responsible for compliance with state and federal laws governing wholesalers. When applying for an initial license and each renewal license, the wholesaler must submit to the Board for approval (on a Board form), the name and license number of the proposed designated representative-in-charge or pharmacist who will serve as the designated representative-in-charge. Within 30 days of the date when a designated representative-in-charge ceases to act in that capacity, his or her replacement shall be named on the same form and submitted to the Board for approval. If disapproved, the wholesaler must propose another replacement within 15 days of the disapproval. The Board will not issue or renew a wholesaler license without the identification of an approved designated representativein-charge.

#### Veterinary Food-Animal Drug Retailer: Requirements B&PC §4196 (Amended)—specifies that every veterinary food-animal drug retailer shall be supervised or managed by a designated representative-in-charge, who shall be responsible for compliance with state and federal laws governing veterinary food-animal drug retailers. When applying for an initial

license and each renewal license, the veterinary food-animal drug retailer must submit to the Board for approval (on a Board form), the name and license number of the proposed designated representativein-charge. Within 30 days of the date when a designated representativein-charge ceases to act in that capacity, his or her replacement shall be named on the same form and submitted to the Board for approval. If disapproved, the veterinary foodanimal drug retailer must propose another replacement within 15 days of disapproval. The Board will not issue or renew a veterinary foodanimal drug retailer license without the identification of an approved designated representative-in-charge.

#### Examination Process to be Reviewed Regularly; Required Standards and Retaking National Examination after Failure; Waiting Period B&PC §§4200.3 and 4200.4

(Amended)—advises that the name of Office of Professional Examination Resources was changed to Office of Professional Examination Services.

#### AB 931 (Fletcher), Chapter 491, Statutes of 2009

### Emergency Supplies; Doses Stored in an Emergency Supplies Container

H&SC §1261.5 (Amended) increases from 24 to 48 the number of oral or suppository dosage forms provided by a pharmacy to a health facility for storage in an emergency supplies container. The State Department of Public Health (SDPH) may limit the number of doses of each drug in each emergency supply to no more than 16. Not more than four doses of the 48 oral or suppository form drugs stored in an emergency supplies container shall be psychotherapeutic drugs. However, the SDPH has authority to increase that number in special circumstances.

#### AB 1071 (Emerson), Chapter 270, Statutes of 2009

### Board of Pharmacy: Appointments; Terms

**B&PC** §4001 (Amended)—requires this section to remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before that date deletes or extends that date.

#### Executor Officer; Records; Revenue

**B&PC §4003 (Amended)**— requires this section to remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before that date deletes or extends that date.

#### **Temporary License to Compound Injectable Sterile Drug Products for Change of Ownership B&PC §4127.8 (Amended)** specifies temporary license fee to be set by the Board, pursuant to B&PC §4400.

### Fees

**B&PC** §4400 (Amended) restructures amounts set for licensure fees and penalties.

### **Regulation Update**

On September 3, 2009, two regulation changes to Division 17, Title 16 of the California Code of Regulations became effective. Section 1773 was amended to include completion of an ethics course as one of the conditions of disciplinary probation. Section 1773.5 was added to detail the contents required of an ethics course.

Additionally, on January 6, 2010, new regulations, sections 1735-1735.8, relating to the compounding of injectable drug products, were adopted, and sections 1751–1751.8 were amended. These new regulations and the amended portions of sections 1751-1751.8 become effective July 6, 2010.

Please review the exact text of these regulatory changes at www.pharmacy.ca.gov/laws\_regs/new\_laws.pdf.

### **Explanation of Disciplinary Terms**

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

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

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

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

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

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

**Voluntary Surrender**—the licensee has agreed to surrender his or her license, and the right to practice or operate Board-licensed entity is ended. The board may agree to accept the surrender of a license through a "stipulation" or agreement. **Suspension**—the licensee is prohibited from practicing or operating a Board-licensed entity for a specific period of time.

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

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

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

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

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

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

### **Disciplinary Actions**

From August 13, 2008, through December 31, 2009, the following licenses were disciplined through actions taken by the Board. To view details of the probation terms and conditions of each case, go to the Board's Web site, *www.pharmacy.ca.gov*, and from the "Quick Hits" menu, select "Enforcement Actions."

#### Revoked Pharmacist and Pharmacy Technician Licenses

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

Allen, La Donna M., TCH 57325, San Quentin, CA—Case 3168 Decision effective 02/05/2009 Andrews, Kelly L., TCH 65210, El Cajon, CA—Case 3268 Decision effective 10/09/09 Armendariz, Manuel, TCH 49698, Downey, CA-Case 3239 Decision effective 10/09/09 Bailey, Kristen A., TCH 32272, La Mesa, CA-Case 3173 Decision effective 02/26/2009 Byrd, Patricia K., RPH 46869, Santa Rosa, CA-Case 3181 Decision effective 02/05/2009 Do, Daniel, TCH 55182, Long Beach, CA-Case 3187 Decision effective 10/09/09 Dolan, Rochelle, TCH 45962, Huntington Beach, CA-Case 3249 Decision effective 07/24/2009 Fujisawa, Laura, RPH 37589, Reedley, CA-Case 3095 Petition to Revoke Probation was granted. The stay of revocation was vacated, probation revoked, and revocation reinstated. Decision effective 07/16/2009 Fuqua, Jimmy L., TCH 3154, Minneapolis, MN-CA 3180 Decision effective 10/15/2009

Goodrow, Olivia, TCH 54846, Roseville, CA-Case 3138 Decision effective 03/11/2009 Haslam, Ronald, RPH 43678, La Mesa, CA-Case 3201 Decision effective 11/25/09 Herring, Dale L., RPH 36500, Gosport, IN-Case 2574 Decision effective 04/08/2009 Hickey, Melanie, RPH 36032, San Diego, CA-Case 3217 Decision effective 08/14/2009 Ibarra, Karen G., TCH 34516, San Diego, CA-Case 3151 Decision effective 02/05/2009 Iriarte, Adrian, TCH 62634, Oceano, CA-Case 3203 Decision effective 05/08/2009 Jenkins, Andrea, TCH 21784, Port Hueneme, CA-Case 3153 Decision effective 03/11/2009 Kime, Donald, TCH 58195, Ontario, CA-Case 3248 Decision effective 05/08/2009 Lewis, Dochelle, TCH 12910, Moreno Valley, CA-Case 3171 Decision effective 07/24/2009 Mailyan, Melik, TCH 14727, Burbank, CA-Case 3128 Decision effective 05/27/2009 McDonald, Kristal R., TCH 33305, Oroville, CA-Case 3255 Decision effective 08/14/2009 McKenzie, Amber, TCH 54104, Lemon Grove, CA-Case 3257 Decision effective 10/15/2009 Minson, Heidi, TCH 46372, Escondido, CA-Case 3188 Decision effective 01/22/2009 Montague, Sarah L., TCH 39166, San Bernardino, CA-Case 3169 Decision effective 02/05/2009 Parish, Sandra Dee, TCH 60425, Citrus Heights, CA-Case 3143 Decision effective 01/22/2009 Phan, Mai Huong, TCH 22618, Westminster, CA-Case 3189 Decision effective 01/22/2009 Pittman, Adam, RPH 51848, Hemet, CA-Case 3198 Decision effective 07/24/2009 Rastocky, David, RPH 44112, Thousand Oaks, CA-Case 3035 By Stipulated Settlement and Disciplinary Order Decision effective 05/08/2009 Rasulov, Sabina, TCH 43095, Studio City, CA-Case 3115 Decision effective 01/22/2009 Roht, Mart, RPH 25106, Glendale, CA-Case 3142 Decision 04/10/2009 Shupe, Bradley A., TCH 71749, Spring Valley, CA-Case 3261 Decision effective 10/30/09 Tabara, Angelica, TCH 63715, Daly City, CA-Case 3218 Decision effective 10/14/2009 Thompson, Christopher M., Santa Clara, CA-Case 3237 Decision effective 10/14/2009 Torres, David, TCH 66714, Garden Grove, CA-Case 3160 Decision effective 01/22/2009 Varderesyan, Yervand, TCH 30864, Van Nuys, CA-Case 3102 Decision effective 12/03/2008 Voshake, Renee R., RPH 45674, Clovis, CA-Case 3226 Decision effective 10/09/2009 Warnecke, Gary, RPH 38265, Yorba Linda, CA-Case 3205 Decision effective 10/15/2009

York, Jennifer, TCH 43949, Corona, CA—Case 3129 Decision effective 12/03/2008

**Revoked Pharmacy Licenses** The following pharmacies are no longer licensed and the right to operate a pharmacy has been terminated.

Hawaii Pharmacy, PHY 46650,
Hawaiian Gardens, CA—Case 3115 Decision effective 01/22/2009
Lombard Pharmacy, PHY 43635,
Thousand Oaks, CA—Case 3035 By Stipulated Settlement and Disciplinary Order Decision effective 05/08/2009
Ringo Pharmacy, PHY 35278,
Compton, CA—Case 2896 Decision effective 11/14/2008
Sav Mart Drugs, PHY 19709,
Burbank, CA—Case 3155 Decision effective 11/25/09

Pharmacy Licenses Revoked, Stayed, Two Years' Probation The following licenses were revoked, revocations stayed, and the licensees placed on two years' probation. If the terms and conditions of probation are not followed, the original revocations can be reinstated.

Cathay Pharmacy, PHY22806, Los Angeles, CA—Case 3086 Probation also includes 7 days suspension. Decision effective 07/24/2009

> Pharmacist Licenses Revoked, Stayed, Three Years' Probation

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

Bui, Noelle Doan, RPH 53005, Garden
Grove, CA—Case 3137
By Stipulated Settlement and
Disciplinary Order, probation terms include the prohibition of functioning as PIC or preceptor.
Decision effective 05/08/2009
Chinn, James, RPH 27782, San Diego,
CA—Case 3094
By Stipulated Settlement and
Disciplinary Order, probation terms

Decision effective 05/27/2009 Fong, David J., RPH 37204, Alhambra, CA-Case 3082 By Stipulated Settlement and Disciplinary Order, probation terms include 30 days' suspension and prohibit functioning as PIC or preceptor. Decision effective 07/24/2009 Jeleti, John M., RPH 49954, Stockton, CA-Case 3219 By Stipulated Settlement and Disciplinary Order, probation terms include 30 days' suspension and prohibits functioning as PIC or preceptor. Decision effective 12/31/2009 Kerley, Robert G., RPH 26099, Porterville, CA-Case 3110 Probation terms include the prohibition of functioning as PIC or preceptor. Decision effective 05/27/2009 Kim, Jonas, RPH 40260, San Marino, CA-Case 3120 Probation terms include the prohibition of functioning as PIC or preceptor. Decision effective 02/26/2009 Patel, Kruti, RPH 57787. San Diego, CA-Case 3174 By Stipulated Settlement and Disciplinary Order; probation terms include prohibition of functioning as PIC or preceptor. Decision effective 04/10/2009 West-Lackey, Jennifer, RPH 41647, Folsom, CA-Case 3531 Probation terms include prohibition of functioning as PIC or preceptor and must take and pass the CPJE. Decision effective 09/22/2009 **Pharmacy License Revoked**, Stayed, Three Years' Probation

include the prohibition of functioning

as PIC or preceptor.

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

College Pharmacy, PHY 36574, Los Angles, CA—Case 3086 By Stipulated Settlement and

See Disciplinary Actions, Page 26

By Stipulated Settlement and

Decision effective 10/21/2009

By Stipulated Settlement and

Decision effective 05/27/2009

By Stipulated Settlement and

Decision effective 01/09/2009

By Stipulated Settlement and

Decision effective 05/27/2009

Decision effective 11/14/2008

probation terms include the

Decision effective 08/19/2009

Decision effective 01/22/2009

suspension from working as a

by the Pharmacy Technician

Decision effective 11/14/2008

By Stipulated Settlement and

prohibit functioning as PIC or

Decision effective 01/22/2009

Disciplinary Order, probation terms

monitor is required.

Oxnard, CA-Case 3038

preceptor.

Nitsche, Steven L., RPH 38997,

Mason, Richard P., TCH 58735,

Martin, Willard C., RPH 30357,

licensed entity.

San Diego, CA-Case 3178

as PIC or preceptor.

San Diego, CA-Case 3117

as PIC or preceptor.

Gold, Ira S., RPH 23079,

San Jose, CA-Case 3070

as PIC or preceptor.

Lovelace, Kenneth, RPH 35049,

Los Angeles, CA-Case 2896

Van Nuys, CA-Ca 2928

Winters, CA—Case 3112

preceptor.

preceptor.

Vista, CA-Case 3119

Fannella, Joseph, RPH 40568,

Oertli, Ellen M., RPH 41806. Disciplinary Order, probation terms Lacey, WA-Case 3344 prohibit ownership of any board By Stipulated Settlement and Disciplinary Order, probation terms include 90 days' suspension and prohibits functioning as PIC or DiBenedetto, Thomas, RPH 46169, preceptor. Decision effective 12/31/2009 Disciplinary Order, probation terms Peters, Roger, EXC 15686, include the prohibition of functioning Stockton, CA-Case 3253 By Stipulated Settlement and Disciplinary Order, probation terms include suspension of duties as designated representative for 10 days, may not be designated Disciplinary Order, probation terms representative-in-charge of any include the prohibition of functioning Board-licensed entity other than Valley Wholesale Drug Company, and must complete 200 hours of community service. Decision effective 12/31/2009 Reynolds, Linda, RPH 37729, Disciplinary Order, probation terms West Sacramento, CA-Case 3039 include the prohibition of functioning By Stipulated Settlement and Disciplinary Order, probation terms prohibit functioning as PIC or preceptor. Decision effective 06/25/2009 Wolfe, Daryl S., RPH 46273, Margolin, Steven M., RPH 36992, Windsor, CA-Case 3152 By Stipulated Settlement and Board decision after Non-Adoption, Disciplinary Order, probation terms include 120 days' suspension and prohibit functioning as PIC or prohibition of functioning as PIC or preceptor. Decision effective 11/25/2009 Zimmerman, William C., RPH 37252, San Jose, CA-Case 3182 Included in the terms of probation By Stipulated Settlement and are supervised practice and the Disciplinary Order, probation terms prohibition of functioning as PIC or prohibit functioning as PIC or preceptor. Decision effective 08/14/2009 Wholesaler License Revoked, The terms of probation include Stayed, Five Years' Probation The following license was revoked, pharmacy technician until certified revocation stayed, and the license placed on five years' probation. If Certification Board, and a worksite

the terms and conditions of probation are not followed, the original revocations can be reinstated.

Valley Wholesale Drug Company, WLS 1410, Stockton, CA-Case 3253 By Stipulated Settlement and Disciplinary Order, probation terms include the posting a notice of probation.

### **Disciplinary Actions**

Continued from Page 25

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Disciplinary Order, probation also includes three days' suspension. Decision effective 07/24/2009

### Pharmacist License Revoked,

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

Palm, James, RPH 41806,

Vacaville, CA-Case 3165 By Stipulated Settlement and Disciplinary Order, probation also includes 60 days' suspension. Decision effective 11/25/2009

Pharmacy License Revoked, **Stayed, Four Years' Probation** The following license was revoked, revocations stayed, and the license placed on four years' probation. If the terms and conditions of probation are not followed, the original revocation can be reinstated.

Raley's Central Pharmacy, PHY 45843, West Sacramento, CA-Case 3165 By Stipulated Settlement and Disciplinary Order, probation also includes seven days' suspension. Decision effective 10/23/2009

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

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

Alexander-Perez, Christy, RPH 53901, Sacramento, CA-Case 3179 By Stipulated Settlement and Disciplinary Order, probation terms include prohibition of functioning as PIC or preceptor. Decision effective 02/26/2009 Arutunyan, Narine, TCH 86550, Sun Valley, CA-Case 3353

Decision effective 12/31/2009

#### **Statement of Issues**

By hearing decision, the following applications for pharmacist, intern, and pharmacy technician registration were granted, licenses issued, revoked, stayed, and placed on probation.

#### Agyeman, Kwaku Yeboah, INT 25490,

Loma Linda, CA—Case SI 3342 By Stipulated Settlement and Disciplinary Order, license placed on five years' probation. Decision effective 12/30/2009

Arelis-Guzman, Lidia, TCH 76381, Stockton, CA—Case SI 3135 By Stipulated Settlement and Disciplinary Order, license placed on three years' probation. Decision effective 05/27/2009

Horwitz, Robert, TCH 77802,

Walnut Creek, CA—Case SI 3163 License placed on ten years' probation. Decision effective 11/14/2008

Otis, Stephen, RPH 62442,

Carlsbad, CA—Case SI 3045 By Stipulated Settlement and Disciplinary Order, license placed on five years' probation. Decision effective 08/13/2008

Rivera, Eric, TCH 79772, Carson, CA—Case SI 3284 By Stipulated Settlement and Disciplinary Order, license placed on three years' probation. Decision effective 12/16/2009

Schreiber, Somer, TCH 73805, Eureka, CA—Case SI 3193 Licensed placed on three years' probation. Decision effective 07/11/2009

### Voluntarily Surrendered Pharmacist and Pharmacy Technician Licenses Through disciplinary actions of the

Board, the following licenses were voluntarily surrendered or retired.

Bagoyo, Trinidad, RPH 22293,
Canyon Lake, CA—Case 3353
By Stipulated Retirement of License and Order, license was retired.
Decision effective 10/21/2009
Chadorbaf, Shahnaz, RPH 43894,
Irvine, CA—Case 3223
By Stipulation, license was retired.
Decision effective 11/25/2009

Johnson, Jeana Marie, TCH 57609, Modesto, CA-Case 3202 Decision effective 04/10/2009 Flores, Roberto, TCH 61788, Santa Barbara, CA-Case 3150 Decision effective 01/09/2009 Godfrey, Karen D., TCH 35412, Encinitas, CA-Case 3204 By Stipulated Surrender of License and Order Decision effective 08/14/2009 Hoang, William Quocthong, RPH 54742, Elk Grove, CA-Case 3091 By Stipulated Surrender of License and Order Decision effective 12/31/2009 Hughes, Dennis, RPH 26090, El Cajon, CA-Case 3175 By Stipulated Surrender of License and Order Decision effective 10/09/2009 Kenison, Cassaundra A., TCH 44918, Newcastle, CA-Case 3146 By Stipulation of Surrender of Disciplinary Order Decision effective 02/26/2009 Mante, Isaac J., TCH 42678, Salinas, CA-Case 3210 By Stipulation of Surrender of Disciplinary Order Decision effective 05/27/2009 Page, Jerry A., RPH 23356, Woodland Hills, CA-Case 3155 By Stipulated Retirement of License and Order Decision effective 11/25/2009 Smith, LaShara, TCH 8245, Lemon Grove, CA-Case 3123 By Stipulation of Surrender of Disciplinary Order Decision effective 04/10/2009 Verduzco, Juana A., TCH 17269, Riverbank, CA-Case 3274 By Stipulated Surrender of License and Order Decision effective 10/14/2009 **Voluntarily Surrendered Pharmacy License** *By stipulation, the following license* 

By stipulation, the following licens was voluntarily surrendered.

Fletcher Med Pharmacy, PHY 44780, La Mesa, CA—Case 3123 By Stipulation of Surrender of Disciplinary Order Decision effective 04/10/2009

#### Kyffin Pharmacy, PHY 46023,

Van Nuys, CA—Case 3161 By Stipulated Surrender of License and Order, and surrender was stayed for 60 days to complete sale of pharmacy

Decision effective 11/25/2009

#### Vermont Pharmacy and Medical Supply, PHY 48275,

N. Hollywood, CA—Case 3353 By Stipulated Surrender of License and Order Decision effective 10/21/2009

#### **Accusation Dismissed**

By hearing decision, the action against this licensee was dismissed.

**Castro, Arnold Aguirre**, RPH 41890, La Mirada, CA—Case 3036 Decision effective 04/10/2009

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