

### CALIFORNIA BOARD OF PHARMACY JANUARY 2006

## **Changes in Pharmacy Law for 2006**

The Assembly and Senate bills listed in this article were enacted in 2005, and unless otherwise specified, took effect January 1, 2006. The new and amended Business and Professions (B&PC) and Health and Safety Codes (H&SC) statutes are paraphrased or summarized below, but you are urged to review the exact language of the statutes at the Board's Web site, *www.pharmacy.ca.gov*.

#### AB 302 (Committee on Business and Professions) Chapter 506, Statutes of 2005

This bill conforms the authorization to write prescriptions or order drugs to the requirements of naturopathic doctors' scope of practice. Naturopathic doctors (pursuant to B&PC 3640.7) are allowed to <u>independently</u> prescribe epinephrine for the treatment of anaphylaxis or natural and synthetic hormones. However, for other prescription products, naturopathic doctors must function as <u>midlevel</u> <u>practitioners under protocol with a</u> <u>supervising physician and surgeon</u> (B&PC 3640.5). Further, drugs furnished or ordered by a naturopathic doctor may include Schedule III-V drugs, but Schedule III controlled substances furnished or ordered by a naturopathic doctor must be in accordance with a patient-specific protocol approved by the treating or supervising physician (B&PC 3640.5).

#### Dispense

**B&P 4024 (Amended)**—adds *naturopathic doctors*, pursuant to B&PC 3640.7, to the list of those who are allowed to prescribe drugs or devices. Naturopathic doctors, pursuant to B&PC 3640.5 and within their scope of practice, can also dispense drugs or devices directly to a patient.

## Physician; Other Practitioners Defined

**B&PC 4039 (Amended)**—adds *naturopathic doctors* to the list of those licensed individuals authorized to practice their professions in this state.

#### Prescription; Content Requirements

**B&PC 4040 (Amended)**—adds *naturopathic doctors* to the list of those who may sign written drug orders.

#### Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions

**B&PC 4059 (Amended)**—adds *naturopathic doctors* to the list of individuals who may write the prescriptions required for dangerous drugs or devices. However, manufacturers, wholesalers, or

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### **President's Message**

#### By Stanley W. Goldenberg, R. Ph. President, Board of Pharmacy

My message today is dedicated and directed to those who are the future of pharmacy—<u>our students</u>. Consequently, this issue will be mailed to each student registered as an intern with the Board. I also am asking all pharmacies and pharmacists to share their newsletters with a pharmacy student.

Preceptors are vitally important to the education and training of future pharmacists. California law now allows a pharmacist to supervise up to two intern pharmacists. <u>I encourage every practicing pharmacist to call a college or school of pharmacy near you, and ask if you can help with their preceptor program.</u>

During my presidency, I have made special efforts to include pharmacy students in the workings of the Board by sending letters to the California schools and colleges of pharmacy, inviting students and faculty to attend the Board meetings. I am pleased to note that students have been attending these meetings. (Registered pharmacists and pharmacy technicians can obtain six hours of continuing education credit for attending.)

Board and committee meetings are held quarterly in various areas of the state, and your attendance and **QUESTION**: How many colleges or schools of pharmacy are in California? **ANSWER**: SEVEN, and they are:

#### Loma Linda University School of Pharmacy

West Hall 1316 11262 Campus Street Loma Linda, CA 92350 (909) 558-7442

#### Thomas J. Long School of Pharmacy & Health Sciences at the University of the Pacific

3601 Pacific Avenue Stockton, CA 95211 (209) 946-2561

#### **Touro University - California College of Pharmacy** 1310 Johnson Lane Mare Island Vallejo, CA 94592 (707) 638-5221

#### University of California, San Diego, Skaggs School of Pharmacy and Pharmaceutical Sciences 9500 Gilman Drive, MC 0657 La Jolla, CA 92093-0657

(858) 534-1366

#### University of California, San Francisco, School of Pharmacy

521 Parnassus Avenue, Room C-156 Box 0622 San Francisco, CA 94143-0622 (415) 476-1225

#### University of Southern California School of Pharmacy 1985 Zonal Avenue Los Angeles, CA 90089-9121 (323) 442-1369

#### Western University of Health Sciences College of Pharmacy

309 E. Second Street Pomona, CA 91766-1854 (919) 469-5581

participation in these meeting is encouraged and welcome. There is no advance reservation needed or fee charged for attending. More detailed information is available on the Board's Web site. Board meeting dates and locations for 2006 are listed on page 20.

#### WHY SHOULD YOU ATTEND?

A major reason for attending the Board meetings is to become involved in the future of pharmacy. By attending the meetings you will learn the systems within which the Board must operate and the Board's procedures. You will become aware of California and national pharmacy issues, including areas where the National Association of Boards of Pharmacy comes into play. By being familiar with this landscape, you can understand how pharmacy laws are developed and contribute to that development with knowledge. This information will give you an "edge" in the marketplace, no matter what aspect of pharmacy you practice.

The Board needs input from all stakeholders so that its members can make fully informed decisions, and those decisions will enable you to contribute to the public health and well-being of all

### **President's Message**

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Californians. Your professional life will be influenced not only by pharmacy law but also by knowledge acquired outside the school. Your input and contributions will influence the direction your professional career takes.

I invite you to attend a Board of Pharmacy meeting and help shape the future for us all. However, for those who cannot attend, you can participate in the Board's strategic planning process by completing a stakeholder's survey, available online in March 2006. For more information regarding the survey, please see "Future Issues Confronting the Board and its Regulatory Role to Protect Consumers" below.

CPJE Update: As you know, to become a registered pharmacist in California, you are required to pass both the North American Pharmacist Licensure Examination (NAPLEX) and the California Pharmacist Jurisprudence Examination (CPJE). Questions for the CPJE are developed according to a content outline that is developed following a job analysis of the pharmacist profession in California. The Board conducted its most recent job analysis in late 2004 and developed a new content outline in 2005. Questions generated by the content outline will be used to construct the CPJE, beginning with CPJE exams administered on and after April 1, 2006. A copy of the new content outline

can be found on Page 8. The outline is also available on the Board's Web site, *www.pharmacy.ca.gov*, then click on "Written Information & Research Tools," then "Pharmacist Exam," then "California Specific Examination CPJE Content Outline for CPJE Exams given on or after April 1, 2006."

On behalf of the Board of Pharmacy, I'd like to extend our wishes to all for a happy and healthy New Year!





#### Future Issues Confronting the Board and its Regulatory Role to Protect Consumers Your comments are sought and needed!

In late March, the Board will offer a survey on its Web site seeking comments from the public, from the profession and from interested individuals. We will be seeking input on future issues facing the Board, the practice of pharmacy and patients concerning prescription medication. These comments will be integrated into the Board's strategic plan, as part of the factors to be considered when developing policy initiatives that will protect the public. The Board is undertaking a major review of its strategic plan this year, and these issues are important in developing a meaningful plan.

There will be a short time frame to provide these comments, which is why the Board's Web site will be used. To make certain you are notified when the survey is available, please become a subscriber to our Web site. It is easy; simply go the Board's Web site, click on "Join our e-mail list," and you will be notified via an e-mail alert when the survey is ready.

Additionally, the Board will create a special mailing list for this survey. To request that a survey be mailed to you, please send your name and address to Board of Pharmacy, 1625 N. Market, Suite N-219, Sacramento, CA 95834, Attn: Stakeholder Survey. We will mail you the survey once it is available.

Thank you in advance for your comments and participation.

### **DOJ** takes over approval process of security printer applications

On January 1, 2006, the Board of Pharmacy transferred the review and approval of applications to become security prescription printers to the Department of Justice, pursuant to SB 734 (Torlakson), Health & Safety Code sections 11161.5 and 11162.1. All new applications must be sent to the DOJ and applications already pending with the Board have been forwarded to the DOJ for final review and approval. The DOJ will maintain a list of approved security printers.

Details of the DOJ's responsibilities relating to security printer applications are outlined in "Changes in Pharmacy Law for 2006" on Page 12.

Please mail current applications and direct any inquiries to:

Department of Justice/Bureau of Narcotic Enforcement CA Security Prescription Printer Program P. O. Box 161089 Sacramento, CA 95816-1089 Phone: (916) 319-9062 Fax: (916) 319-9448

#### New Phone Numbers at the Board

When the Board of Pharmacy moved to the new location, our phone system and numbers changed: The main telephone number is (916) 574-7900, but staff members now have their own individual phone numbers instead of extension numbers. For your convenience, we are listing a few of the most frequently called staff members and their numbers.

For site licenses (pharmacies, hospitals, clinics, licensed correctional facilities, wholesalers and nonresident wholesalers), Changes of Permit and duplicate site licenses:	Brenda Cartwright (916) 574-7943
For site licenses (pharmacies, hospitals, clinics and sterile compounding facilities, PIC changes and discontinuances of business:	Suelynn Yee (916) 574-7945
For the pharmacist licensure exam, duplicate personal licenses, wall certificates, license verifications, transfer of intern hours, and pharmacists from foreign countries:	Amber Crosby (916) 574-7936
For pharmacy intern and pharmacy technician applications:	Angel Kenoly (916) 574-7937
For Board and Committee meetings information:	Candy Place (916) 574-7912

Other staff numbers can be obtained via recorded instructions on the Board's main number.

## Our Thanks to Those who Helped when it Counted



Michael J. Sohmer, R.PH., DMAT-San Diego, and family with Stanley Goldenberg, President, Board of Pharmacy

Following the tragedy of September 11, 2001, an article describing the role of the pharmacist as a member of a Disaster Medical Assistance Team (DMAT) was included in The Script.

DMAT members are intermittent federal employees (who have full time jobs elsewhere) and subject to responding to medical disasters. Teams consist of about 35 people including doctors, nurses, pharmacists, security personnel and others who deploy usually for 14 days with tents, generators, medical supplies, drugs, etc., and are expected to be self-sufficient for the first 72 hours. The Board wishes to recognize one such team of pharmacists and pharmacy technicians and share their heroic actions with you.

The following account was provided by the team leader, Charles Valencia, Pharm.D., of Port Orchard, WA. His assistant, Michael Sohmer, RPh, Craig Steinberg, Pharm.D., Dana Lee, Pharm.D., Susana Leung, RPh, and pharmacy technician Michael D. Jones were all from California. Other out-of-state team members included:

> Cynthia Parks, RPh (OR) Bonnie Vance, RPh (AL) Jim Gervase, RPh (PA) Dana Hurley, RPh (WA) Emelio (Mel) Mastrodomenico, RPh (MA) Craig Lequatte, RPh (USAF) Jim Condron, Pharm Tch (USAF) Lou Gutfleish, RPh (FL) Colleen Grunow, RPh (OR) Vickie Delgado, RPh (TX) Kevin McEnaney, RPh (MA) Kitty Dreisbach, Pharm Tch (PA) Jodi Grim, RPh (NV)

Bill Drake, RPh (MI), was not among those deployed to the New Orleans Airport, but he played a critical role

## Thanks to those who helped

Continued from Page 4

serving as a regional pharmacy supervisor coordinating not only the airport pharmacy operation but also pharmacists at other team deployments.

The team was deployed and after several stops, established a medical base of operations inside the New Orleans Airport lobby on 08/31/05. For the first 36 hours they had no power (only limited emergency power and their own generator power) and no potable water. A pharmacy was set up outside in a FedEx 24 ft. refrigerated truck which contained a FEMA pharmacy cache.

However, before being fully set up, they started to receive large numbers of medical casualties and evacuees from New Orleans. The evacuees arrived by helicopters, paramedic ambulances, buses, and private cars. Helicopters were landing 4-6 at a time (stopping only long enough to unload and take off again), and there was a line of ambulances stretching all the way down the airport ramps, and busloads of nursing home, hospice and other patients.

The operation started with five pharmacists and one technician working nonstop to operate a 24-hour pharmacy. Most of the team had little or no sleep during the first 60 hours. After airport power was restored, the pharmacy operation moved to a bar inside the terminal (The Legends Bar and Grill) where the pharmacy area became known as "The Barmacy."

In the first few days, the team ran out of a lot of drugs including some ACLS drugs, and at one point had no opiate pain medicine for 6-8 hours. There were many patients (nursing home and hospice) for whom they could do little or nothing. They treated some very sick, life-threatening cases (heart attacks, etc.), delivered some babies, and treated many urgent-care wounds and serious injuries. They also triaged and provided three-day supplies of medication for thousands of patients who had run out of maintenance medications. One USAF Gulf War

See Thanks to those who helped, Page 18

## Surety Bond requirement for Wholesalers and Nonresident Wholesalers began January 1, 2006

Beginning January 1, 2006, wholesalers and nonresident wholesalers must post a \$100,000 bond or other means of security acceptable to the Board before they can be issued an original wholesaler license or renew their current licenses. Instead of the bond, applicants can submit other equivalent means of security acceptable to the Board, including a standby letter of credit or cash deposit.

The surety bond form that wholesalers may need to complete is now available on the Board's Web site, *www.pharmacy.ca.gov*, as is information about the other means of security acceptable to the Board.

**Please Note**: The law provides that wholesalers with less than \$10 million in annual sales may qualify for a \$25,000 bond (instead of \$100,000). The surety bond form for this group is still undergoing review by the Administration, which requires the approval of the Office of Administrative Law. We hope to have approval of this bond form in place before April 1.

Individuals with questions may e-mail

Brenda\_Cartwright@dca.ca.gov or Anne\_Sodegren@dca.ca.gov.

## Updated Pharmacy Self-Assessment Forms Available Online

California Code of Regulations section 1715 requires the pharmacist-incharge (PIC) of each California pharmacy to complete a self-assessment of the pharmacy's compliance with federal and state law. The assessment must be performed before July 1 of each odd-numbered year and within 30 days whenever (1) a new pharmacy permit has been issued or (2) there is a change in the PIC. There are separate forms for community and for inpatient pharmacies, which can be downloaded from the Board's Web site, *www.pharmacy.ca.gov*.

The latest version of the selfassessment was formally adopted as a board regulation in early October 2005. Pharmacies are expected to be using the 2005 version of the self-assessment form to assess their compliance with state and federal laws. Board inspectors will continue to check for completion of the 2005 self-assessment form during inspections.

## Prescription medication container labels must contain physical description of the drug

On January 1, 2006, a new requirement for labels on prescription containers dispensed from outpatient pharmacies became effective. This requirement is the physical description of the dispensed medication, including its color, shape and any identification code that appears on the tablets or capsules, pursuant to Business & Professions Code section 4076(a)(11)(A).

For example, a prescription label for Ibuprofen Tab 400mg might include the notation, "*This medicine is a white, oval-shaped, film-coated tablet imprinted with IBU 400.*" A label for Pravachol might include, "*Square yellow tablet, Side 1: P, Side 2: PRAVACHOL #20.*"

See Prescription container, Page 19

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JANUARY 2006



Board honorees and guests

## Board honors pharmacists registered for at least 50 years

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

Fifty additional pharmacists were recently awarded certificates commemorating 50 years of service and invited to attend future Board meetings where they could be publicly honored. At least 18 honorees attended the October meeting, and we are pleased to share some of their comments with you.

• John R. Kenny, Jr., who graduated from pharmacy school in 1943, traveled from Maryland to attend the Board meeting.

Anderson, Jr., Oliver R **Baker** Nubert Behler, Robert D Cholakian, George Chow, Calvin C Costello, Kenneth R Elkin, Eugene Espinosa, William C Farnworth, Glenn T Gelfand, Sander Grimstead, Donna L Hays Fern L Hill, Donald E Hiura, Robert A Jones, Stanley F Kato, Shigemi M Kenwood, Frank Kobayashi, Earl Kuschnereit. Milton Lawrence, Gregson D Lee, David S Leonard, Oscar L Lester, Leland K Lew William McDougald, Charles A McIntosh, Earl G Moreno, Oswald J Neumen, Joseph R Pallares, Oscar Persson, Niles L Petersen, Wayne A Peterson, Lawrance L Petrulakis, Anthony Plake, John H Potash, Stanley Pullen, Robert J Rotenberg, Joseph I Sain, Kenneth E Sarboraria, John A Schieser, David W Shahin, Philip H Sheu, George Siouris, George C Steo, Daniel F Takeda, Edward K Turner, George W Wilson, Byron N Wright, Richard W Zosel, Jr., Harold A

San Rafael, CA Fresno, CA Stockton, CA Fresno, CA Burlingame, CA Brentwood, CA Riverside, CA Yucaipa, CA Rocklin, CA Huntington Beach, CA Murphys, CA Healdsburg, CA Pleasanton, CA West Covina, CA Fresno, CA Los Angeles, CA Pacific Grove, CA San Mateo, CA Sacramento, CA Montague, CA Los Angeles, CA Paradise, CA Castro Valley, CA Rancho Palos Verdes, CA Corcoran, CA San Jose, CA Santa Barbara, CA Redlands, CA Glendale, CA Madera, CA Hemet, CA Santa Rosa, CA Modesto, CA Seauim, WA Los Angeles, CA Visalia, CA Tiburon, CA Altadena, CA Livermore, CA Sausalito, CA Apple Valley, CA San Gabriel, CA Elk Grove, CA Northridge, CA San Jose, CA Sage, AR Crescent City, CA San Jose, CA

Pleasanton, CA

Mr. Kenny praised the profession, is licensed in six states and still working as a pharmacist.

- Wayland C. Fuller and his daughter thanked the Board and noted that he had owned his own pharmacy from 1962 to 1998. He continues to renew his license and obtain continuing education credit.
- George T. Golish began working at Walgreens at age 10 and acknowledged that Walgreens put him through college. He owned his own pharmacy for 24 years in Castro Valley where he enjoyed the pharmacy profession very much.
- Billy Bob Speck, a 1953 graduate of UCSF, was working (he owns three independent pharmacies in Richmond, California) and could not be present, but his recognition by the Board was accepted by his grandson who is also pursuing a career in pharmacy.
- Nicholas J. Ivans, a graduate of USC and licensed in 1950, and his wife are both pharmacists. In 1954, Mr. Ivans was paralyzed by Polio, but with his wife's assistance, they managed to keep their pharmacy open. He added that he loved the pharmacy profession and the people he met.
- Richard G. Barberian, licensed in 1953, owned a neighborhood pharmacy for 38 years. Mr. Barberian noted that the profession represents a health care bargain for patients and thanked the Board for its recognition of his service.
- William A. Rose was able, through the GI Bill of Rights following World War II, to obtain his pharmacy education at Oregon State University in 1952 and eventually settled in Modesto. Mr. Rose thanked the Board.
- William A. Siskin, a graduate of UCSF in 1940, was a registered pharmacist for 65 years and owned his own pharmacy for 31 years. He added that he was proud of his profession and enjoyed his relationship with his customers.
- Robert D. Gibson, a University of Oregon graduate in 1954, stated that he had enjoyed a successful and rewarding career and recommended the profession to students present at the meeting. He also noted that he was very proud of Board Members Ruth Conroy, Ken Schell and Dave Fong, who were former students of his.
- Robert A. Brown graduated from Purdue University in 1951 and owned a pharmacy in Culver City for 25 years. He recommended to those interested in a pharmacy career to open a small compounding pharmacy.
- Burt Freeman noted that he was a second-generation pharmacist and was in the first graduating class at Northeastern University (Massachusetts) to test for a pharmacist license in 1954. He also thanked the Board for this recognition.
- Frederick S. Mayer was licensed in 1954 and owned his own pharmacy in Sausalito, California, for 40 years. Mr. Mayer praised the pharmacy profession and stated that he had enjoyed his career. He acknowledged the students in the audience and thanked the Board for honoring him.
- Howard J. Murphy graduated from USCF and was licensed in 1952. He thanked the Board for this recognition and

### California Pharmacist Jurisprudence Exam (CPJE) Content Outline (4/1/06)

Questions for the CPJE exam to be administered on or after 4/1/06 will be developed from the following criteria (based on a job analysis of the pharmacist profession in California in 2004).

#### 1. Provide Medication to Patients

#### 25 Items

#### A. Organize and Evaluate Information

- 1. Interpret prescription/medication order
- 2. Obtain information from the patient/patient's representative for patient profile (diagnosis or desired therapeutic outcome, allergies, adverse reactions, medical history, etc.)
- 3. Obtain information from prescriber and/or health care professionals for patient profile (diagnosis or desired therapeutic outcome, allergies, adverse reactions, medical history, etc.)
- 4. Assess prescription/medication order for completeness, correctness, authenticity, and legality
- 5. Assess prescription/medication order for appropriateness (e.g., drug selection, dosage, drug interactions, dosage form, delivery system)
- 6. Evaluate the medical record/patient profile for any or all of the following: disease states, clinical condition, medication use, allergies, adverse reactions, disabilities, medical/surgical therapies, laboratory findings, physical assessments and/or diagnostic tests
- 7. Evaluate the pharmaceutical information needs of the patient/patient's representative

#### **B.** Dispense Medications

- 1. Enter prescription information into patient profile
- 2. Prepare IV admixtures
- 3. Document preparation of medication in various dosage forms (e.g., compounded, unit dose)
- 4. Document preparation of controlled substances for dispensing
- 5. Verify label(s) for prescription container(s)
- 6. Select auxiliary label(s) for container(s)
- 7. Perform the final check of the medication prior to dispensing 25 Items

#### 2. Monitor and Manage Patient Outcomes

#### A. Determine a Course of Action and Manage Patient Outcomes

- 1. Determine desired therapeutic outcomes
- 2. Develop a therapeutic regimen for prescription medications (e.g., recommend alteration of prescribed drug regimen; select drug if necessary)
- 3. Determine the need for a referral
- 4. Communicate the therapeutic plan to the patient/patient's representative, the prescriber and other health care professionals
- 5. Recommend/order necessary monitoring and screening procedures (e.g., blood pressure, glucose levels, drug levels)
- 6. Communicate results of monitoring to patient/patient's representative, prescriber and/or other health care professionals
- 7. Manage drug therapy according to protocols

#### **B.** Educate Patients and Health Care Professionals

- 1. Assess the patient's understanding of the disease and treatment
- 2. Counsel patient/patient's representative regarding prescription medication therapy and devices
- 3. Counsel patient/patient's representative regarding nonprescription medication (OTC)
- 4. Counsel patient/patient's representative regarding herbal/complementary therapies
- 5. Counsel patient/patient's representative regarding non-drug therapy
- 6. Counsel patient/patient's representative regarding self-monitoring of therapy (e.g., devices, symptoms)
- 7. Verify the patient's/patient representative's understanding of the information presented
- 8. Educate health care professionals (e.g., physicians, nurses, medical residents/fellows, other health care providers/students, precepting intern pharmacists)

#### 3. Manage Operations

#### 25 Items

- A. Procure Pharmaceuticals, Devices and Supplies and Control Inventory
  - 1. Place orders for pharmaceuticals, durable medical equipment, devices and supplies, including expediting of emergency orders
  - 2. Maintain a record-keeping system of items purchased/received/returned in compliance with legal requirements
  - 3. Maintain a record of controlled substances ordered, received, stored and removed from inventory
  - 4. Store pharmaceuticals, durable medical equipment, devices and supplies under proper storage conditions
  - 5. Dispose of expired or recalled pharmaceuticals, durable medical equipment, devices, supplies and document actions taken
  - 6. Communicate changes in product availability (e.g., formulary changes, recalls, shortages) to pharmacy staff, patient/patient's representative, physicians and other health care professionals
  - 7. Maintain policies and procedures to prevent theft and/or drug diversion

#### **B.** Perform Quality Assurance/Improvement

- 1. Assess pharmacist and/or pharmacy technician competence
- 2. Ensure the accuracy of medication administration
- 3. Implement a system for medication error prevention, assessment, and reporting (e.g., root cause analysis, National Patient Safety Goals)
- 4. Implement a system by which adverse drug reactions are documented, analyzed, evaluated and reported

#### C. Manage Operations, Human Resources and Information Systems

- 1. Monitor the practice site and/or service area for compliance with federal, state and local laws, regulations and professional standards
- 2. Supervise the work of pharmacy staff
- 3. Ensure the availability, control, and confidentiality of patient and prescription information (e.g., patient profiles, medication administration records)

#### D. Manage Medication Use System

- 1. Maintain a formulary system
- 2. Apply therapeutic interchange
- 3. Conduct medication use evaluations

#### TOTAL: 75 questions plus 15 unscored pretest items

Continued from Page 1

pharmacies may furnish dangerous drugs or devices to a naturopathic doctor pursuant to B&PC 3640.7 without a prescription, but must maintain all sales and purchase records on the transaction.

#### Who May Order Dangerous Drugs or Devices: Exceptions; Compliance With Laws of All Involved Jurisdictions

**B&PC 4059.5 (Amended)**—allows a dangerous drug or device to be ordered by and provided to a *naturopathic doctor* acting pursuant to B&PC 3640.7. Recipients of the dangerous drugs or devices must be authorized by law to receive the drugs or devices and must comply with all state and federal laws of the state or country to which the drugs or devices are delivered.

#### Controlled Substance – Prescription Required; Exceptions

**B&PC 4060 (Amended)**—requires a prescription or a drug order for the possession of controlled substances and adds *naturopathic doctors* to the list of those may furnish controlled substances. However, this possession requirement does not apply to controlled substances that are in stock in correctly labeled containers that include the name of the supplier or producer. Naturopathic doctors are not authorized to order their own stock of dangerous drugs and devices.

#### Distribution of Drug as Sample; Written Request Required

**B&PC 4061 (Amended)**—requires *naturopathic doctors* who want complimentary samples of dangerous drugs or devices, to submit written requests to the manufacturer's sales representative. A naturopathic doctor who functions pursuant to B&PC 3640.5 may sign for the request and receipt of complimentary samples of a dangerous drug or device that has been identified in the standardized procedure, protocol or practice agreement that includes specific approval by a physician.

#### Prescription Container – Requirements for Labeling

B&PC 4076 (Amended)—prohibits a pharmacist from dispensing any prescription in a container that is not correctly labeled and does not meet state and federal law. If prescribed by a naturopathic doctor, his or her name must be included in the container's label. However, if a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to H&SC 1250, it is not necessary to include on individual unit dose containers for a specific patient, the name of the naturopathic doctor who functions under a standardized procedure or protocol developed by the naturopathic doctor and his or her supervising physician (B&PC 3640.5).

### Prescription Required

**B&PC 4142 (Amended)**—requires a prescription for the retail sale of a hypodermic needle or syringe. Prescriptions written by *naturopathic doctors* for hypodermic needle and syringes are authorized for use with epinephrine to treat anaphylaxis and natural and synthetic hormones (B&PC 3640.7).

#### Dispensing by Prescriber: Requirements and Restrictions; Enforcement

B&PC 4170 (Amended)authorizes a naturopathic doctor who functions pursuant to B&PC 3640.5 to hand to a patient of the supervising physician and surgeon a properly labeled prescription drug prepackaged by a physician and surgeon, a manufacturer or a pharmacist. The Bureau of Naturopathic Medicine shall have authority with the California State Board of Pharmacy to ensure compliance of their respective licensees with this section and is charged with its enforcement. "Prescriber" in this section includes a person who holds a Bureau of Naturopathic Medicine license to practice naturopathic medicine.

#### Dispensing by Pharmacist Upon Receipt of Drug Orders B&PC 4174 (Amended)—adds

naturopathic doctors to the list of those to whom a pharmacist is authorized to dispense drugs or devices upon receipt of a drug order. Naturopathic doctors must function under standardized procedures or protocols with a supervising physician pursuant to B&PC 3640.5 (i.e., Drugs furnished by a naturopathic doctor may include Schedules III through V controlled substances and limited to those drugs agreed upon in the procedures or protocols. Schedule III controlled substances furnished or ordered by a naturopathic doctor must be in accordance with a patient-specific protocol approved by the treating or supervising physician.)

#### **Processing of Complaints**

**B&PC 4175 (Amended)**—requires the Board of Pharmacy to promptly forward all complaints related to dangerous drugs or devices dispensed by a *naturopathic doctor* and complaints involving serious bodily harm, to the Bureau of Naturopathic Medicine.

#### Persons Authorized to Write or Issue a Prescription

**H&SC 11150 (Amended)**—adds *naturopathic doctors* acting within the scope of B&PC 3640.5 to the list of those authorized to write or issue a prescription.

#### Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature

**H&SC 11165 (Amended)**—allows the Department of Justice to maintain the CURES program, contingent on



the availability of adequate funds from the various health professions boards. However, funds for the reporting of Schedule III controlled substances to CURES shall not be appropriated from, among other health professions board funds, the Naturopathic Doctor's Fund.

#### Issuing Prescription: By Whom; For What Purpose; Quantity to be Prescribed

H&SC 11210 (Amended)authorizes a naturopathic doctor to prescribe for, furnish to, or administer controlled substances (epinephrine to treat anaphylaxis and natural and synthetic hormones [B&PC 3640.7]) to his or her patient when the patient is suffering from a disease, ailment, injury, or infirmities attendant upon old age, other than addiction to a controlled substance, when the naturopathic doctor believes that treatment is required. The naturopathic doctor shall prescribe, furnish, or administer controlled substances only in the quantity and for the length of time as are reasonably necessary.

#### AB 497 (Negrete McLeod) Chapter 301, Statutes 2005

#### Renewal of Nonresident Wholesaler License; Surety Bond

B&P 4162.5 (Amended)—allows a nonresident wholesaler of pharmaceutical drugs to submit a single surety bond for all licensed sites under common control, rather than a surety bond for each individual site. Additionally, this section exempts from the requirement of wholesalers to post a surety bond, a manufacturer who may also be licensed as a nonresident wholesaler, has received a new drug application issued by the Food and Drug Administration, and who distributes only the drug specified in the new drug application.

#### Fees

**B&P 4400 (Amended)**—reduces the application fee for a *nonresident wholesaler* when the owner of the

nonresident wholesaler has more than 20 locations nationwide. The application fee for the first 20 facilities is \$550. The application fee for each facility over 20 is \$225. The annual renewal fee for each nonresident wholesaler's license is \$550.

#### AB 522 (Plescia) Chapter 469, Statutes 2005 Effective October 4, 2005

## Automated Drug Delivery System

H&SC 1261.6 (Amended)provides additional changes to amendments involving automated delivery machines used in healthcare facilities licensed under H&SC 1250(c) and (d). This section allows the provision of both routine and emergency drugs and biologicals to meet the needs of patients from an automated drug delivery system. When a pharmacy provides pharmacy services to a licensed health facility pursuant to B&PC 4119.1, the automated drug delivery system is subject to existing and the following new requirements:

- After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated delivery system must be limited only to the drug ordered, specific to the patient and reviewed by the pharmacist.
- When the prescriber's order requires a dosage variation of the same drug, licensed personnel shall only have access to the drug ordered for that scheduled time of administration.

#### SB 644 (Ortiz) Chapter 417, Statutes 2005

#### Dispensing Prescription Drug And Devices Pursuant to Lawful Order

**B&PC 733 (New)**—requires any healing arts licentiate to dispense drugs and devices pursuant to a lawful order or prescription **UNLESS** one of the following circumstances exists:

- Based solely on the licentiate's professional training and judgment, dispensing pursuant to the order or the prescription is contrary to law or the licentiate determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition.
- The prescription drug or device is not in stock. If an order or prescription cannot be dispensed because the drug or device is not in stock, the licentiate must:
  - 1. Immediately notify the patient and arrange for the drug or device to be delivered to the site or directly to the patient in a timely manner; or
  - 2. Promptly transfer the prescription to another pharmacy known to stock the prescription drug or device and that is near enough to the site from which the prescription or order is transferred, to ensure the patient has timely access to the drug or device; or
  - 3. Return the prescription to the patient and refer the patient to a pharmacy that stocks the prescription drug or device that is near enough to the referring site to ensure that the patient has timely access to the drug or device.
- The licentiate refuses on ethical, moral, or religious grounds to dispense a drug or device pursuant to an order or prescription, if:
  - 1. The licentiate has previously notified his or her employer, in writing, of the drug or class of drugs to which he or she objects;
  - and
  - 2. The licentiate's employer can, without creating undue hardship, provide a reasonable accommodation of the licentiate's objection by establishing protocols that

Continued from Page 11

ensure that the patient has timely access to the prescribed drug or device despite the licentiate's refusal to dispense the prescription or order.

A licentiate must not obstruct a patient from obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of B&PC 733 constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary action by his or her licensing agency. Disciplinary action could include, but is not limited to, citations, fines, a letter of abatement, or a letter of admonishment.

#### Board May Issue Citations Containing Fines and Orders of Abatement

**B&PC 4314 (Amended)**—adds a violation of B&PC 733 to the list of violations for which the Board may issue citations containing fines and orders of abatement.

#### Letter of Admonishment; Issuance, Action by Licensee; Review

**B&PC 4315 (Amended)** authorizes the executive officer, or his or her designee, to issue a letter of admonishment to a licensee for failure to comply with *B&PC 733*.

#### SB 734 (Torlakson) Chapter 487, Statutes 2005

#### Exception to Triplicate Prescription Requirement; Terminally III Patient

H&SC 11159.2 (Amended)—allows the prescriber to write a prescription for <u>all</u> controlled substances (Schedules II, III, IV and V) for a terminally ill patient on a prescription form that does <u>not</u> meet the security requirements of H&SC 11164. This provision expands the "11159.2 exception" that formerly allowed only Schedule II prescriptions for terminally ill patients to be written on non-security prescription forms.

#### Unlawful Possession of Controlled Substance Prescription Forms

H&SC 11161 (Amended) authorizes the court to order a practitioner, who is named in an arrest warrant or charged with a H&SC violation, to surrender all controlled substance prescription forms, and prohibits the practitioner from obtaining, ordering, or using any additional forms. A practitioner possessing prescription forms in violation of the order is guilty of a misdemeanor.

#### Prescription Forms For Controlled Substance Prescriptions; Requirements

H&SC 11161.5 (Amended) transfers responsibility from the Board of Pharmacy to the Department of Justice (DOJ) for approval of security prescription printers. The DOJ now is solely responsible for:

- Determining whether to approve or deny the a security printer application or to revoke a security printer's approval; and
- Maintaining a list of approved security printers and providing that information to the Board of Pharmacy.

This amendment also authorizes the DOJ to:

- Collect applicant's fingerprints and a fee to cover fingerprint processing, maintenance, and investigative costs;
- Extend from 30 days to 60 days the period within which the DOJ may deny an application;
- Retain fingerprint impressions for subsequent enforcement and arrest; and
- Examine the books and records of security printers.

#### Prescription Forms for Controlled Substances; Requirements

#### H&SC 11162.1 (Amended)—

authorizes the following changes to security prescription form requirements:

- The use of <u>only one statement</u> related to the number of drugs indicated on a security prescription form; specifically: *"Prescription is void if the number of drugs prescribed is not noted.*"
- The identification number assigned to each approved security printer by the DOJ must be preprinted on each prescription form;
- A check box must be located next to the name of each prescriber when a prescription form lists multiple prescribers, and each prescriber who signs the prescription form must identify him/herself as the prescriber by checking the box by his or her name;
- A prescriber designated by a licensed health care facility (inpatient facility licensed under H&SC 1250) or a clinic (outpatient facility licensed under H&SC 1200) or a clinic (medical group licensed under H&SC 1206) that has 25 or more physicians may order controlled substance prescription forms for use by prescribers when treating patients in that facility without the requirement of the actual prescriber's preprinted name, license and federal registration numbers. Instead, the actual prescriber's information may be handwritten, typed, or computergenerated on the prescription form.

#### Prescribing, Filling, Compounding or Dispensing Prescription for Controlled Substance; Requirements

**H&SC 11164 (Amended)**—adds the requirement that any person who transmits, maintains, or receives any electronically transmitted prescription must ensure the security,

integrity, authority, and confidentiality of the prescription.

#### **Real Time Reporting to CURES**

H&SC 11165.5 (NEW)-requires the Board, when funds are available, to join with the Medical Board of California and the Department of Justice to contract with a vendor to prepare a feasibility report for evaluating the viability of implementing "real time reporting" to CURES. Real time reporting is defined as the ability to send and access prescription data simultaneously in the operation of CURES. The feasibility report is to be submitted to the Legislature on or before July 1, 2007, or within 18 months of receipt of sufficient funding.

#### Prescriber's Record for Schedule II Controlled Substance; Requirements

**H&SC 11190 (Amended)**—requires every prescriber that dispenses Schedule II or Schedule III controlled substances to provide the Department of Justice the information required by this subdivision on a monthly basis, *using a format set by the DOJ*.

#### SB 798 (Simitian) Chapter 444, Statutes of 2005

#### Unused Prescription Drugs: Collection and Distribution Division 116, H&SC 150200

(New)—authorizes the establishment of a voluntary drug repository and distribution program to distribute specific surplus medications to medically indigent persons to ensure access to necessary pharmaceutical therapies.

#### **Medication Defined**

**H&SC 150201 (New)**—for purposes of this division, defines "medication" as a dangerous drug.

#### Donation of Unused Medications by a Licensed Skilled Nursing Facility

H&SC 150202 (New)—allows a licensed skilled nursing facility (H&SC 1250), including a skilled

nursing facility designated as an institution for mental disease, to donate unused medications to the drug repository and distribution program.

#### Donation of Unused Medications by a Wholesaler or Manufacturer

H&SC 150203 (New)—permits wholesalers and manufacturers, who are legally authorized to manufacture and sell pharmaceutical drugs, to donate unused medications to the *voluntary drug repository and distribution program* established by a county.

#### County Program For Repository and Distribution of Unused Medications

H&SC 150204 (New)—authorizes a county to establish, by ordinance, a *repository and distribution program*. Only county-owned pharmacies or pharmacies that contract with the county may participate in this program. A county that elects to establish such a program must establish procedures for, at least, the following:

- Establishing eligibility for medically indigent patients who may participate in the program;
- Ensuring that eligible patients are not charged for medications under this program;
- Developing a formulary of medications appropriate for this program;
- Ensuring proper safety and management of any medications collected under this program; and
- Ensuring the privacy of individuals for whom the medications were originally prescribed.

Any donated medication must:

• Not be a controlled substance, nor have been adulterated,



misbranded or stored contrary to USP or manufacturer standards;

- Not have been in the possession of a patient or any public individual, and only under control of the medical staff if donated by a skilled nursing facility; and
- Be donated only if in unopened, tamper-evident packaging or modified unit dose containers;

A pharmacist must use his or her professional judgment in determining whether donated medications meet the standards of this division before accepting or dispensing medications under this program, and he or she must adhere to standard pharmacy practices when dispensing these medications. Donated medications:

- Must be dispensed to an eligible patient;
- Must be destroyed or returned to a reverse distributor;
- May not be sold, dispensed, or otherwise transferred to any other entity;
- Must be maintained in the donated packaging units until dispensed to an eligible patient who presents a valid prescription. The medication will then be dispensed in a new and properly labeled container, specific to the patient.
- Must be segregated from the pharmacy's other drug stock; and
- Expired medication cannot be dispensed.

The pharmacy must keep acquisition and disposition records of the donated medications separate from the pharmacy's other transactions; and protocols must be established for packaging, transporting, storing; and dispensing medications that require refrigeration.

Persons or Entities Not Subject to Criminal or Civil Liability H&SC 150205 (New)—provides criminal and civil immunity to the following persons and entities for injury caused when donating, accepting, or dispensing prescription

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drugs in compliance with this division:

- A prescription drug manufacturer, wholesaler, governmental entity, countyowned or contracted licensed pharmacy, or skilled nursing facility; or
- A pharmacist or health care professional who accepts or dispenses prescription drugs.

#### Liability Restored in Noncompliance Cases

H&SC 150206 (New)—does not provide immunities in cases of noncompliance with this division, bad faith, or gross negligence.

#### **Disciplinary Actions Unaffected**

H&SC 150207 (New)—allows disciplinary actions taken by licensing and regulatory agencies to be unaffected by operation of this division.

#### SB 1111 (Committee on Business, Professions and Economic Development) Chapter 621, Statutes 2005 Omnibus Measure 45455

## Adoption of Rules and Regulations

**B&P 4005 (Amended)**—eliminates the specific requirement for the Board to promulgate *Rules of Professional Conduct* for pharmacists. Pharmacists are required to comply with all pharmacy laws and regulations, not just those referenced in the "Rules of Professional Conduct."

#### Standard for Pharmacist Supervision of Ancillary Personnel

**B&P 4023.5 (New)**—establishes *"direct supervision and control"* as the standard for pharmacist supervision of pharmacist interns, pharmacy technicians, and pharmacy technician trainees. While supervising, the pharmacist must be on premises at all times and fully aware of all activities performed by these individuals.

#### Exemptions From Section 4051: Requirements

**B&P 4053 (Amended)**—changes the name of "exemptee" to "designated representative." This section authorizes the use of designated representatives (formerly called "exemptees") to supervise the operations of wholesalers, veterinary food-animal drug retailers and laboratories when there is no pharmacist on the premises.

#### Licensed Employee, Theft or Impairment: Pharmacy Procedures

**B&P 4104 (Amended)**—recasts existing language and adds that every pharmacy must report to the Board, within 30 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy:

- Any admission by a licensee of chemical, mental, or physical impairment affecting his or her ability to practice;
- Any admission by a licensee of theft, diversion, or self-use of dangerous drugs;
- Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensee to the extent it affects his or her ability to practice;
- Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensee;
- Any termination based on chemical, mental, or physical impairment of a licensee to the extent it affects his or her ability to practice;
- Any termination of a licensee based on theft, diversion, or self-

use of dangerous drugs; Anyone making a good faith report authorized or required by this section is granted immunity from any liability, civil or criminal. Additionally, anyone making a report will have the same immunity with respect to participation in any administrative or judicial proceeding resulting from reporting to the Board.

#### License Verification Using Board Web Site

**B&PC 4106 (Amended)**—recasts language to specify that licensing information on the Board's Web site, including the issuance and expiration dates of any license issued by the Board, is proof of licensure.

#### Intern Pharmacist: Activities Permitted

**B&PC 4114 (Amended)**—clarifies that intern pharmacists may perform all functions of a pharmacist under the "*direct supervision and control*" of a pharmacist whose license is in good standing with the Board.

#### Pharmacy Technician: Activities Permitted; Required Supervision; Activities Limited to Pharmacist; Registration; Requirements for Registration; Ratios

**B&P 4115 (Amended)**—eliminates duplicative language regarding the duties of pharmacy technicians and deletes an exemption to unlicensed personnel from pharmacy technician registration requirements during their first year of employment in one the following agencies: Department of Corrections, California Youth Authority, Department of Mental Health, Department of



Developmental Services, or the Department of Veterans Affairs. Experience is no longer a qualifying method to become a licensed pharmacy technician.

#### Pharmacy Technician Trainee; Placement; Supervision; Requirements

**B&P 4115.5 (Amended)**—recasts language while continuing to standardize the supervisory responsibilities of a pharmacist to that of "*direct supervision and control*" over a pharmacy technician trainee.

#### Fee

#### B&PC 4127.5 (Amended)-

specifically exempts government and tribal governments from the license fee for sterile injectable compounding pharmacies.

#### Nonresident Wholesaler; Requirements

**B&PC 4161 (Amended)**—deletes a technical subsection that does not impact the profession.

#### Pharmacy Technician: License Requirements for Education, Experience; Board Regulations; Criminal Background Check; Discipline

**B&PC 4202 (Amended)**—recasts the language of this section, but the requirements remain the same.

#### Sale or Dispensing of Hypodermic Syringes and Needles: When Separate License Required; Form and Content of Application; Renewability; Discipline

**B&PC 4205 (Amended)**—recasts the language of this section and deletes the specific and unnecessary authorization to issue a license for the sale and dispensing hypodermic syringes and needles for use on poultry (which is covered by the retained phrase, "for animal use").

#### Rules of Professional Conduct as Part of Application; Applicant Subscription to the Rules

**B&PC 4206 (Repealed)**—repeals the requirement for a signed "*Rules* of *Professional Conduct*" as part of license applications.

#### Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New License

B&PC 4231 (Amended)-exempts pharmacists, who are renewing their license for the first time, from the continuing education requirement. Additionally, this section adds the requirement that an applicant, who submits the renewal application and fee but does not submit proof of completion of 30 hours of continuing pharmacy education, will be issued an inactive pharmacist license that prohibits the practice of pharmacy. A licensee with an inactive license issued pursuant to this section may obtain an active pharmacist license by paying the renewal fees due and submitting proof that the licensee has completed 30 hours of continuing pharmacy education.

#### Content of Continuing Education Courses

**B&PC 4232 (Amended)**—makes a technical change to alter the term "pharmaceutical education" to "pharmacy education," when referring to course content for continuing education courses.

#### Letter of Admonishment; Issuance, Action by Licensee; Review

**B&PC 4315 (Amended)**—deletes the requirement that a copy of a pharmacist's letter of admonishment be kept on the pharmacy's premises.

The following statutes contain updated and recast provisions dealing with the Pharmacists Recovery Program in sections 4360-4373.



#### Impaired Pharmacists

**B&P 4360 (Amended)**—makes technical changes to provisions allowing the Board to operate a recovery and rehabilitation program for pharmacists (and interns) whose competency may be impaired due to alcohol or drug abuse or mental illness.

#### Definitions

pharmacists).

**B&PC 4361 (Repealed and New section added)**—specifically defines "participant" as a pharmacist or intern pharmacist who has entered the "pharmacists recovery program" (i.e., a rehabilitation program created by this article for interns as well as

#### Function of Program: Board Referrals; Voluntary, Confidential Participation

**B&PC 4362** (Repealed and New section added)-updates a provision involving the confidentiality of a pharmacist or intern who enters the pharmacists recovery program voluntarily, through referral by the Board or through disciplinary action. Self-referred licensees will not be subject to discipline or other enforcement action by the Board solely on their entry into the program or on information obtained while participating in the program unless the individual poses a threat to the health and safety of the public. However, if the Board receives information regarding the conduct of the pharmacist or intern from another source, that information may serve as the basis for discipline or other enforcement by the Board.

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#### Criteria for Participation to be Established by Board

**B&PC 4364 (Amended)**—makes technical changes and allows the Board to adopt criteria for participation in the pharmacists recovery program and deny entry to the program to those who do not meet the criteria.

## Contracting With Qualified Contractors

**B&PC 4365 (Amended)**—directs the Board to contract with one or more qualified contractors to administer the pharmacists recovery program.

#### Function of the Contractor B&PC 4366 (Amended)—stipulates

that along with evaluating and monitoring participants in the pharmacists recovery program, the contractor must also inform each participant of the program's procedures, of their rights and responsibilities, and of the possible consequences of noncompliance with the program.

#### Termination for Noncompliance B&PC 4369 (Amended)—

authorizes termination from the program if a participant fails to comply with the treatment contract or derive benefit from the program. The names of those terminated will be reported to the Board.

Voluntary Participation: Written Information Provided to Licensee; Consequences of Noncompliance; Report to Board of Termination When Public Safety Threatened; Authority to Discipline

**B&PC 4370 (Repealed)**—repeals this section as its stipulations are moved to other sections.

### Review of Activities of Program

**B&PC 4371 (Amended)** authorizes quarterly review of the Pharmacists Recovery Program and participants' files by the Board.

#### Confidential Records; Exception for Disciplinary Proceeding

**B&PC 4372 (Amended)**—recasts language stating that Board records and Pharmacists Recovery Program records are confidential and not subject to disclosure except when relevant to a participant's conduct that led to termination from the program.

#### Immunity from Civil Liability

**B&PC 4373 (Amended)**—removes "contracting professional association" and "volunteer intervenor" from those who shall not be liable for civil damages because of acts or omissions that occur while acting in good faith.

#### Fees

**B&PC 4400 (Amended)**—modifies the following fees:

- Consolidates existing application and issuance fees for a designated representative to \$185. If an applicant is not issued a license, \$110 of the fee will be refunded (which is the current issuance fee).
- Consolidates existing application and issuance fees for a designated representative for a veterinary food-animal drug retailer to \$250. If the license is not issued, \$150 will be refunded.



- Exempts government operated clinics from licensure fees.
- Eliminates the foreign pharmacist graduation evaluation fee, a service that is no longer required by provisions enacted last year by SB 1913 (2004, Chapter 695).
- Eliminates the fee to extend a pharmacist intern license, a function no longer authorized by SB 1913 (2004, Chapter 695).

#### SCR 49 (Speier) Chapter 123 Medication Errors Panel (New)

Creates a panel to study the causes of medication errors and recommend changes in the health care system that would reduce errors associated with the delivery of prescription and over-the-counter medication to consumers. The panel was required to convene by October 1, 2005, and to submit to the Assembly Committee on Health and the Senate Committee on Health a preliminary report by March 1, 2006, and a final report by June 1, 2006. Panel members include a faculty member of a school of pharmacy, a representative of the California Pharmacists Association, the California Association of Health Plans, the Pharmaceutical Research and Manufacturers of America. the California Medical Association, the Assembly Democratic Caucus, the Assembly Republican Caucus, and a consumer.

## Six Hours of CE Approved for the PSAM

The Board has approved the National Association of Boards of Pharmacy program, the Pharmacist Self-Assessment Mechanism (PSAM), for six hours of continuing pharmacy education. The PSAM is a valuable evaluation and learning tool that can be used to assist pharmacists in obtaining objective, non-punitive feedback on their individual knowledge of current practice therapies. It will subsequently assist the pharmacist in selecting future CE programs that address the self-assessment results.

Questions in the PSAM are based on patient profiles and simulate real-life practice situations and patient therapies. Because the PSAM is an assessment and learning tool, the pharmacist is provided with feedback on each question. The feedback information displays each question, the answer selected, the correct answer, a brief rationale for the correct answer, and a reference to where more information about the answer or related material can be obtained.

Upon completion of the PSAM, pharmacists will receive a Record of Completion, which can be used to satisfy CE requirements for license renewal in California and in other states where the program is board-approved. The pharmacist will also receive a separate report containing the assessment evaluation score—which will not be released to the Board of Pharmacy, NABP or any other person unless so directed by the pharmacist.

The online assessment evaluation is \$75, consists of 100 multiple-choice questions and is divided into three sections of equal length. Each section can be completed in less than one hour, but a maximum of three hours per section is allowed. All three sections may be taken in one sitting, or one section may be completed at a time. However, once a section is begun, it must be completed in its entirety. Once the PSAM is begun, all sections must be completed in three weeks.

For more information about the PSAM, visit *www.nabp.net*, e-mail *custserv@nabp.net*, or contact NABP at (847) 391-4406.



## **Security Prescription Forms to be Changed**

Effective January 1, 2006, the law requires changes to the security prescription forms. These changes were enacted under SB 734 (Torlakson), Health & Safety Code (H&SC) section 11162.1.

The changes expand the use of "institutional style" controlled substance prescription forms to include:

- clinics (outpatient facilities licensed under H&SC 1200),
- clinics (medical groups licensed under H&SC 1206[a], that have 25 or more physicians and surgeons, and
- hospitals licensed under H&SC 1250. SB 734 makes the following format changes to controlled substance prescription forms. However, these new requirements do not invalidate controlled substance security prescription forms produced prior to these new requirements. Pharmacists should simply be aware of these changes as security prescription vendors begin to transition to the new form style.
- All controlled substance prescription forms must have the statement, "Prescription is void if the number of drugs prescribed is not noted," printed on the bottom and a line provided for the practitioner to write in the number of drugs prescribed (H&SC 11162.1[a][8]).
- The controlled substance prescription forms must include an identifying number assigned by the Department of Justice to the approved security prescription form vendor (H&SC 11162.1[a][11]).
- A check box next to the name of each prescriber must be included when the prescription form lists multiple prescribers. Prescribers signing the prescription forms are required to identify themselves by checking the box by their name (H&SC 11162.1[a][12]).

#### BOARD OF PHARMACY

## Honored Pharmacists

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added that he is proud to be a pharmacist.

- Joseph I. Rotenberg, a graduate of University of Colorado, was licensed in California in 1955. Mr. Rotenberg owned a pharmacy in San Francisco where at that time students Dave Fong (Board Member) and Dennis Ming (Board Supervising Inspector) worked as interns. He also declared that it was a great honor to receive such recognition by the Board.
- David W. Schieser began his career as a delivery boy while in grammar school. He ultimately graduated from UCSF and was licensed in 1955. He, too, thanked the Board.
- Warren W. Hirsch, after escaping Hitler in Germany, became licensed in 1944. Mr. Hirsch stated that he was honored to accept the Board's recognition after having worked 61 years in pharmacy. He added that it was wonderful to hear the comments of his colleagues.
- Roy S. Nishimura was licensed in 1954 and thanked the Board for this recognition and honor.
- John Benelli, licensed in 1946 and retired in 2002, spoke of his long career and also thanked the Board for this recognition and honor.

The Board also extends an invitation to pharmacists on <u>retired</u> status, who were on active status for at least 50 years, to submit to the Board a request with their name and address if they would like to receive the certificate. They, too, are welcome for recognition at a Board meeting held in their area.

The following list includes the names of all pharmacists still on active status who received their license between July 1, 1955, and October 31, 1955.





## www.pharmacy.ca.gov

### Thanks to those who helped

Continued from Page 5

veteran said that it was very similar to combat medicine in a war zone.

By the fourth day, the volume started to decrease and with additional personnel, help from the USAF and US Forest Service, the situation stabilized. Air Force statistics for that first week of operation, estimated that the team had treated about 2,700 patients and medically triaged an additional 19,000 evacuees. They did not keep count of prescriptions and medication orders, but the team estimated that they filled between 6,000 and 8,000 orders in that seven-day period. And it was all done without computers! Every label was handwritten by a pharmacist or technician. They also prepared a lot of IVs and did some creative compounding.

After 14 days in Louisiana, Dr. Valencia went home, only to be called

back a week later for Hurricane Rita. He was then deployed to Lafayette, LA, were his team operated an extended emergency room, pharmacy, and hospital in the Heymann Performing Arts Center. There they saw about 1,500 patients, filled about 1,300 prescriptions, and had a bed count of anywhere from 40 to 120 patients per day in a seven-day period. Again, Dr. Valencia was the pharmacist in charge, operating a 24-hour pharmacy with only four pharmacists.

Despite the monumental problems they faced, this team displayed the very finest pharmacy has to offer. Their generosity of heart and spirit personifies the image of pharmacists everywhere. The Board of Pharmacy commends and thanks you.

## Prescription container label...

Continued from Page 5

The following are exceptions to this labeling requirement:

- Prescriptions dispensed by a veterinarian;
- Dispensed medications for which no physical description exists in any commercially available database;
- New drugs for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file; and
- When a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to section 1250 of the Health and Safety Code (e.g., acute care hospital, skilled nursing facility, and correctional treatment center) and the prescription drug is administered to a patient by a licensed certified nurse-midwife, nurse practitioner, physician assistant or pharmacist who is acting within his or her scope of practice.

Although this new requirement was enacted in 2004, the Board is aware that this change may have significant impact to the operation of some pharmacies that have not yet made the changes to their prescription labels. Consequently, as with all new laws, the Board's primary focus will be to seek compliance through education during the first six months of 2006.

After July 1, 2006, during an inspection, the inspector will review a pharmacy's operation to ensure compliance. If a pharmacy has not implemented the new labeling requirement, the inspector will note this on the inspection report and will followup to assure compliance. If during the follow-up the inspector determines that the pharmacy still has not implemented the new labeling requirement, an investigation will be opened to document the non-compliance, which may result in some type of action by the Board.

# Incomplete CE will generate an <u>inactive</u> license

Effective January 1, 2006, pharmacists who fail to complete the continuing education (CE) portion of their renewal application <u>or</u> fail to earn the CE required for license renewal now will be issued an *inactive* license. Practicing pharmacy without an active license is considered "unlicensed activity" and may be subject to disciplinary action.

To ensure the timely issuance of an active license, always read the renewal application carefully, and be sure the form is completed in its entirety.

Additionally, since the processing time for license renewals by the Department of Consumer Affairs is approximately four weeks, delay in submitting your renewal application and fee or submitting an incomplete application may result in not receiving your active renewal before your current license expires. However, license renewals can be verified by checking the Board's Web site under License Verification in advance of receiving the renewed license.

The exact language for this change is contained in the Business and Professions Code section 4231 and can be found on the Board's Web site, *www.pharmacy.ca.gov*.

## **Complete Social Security Numbers no longer visible on renewal forms**

Under California law, Board of Pharmacy licensees' Social Security Numbers are required on renewal application forms as identifiers. However, to protect the licensees' confidential information, the SSNs on the renewal forms are now partially masked.

Since December 1, 2005, all Department of Consumer Affairs computer-generated license renewal forms have the first five digits of the licensee's SSN has been masked out. For example, a SSN of 123-45-6789 would appear on the renewal form as \*\*\*\*\*6789.



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## Six hours of CE awarded for attending one full day of a Pharmacy Board meeting

Continuing education (CE) hours are being awarded to encourage pharmacists and pharmacy technicians to learn more about the issues and operation of the Board. You may acquire six hours once a year by attending one full day of the Board's quarterly meetings. The meetings are held at different sites throughout California to give as many licensees as possible the opportunity to attend. All interested parties are urged to attend. Board members are not eligible for this CE.

It is the pharmacy technician's responsibility to determine from the PTCB how many of the six CE hours are acceptable for recertification.

To attend a Board meeting, no reservations are needed. You simply arrive at the meeting location at the start of the business session. The business day eligible for CE is designated on the agenda.

Meeting dates for 2006 are:

April 26 & 27 July 19 & 20 October 25 & 26

February 1 & 2

Hilton LA Airport Hotel 5711 W. Century Blvd. Los Angeles, CA 90045 Sacramento Area

San Diego Area

San Francisco/Bay Area

Additional information regarding sites and agendas will be posted on the Board's Web site, *www.pharmacy.ca.gov*, approximately 10 days prior to the meetings. Also, you may download information packets for the meeting; these packets contain action items and background information that will be discussed during the meeting. These materials are placed on the Board's Web site about five days before the meeting.