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October 11, 2023

VIA EMAIL - Anne.Sodergren@dca.ca.gov

Anne Sodergren
Executive Officer
California State Board of Pharmacy

Re: Board Confirmation of Central Fill and Technology-Assisted Final Verification

Ms. Sodergren,

We are writing in advance of the California Board of Pharmacy's Licensing Committee Meeting on October 18, 2023 regarding Agenda Item VII, Discussion and Consideration of Central Fill Pharmacies. As you are aware, this firm represents multiple clients holding both resident and nonresident pharmacy permits in the state. On behalf of these clients, we are respectfully requesting that the California Board of Pharmacy (the "Board") confirm that it still maintains its broad and permissive interpretation of central fill services and technology-assisted final verification in the state.

History of the California Board of Pharmacy's Position on Central Fill

For more than a decade, the Board has maintained a permissive view of central fill and shared services in the state. While there is no California statue or regulation expressly governing central fill operations and shared services more generally, prior communications from Board staff confirm that it has taken an expansive reading of Title 16, California Code of Regulations Section 1707.4, Procedures for Refill Pharmacies.

This rule expressly permits a pharmacy licensed by the Board to process a request for a *refill* of a prescription received by another pharmacy, inferring that the first or original fill has already been made by the originating pharmacy (the pharmacy that initially receives the prescription). However, since the promulgation of this rule in 2000, shared services and central fill operations

have evolved and so has the Board's interpretation of Section 1707.4. Through the use of technology and integrated pharmacy systems, central fill pharmacies are now commonly engaged in the first fill of a prescription. These pharmacies may also dispense directly to the patient from the central fill pharmacy (as opposed to shipping a filled prescription back to the originating pharmacy for dispense). As a result of the evolution of central fill models, multiple stakeholders in the state sought guidance from the Board regarding its interpretation and enforcement posture for such models.

California Board Staff Confirm Expansive Interpretation

In 2010 and again in 2016, when posed with questions regarding whether a central fill pharmacy could fill original prescriptions on behalf of another pharmacy, Board staff confirmed that it was permissible. Specifically, former Chief Inspector Bob Ratcliff confirmed this position in 2010. In 2016, this firm sought confirmation of that interpretation from former Executive Officer, Virginia Herold. Ms. Herold expressly confirmed that such models were permissible. See attached email.

Based on this confirmation, multiple stakeholders in the state began to implement robust modern central fill arrangements. As these and new stakeholders aim to establish additional central fill facilities in the state, we ask the Board to confirm the following: Does the Board still permit pharmacies to engage in central fulfillment of original prescriptions?

Technology-Assisted Final Verification

Note also, the use of technology-assisted final verification is also commonly utilized by central fill pharmacies. Such technology may involve the use of canisters to fill common prescriptions. Through the use of multi-level verification processes during the stocking of these canisters and filling of prescriptions (e.g. visual verification, barcode technology, chemical assay, weight checks, etc.), these systems have been shown to exponentially reduce fulfillment errors. In turn, such technology makes human PV2 or final verification of vials filled in such systems unnecessary as long as the initial cannister fill was appropriately verified by pharmacists.

It is important to note that these systems are utilized in not only central fill models, but other automated fulfillment systems (including systems in long-term care and institutional settings, e.g., Pyxis and Omnicell machines).

California Board has Indicated that Technology-Assisted Verification is Permissible

Similar to central fill, the Board has opined on the use of such technology, in a permissive way. In 2005, the Board generally addressed the use of such technology in The Script, the Board's formal newsletter, noting that the accuracy of every dispense falls on the pharmacist and pharmacy, regardless of the manner or method used to verify the prescription. The following excerpts are taken form the Board's 2005 January and October Newsletters and are included as attachments for reference:

January 2005 Newsletter:

- "There is no statute or regulations specifically requiring that a pharmacist check every dose dispensed by an automated drug delivery system."
- "Any licensee implementing such a protocol will be subject to discipline for any errors that occur (as would any licensee responsible for errors from any other delivery system)."
- In the absence of any statutes or regulations exempting a dispensing pharmacist or pharmacy working with an automated drug delivery system from general requirements pertaining to prescription accuracy and propriety of drug delivery, it is the responsibility of the dispensing pharmacist and pharmacy to ensure 100 percent accuracy of the dispensing."

October 2005 Newsletter:

- "The bottom line here is that it is the responsibility of the dispensing pharmacist and pharmacy to ensure 100 percent accuracy of the dispensing. Licensees electing to save costs or time by reducing their level of error checking do so at their own risk."

In response to this guidance, stakeholders began to utilize technology in their pharmacies to reduce misfills and improve overall patient safety. Given the time since this formal guidance, we are asking the following: Does the Board still hold the position that pharmacies may utilize automated verification technology pursuant to the professional judgement of the pharmacist?

In the absence of such confirmation, we are requesting that these issues be brought to the Board for consideration and issuance of a formal policy statement.

We thank this Committee and the Board for its review and consideration of these issues. Ultimately, our clients seek to improve patient outcomes through the use of proven technology and models. Further, these models have been shown to alleviate workload concerns of pharmacy staff, allowing them to focus on patient interactions and care, not counting by five when filling prescriptions.

Yours very truly,

Nicholas H. Meza

ATTACHMENT 1

From: Herold, Virginia@DCA
To: Meza, Nicholas H. (PHX x3439)
Subject: RE: Clarification on CABOP"s Position on Central/Refill Pharmacies [QBLLP-ACTIVE.FID38112070]
Date: Thursday, October 20, 2016 6:57:57 AM
Attachments: image001.jpg

Good Morning Nick,

I hope this helps:

- Can a Refill Pharmacy fill new prescription orders on behalf of another pharmacy for drugs that have previously been filled by the refill pharmacy (i.e. renewals)?
  A: Yes
- Can a Refill Pharmacy fill new prescription orders on behalf of another pharmacy for drugs that have not previously been filled by either pharmacy (i.e. a standard central fill relationship permitting the central fill pharmacy to conduct the original fill on behalf of another pharmacy)?
  A: Yes

Giny

Virginia Herold
Executive Officer
CA State Board of Pharmacy
(916) 574-7911

ATTACHMENT 2

BE AWARE & TAKE CARE:
Talk to your pharmacist!

The Script

CALIFORNIA BOARD OF PHARMACY JANUARY 2005

Changes in Pharmacy Law for 2005

The Assembly and Senate bills listed in this article were enacted in 2004, and unless otherwise specified, took effect January 1, 2005. The new and amended 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 2184 (Plescia)
Chapter 342, Statutes of 2004

Automated Drug Systems in Skilled Nursing and/or Intermediate Care Facilities (New)

B&PC 4119.1—allows a pharmacy to provide pharmacy services to a skilled nursing facility or an intermediate care facility through the use of an automated drug delivery system that need not be located at the same location as the pharmacy. Operation of the drug delivery system must be under supervision of a pharmacist who need not be physically present and is allowed to supervise the system electronically.

AB 2660 (Leno)
Chapter 191, Statutes of 2004

Prescription Labeling Requirements (Amended)

B&PC 4040, 4052, 4060, 4076, 4111and H&SC 11150—permits pharmacists to sign orders for controlled substances when initiating or adjusting drug regimens under protocol; requires pharmacists to register with the DEA **if** they are authorized to initiate or adjust drug therapy involving controlled substances under protocol; permits the possession of a controlled substance dispensed pursuant to a drug order signed by a pharmacist; requires a prescription label to include the name of the practitioner, including a pharmacist, who ordered the drug; permits pharmacists to order controlled substances pursuant to a protocol; no longer requires the name of the supervising physician (of certified nurse midwives, nurse practitioners, physician assistants) to be on prescription labels.

AB 2682 (Negrete McLeod)
Chapter 887, Statutes of 2004

Out-of-State Distributor to Become Nonresident Wholesaler and Exemptee-in-Charge to Become Designated Representative-in-Charge (New)

B&PC 4161—requires any person located outside California that ships, mails, or delivers dangerous drugs or devices into this state at wholesale to be considered an "**out-of-state distributor**" and be licensed by the Board. An out-of-state distributor's license may not be issued or renewed until the out-of-state distributor identifies and notifies the Board of the designation of an exemptee-in-charge. The exemptee-in-charge will be responsible for the company's compliance with all laws governing wholesalers. The nonresident wholesaler must notify the Board of a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be the exemptee-in-charge. This section is in effect until January 1, 2006.

On and after January 1, 2006, an out-of-state distributor will be known as a "**nonresident wholesaler**" and still require a license issued by the Board. A separate license will be required for each place of business owned or operated by a nonresident wholesaler. The license must be renewed annually and is non-transferable. At the time of initial application or renewal of a nonresident wholesaler license, the applicant must submit in writing to the Board the following information or within 30 days of any change in the specified information:

- Its agent for service of process in this state;
- Its principal corporate officers, if any, as specified by the Board;
- Its general partners, if any, as specified by the Board; and
- Its owners if the applicant is not a corporation or partnership.

A nonresident wholesaler must comply with all directions or requests for information from the Board, or regulatory or licensing

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President's Message

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

Editor's Update: President Goldenberg adds the following notice to his President's Message, which is current as of press time (January 21, 2005):

On January 5, 2005, Governor Schwarzenegger proposed to merge all autonomous boards within the Department of Consumer Affairs directly into the department's structure, and abolish the 279 board member positions on all these boards. This action would dissolve the Board of Pharmacy. Under this plan, boards will become bureaus under the Department of Consumer Affairs, and the executive officer and all staff would report to the director of the Department of Consumer Affairs. Unless the Legislature votes to deny the Governor's reorganization plan, the consolidation is scheduled to occur by July 1, 2005. Therefore, the current board may be the last Board of Pharmacy for California. The Board will maintain its current activities and involvement in consumer protection until any and all actions take place through the legislative process. More information about the process can be obtained at the Little Hoover Commission's Web site: *http://www.lhc.ca.gov/lhc.html*.

For the first 25 years of my career, I worked in and owned pharmacies in California. The Board of Pharmacy was never on my "radar screen" until inspection time. But my perspectives changed in 2001 when I became a Board member and again more recently when I was elected president of the Board. I now want to "give back" to the profession of pharmacy, and I am seeking your help.

I now know that I missed opportunities, both entrepreneurial and professional, by not making time to be more involved. For these reasons, I am dedicating a major portion of my first presidential message to encourage you to become involved. There are a number of ways for you to do so.

Emerging pharmacy and political issues face the Board, the professionals it oversees and the consumers of California. In my opening message at our quarterly board meeting in July, I stressed the importance of well-informed, evidence-based decisions by the members.

First and foremost, the Board's mandate is to protect the public. To do this, the Board seeks to create policies and requirements that advance the pharmacist care available to patients, while minimizing the costs of regulatory compliance on licensees. So your involvement is important and desired.

Even with our current budget constraints, there are a number of ways you can participate in and keep abreast of Board activities and priorities. Listed below are avenues and opportunities for you to interact with us.

Public Meetings of the Board

The Board actively seeks the participation of interested individuals in emerging policy areas. There are a number of public meetings annually where public comment is sought. A description of these committees is provided here.

A. Board of Pharmacy quarterly meetings

At these meetings, the Board takes action to achieve its purpose of consumer protection. Topics are divided into five major areas that correspond to a Board committee (see below), and six hours of continuing education is awarded for attending one full day of a Pharmacy Board meeting. Committee activities are reviewed and public input on all topics is an integral part of each segment. Space is included in the agenda to encourage open discussion of new and old business. Copies of the Board meeting agenda and materials are available on the Board's Web site.

Meetings for 2005 are scheduled for the following months and areas:

- January—Los Angeles
- April—Sacramento
- July—San Diego
- October—Bay Area

B. Committee Meetings

Committee meetings are held three to six weeks before the quarterly Board meetings and provide opportunities for information gathering and discussions on emerging topics. An example of how communicating at these meeting can impact pharmacy practice occurred at the June meeting of the Enforcement Committee. A written request was discussed to use new technology to replace the pharmacist's having to initial the prescription label of a medication prepared by a technician. Biometric identifiers were suggested in place of initialing, a recommendation that was approved by the Committee, and subsequently by the full Board, and added to the Board's Omnibus legislation. If enacted, the new provision allowing this technology will be in effect in January 2005.

Meeting agendas and materials are available on the Board's Web site.

Organizational Development Committee

Coordinates strategic planning, budget management and staff development activities to ensure the

efficient achievement of the Board's mission and goals.

John Tilley, *R. Ph.*, Chair
Stanley W. Goldenberg, *R. Ph.*

Communication and Education Committee

Promotes and develops educational materials for the public and licensees. For example, material developed for the public encourages patients to discuss their medication with their pharmacist and emphasizes the importance of patients complying with their medication treatment regimens. Other materials developed by the Committee assist pharmacists in understanding Pharmacy Law (e.g., *The Script*).

Andrea Zinder, *Public Member*, Chair
Richard L. Benson, *Public Member*
William Powers, *Public Member*
Kenneth H. Schell, *Pharm. D.*

Enforcement Committee

Pursues policies that protect the public by preventing violations and effectively enforcing federal and state pharmacy laws when violations occur.

William Powers, *Public Member*, Chair
David J. Fong, *Pharm. D.*
Stanley W. Goldenberg, *R. Ph.*

Licensing Committee

Ensures that the professional qualifications of those entering the practice of pharmacy, as well as those continuing to practice, meet minimum requirements for education, experience, and knowledge and ensures that facilities licensed by the Board meet minimum standards.

Ruth Conroy, *Pharm. D.*, Chair
Richard L. Benson, *Public Member*
Clarence Hiura, *Pharm. D.*

Legislation and Regulation Committee

Pursues legislation that ensures better patient care and that provides effective regulation of the individuals and firms who handle, dispense, furnish, ship and store prescription drugs and devices in California.

John Jones, *R. Ph.*, Chair
James E. Acevedo, *Public Member*
Kenneth H. Schell, *Pharm. D.*

The Board's Web site

The Web site is the Board's main platform for disseminating information. We now have a system in place for e-mailing updated information to those who have requested (or subscribed) to receive it. The Web site contains a wealth of information, including:

- All meeting dates, times, locations, materials and agendas of Board and committee meetings
- All applications and other forms
- Help for complying with new regulatory requirements (e.g., questions and answers on the new controlled substances dispensing requirements);
- Board publications (*The Script, Health Notes*)

Newsletter (*The Script*)

The Script, currently published twice per year, provides information about new Board policies and pharmacy law changes and is mailed by the Board to all California licensed **pharmacies**. In partnership with the Board, the Pharmacy Foundation of California publishes and mails the *The Script* to all licensed **pharmacists**.

Continuing Education Outreach Programs

The Board has developed an outreach presentation about the Board and new pharmacy laws. A Board member and a Supervising Inspector present this information. The Board will schedule these presentations to groups of 50 pharmacists:

- Timely topics covered
- Question and answer periods
- Two hours of CE awarded
- Examples of recent outreach programs include (1) new prescribing and dispensing requirements for controlled substances and (2) information about the Board programs and new laws impacting pharmacy

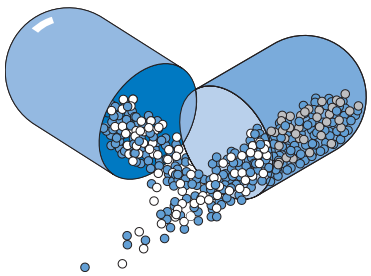
To schedule an outreach program for your group, send a written request describing your organization and requested date(s) to the Board or contact Patricia Harris at (916) 445-5014.

Emerging issues being discussed by the Board

- Importation of drugs from other countries—the pursuit of "affordable" medication by individuals and states—has challenged our drug distribution system. The final solution will require federal and state actions.

- Terrorism—We must remember that the United States and the world changed after September 11, 2001. A letter, dated August 12, 2004, by FDA Commissioner Lester Crawford warned of "terrorist chatter" indicating that terrorists could target the United States food and drug supply—particularly prescription drugs imported illegally. Let us not forget the 1982 incident where Tylenol was removed from shelves, filled with cyanide and returned for sale, causing seven deaths.

Let us make this year one in which we address our goals with interaction to create a more dynamic profession and focus on our #1 mission—THE SAFETY OF CALIFORNIA CONSUMERS.



SB 151 Requirements for Prescribing and Dispensing Controlled Substances

Senate Bill 151 has brought changes in controlled substance prescribing and dispensing requirements. A major change is the elimination of the triplicate forms used for prescribing Schedule II controlled substances and use of easier to order tamper-resistant prescription forms that are purchased from designated security printing companies.

The Board has a number of educational materials on its Web site to aid pharmacists, prescribers and patients in understanding the new requirements, which will be in effect January 1, 2005.

To help you in finding answers to prescribing questions regarding these changes, an annotated index for the contents of the key prescribing laws (Health & Safety Code) is offered below. This index provides a quick overview of where in law particular provisions can be found. The exact text of SB 151 can be found at the Board's Web site, *www.pharmacy.ca.gov*, and a question and answer segment is also at that site.

Tamper-resistant prescription forms

H&SC 11029.5 Defines "security printer"

A person approved to produce controlled substance prescription forms pursuant to Section 11161.5.

H&SC 11161.5 Applying to become an approved security printer

Contains the requirements for applying for approval by the Department of Justice and the Board of Pharmacy to print tamper-resistant prescription forms, delivery of forms to the prescriber, and record-keeping requirements for printers.

H&SC 11162.1 Requirements for tamper-resistant prescription forms

Describes all the features required for tamper-resistant forms and information to be entered on the forms by the prescriber. Included is a requirement that the form contains either (A) a statement printed on the bottom of the prescription blank that the "Prescription is void if more than one controlled substance prescription is written per blank" or (B) contain a space for the prescriber to specify the number of drugs prescribed on the prescription and a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."

Details tamper-resistant prescription form requirements for the designated prescriber of a *licensed health care facility*.

Prescribing Schedules II – V controlled substances

H&SC 11159.2 Exception to triplicate prescription requirements; terminally ill patient

Includes retention of requirements for a Schedule II prescription written on a regular plain prescription form for a "terminally ill" patient—must still include notation "11159.2 exemption."

H&SC 11164 Requirements for writing and dispensing Schedule II-V prescriptions

Includes all entries required on a controlled substance prescription. Directions for handling a Schedule II prescription that contains errors or uncertainties are found in Title 16 of the California Code of Regulations section 1761(a).

H&SC 11164.1 Controlled substance prescriptions written by out-of-state prescribers

Allows filling such prescriptions when delivered to out-of-state patients and requires the reporting of Schedules II and III prescriptions to the Department of Justice

B&PC 4170 Dispensing by the prescriber: requirements and restrictions

Includes definition of "prescriber" and details labeling and packaging requirements

Oral and faxed prescriptions

H&SC 11164 Faxing of prescriptions for Schedule III-V controlled substances

Permits Schedule III-V controlled substances to be dispensed upon an oral or electronically transmitted prescription. Note: Faxing a prescription written on the tamper-resistant forms will produce the word "*VOID*" across the face of the prescription, so prescribers are encouraged to use a regular form when faxing.

H&SC 11167 Faxing of Schedule II controlled substance prescriptions allowed in an emergency

Describes the emergency circumstances that allow the faxing of a Schedule II controlled substance prescription. This section lists all the requirements for a pharmacist who receives an oral, electronic data transmission, or a written order not made on a tamper-resistant prescription form.

H&SC 11167.5 Faxing of Schedule II controlled substance prescriptions for specified inpatients, residents, and home hospice patients

Contains pharmacists' procedures upon receipt of an oral or faxed

Schedule II prescription for a patient of a licensed skill nursing facility, a licensed intermediate care facility, a licensed home health agency, or a licensed hospice.

See Article 1 (commencing with Section 1250) of Chapter 2 of Division 2 of the Health & Safety Code for definitions of "*licensed health care facility.*"

Controlled Substance Utilization, Review, and Evaluation System (CURES)

H&SC 11164.1 Schedule III added to CURES data collection

Beginning January 1, 2005, all Schedule II and III prescriptions must be reported to the CURES data collection vendor, Atlantic Associates (see below).

H&SC 11165 CURES

Fully describes the purpose of and procedures for pharmacies to report Schedules II and III prescriptions to the CURES data collection vendor. Questions regarding the reporting procedures should be directed to Atlantic Associates at 1-888-492-7341.

Dispensing physicians with questions regarding CURES should contact the Bureau of Narcotic Enforcement (BNE) at (916) 227-4051.

H&SC 11165.1 Obtaining patient's medical history from CURES data

Allows prescribers to request patient's history from the Department of Justice.

To request a patient history of controlled substance prescriptions from the CURES, pharmacists or physicians can download a Patient Activity Report (PAR) request form by visiting the Board of Pharmacy Web site, *www.pharmacy.ca.gov/app_forms.htm.* Complete the appropriate PAR form and fax it to the BNE at (916) 227-5079.

Changes in Pharmacy Law

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agency of the state in which it is licensed. Nonresident wholesalers must maintain records in a readily retrievable form of dangerous drugs and devices sold, traded, or transferred to persons in California and must maintain a valid, unexpired license, permit or registration in the applicant's state of residence.

The Board will not issue or renew a nonresident wholesaler license until the applicant identifies a "**designated representative-in-charge**" (previously called an exemptee-in-charge) and notifies the Board in writing of that person's identity and license number. Additionally, the Board must be notified within 30 days of a change in the designated representative-in-charge. The designated representative-in-charge will be responsible for the company's compliance with all laws governing wholesalers. The Board may issue a temporary license under certain conditions and for periods of time that the Board determines to be in the public interest.

Surety Bond for Nonresident Wholesaler License (New)

B&PC 4162.5—effective January 1, 2006, requires an applicant for the issuance or renewal of a nonresident wholesaler license to submit a surety bond of $100,000 for each site to be licensed, or other equivalent means of security acceptable to the Board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The Board may accept a surety bond of $25,000 if the nonresident wholesaler's annual gross receipts of the previous tax year are $10 million or less, but the surety amount would revert to $100,000 if the nonresident wholesaler has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this section. The Board may make a claim against the bond if the licensee fails to pay a fine with 30 days of the issuance of the fine or when the costs become final. A single surety bond or other equivalent means of security acceptable to the Board will satisfy the bond requirement for all licensed sites under common control as defined in Section 4126.5. This section repeals on January 1, 2011, unless an enacted statute repeals or extends those dates.

SB 1159 (Vasconcellos)
Chapter 608, Statutes of 2004

Furnishing Hypodermic Needles and Syringes Without Prescription (New)

B&PC 4145, 4147 and H&SC 11364—until December 31, 2010, authorizes a pharmacist to sell or furnish 10 or fewer hypodermic needles or syringes to a person for human use without a prescription if the pharmacy is registered with a local health department in the Disease Prevention Demonstration Project, which would be created to evaluate the long-term desirability of allowing licensed pharmacies to sell or furnish nonprescription hypodermic needles or syringes to prevent the spread of blood-borne pathogens, including HIV and hepatitis C. Detailed records of nonprescription sales of hypodermic needles and syringes are no longer required.

SB 1307 (Figuroa)
Chapter 857, Statutes of 2004

Electronic Pedigree for Dangerous Drugs (New)

B&PC 4034—requires an electronic "pedigree" by January 1, 2007. The pedigree will contain information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a

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manufacturer, through acquisition and sale by a wholesaler, until final sale to a pharmacy or other person furnishing, administering, or dispensing the drug. The application of the pedigree requirement in pharmacies will be subject to review during the Board's sunset review in 2008. (Extension provisions for activation of this requirement exist in sections 4163.5 and 4163.6)

Records of Manufacture, Sale, Acquisition and Disposition of Dangerous Drugs or Devices (New)

B&PC 4081—existing law requires all records of manufacture, sale, acquisition, or disposition of dangerous drugs or devices to be open to inspection during business hours and retained for at least three years from the making. A current inventory must be kept by every manufacturer, wholesaler, pharmacy, veterinarian, laboratory, clinic, hospital, or institution who maintains a stock of dangerous drugs or devices. The name "exemptee-in-charge" will be changed to "designated representative-in-charge" on January 1, 2006. After that date, the owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible with the pharmacist-in-charge or representative-in-charge for maintaining the records and inventory. The pharmacist-in-charge or representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

Embargoed Dangerous Drugs or Devices (New)

B&PC 4084 and 4085—allows Board inspectors to embargo dangerous drugs or devices that are suspected of being adulterated or counterfeit by affixing a tag or other marking to the drug. If a Board inspector determines that an embargoed dangerous drug or device is not adulterated or counterfeit, the inspector may remove the tag or marking. It is unlawful for any person to remove, sell, or dispose of an embargoed dangerous drug or device without the Board's permission.

Furnishing Dangerous Drugs to Specified Entities and Violation Penalty (New)

B&PC 4126.5—permits pharmacies to furnish dangerous drugs only to:

- A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired;
- The pharmaceutical manufacturer from whom the dangerous drug was acquired;
- A licensed wholesaler acting as a reverse distributor;
- Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.
- A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law;
- A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs; and
- Another pharmacy under common control.

Violation of this section by either a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities or a person engaged in a prohibited transaction with such a pharmacy may result in a fine of $5,000 for each occurrence.

Surety Bond for Wholesalers (New)

B&PC 4162—requires applicants for the issuance or renewal of a wholesaler license to submit a surety bond of $100,000 or other equivalent means of security to the Board. The purpose of the bond is to secure payment of any administrative fine imposed by the Board and any cost recovery ordered. If the applicant's annual gross income for the previous tax year is less than $10 million a surety bond for $25,000 will be accepted. Additionally, a surety bond of $100,000 may be required for any licensee who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to the Pharmacy Law. This section becomes effective January 1, 2006.

Pedigree Required (New)

B&PC 4163—presently allows manufacturers and wholesalers to acquire or furnish dangerous drugs or devices only from or to those authorized by law to possess or furnish those dangerous drugs or devices. This section is in effect until January 1, 2007, when it will be repealed unless a later enacted statute is enacted before that date. If this section is repealed, the new section will prohibit a wholesaler or pharmacy from selling, trading, or transferring a dangerous drug at wholesale without a pedigree. Additionally, a wholesaler or pharmacy may not acquire a dangerous drug without receiving a pedigree. This section becomes operative on January 1, 2007.

Extension May be Allowed for Implementing Pedigree Requirement for Wholesalers (New)

B&PC 4163.5—authorizes the Board to extend the time allowed for implementing electronic

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technologies to track the distribution of dangerous drugs within the state if the Board determines that manufacturers or wholesalers cannot meet the requirement by January 1, 2007. The pedigree requirement compliance date may then be extended until January 1, 2008.

Extension May be Allowed for Implementing Pedigree Requirement for Pharmacies (New)

B&PC 4163.6—authorizes the Legislature to extend the time allowed for pharmacies to implement electronic tracking the distribution of dangerous drugs within the state if the Legislature determines that it is not economically and technically feasible for pharmacies to comply with the requirement by January 1, 2007. The date for compliance with the requirement may be extended to January 1, 2009.

Wholesaler Tracking System of Individual Sales of Dangerous Drugs (Amended)

B&PC 4164—effective January 1, 2006, will require licensed wholesalers that distribute controlled substances, dangerous drugs or devices within or into California to report all sales of those products that are subject to abuse. Wholesalers will be required to develop and maintain a system for tracking individual sales of dangerous drugs at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities.

No Business License for any Wholesaler Not Licensed by the Board (New)

B&PC 4168—prohibits a county or municipality from issuing a business license to a wholesaler who does not have a current wholesaler license issued by the Board.

Wholesaler Sales Requirements (New)

B&PC 4169—prohibits the following:

- The purchase, trade, sale, or transfer of dangerous drugs or devices at wholesale to a person or entity that is not licensed with the Board as a wholesaler or pharmacy;
- The purchase, trade, sale, or transfer of dangerous drugs that the person knew or should have known were adulterated or misbranded;
- The purchase, trade, sale, or transfer of dangerous drugs or devices after the beyond use date on the label; and
- The failure to maintain records of the acquisition or disposition of dangerous drugs or devices for at least three years.

Violation of this section may result in a fine for each violation.

Excessive Furnishing of Dangerous Drugs by a Wholesaler to a Pharmacy (Amended)

B&PC 4301—defines acts of unprofessional conduct and authorizes the Board to take action against a wholesaler who clearly excessively furnishes dangerous drugs to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term facilities.

Fee Bases Increased (Amended)

B&PC 4400—authorizes an increase in the fee bases for initial and renewal license applications and penalties.

SB 1913 (Business and Professions Committee) Chapter 695, Statutes of 2004 Omnibus Measure

Delivery of Dangerous Drugs or Devices (New)

B&PC 4059.5—requires dangerous drugs or devices delivered to a pharmacy to be signed for by and delivered to a pharmacist but also authorizes a pharmacy to take delivery of dangerous drugs or devices when the pharmacy is closed and no pharmacist is on duty if:

- The drugs are placed in a secure storage facility in the same building as the pharmacy;
- Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or devices have been delivered;
- The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or devices have been delivered;
- The pharmacy maintains written policies and procedures for the delivery of dangerous drugs or devices to a secure storage facility; and
- The agent delivering dangerous drugs or devices leaves documents indicating the name and amount of each dangerous drug or device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and devices delivered to the secure storage facility and for obtaining and maintaining records relating to the delivery.

Prescriber Dispensing Dangerous Drug to Emergency Room Patient (New)

B&PC 4068—permits a prescriber to dispense a dangerous drug, including a controlled substance, to an emergency room patient if **all** of the following apply:

- The hospital pharmacy is closed and there is no pharmacist available in the hospital;
- The dangerous drug is acquired by the hospital pharmacy;
- The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens;

See **Changes in Pharmacy Law,** Page 8

Changes in Pharmacy Law

Continued from Page 7

- The hospital pharmacy retains the dispensing information and, if the drug is Schedule II or III controlled substance, reports the dispensing information to the Department of Justice pursuant to H&SC 11165;
- The prescriber determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and
- The prescriber reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patient.

Site Licenses (New)

B&PC 4107—prohibits the Board from issuing more than one site license to a single premise except to issue a veterinary food-animal drug retailer license to a wholesaler or to issue a license to compound sterile injectable drugs to a pharmacy.

Environment for Compounding Sterile Injectable Products (New)

B&PC 4127.7—as of July 1, 2005, requires a pharmacy to compound sterile injectable products in one of the following environments:

- An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom with a positive air pressure differential relative to adjacent areas;
- An ISO class 5 cleanroom; or
- A barrier isolator that provides an ISO class 5 environment for compounding.

Veterinary Teaching Hospital (New)

B&PC 4170.5—permits veterinarians in a veterinary teaching hospital operated by an accredited veterinary medical school to dispense and administer dangerous drugs and devices and controlled substances from a common stock.

Foreign Graduates (Amended)

B&PC 4200—adds certification by the Foreign Pharmacy Graduate Examination Committee as an application requirement for foreign-educated pharmacists seeking licensure as a pharmacist in California.

Pharmacist/Intern Ratio and Intern Hours Requirement Changed (New)

B&PC 4208 and 4209— defines "intern," details requirements for registration and qualifying for pharmacist licensure examinations. Intern affidavits (hours and experience) must be certified under penalty of perjury by a pharmacist under whose supervision such experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience. Interns must have at least 1,500 hours of intern experience before applying to take the pharmacist licensure examination. Section **4114** authorizes pharmacists to **supervise two intern pharmacists at one time**.

Compounding by Pharmacy Technicians (Amended)

Health & Safety Code 11207—clarifies language that permits a pharmacy technician to compound or prepare a prescription for a controlled substance when assisting a pharmacist.

Join Our E-mail List

The Board has recently established a service to notify anyone who is interested in receiving e-mail alerts about major updates to the Board's Web site. The updates would include information related to when:

- Regulations are implemented or released for public comment
- Board newsletters are published
- Agendas about public meetings are released
- Questions and answers about new laws are added
- Board actions from Board meetings are available
- Drug recalls have occurred

There is no charge for this service, and you can subscribe to receive the e-mail alerts by accessing the Board's Web site, *www.pharmacy.ca.gov*, and clicking on "Join Our E-mail List" under "Online Services." Then submit your name and e-mail address in the provided spaces.

To confirm your identity, a message requesting confirmation will be sent to the e-mail address you provide. It will be necessary for you to keep your e-mail address current on this list.

Regulation Update Summaries

This article contains information relating to new and amended sections of Division 17, Title 16, of the California Code of Regulations. The noted regulations have been paraphrased or summarized below, but you are urged to review the exact language of the regulations at the Board's Web site *www.pharmacy.ca.gov*.

1709.1 – Designation of Pharmacist-In-Charge (Amended)

Effective October 3, 2004, a pharmacist may serve as pharmacist-in-charge at a second pharmacy if that pharmacy is located within 50 driving miles of the first pharmacy. The regulation allows a pharmacist to refuse to act as pharmacist-in-charge at a second pharmacy and prohibits the employer from taking disciplinary action or discriminating against the pharmacist for such a refusal.

1710 – Inpatient Hospital Pharmacy (Amended)

Effective October 22, 2004, this regulation authorizes the use of central fill pharmacies in hospitals.

1711 – Quality Assurance Programs (Amended)

Effective October 22, 2004, this regulation clarifies the patient and prescriber prescription error notification requirements of the existing regulation. Prescribers must be informed of a prescription error only when the drug was administered to the patient.

1717.1 – Common Electronic Files (Amended)

Effective October 22, 2004, this section clarifies that pharmacies employing common electronic prescription files must secure those files from unauthorized disclosure of confidential medical information and establish written policies and procedures to prevent unauthorized disclosures.

1717.4 – Electronic Transmission of Prescriptions (Amended)

Effective October 22, 2004, this regulation clarifies that pharmacists must ensure the authenticity of a prescription.

1720 – Application for Examination and Registration (Amended)

Effective October 22, 2004, applicants for a pharmacist license must comply with the requirements established by the administrators of the pharmacist licensure examinations and requires applicants to complete the licensing examinations within one year of being approved by the board to take the examinations.

1721 – Dishonest Conduct During Examination (Amemded)

Effective October 22, 2004, candidates cheating on the pharmacist licensure examinations are prohibited from retaking the examinations for one year and may not become licensed as a pharmacy technician in that time period.

1723.1 – Confidentiality of Examination Questions (Amended)

Effective October 22, 2004, text was rewritten to clarify existing requirements.

1724 – Passing Grade in Examination

Effective October 22, 2004, text was rewritten to clarify existing requirements.

1749 – Fee Schedule

Effective October 22, 2004, fees for discontinued applications were deleted, keeping the Board's fee schedule current.

1793 – Definitions

Effective October 22, 2004, text was rewritten to clarify existing requirements.

1751 – Compounding Area for Parenteral Solutions (Amended)

Effective October 29, 2004, changes to this section update standards for compounding areas, delete obsolete language, reflect changes in referenced code section numbers and revise standards for certifying clean rooms and other compounding environments.

1751.01 – Facility and Equipment Standards for Sterile Injectable Compounding from Non-Sterile Ingredients (New)

Effective October 29, 2004, this section establishes additional facility and procedure requirements for compounding sterile injectable drug products from non-sterile ingredients. These standards are based on standards adopted by the United States Pharmacopeia and the American Society of Health System Pharmacists that reflect good professional practice.

1751.02 – Policies and Procedures (New)

Effective October 29, 2004, this section incorporates existing requirements for policies and procedures and adds new policy and procedure requirements for compounding from non-sterile ingredients. These policies and procedures are drawn from standards adopted by United States Pharmacopeia and the American Society of Health System Pharmacists that reflect good professional practice.

1751.2 – Labeling Requirements (Amended)

Effective October 29, 2004, this section is amended to update the terminology and conform to the usage in other portions of the regulation.

1751.3 – Recordkeeping Requirements (Amended)

Effective October 29, 2004, this section is amended to eliminate

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Continued from Page 9

recordkeeping requirements that are duplicated in other board regulations and to establish additional recordkeeping requirements for pharmacies compounding sterile injectable products from non-sterile ingredients. These recordkeeping requirements are drawn from standards adopted by United States Pharmacopeia and the American Society of Health System Pharmacists that reflect good professional practice.

1751.4 – Attire (Amended)

Effective October 29, 2004, this section amends existing requirements for protective clothing and establishes attire standards for pharmacy personnel compounding sterile injectable drugs from non-sterile ingredients. These requirements are drawn from standards adopted by United States Pharmacopeia and the American Society of Health System Pharmacists that reflect good professional practice.

1751.5 – Training of Staff, Patient, and Caregiver (Amended)

Effective October 29, 2004 This section is amended to establish additional training standards for pharmacy staff involved in the compounding of sterile injectable drug products from non-sterile ingredients. These training standards are drawn from standards adopted by United States Pharmacopeia and the American Society of Health System Pharmacists that reflect good professional practice.

1751.6 – Disposal of Waste Material (Amended)

Effective October 29, 2004, this section is amended to make the terminology consistent with other aspects of the regulation and to eliminate obsolete provisions.

1751.7 – Quality Assurance (Amended)

Effective October 29, 2004, this section updates existing quality assurance requirements and adds process validation requirements for pharmacies compounding sterile injectable drug products from non-sterile ingredients. The process validation requirements are drawn from standards adopted by United States Pharmacopeia and the American Society of Health System Pharmacists that reflect good professional practice.

1751.8 – Policies and Procedures (Repealed)

Effective October 29, 2004, this section is repealed and elements of its former provisions are incorporated in section 1751.02.

1751.9 – Reference Materials (Amended)

Effective October 29, 2004, this section is amended to update the requirements for reference materials in pharmacies compounding sterile injectable drug products.

1793.3 – Ancillary Personnel (Amended)

Effective October 2, 2004, there is no limit on the number of clerk/typists that may be supervised by a pharmacist. The regulation allows a pharmacist to limit the number of clerk/typists that they supervise and prohibits the employer from taking disciplinary action or discriminating against the pharmacist for exercising that right.

Mandatory Reporting of Child and Elder Abuse

Under California law, all licensed health practitioners are "mandated reporters" for child or elder abuse.

Reporting Child Abuse

California Penal Code 11166 requires that all mandated reporters make a report to an agency specified in Penal Code 11165.9 (generally law enforcement agencies) whenever the mandated reporters, in their professional capacity or within the scope of their employment, have knowledge of or observe a child whom the mandated reporters know or reasonably suspect has been the victim of child abuse or neglect. The report must be telephoned to the appropriate agency as soon as possible and a written report sent within 36 hours of the receiving the information concerning the incident. Failure to comply with the requirements of Section 11166 is a misdemeanor, punishable by up to six months in a county jail, by a fine of $1,000, or both.

Reporting Elder Abuse

Welfare and Institutions Code sections 15630-15632 designate persons (including health practitioners) who have assumed full or intermittent responsibility for the care or custody of an elder or dependent adult as mandated reporters. These practitioners are those who, in their professional capacity, or within the scope of their employment, observe or have knowledge of an incident that appears to be physical abuse, abandonment, abduction, isolation, financial abuse, or neglect. A report of the known or suspected abuse must be made by telephone immediately or as soon as possible. A written report must be submitted within two working days. Section 15630 details the appropriate agencies to whom the abuse must be reported.

Necessity for Pharmacist to Check Automation/Robotic Dispensing

The Board of Pharmacy recently reviewed a request from McKesson Automation, Inc. (McKesson) to approve a proposed protocol for use in hospital and institutional pharmacies that would not require licensed pharmacists to check every medication dispensed by its automated dispensing system, ROBOT-Rx. McKesson proposed a protocol whereby a pharmacist would check 100 percent of the medications packaged by the ROBOT-Rx on a daily basis for at least 30 days after the ROBOT-RX is deployed. After the 30 days, the pharmacist would then taper off to sampling only 5-10 percent of the doses dispensed.

Pharmacy Law is silent on the question about how a pharmacist must check medication dispensed from automated delivery systems, aside from those provisions relating to placement of such a system in nonprofit or free clinics (Business & Professions Code [B&PC] section 4186). There is no statute or regulation specifically requiring that a pharmacist check every dose dispensed by an automated drug delivery system located in an inpatient setting, nor is there any statute or regulation absolving the dispensing pharmacist of this responsibility. Because of this silence, McKesson concluded that it is within the Board's discretion to approve a protocol that would apply specifically to ROBOT-Rx technology.

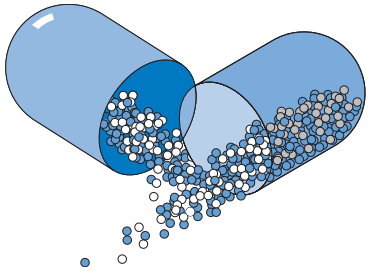
In denying McKesson's request, the Board considered the opinions of its counsel, which follow, in relevant part:

The Board has no relevant statutory authority to approve a protocol, and to do so may constitute an impermissible underground regulation. Under current law, it is the responsibility of individual licensees to determine the level of error risk they are willing to assume, and the steps they take to reduce or eliminate that risk.

Pharmacy Law is violated where a prescription is dispensed in an insufficiently or inaccurately labeled container (B&PC sections 4076-4078), where the drug dispensed deviates from requirements of a prescription (Title 16, California Code of Regulations [CCR] section 1716), or where the prescription is dispensed containing significant errors, omissions, irregularities, uncertainties, ambiguities, or alterations (CCR section 1761). These provisions apply to all dispensing, regardless of the setting.

Any licensee that chooses to implement a reduced-error-checking protocol like that suggested by McKesson is assuming the risk of any errors that result. Even if such errors are less likely with the ROBOT-Rx system, the licensee is responsible for any errors that do occur. It may therefore be a risk for licensees to implement a protocol that increases the chance of such an error, however minor, by eliminating 100 percent of the human double-checking that could perhaps catch and correct those few errors made by the machine(s). Any licensee implementing such a protocol will be subject to discipline for any errors that do occur (as would any licensee responsible for errors from any other delivery system). It is possible the severity of the violation may even be greater where the error could have been caught had not such a sampling protocol been in place.

In the absence of any statutes or regulations exempting a dispensing pharmacist or pharmacy working with an automated drug delivery system from the general requirements pertaining to prescription accuracy and propriety of drug delivery, it is the responsibility of the dispensing pharmacist and pharmacy to ensure 100 percent accuracy of the dispensing. Licensees electing to save costs by reducing their level of error checking do so at their own risk and that of the patient.



Naturopathic Doctors Added to Prescriber List

Section 3640.5 of the Business & Professions Code authorizes naturopathic doctors (NDs) to furnish or order Schedule III-V drugs, and emergency regulations authorizing NDs to prescribe have recently been approved.

Licensing of NDs by the Bureau of Naturopathic Medicine has begun and will be limited to those who have completed educational and other licensing requirements. Licensed NDs will function in accordance with standardized procedures or protocols developed with his or her supervising physician and surgeon.

Prescriptions written by NDs must contain:

- The printed or stamped name, license number and **furnishing number** of the ND,
- The ND's federal controlled substances registration number, if the prescription is for a controlled substance. This requirement may be met by stamping the ND's federal registration number on the prescription.
- The signature of the ND.

Updated information regarding this issue will be published in this newsletter when it becomes available.

PRESERVE A TREASURE

Antibiotics are precious resources but they are not cure-alls for all that ails your patients. Let us help you keep antibiotics potent resources that you and your patients can count on.

Contact FDA for bulk copies of **"Preserve a Treasure: Know When Antibiotics Work"** an easy-to-read brochure of frequently asked questions to help your patients understand the importance of prudent antibiotic use.

dpapubs@cder.fda.gov or 1-888-INFO-FDA

U.S. Department of Health and Human Services
Food and Drug Administration

Contact Your Doctor Again if:

- Your symptoms get worse.
- Your symptoms last a long time.
- After feeling a little better, you develop signs of a more serious problem. Some of these signs are a sick-to-your-stomach feeling, vomiting, high fever, shaking chills, chest pain.

A message from the
"Get Smart: Know When Antibiotics Work"
campaign.

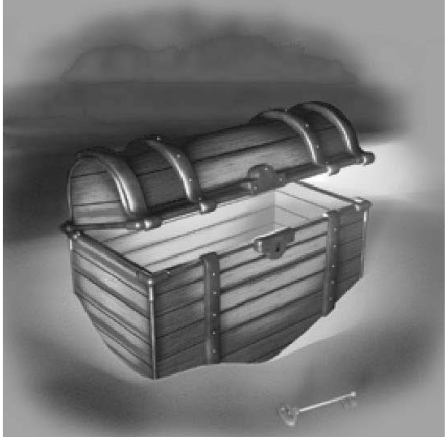
For more information:
http://www.fda.gov/oc/opacom/hottopics/anti_resist.html

U.S. Department of Health and Human Services
Food and Drug Administration

(FDA) 05-1513A

U.S. Department of Health and Human Services
Food and Drug Administration

PRESERVE A TREASURE



Know When Antibiotics Work

Cough? Sore throat? Runny nose?

You or a loved one feels miserable and you've come to the doctor looking for help.

Q: I'm sick. Don't I need a prescription for an antibiotic?
A: Your doctor has examined you and determined that your illness is caused by a viral infection. Antibiotics do NOT treat viral illnesses like colds, flu and most sore throats.

Q: If antibiotics don't treat viral illnesses like cold and flu, what do they treat?
A: Antibiotics are used to treat illnesses caused by bacteria. Examples of illnesses caused by bacteria include strep throat, tuberculosis and many types of pneumonia.

Q: Even though my illness may be caused by a virus, what harm can it do to take an antibiotic?
A: Taking antibiotics when they aren't needed contributes to the serious problem of antibiotic resistance.

Q: What is antibiotic resistance?
A: This is when bacteria cannot be killed by antibiotics. The bacteria have become resistant. If this continues, over time some recurring infections may have to be treated with different and stronger antibiotics and the very real possibility that eventually no antibiotic will be effective in killing the bacteria.

Q: If antibiotics will not help me, what will?
A: There are many over-the-counter products available to treat the symptoms of your viral infection. These include cough suppressants which will help control coughing and decongestants to help relieve a stuffy nose. Read the label and ask your pharmacist or doctor if you have any questions about which will work best for you.

Help Yourself Feel Better While You Are Sick

A cold usually lasts only a couple of days to a week. Feeling tired from the flu may continue for several weeks.

To feel better while you are sick:

- Drink plenty of fluids.
- Get plenty of rest.
- Use a cool mist vaporizer or a humidifier — an electric device that puts water into the air.
- Use saline nose spray to ease dry nasal passages.
- Use a fever reducer when needed.

Schedule III controlled substance prescriptions added to CURES reporting requirements

Since September 1998, all California pharmacies dispensing Schedule II controlled substances have been required to submit that prescription data electronically to the Controlled Substance Utilization Review and Evaluation Systems (CURES). Effective January 1, 2005, all Schedule III prescriptions must also be reported. The Bureau of Narcotic Enforcement (BNR) within the Department of Justice has made arrangements for collection of CURES data with the vendor, Atlantic Associates, Inc. For most pharmacies, compliance with this directive means that their **software must be modified so that Schedule III prescription information, as well as Schedule II prescription information,** can be transmitted to Atlantic Associates, Inc.

Atlantic Associates, Inc.
Phone: (888) 492-7341
New FAX: (877) 508-6704

Prescribers who dispense Schedule II and III medications are also required to submit prescription information to the Department of Justice. Section 11165 of the H&SC requires both pharmacies and dispensing prescribers to submit the following information for each Schedule II and III prescription filled:

- Full name, address, gender, and date of birth of the patient;
- Prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility;
- Pharmacy prescription number, license number, and federal controlled substance registration number;
- NDC (National Drug Code) number of the controlled substance dispensed;
- Quantity of the controlled substance dispensed;
- ICD-9 (diagnosis code), if available;
- Date of issue of the prescription; and
- Date of dispensing of the prescription.

Delayed Renewal Notices and Licenses

Please renew your license early

All Board of Pharmacy licenses, permits and license renewal notices (as well as those of all other health professions) are printed and mailed by the California State Employment Development Department (EDD). In the past, EDD was able to mail renewal notices approximately six weeks before a license's expiration date. Unfortunately, budget constraints at EDD are impacting these mailings. As a result, the renewal notices are being received by licensees only three to four weeks before the license expiration date. Then, because it takes an additional three to four weeks to process renewals once the Department of Consumer Affairs receives the renewal application and fee, some licenses expire before the renewed licenses are actually processed.

A similar delay occurs in the mailing of issued and renewed licenses. Whereas updating the Board's Web site information (relating to new and renewed licenses) generates the printing of the licenses, it actually takes two to three weeks longer to mail the licenses. An additional week is then required for delivery by the US Postal Service.

mail your renewal notice and fee immediately upon receiving the notice

To alleviate some of the delay, the Board has requested EDD to print license renewal notices earlier. Another important step is for you to mail your renewal notice and fee immeditely upon receiving the notice.

The longer you wait to submit the renewal, the greater the chances are that you will not receive your license before your old one expires.

If you have submitted your renewal application and fee, but your present license has expired before receiving the renewed license, interested parties may verify your licensure status by checking the Board's Web site (*www.pharmacy.ca.gov/verify_lic.htm*). However, since it now takes at least three weeks for the department to process your renewal, the Web site may not reflect that you have renewed your license.

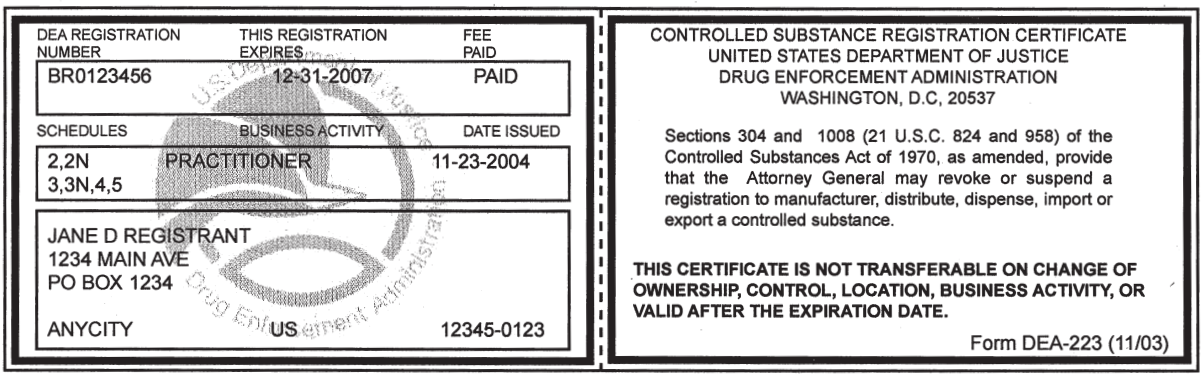
Again, avoid problems by renewing your license as soon as you receive your renewal application. And use the license verification site (*www.pharmacy.ca.gov/license_lookup.htm*) to ascertain whether or when your license was renewed.

www.pharmacy.ca.gov

New Look for DEA Controlled Substance Registration Certificates

The Drug Enforcement Administration's (DEA), Office of Diversion Control, has changed the style and appearance of the DEA Controlled Substance Registration Certificate. As of October 1, 2004, the revised Certificate Registration consists of two parts (see below). The certificate has an embedded watermark logo, which will provide authentication of the certificate and also deter counterfeiting.

Registrants that are currently allowed to renew their DEA registration via the Diversion Control Program's Web site (i.e., retail pharmacies, hospitals, practitioners, mid-level practitioners and teaching institutions) may print their registration certificate upon completion of the registration renewal process as long as no changes have been made to their registration since their last renewal. The Diversion Control Program's Web site may be accessed at *www.DEAdiversion.usdoj.gov*. New registrants and all other renewing registrants will receive their certificates through the mail.



DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
BR0123456	12-31-2007	PAID

SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
2,2N 3,3N,4,5	PRACTITIONER	11-23-2004

JANE D REGISTRANT
1234 MAIN AVE
PO BOX 1234

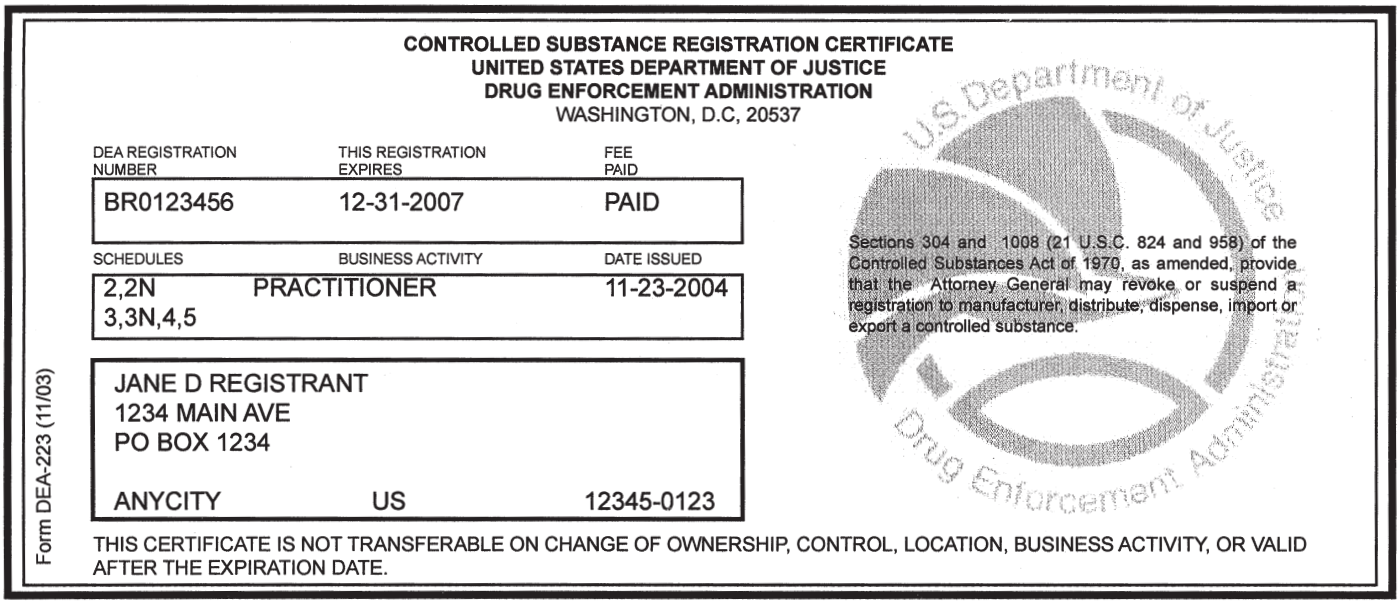
ANYCITY US 12345-0123

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON, D.C, 20537

Sections 304 and 1008 (21 U.S.C. 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacturer, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, BUSINESS ACTIVITY, OR VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (11/03)



CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON, D.C, 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
BR0123456	12-31-2007	PAID

SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
2,2N 3,3N,4,5	PRACTITIONER	11-23-2004

JANE D REGISTRANT
1234 MAIN AVE
PO BOX 1234

ANYCITY US 12345-0123

Sections 304 and 1008 (21 U.S.C. 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacturer, distribute, dispense, import or export a controlled substance.

Form DEA-223 (11/03)

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, BUSINESS ACTIVITY, OR VALID AFTER THE EXPIRATION DATE.

What to Look for on the New Tamper-Resistant Prescription Forms

Beginning January 1, 2005, written prescriptions for controlled substances must be on tamper-resistant security prescription forms that have been printed by a Board-approved printing company. To prevent fraud or diversion, these forms must contain specific security features (Health & Safety Code section 11162.1 et seq.). There is no one specific format, size or color for the security prescription forms, so pharmacists need to be aware of the required features.

Security Features

The law requires that the list or description of the required security features must be printed on the security prescription form. The list/description may be printed **anywhere on the form** (e.g., in warning bands along the edges of the form's face or listed on the back of the form). The description should tell what and where the features are on the form and how to test them.

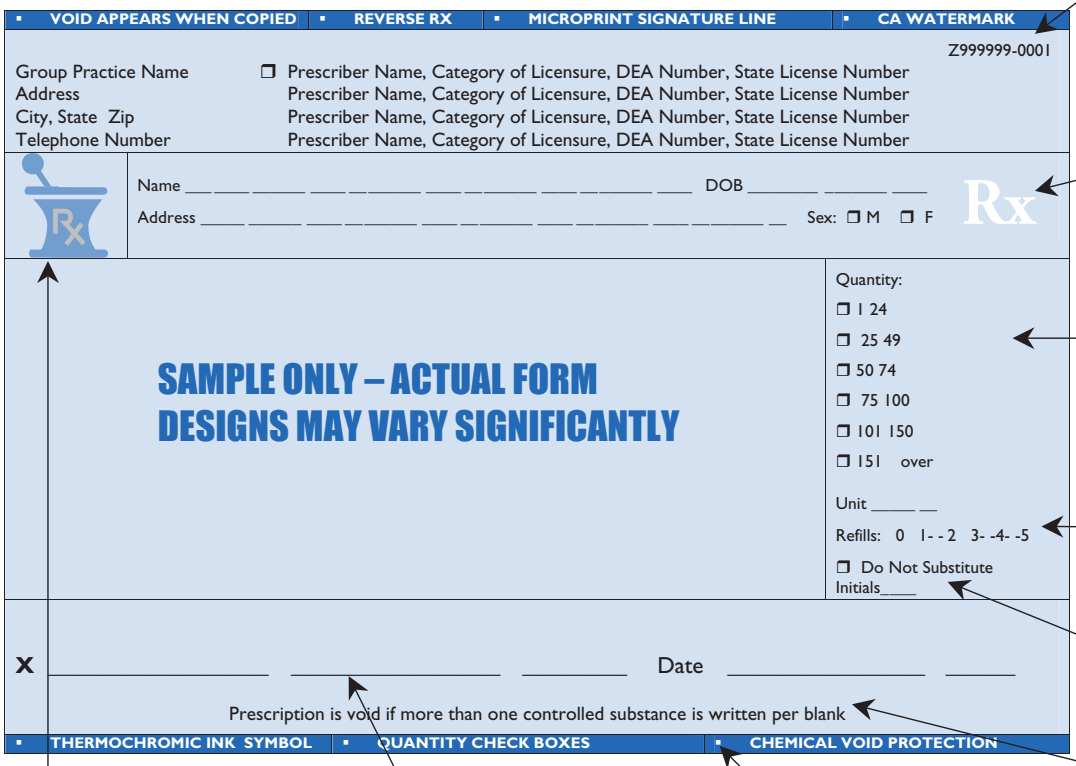
Examples of what a new security form might look like are on the following pages. These are examples only—actual form designs and security feature application will vary significantly from form to form and from printer to printer. However, all forms are required to have specific security features and preprinted prescriber information.

More specific information about the security features required on these forms, as well as other new requirements for prescribing and dispensing controlled substances can be found on the Board's Web site at *www.pharmacy.ca.gov*.

If the form does not contain the proper features, it may indicate that it was not printed by a Board-approved printer. Such prescriptions should be reported to the Bureau of Narcotic Enforcement at (916) 319-9062.

Important Note: If you have questions concerning the validity of a prescription, treat it like any other questionable prescription—call the prescriber to verify the prescription.

SINGLE PRESCRIBER OR GROUP PRACTICE SECURITY PRESCRIPTION FORM SAMPLE



Batch/Lot Numbers Unique batch and sequential lot numbers assigned by approved security printers. Not tracked by the State,

Opaque Writing fades or disappears when photocopied repeatedly

Six quantity check boxes allow quick confirmation that the quantity prescribed has not been altered.

Refills CII drugs cannot be refilled, only CIII V can be refilled.

Do Not Substitute prescriber must check box and initial

Statement that Identifies form as a **single drug** prescription form

Thermochromic ink feature changes color or disappears temporarily with hot breath or when rubbed briskly. It slowly returns to normal as it cools.

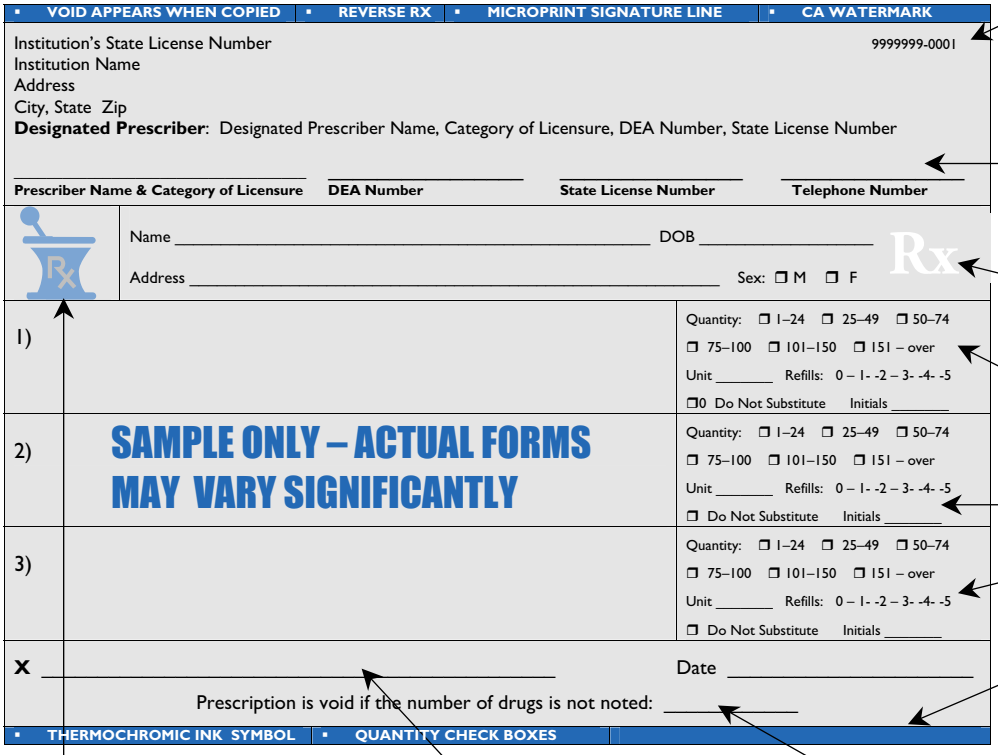
Microprint signature line seen only with a magnifier and becomes a solid line when copied, faxes or scanned.

Description of security features in warning bands on face or listed on back of prescription.

Alternatively, prescribers may order a form designed to write multiple prescriptions on one form. See the next form sample using a multiple drug prescription format. 12/04

INSTITUTION OR FACILITY SECURITY PRESCRIPTION FORM SAMPLE

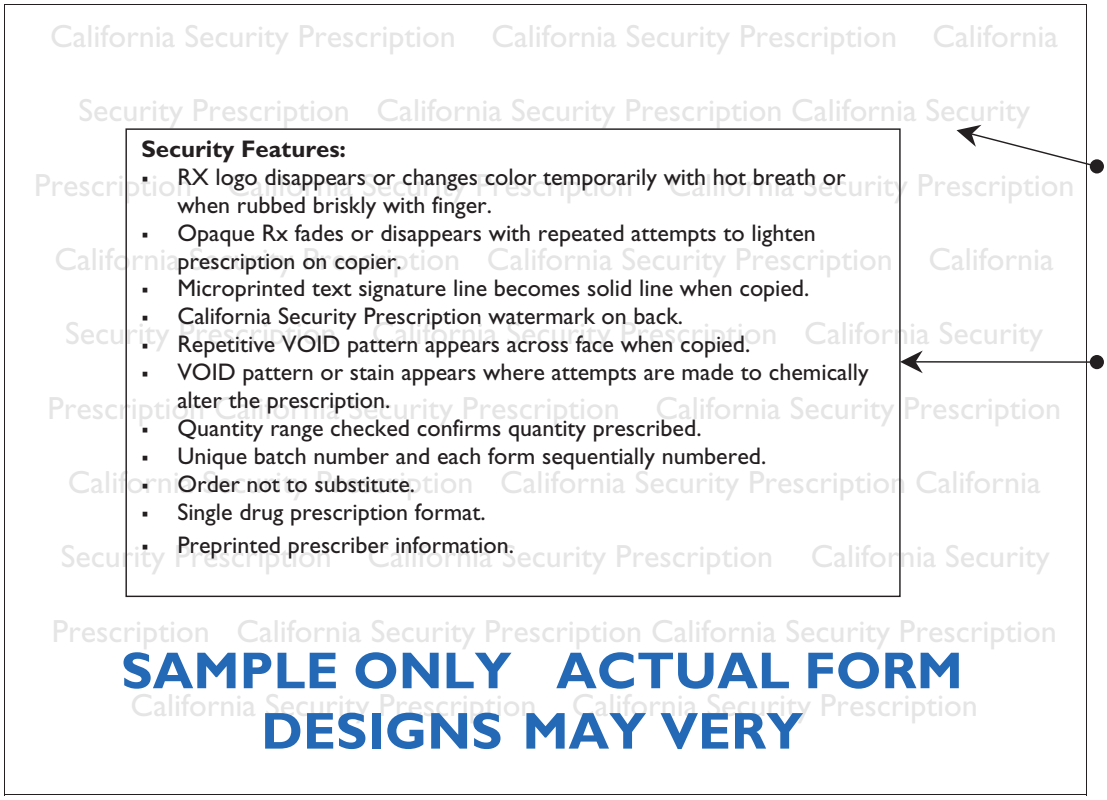
Institution forms can only be used by health care facilities licensed under Health & Safety Code section 1250. Generally, these are 24-hour acute care hospitals, skilled nursing facilities, etc. The forms are preprinted with the facility and the facility's "designated prescriber" information as indicated below. The actual prescriber information will be printed, handwritten, or stamped on the form when the prescription is written.



- **Batch/Lot Numbers** – Unique batch and sequential lot numbers assigned by approved security printers. Numbers are not tracked by the State.
- **Actual Prescriber** – the prescription is not valid without the actual prescriber information filled in.
- **Opaque Writing** fades or disappears when photocopied repeatedly to lighten.
- **Six quantity check boxes** allow quick confirmation that the quantity prescribed has not been altered.
- **Do Not Substitute** –prescriber must check box and initial
- **Refills** – CII drugs cannot be refilled, only CIII – V can be refilled.
- **Description of security features** in warning bands on face or listed on back of prescription. (see sample of backside)
- **Thermochromic ink** feature changes color or disappears temporarily with hot breath or when rubbed briskly. It slowly returns to normal as it cools.
- **Microprint signature line –** seen only with a magnifier, which becomes a solid line when copied.
- **Statement** allows multiple prescriptions on one form.) Prescribers must note the number of drugs prescribed.

Alternatively, prescribers may order a form designed to write only single drug prescriptions. See the previous form sample using a single drug prescription format.

SAMPLE BACKSIDE OF SECURITY PRESCRIPTION FORMS



- **California Security Prescription Watermark** printed in opaque ink—hold at an angle to view.
- **Description of Security Features** may be on the face of prescription in warning bands instead, see blue bands on sample forms

Letter to California Pharmacists and Physicians and Surgeons

From: **Patricia F. Harris**
Executive Officer
State Board of Pharmacy

David T. Thornton
Executive Director
Medical Board of California

Re: Schedule II Prescriptions and Section 11167 of the Health & Safety Code

Effective January 1, 2005, all written prescriptions for Schedule II-V controlled substances must be on tamper-resistant prescription forms that are purchased from state-approved, designated security printing companies.

Prescribers who do not have the tamper-resistant prescription forms may have difficulty providing good patient care when that care necessitates prescribing a Schedule II controlled substance. Prescriptions for Schedule III-V can be dispensed upon an oral or electronically transmitted prescription. Prescribers can also fax a regular prescription form for Schedule III-V drugs.

With regard to Schedule II prescriptions, prescribers without the required security forms may in limited emergency circumstances use the exception to the security form requirement offered by Section 11167 (copied below) of the Health and Safety Code to prescribe a Schedule II controlled substance for a patient in need.

The Board of Pharmacy and the Medical Board of California are most concerned that the healthcare needs of legitimate patients be met during the implementation period for the new security prescription forms. Pharmacists receiving prescriptions with the 11167 notation should exercise their professional judgment in filling these prescriptions, with the highest priority given to evaluating whether a prescription is authentic and issued for a legitimate medical purpose. This may require contacting the prescriber's office to verify the prescription. In addition, if pharmacists have reason to believe that a prescriber is delaying or avoiding use of security prescription forms, relying on Section 11167 for non-emergent Schedule II prescriptions, or otherwise misusing the limited emergency authority given by Section 11167, pharmacists may choose to file a complaint with the appropriate licensing board for the prescriber in question.

For their part, physicians need to make a good faith effort to obtain the new tamper-resistant security forms in compliance with the law and provide the written prescription on the new form by the seventh day after the initial order. The boards are concerned that patient care is not interrupted as long as both the prescribers and pharmacists are making good faith efforts to comply with this new law. There are nearly 50 approved printers with more than 1,000 distributors, so obtaining the new security forms should not be a problem.

Additional information on SB 151 is available on the Board of Pharmacy Web site: *www.pharmacy.ca.gov* and the Medical Board of California's Web site: *www.caldocinfo.ca.gov*.

11167. Notwithstanding subdivision (a) of Section 11164, in an emergency where failure to issue a prescription may result in loss of life or intense suffering, an order for a controlled substance may be dispensed on an oral order, an electronic data transmission order, or a written order not made on a controlled substance form as specified in Section 11162.1, subject to all of the following requirements:

(a) The order contains all information required by subdivision (a) of Section 11164.

(b) Any written order is signed and dated by the prescriber in ink, and the pharmacy reduces any oral or electronic data transmission order to hard copy form prior to dispensing the controlled substance.

(c) The prescriber provides a written prescription on a controlled substance prescription form that meets the requirements of Section 11162.1, by the seventh day following the transmission of the initial order; a postmark by the seventh day following transmission of the initial order shall constitute compliance.

(d) If the prescriber fails to comply with subdivision (c), the pharmacy shall so notify the Bureau of Narcotic Enforcement in writing within 144 hours of the prescriber's failure to do so and shall make and retain a hard copy, readily retrievable record of the prescription, including the date and method of notification of the Bureau of Narcotic Enforcement.

(e) This section shall become operative on January 1, 2005.

Pharmacists prescribing controlled substances must apply for personal DEA registration

Effective January 1, 2005, any pharmacist who is authorized to write or issue prescriptions for a Schedule II through V controlled substance, pursuant to a protocol with a physician, must now apply for personal registration as a Mid-Level Practitioner with the Drug Enforcement Administration (DEA). (Business and Professions Code 4052.) If the protocol does not include controlled substance therapy, the pharmacist is not required to obtain DEA registration.

You may apply online for DEA registration as a new Mid-Level Practitioner (DEA Form 224) at *www.deadiversion.usdoj.gov*. Any questions related to registration must be directed to the DEA:

Los Angeles area (213) 621-6960
San Diego area (858) 616-4542
San Francisco area (888) 304-3251

Board Competency Committee to be restructured— item writers needed

The Board's Competency Committee develops and oversees the administration of the California Pharmacist Jurisprudence Examination or CPJE. This exam consists of 90 multiple-choice items that assess minimal competency in patient communication skills, pharmacy law and clinical knowledge in practice situation in California.

The Board is restructuring the Competency Committee into two groups: 1) a core committee that selects and refines the items for the examination, selects a cut-score and oversees the administration of the examination and 2) item writers. The Board is now seeking new members for both committees, and pharmacists are encouraged to apply.

1. Core Committee

Besides the main functions of the committee described above, related duties of the committee include the oversight of a job analysis of the pharmacist profession every five years to assure that the exam remains valid for entry-level pharmacist practice. From this analysis, the committee develops the content outline for the examination.

Appointment to the core committee is an honor, but the work required is demanding. There are six two-day meetings annually, and attendance at the committee meetings is a requirement. Those members who cannot attend all meetings each year may become item writers where attendance at periodic meetings is not required.

The committee will consist of 19 members and will be structured to ensure a balance of practitioners from all practice settings:

Schools of Pharmacy (1 member each)	6 members
Community Practice	6 members
Institutional Practice	5 members
Board Member:	1 member
Board Inspector	1 member

2. Item Writers

Item writers will meet only once annually for an item-writing workshop and training. Then throughout the year, assignments to write questions in specific areas of the content outline will be distributed to the item writers. The finished questions will be reviewed by the core committee for inclusion in future examinations. No other meetings are required for item writers.

How to Apply

The Board's president appoints all committee members to terms of four years, with reappointment possible for another four years. Practicing California pharmacists who have been licensed within the last five years are especially encouraged to apply. Applications must include your curriculum vitae, a cover letter describing your area of pharmacy experience or practice, and three letters of reference from pharmacists who are familiar with your work. Please submit applications to:

Competency Committee Appointments
Board of Pharmacy
400 R Street, Suite 4070
Sacramento CA 95814

NOTE: The National Association of the Boards of Pharmacy (NABP) also is seeking item writers. If you are a pharmacy practitioner, educator, or regulator, the NABP can use your expertise as an item writer for the North American Pharmacist Licensure Examination, Foreign Pharmacy Graduate Equivalency Examination, and the Disease State Management Examination. Those interested should send or fax a letter of interest and a current resume or curriculum vitae to:

NABP
Executive Director/Secretary, Carmen A. Catizone
700 Busse Highway, Park Ridge IL 60068
(fax: 847-698-0124)

Item writers may write questions for either the California Board of Pharmacy or the NABP—**not both**.

Pharmacist Protocol for Dispensing Emergency Contraception

Pharmacists may furnish emergency contraception drug therapy based on a statewide protocol adopted by the California State Board of Pharmacy and the Medical Board of California. Development of the protocol was authorized by Senate Bill 490 (Chapter 651, Statutes of 2003). The protocol is located in section 1746 of the Code of Regulations and also can be viewed at *www.pharmacy.ca.gov*.

The Board-approved protocol was prepared with the intent to keep it simple and to comply with the statutory requirements established by Senate Bill 490. Statutory provisions for pharmacists furnishing emergency contraception drug therapy are found in section 4052 of the Business & Professions Code.

Pharmacists may use this protocol after they have completed and been awarded one hour of continuing education credit in emergency contraception (a requirement of the new law).

Prior legislation (Senate Bill 1169, Chapter 900, Statutes of 2001) permits pharmacists to furnish emergency contraception medications to patients, based on a protocol with a single licensed prescriber. Protocols developed with a prescriber under these requirements remain valid.

Who can sign pharmacist intern affidavits?

The Board is finding that newly licensed pharmacists are acting as preceptors by signing pharmacy intern hours and experience affidavits for periods of time *before* they were actually licensed as pharmacists. For example, an intern's training began in 2002, but the preceptor signing the affidavit did not become a licensed pharmacist until 2003. In most of the cases, these newly licensed individuals are pharmacy managers and mistakenly required by company policy to sign off on all intern affidavits. California pharmacy law prohibits such action.

Section 1726 of the California Code of Regulations defines a "preceptor" as a licensed pharmacist whose license "…is not revoked, suspended or on probation in any state in which he or she is now or has been registered." Preceptors are responsible for the supervision and training of interns and ultimately confirm that training by signing off the interns' hours and experience affidavits—those signatures being affixed under penalty of perjury.

Another problem is that preceptors are signing off on intern hours affidavits, based on the intern's employment dates. However, occasionally individuals are hired initially as pharmacy clerks and begin their internship training at a later date. The dates on the intern hours affidavit should include only the actual dates the individual worked and trained as an intern and not be based on hiring and termination dates.

The consequences of erroneously signed affidavits include (1) seriously interfering with an intern's ability to complete his or her application for the Board's licensure exam; (2) being viewed as performing unlicensed activity and subject to citation and fine; and (3) criminal penalties for perjury.

How does wholesalers' electronic billing affect pharmacies' drug purchase recordkeeping?

The Board was recently asked for clarification of a pharmacy's recordkeeping duties when a wholesale supplier decides to convert from paper to electronic invoices. Specifically, is the pharmacy permitted to store invoices electronically and no longer required to keep paper copies of invoices on file? If so, how long is the pharmacy required to keep electronic invoices available for inspection?

California law requires that records of the manufacture, sale, acquisition and distribution of dangerous drugs and devices be available on the licensed premises for three years from the date of making (Business & Professions Code sections 4081, 4105 and 4333). Also, records may be kept electronically so long as a hard copy and an electronic copy can always be produced (B&PC 4105).

The answer is that pharmacies can keep drug purchase records from wholesalers electronically rather than on paper so long as these records are retained on site, immediately available for inspection for a period of three years, and can at all times be produced in both hard copy and electronic form by an on-duty pharmacist.

Ignoring restrictions on ephedrine sales can lead to disciplinary action and criminal conviction

In 2000, California laws restricted the sales of over-the-counter (OTC) medications for allergy, asthma, colds, sinus, and weight loss—products that could be used in the illicit manufacture of methamphetamine. Sales of these products must be reported to the Bureau of Narcotic Enforcement (BNE) on forms furnished by the BNE. The reporting requirements apply to sales by manufacturers, wholesalers, pharmacies and other unlicensed retailers.

Failure to comply with these requirements (Health & Safety Code 11100-11107.1) led to the conviction and of a San Jacinto pharmacist, Jae Gab Kim, for the distribution of pseudoephedrine to manufacture methamphetamine in May 2004.

Retail sales of products containing ephedrine, pseudoephedrine, norpseudoephedrine or phenylpropanolamine are limited to **no more than three packages or no more than nine grams** (or 150 60 mg. pills) **in a single transaction**. However, since most of these products are packaged in quantities of less than three grams per package, three packages of commercial products containing these substances will not ordinarily exceed the nine grams limit. Prescriptions for such products are exempt from the limit and reporting requirements.

Though abiding by the letter of the 9-gram-per-transaction limit, Kim's sales of pseudoephedrine skyrocketed more than 20 times during the first seven months of 2000. He regularly sold consumers generically labeled, 100-count bottles of 60 mg. pseudoephedrine pills that typically are used by pharmacists to fill prescriptions. His average sales rose to about 24 of these bottles per day. Employee testimony revealed that about half the people purchasing a bottle would also purchase two 24-count boxes of 60 mg. pseudoephedrine tablets and little else, and some customers bought pseudoephedrine almost daily.

The evidence further showed that while Kim sold 5,000 bottles of 60 mg 100-count pseudoephedrine in 2000, 15 other pharmacies in the region had purchased a total of only two 60 mg. 100-count bottles during the same time period.

For more details regarding the laws relating to the limiting and reporting of ephedrine products and the sales and reporting exceptions, visit the Board's Web site, *www.pharmacy.ca.gov* and click on Written Information & Research Tools, then select the January 2000 *The Script* newsletter. An in-depth article begins on page 6 and is followed by questions and answers.

Can retired physicians prescribe?

The Medical Board of California recently asked the Board of Pharmacy to advise pharmacists that physicians with retired licenses cannot write prescriptions.

After July 1, 2004, a physician who is licensed as a physician in retired status with the Medical Board of California is no longer eligible to practice medicine and consequently may not write prescriptions.

Pharmacists with questions about the license status of a physician should contact the Medical Board of California at (916) 263-2382 or via the Internet at *www.medbd.ca.gov*.

Reporting Misconduct by Health Practitioners

The Medical Board of California Chief of Enforcement Joan Jerzak has requested that the Board of Pharmacy publish the following letter:

As chief of enforcement for the Medical Board of California, I am extremely interested in advancing the board's mission of consumer protection. Recently, a nurse in a California hospital was quoted in a major newspaper article stating that she knew (without naming anyone) of many physicians who deserved to have their licenses revoked by this board. The context for this was within a story about a licensee whose license was being revoked by our board. Such a statement is of concern to us because we rely in part on peer review and input from allied health professionals to help us in doing our job of patient protection. In my opinion, healthcare workers are in a uniquely qualified position of trust and obligation to report to regulatory agencies problems they see with other healthcare providers that lead to or could lead to patient harm.

I am asking those "on the front line" to recognize and act on this obligation by informing the Medical Board of physician misconduct of which they become aware. While we can take complaints anonymously, they are impossible to pursue if we cannot find witnesses to corroborate the allegations. I cannot guarantee your name will not surface, but we will work with you to avoid that if possible. I can guarantee you that you will be doing the right thing by your patients and your profession. We, at the board, are deeply committed to our mission of consumer protection and the proper licensing and regulation of physicians in California. We hope you will work with us and your constituencies toward that end.

Please call our toll-free complaint line at (800) 633-2322, or download our complaint form from our Web site at www.caldocinfo.ca.gov or www.medbd.ca.gov. Thank you on behalf of the consumers of the state of California.

Changes at the Board

New Board officers were elected at the April 2004 meeting:

Stanley W. Goldenberg, *R. Ph.*, President

William Powers, *Public Member*, Vice President

David J. Fong, *Pharm D.*, Treasurer

Additionally, Ms. Andrea Zinder, *Public Member*, was recently reappointed to the Board by Speaker of the Assembly Fabio Nunez. Mr. William Powers was reappointed by Senate President Pro Tempore John Burton.

www.pharmacy.ca.gov

Clerk/Typist ratio for pharmacist is eliminated

Section 1793.3 of the California Code of Regulations was recently amended to remove the limits on the number of clerk/typists that may be supervised by a pharmacist. The regulation now allows a pharmacist to determine the number of clerk/typists the pharmacist will supervise. Employers are prohibited from taking disciplinary action or discriminating against the pharmacist for exercising this right. This amended regulation became effective October 2, 2004.

Board of Pharmacy needs inspectors

The Board of Pharmacy has inspector vacancies statewide and is seeking to fill these positions with self-starting pharmacists who have a solid understanding of pharmacy practice and pharmacy law.

Board 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 (e.g., report writing) and those requiring travel. Travel, including both local and statewide, is approximately 20-25 percent of the workweek. Inspectors are provided the use of home office equipment (telephone, cell phone, computer, etc.), a state car and business and travel expense reimbursement.

To be considered, you must be a California-registered pharmacist with at least two years' experience in the practice of pharmacy and possess a valid California driver's license. This is a civil service classification, so you will be required to participate in a qualifications assessment interview. The results of the interview will determine your ranking on a civil service hiring list. Based on this ranking, you may be called to appear for the Board's employment interview and writing skills evaluation.

To obtain an application for examination and employment, access the Board's Web site, *www.pharmacy.ca.gov* and click on What's New. Your completed examination application and résumé must be mailed to the address below and **postmarked no later than 2/8/05**.

Department of Consumer Affairs
P. O. Box 980428
West Sacramento CA 95798-0428

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

Continuing education (CE) hours are being awarded to encourage pharmacists 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 the state 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.

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 **2005** are:

April 27 & 28	Sacramento Department of Consumer Affairs 400 R Street, 1st Floor Hearing Room Sacramento, CA 95814
July 20 & 21	San Diego
October 25 & 26	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. The materials are placed on the Board's Web site about five days before a meeting.

This newsletter is published by the

California State Board of Phamacy
Department of Consumer Affairs
400 R Street, Suite 4070
Sacramento CA 95814
(916) 445-5014
Fax: (916) 327-6308
www.pharmacy.ca.gov

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Pharmacy Law 2005 is available

The 2005 edition of the California Pharmacy Law book can be purchased for $26.41 each. That amount includes tax and shipping charges.

For credit card orders or quantity discount pricing, call (800) 498-0911, extension 5, or visit *www. Lawtechpublishing.com.*

Purchase orders for over $100 can either be mailed to:

LawTech Publishing
1060 Calle Cordillera, Suite 105
San Clemente, CA 92673

Or faxed to:
(949) 498-4858

OSP 04 87764

ATTACHMENT 3

BE AWARE & TAKE CARE:
Talk to your pharmacist!

The Script

CALIFORNIA BOARD OF PHARMACY OCTOBER 2005

Board Honors Those Who Have Been Pharmacists for At Least 50 Years



Honored at the July Board meeting: (left to right) Jesse N. Drake, Jr. from Los Angeles; Albert J. Galloway from LaMesa; Samuel Perlman from LaMesa.

In this issue, *The Script* initiates a new, permanent segment dedicated to those who have been registered California pharmacists for at least 50 years. Those pharmacists (438) were awarded certificates commemorating 50 years of service and invited to attend future Board meetings where they could be publicly honored.

The Board also extends an invitation to pharmacists on retired 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.

See **Board Honors**, Page 17

Give Us Your Katrina Stories

Following the disastrous hurricane Katrina, California pharmacists and pharmacies have reached into their hearts and pockets to help the survivors. The Board wants to recognize your efforts, so we need to know who you are and how you helped.

Examples of the generosity of California's pharmacy profession include:

- **Burton Sacks, Pharm. D.**, of the Rancho Park Compounding Pharmacy in Los Angeles, established a program to match every dollar contributed for relief—up to $1,000 per day.
- **Rite-Aid Corporation** immediately established money donation centers for the survivors.
- For cancer and dialysis patients who were unable to connect with their doctors or medical records and whose critical therapies were interrupted, **Walgreen Company** has become a de facto emergency health provider. Not only are they filling many prescriptions for free, they are also collecting money donations.
- **Modern HealthCare** in Monrovia, California, and owned by RPh Ira Halpern and RPh Richard Katz, has more than 180 employees and plans to donate $5,000 to the Katrina survivors in lieu of having a company holiday party. In addition, Modern also is asking each employee to contribute to the fund.
- **Omnicare Incorporated**, a national holding with several pharmacies in California, is providing medications from their pharmacies in the hurricane area to displaced and relocated patients without any consideration for payment.

We know there are many more stories like these. Please write the Board with the details of your efforts so that you and/or your pharmacy can be publicly acknowledged and thanked. Send your letters to:

Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814

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President's Message

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

I would like to begin my message by thanking and commending all the pharmacists and pharmacies that have contributed to disaster relief and volunteered to become donation centers to help our fellow Americans in the wake of hurricane Katrina's devastation. As always, the most trusted profession is living up to its tradition of providing help to those in need.

The Board of Pharmacy realizes that there may be patients in California who have been relocated from the Gulf Coast and require prescribed medication but are unable to provide the prescription. Guidelines for emergency dispensing can be found on the board's Web site, *www.pharmacy.ca.gov* under "What's New."

I am pleased to announce that Governor Arnold Schwarzenegger has honored me by reappointing me to serve a second term on the Board. My colleagues on the Board also have honored me by electing me to serve a second term as president of the Board.

As president, I will continue my campaign to encourage the pharmacy profession's involvement and interaction with the Board through our open meeting process. The information brought to us via these meetings is vital to the Board's ability to make informed decisions—as both the Board and the profession strive to serve and protect the public.

I wish to congratulate Patricia Harris, the Board's executive officer, who was elected to the National Association of Boards of Pharmacy Executive Committee at the NAPB national meeting in New Orleans in May. Ms. Harris will represent the NABP's District Seven, which includes six western states and Guam. As so many of today's pharmacy issues cross state borders, we are indeed fortunate that Ms. Harris will be participating in the adoption of policies by the association.

At the April 2005 Board meeting, Board Member John Tilley, then Chairman of the Organization and Development Committee, advocated providing a "Certificate of Recognition" to pharmacists licensed in California for 50 years or more and publishing their names in *The Script*. The Board approved this proposal and in July mailed 438 of the certificates. Some of the pharmacists who received certificates were personally honored when they attended the July Board meeting in San Diego. I hope this will become a new tradition, and perhaps in the future the Board can honor individual practitioners for their superior accomplishments.

Now is the time that you, as a pharmacist, can become involved in the process of changing your profession or accepting and complaining about the decisions made for you by others. Here are just a few of the issues facing our profession:

1. **MMA (Medicare Prescription Drug, Improvement, and Modernization Act):**

This act contains the most significant changes to Medicare benefits in 40 years. These changes are so dramatic that it behooves pharmacists to understand and be able to explain the program to patients.

This program, enacted in 2003, initially offered drug discount cards that Medicare beneficiaries could use to lower their prescription costs until the comprehensive benefit plan described below takes effect January 1, 2006. The new law is very complex:

- **Part D:** A new prescription drug benefit plan for Medicare beneficiaries has been developed through competing prescription drug plans. Beginning in October 2005, the Center for Medicare and Medicaid Services will mail to each Medicare beneficiary a booklet containing details about the specific drug plans being offered. Those wishing to enroll in a Part D program may do so during the open enrollment period beginning November 15, 2005 and ending May 15, 2006, to ensure that they will pay the lowest possible premiums. Failure to enroll during the open period may result in higher future premiums.

The Board has established a sub-committee of the Communication and Public Education Committee to focus on MMA and Part D. Our goal is to gather information to educate our own board and other health profession boards.

I encourage you to attend these meetings.

See **President's Message**, Page 22

Continuing Education for Pharmacists and Pharmacy Technicians

Since April 2003, the Board of Pharmacy has awarded six contact hours of continuing education (CE) once a year to pharmacists who attend a full business day at one of the Board's quarterly meetings. In January 2005, the Board approved offering this same CE opportunity to registered California pharmacy technicians. However, it is the pharmacy technician's responsibility to determine from the PTCB how many of the six CE hours are acceptable for recertification.

Board meetings are held at different sites throughout the state to give as many people as possible the opportunity to attend. No reservations are needed; interested parties simply arrive at the meeting location at the start of the business session and remain until the day ends. Certificates reflecting completion of six hours of CE are mailed to those who sign in and out on the CE roster.

Information regarding Board meeting dates, sites and agendas are posted on the Board's Web site (*www.pharmacy.ca.gov*) approximately 10 days prior to 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. The business day eligible for CE is designated on the agenda.

The remaining Board meeting for **2005** is:

October 25 & 26
Crowne Plaza Hotel
1177 Airport Boulevard
Burlingame, CA 94010
650-342-9200

FDA Offers Free Online CE

Do you know how the Food and Drug Administration (FDA) approves generic drugs? Becoming familiar with the process can help you assure your patients of the safety, effectiveness and lower cost of generic drugs. You can learn about generics and earn one contact hour of continuing education (CE)—accredited by the Accreditation Council for Pharmacy Education—by taking FDA's web-based CE course on generic drugs, "The FDA Process for Approving Generic Drugs:"

Examples of valuable information included in the program are that generic drugs:

- are approved by the FDA to be safe, effective, high quality, and reliable;
- save an average of $45.50 for every prescription sold;
- currently save consumers about $56.7 billion per year, and can save consumers an additional 1.3 billion per year for every 1% increased use of generic drugs; and
- are lower in cost than Canadian brand name or generic drugs.

To take the program, go to *http://www.fda.gov/cder/learn/CDERLearn/default.htm* and follow the instructions.

Posters for helping educate consumers about brand and generic drugs can be downloaded at *www.regencerx.com/prescription/physicianTools/generics/posters/*. These can be posted in the pharmacy or used as handouts.

New NABP Evaluation and Learning Tool: Pharmacist Self-Assessment Mechanism (PSAM)

The National Association of Boards of Pharmacy (NABP) has developed a new program that is designed to satisfy four hours of the continuing education (CE) requirement for pharmacist license renewal in some states. While not yet Board-approved for CE in California, 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.

With the continuous introduction of new therapeutic and diagnostic agents and the changing concepts in the delivery of health services in pharmacy practice, it is essential that pharmacists maintain, improve and broaden their knowledge and skills. An excellent approach to maintaining and updating these skills is for pharmacists to avail themselves of this self-assessment program.

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

See **NABP Evaluation**, Page 20

Regulation Update Summaries

This article contains summaries of changes to Division 17, Title 16 of the California Code of Regulations that become effective October 7, 2005. To view the exact language of the affected regulations, visit the Board of Pharmacy Web site at *www.pharmacy.ca.gov,* and click on Laws and Regulations.

1706.2 Abandonment of Application Files

Applications for licensure with the Board may be considered abandoned if the applicant fails to complete the application within **60 days** of having received an application deficiency letter from the Board.

Failure to pay the pharmacist licensure fee within **12 months** of being notified of eligibility will result in the file being abandoned, and if a pharmacist licensure examination applicant has not taken the examination within **12 months** of eligibility notification, the file will be abandoned. In all these cases, applicants would be required to submit a new application and meet all the requirements in effect at time of reapplication.

1712. Use of Pharmacist Identifiers

For pharmacists who are required to initial or sign a prescription record or label, their identity may be recorded in a secure computer system that must be readily retrievable in the pharmacy. The computer system must not permit such a record to be altered after it is made.

1715. Self-Assessment of Pharmacy by the Pharmacist-in-Charge

Pharmacy self-assessment form names are changed to "Community Pharmacy & Hospital Outpatient Pharmacy Self-Assessment" (Form 17M-13) and "Hospital Pharmacy Self-Assessment" (Form 17M-14).

1717. Pharmacy Practice

The only substantive change to this regulation is a correction of the citation listed for prescription requirements. The correct citation is Business and Professions Code section 4040.

1719. Recognized Schools of Pharmacy

This regulation defines a "recognized school of pharmacy" as a school that is accredited, or granted candidate status, by the Accreditation Council for Pharmacy Education or otherwise recognized by the Board.

1720. Application for Pharmacist Examination and Licensure

Language in this section has been recast. Portions of the section have been deleted but are included in other regulations.

1720.1 Graduate of Foreign Pharmacy Schools

The education of most foreign pharmacy school graduates who have been certified by the Foreign Pharmacy Graduate Equivalency Committee (FPGEC) satisfies the education requirement to qualify for taking the California pharmacist licensure examination. However, candidates who were certified by the FPGEC before January 1, 1998, must also provide the Board with documentation indicating a score of at least 50 on the Test of Spoken English (TSE). Candidates who took the TSE before June 30, 1995, must provide documentation of a score of at least 220.

1725. Acceptable Pharmacy Coursework for Examination Candidate with Four Failed Attempts

Candidates who have failed the pharmacist licensure examination four times must obtain at least 16 semester units of additional coursework from a "recognized school of pharmacy."

1726. Supervision of Intern Pharmacists

The term "preceptor" has been removed. The new language names the pharmacist supervising an intern pharmacist as the person responsible for all professional activities performed by the intern.

1727. Intern Pharmacist

This section, outlining an intern's requirements for taking the pharmacist licensure examination and other requirements, was repealed.

1728. Requirements for Examination

This section recasts the language outlining the eligibility requirements for taking the pharmacist licensure examination.

1732. Definitions

This section defines "accreditation agency" as an organization that evaluates and accredits providers of continuing education for pharmacists and defines an "hour" of continuing education as at least 50 minutes of contact time.

1732.0.5 Accreditation Agencies for Continuing Education

This section names the two continuing education accreditation agencies—the Accreditation Council for Pharmacy Education and the Pharmacy Foundation of California—and details their functions relating to continuing education providers.

1732.1 Requirements for Accredited Providers

The language of this section is recast to require the issuance of "statements of credit" instead of certificates of completion. Requirements for continuing education providers' promotional brochures have been added. Continuing education providers must be accredited pursuant to section 1732.2 and each course must comply with requirements of section 1732.3.

1732.2 Board Accredited Continuing Education

This section recasts the language that allows continuing education providers, who are not accredited by one of the two accreditation agencies, to petition the Board for approval of their courses that meet the standards of section 1732.3.

1732.3 Requirements for Continuing Education Courses

Some of the language in this section has been recast, and specific requirements for continuing education courses have been added.

1732.4 Provider Audit Requirements

The requirements are the same, but the language has been recast.

1732.5 Renewal Requirements for Pharmacist

This section provides that continuing education for pharmacist license renewal must have been completed within the 24 months prior to renewal.

1732.6 Exemptions

The language here is recast, indicating there is no longer a form with which a pharmacist may seek exemption from the continuing education requirement for license renewal: a letter to the Board suffices.

1732.7 Complaint Mechanism

This section allows a continuing education provider to request reconsideration of any adverse action taken against the provider by an accreditation agency. Following such reconsideration, the provider may request the Board to review the accreditation agency's decision.

1745. Partial Filling of Schedule II Prescriptions

Reference to triplicate prescription requirements is deleted here. Language has been added to this section allowing a pharmacist to partially fill a Schedule II controlled substance prescription if unable to supply the full quantity. However, there are changes in the time frames in this section. Prescriptions now must be tendered and at least partially filled within **60 days** from the prescription issuance date, and no portion of the prescription can be dispensed more than **60 days** from the issuance date. The remaining portion may be filled within 72 hours of the first filling, but if the remainder is not filled within the 72-hour period, the pharmacist must notify the prescriber. The pharmacist may not supply the drug after the 72-hour period has expired without a new prescription.

1749. Fee Schedule

The fee for reissuance of any permit, license, certificate or renewal thereof is increased to $60. All other fees remain the same, but there is some recasting of the language.

1750. Fee Schedule—Health and Safety Code

Warehouse license issuance and renewal fees are repealed.

Compromising Pharmacist Examination Questions Can Lead to Disciplined Licenses

Section 123 of the Business and Professions Code states, "It is a misdemeanor for any person to engage in any conduct which subverts or attempts to subvert any licensing examination or the administration of an examination…" Such subversive conduct includes, but is not limited to:

- The unauthorized reproduction of any portion of the actual licensing examination;
- Paying or using professional or paid examination-takers for the purpose of reconstructing any portion of the examination;
- Using or purporting to use any examination questions or materials which were improperly removed or taken from any examination for the purpose of instructing or preparing any applicant for examination; and
- Obtaining questions or other examination material, except by specific authorization either before, during or after an examination.

Section 1723.1 of the California Code of Regulations relates to the confidentiality of examination questions: "Any applicant for any license issued by the board who removes all or part of any qualifying examination to any other person may be disqualified as a candidate for a license."

Recently, the Board completed disciplinary action (Administrative Case 2003 2724) against Morris Hyman Cody, RPH 26302, founder of Morris Cody and Associates (MCA). MCA provides a preparation course for those who take the pharmacist licensure examination. In the Board's disciplinary action, MCA and Mr. Cody were charged with allegedly obtaining or accepting pharmacist examination questions and answers—taken without the Board's authorization from students who were enrolled in MCA's refresher course and had taken the examination. The Board also alleged that the questions were reconstructed and reproduced in at least two of MCA's study booklets and distributed to MCA students.

In the same administrative case, the Board also disciplined a pharmacist who had provided questions to MCA and Mr. Cody. After signing an examination instruction sheet acknowledging the confidentiality of the pharmacist examination in January 2001, Jennifer Hoerrner, RPH 52366 (an enrollee of MCA), allegedly revealed more than 30 questions from that examination in a letter to Mr. Cody. Portions of the illegally removed questions were allegedly reconstructed and reproduced in at least one of MCA's study booklets and distributed to MCA students.

Based on the alleged violations of statutes and regulations, Mr. Cody and Ms. Hoerrner agreed, for purposes of settlement only, that the charges, if proven, would constitute cause for the imposition of discipline.

As settlement, Mr. Cody's pharmacist license was revoked, stayed and placed on five years' probation. He was ordered to pay the Board $20,000 to cover the costs of investigation, prosecution and reconstruction of examination questions and to pay probation monitoring costs, not to exceed $1,000 per year. Additionally, all MCA sample examination questions, study booklets, and audio and visual recordings that contain sample examination questions must be reviewed by the Board. Mr. Cody was also ordered to write a letter for publication in the Board newsletter.

Ms. Hoerrner's pharmacist license was revoked, stayed and placed on three years' probation. She was ordered to pay $2,000 for recovery of investigation and prosecution costs and submit a letter for publication by the Board and an audio/video recording for distribution to schools of pharmacy.

Letters from Mr. Cody and Ms. Hoerrner can be viewed below and on page 7.

Open Letter to Pharmacy Students and Examinees:

Dear Students and Examinees:

Recently, I was disciplined by the California Board of Pharmacy for sharing confidential examination information.

Like most of you, I took an examination preparation course in order to update my knowledge. One of the teachers who worked at the school asked students to share with him any exam questions that they recalled. Naively, I shared this information which I later realized was a great mistake, as the exam information was confidential.

I violated the Business and Professions Code and now have a record of discipline. This experience has taught me several lessons. Also, it has reminded me that it is important to read what I sign and reinforced my commitment to uphold the integrity of the profession.

I have learned from this mistake and that it is important that the integrity and confidentiality of the pharmacist licensure examination is protected. If you discover yourself in a similar situation, never share confidential exam questions, and contact the Board of Pharmacy if you have any concerns.

Sincerely,

Jennifer Hoerrner

Letter From Morris H. Cody:

May 6, 2005

Patricia Harris
Executive Officer
Board of Pharmacy

Dear Ms. Harris:

I am writing to confirm our agreement in regards to the use of information provided from time to time by students of Morris Cody & Associates Inc. of California ("MCA") about questions appearing on the Board's license exam.

MCA fully supports the Board's efforts to protect the integrity of the examination process. MCA's mission is to provide applicants for a pharmacy license the necessary training and education to provide professional pharmacy services so that they can meet the Board's high standards for the practice of pharmacy in California. We understand the Board's position that it undercuts the integrity of the examination process to provide students information on specific questions appearing on prior exams. For this reason, MCA has, as requested by the Board, taken the following steps:

First, MCA has eliminated from its written program materials all sample questions that might be considered improper copies or reproductions of specific questions appearing on prior exams. While MCA will continue, of course, to provide necessary training and instruction on all issues covered by the license examination, care is being taken to avoid use of sample questions that improperly reproduce actual questions appearing on prior exams.

Second, MCA has implemented policies, consistent with the Board's request, that MCA does not solicit from its existing or former students any information about actual test questions appearing on prior exams, and advises students not to volunteer or provide such material as the Board considers this contrary to the integrity of the public safety mandate of the Board.

MCA regrets if past practices involving occasional receipt from students of exam question information may have undermined the Board's important role to ensure that exam process in not subverted. MCA's intent, of course, is to strictly adhere to all applicable regulations governing the examination process and to support the Board's efforts to protect the integrity of the test. We are pleased to have reached an agreement with the Board on the above-referenced matters that will promote this result.

Very truly yours,

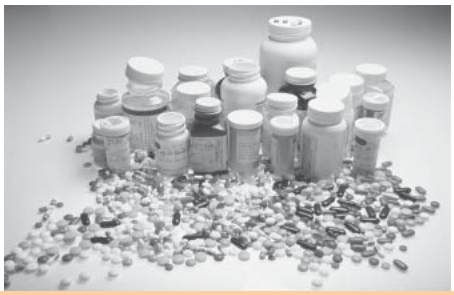
Morris H. Cody

Development of Fact Sheet Series for Consumers

One year ago, the Board approved a proposal by the Communication and Public Education Committee to integrate pharmacy students into public outreach activities. The project chosen was the development of a consumer fact sheet series by student interns. This project is being coordinated by the UCSF Center for Consumer Self Care under the direction of R. William Soller, Ph.D.

So far, four fact sheets have been developed: "Lower Your Drug Costs to Help you Keep on Taking your Medicines," "Generics," "Antibiotics—A National Treasure," and "Is your Medicine in the News?" The fact sheets contain general information on the topic but also include questions that consumers can discuss with their pharmacists and make informed decisions on the subjects covered. A fifth fact sheet is undergoing work by the Board, and the Board's goal is to produce total of 12 per year for the next three years.

The fact sheets may be downloaded from the Board's Web site, *www.pharmacy.ca.gov*, for distributing to consumers or posting in the pharmacy.



Significant Changes Coming for Wholesalers, Out-of-State Distributors and Exemptees

Beginning January 1, 2006, several license category names will change.

Out-of-state distributors licensed with the California Board of Pharmacy will be known as "**nonresident wholesalers**" (Business and Professions Code [B&PC] section 4161).

A separate license will still be required for each place of business owned or operated by a nonresident wholesaler that ships medications into California. The licenses must be renewed annually and are non-transferable (B&PC 4161). However, manufacturers who ship their own products from the manufacturing site directly into California are exempt from this license requirement (B&PC 4160[e]).

A registered pharmacist, or an exemptee pursuant to B&PC 4053 or 4054, must be present and in control of a wholesaler's premises during the conduct of business. Exemptees will be known and licensed as "**designated representatives**" (B&PC 4161).

The Board cannot issue or renew a nonresident wholesaler license until the applicant identifies a **"designated representative-in-charge"** (previously known as an "exemptee-in-charge") and notifies the Board in writing of that person's identity and license number. The designated representative-in-charge will be responsible for the company's compliance with all laws governing wholesalers (B&PC 4161[d]).

Wholesaler Tracking System

Also effective January 1, 2006, wholesalers will be required to develop and maintain a system for tracking individual sales of dangerous drugs at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities (B&PC 4164).

Pedigree Required by January 1, 2007

By January 1, 2007, wholesalers or pharmacies will be prohibited from selling, trading, transferring or receiving a dangerous drug at wholesale without a "**pedigree**" (B&PC 4163). An electronic pedigree will be required and must contain information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by the manufacturer, through acquisition and sale by a wholesaler, until final sale to a pharmacy or other person furnishing, administering, or dispensing the drug (B&PC 4034).

However, if the Board believes that the technology for such pedigrees is not fully ready by 2007, the Board may delay the effective date for requiring electronic pedigrees for wholesalers to 2008 and 2009 for pharmacies.

Updated information on these subjects will be posted on the Board's Web site, *www.pharmacy.ca.gov*, as it becomes available.

New Self-Assessment Forms

The Board has recently revised the pharmacy self-assessment forms to conform to current pharmacy law, which has changed significantly since early 2001 when the last versions of the forms were created. Additionally, the names of the forms were changed to:

- "Community Pharmacy & Hospital Outpatient Pharmacy Self-Assessment" (Form 17M-13)
- "Hospital Pharmacy Self-Assessment" (Form 17M-14)

Section 1715 of Title 16 of the California Code of Regulations requires the pharmacist-in-charge (PIC) of each pharmacy to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law by July 1st of each odd-numbered year. In addition, within 30 days of a new pharmacy's permit issuance date and any change in a pharmacy's PIC, a new self-assessment is required.

All self-assessment must now be done on the 2005 version of the forms. The forms can be downloaded online at *www.pharmacy.ca.gov*.

The completed self-assessments are to be retained in the pharmacy for three years after it is performed. Please do not mail the self-assessment to the Board.

Surety Bonds Required for Wholesalers and Nonresident Wholesalers

Effective January 1, 2006, all wholesalers and nonresident wholesalers licensed in California are required to secure a surety bond made payable to the Pharmacy Board Contingency Fund as a condition for initial licensure or renewal of an existing license. The Board is allowed to make claim against the surety bond if the licensee fails to pay a Board-imposed fine within 30 days after an order is issued or costs become final.

Section 4043 of the Business and Professions Code (B&PC) defines a drug **wholesaler** as a person or business who sells or negotiates for the distribution of dangerous drugs or dangerous devices to pharmacies, other practitioners or licensed facilities. Wholesalers must be licensed by the Board (B&PC 4160).

Section 4161 of the B&PC defines a **nonresident wholesaler** as a person or business located outside of California who ships, mails or delivers dangerous drugs or dangerous devices into this state. A nonresident wholesaler must be licensed by the Board before these activities begin.

The bonding requirements for wholesalers are detailed in B&PC 4162 and for nonresident wholesalers in section 4162.5. The requirements mirror each other and are listed below:

See **Surety Bonds**, Page 21

Program Required for Furnishing Hypodermic Needles and Syringes Without a Prescription

A new law went into effect on January 1, 2005, requiring a program for furnishing hypodermic needles and syringes without a prescription. The goal of the law is to further efforts across the state to prevent the spread of HIV, Hepatitis C and other blood-borne diseases by allowing pharmacies to sell sterile syringes without a prescription if one of the following conditions is met:

1. The person is known to the pharmacist to have a medical need for a syringe; **or**
2. If the pharmacy is located in a county or city that has authorized non-prescription syringe sale and established a Disease Prevention Demonstration Project (DPDP).

In cities and counties with a DPDP, pharmacies that opt to participate in the project may sell ten or fewer syringes to individuals 18 years of age or older without a prescription. Pharmacies participating in a DPDP are not required to make any record of syringe sale to customers without a prescription, nor are pharmacists required to record any information about the sale or the customer. Additionally, there is no requirement for pharmacists to require identification from the customer, although they may do so if the customer appears to be under the age of 18. These provisions of the law expire on December 31, 2010. (Business and Professions Code sections 4145 and 4147, Health and Safety Code section 11364).

As of June 2005, eight counties and two cities have approved a DPDP: Alameda, Contra Costa, Los Angeles, Marin, San Francisco, Santa Cruz, Yolo, Yuba counties and the cities of Los Angeles and West Hollywood. More than twenty other areas are in the process of establishing a DPDP.

For pharmacies that choose to participate in a DPDP, the law requires the pharmacy to:

1. Register with the city or county health department;
2. Certify that the pharmacy will provide the purchaser with written information or verbal counseling on how to access drug treatment, how to access testing and treatment for HIV and Hepatitis C virus, and how to safely dispose of sharps (needle and syringe) waste;
3. Store hypodermic needles and syringes so that they are available only to authorized personnel; and
4. Provide for the safe disposal of hypodermic needles and syringes. Safe disposal of sharps can be done by providing an on-site safe hypodermic needle and syringe collection and disposal program; furnishing or making available for purchase mail-back sharps disposal containers that meet state and federal standards; or furnishing or making available for purchase personal sharps disposal containers.

If you would like more information about establishing a DPDP in your county or city, or would like to find out about an existing program, please contact Alessandra Ross, California Department of Health Services, Office of AIDS, at (916) 449-5796, or e-mail her at *aross@dhs.ca.gov*.

Answers to Pharmacy Practice Questions

Frequently, the Board receives inquiries regarding pharmacy practice issues that are not addressed specifically in the Pharmacy Law. In responding to these inquiries, the Board is not issuing any regulation, guideline, criterion, or rule of general application outside the processes of the Administrative Procedures Act. The Board does not offer or suggest the following as binding interpretations of law or as supplements to existing law.

Performance of "Pharmacist" Tasks by Intern Pharmacists

Q. Can a licensed intern pharmacist perform "advanced" procedures such as: 1) emergency contraception (EC) protocols under section 4052 of the Business & Professions Code (B&PC); 2) skin puncture under B&PC 4052.1; or 3) final checks on prescriptions.

A. These questions are raised because there are concerns that certain "advanced" or "responsible" tasks are not appropriate for intern pharmacists who are not yet fully trained as pharmacists and/or are not yet established as professionals in pharmacy practice. While these concerns may be valid, the Board has heard from others that while intern pharmacists are still training, it is crucial for them to get experience in all techniques and tasks they will later perform unsupervised, and they should become accustomed to being responsible for pharmacy conduct.

The scope of an intern's performance in pharmacy practice is limited by B&PC 4114 which states, "An intern pharmacist may perform all functions of a pharmacist at the discretion of and under the supervision of a pharmacist whose license is in good standing with the board." Consequently, anything a pharmacist may do, an intern pharmacist may do, so long as the pharmacist by whom the intern is supervised agrees/permits it.

Included in the authorized functions for both pharmacists and interns are EC therapies (B&PC 4052[a][8]), skin punctures (B&PC 4052.1), and final check on prescriptions (B&PC 4051, 4115; California Code of Regulations [CCR] 1793.1).

However, both the intern pharmacist and the supervising pharmacist must meet all necessary prerequisites to the performance of any particular function before that function may be properly performed by the intern pharmacist. For example, regarding the provision of EC drug therapy, prior to performing any procedure authorized by B&PC 4052(a)(8)(B), both the intern pharmacist (to ensure appropriate provision of services) *and* the supervising pharmacist (to ensure appropriate supervision thereof) must first have participated in instituting and implementing standardized procedures/protocols and have received the required training. Obviously, intern pharmacists cannot receive CE credit for the training, but they must nonetheless have participated in an approved course of training on EC therapy.

Orally and Electronically Transmitted Prescriptions and Acceptance/Filling of Non-Security Prescription Form Prescriptions

Q. If the Board directs pharmacists to treat Schedule III-V prescriptions that are not written on security prescription forms as "oral" prescriptions, is the pharmacist required to rewrite the prescriptions?

A. Section 11164(a) of the Health & Safety Code (H&SC) directs that Schedule II-V prescriptions must be written on security prescription forms, excepting H&SC 11159.2 exempt prescriptions and ***oral*** prescriptions for Schedule III-V, *which shall be produced in hard copy form*. Present law further specifies that where a controlled substance prescription is transmitted orally or electronically, the pharmacist shall, prior to filling the prescription, produce a hard copy of the prescription, signed and dated by the pharmacist(s) or other authorized person(s) filling the prescription, containing the date and time of transmission, as well as specified information on the patient, prescriber, and pharmacist (H&SC sections 11164(b)(1), 11167 and 11167.5).

Consequently, for a pharmacist faced with a written prescription (Schedule III-V) not made on a security prescription form, the alternative to refusing to dispense is to treat that prescription as if it had been orally transmitted. In doing so, however, the pharmacist must actually *transform* the writing into an oral prescription. In other words, the pharmacist *cannot rely* on the written document as assurance of the validity or accuracy of the prescription, and must contact the authorized prescriber and orally verify and record all of the information that is required by B&PC 4070 (dangerous drugs), H&SC 11164(b)(1) (Schedule III-V drugs), or H&SC 11167/11167.5 (Schedule II drugs in applicable circumstances).

Q. What if the pharmacist takes the oral order over the telephone and enters it directly into the computer, what is then required of the pharmacist?

A. It does not appear that this procedure would exempt the pharmacist from the requirement(s) of hard copy production, personal signature and

See **Questions**, Page 23

Answers to Questions Relating to Naturopathic Doctors

Q. If a naturopathic doctor furnishes or orders under standardized procedures or protocol with an MD, which drugs may he/she furnish or order?

A. Section 3640.5 of the Business and Professions Code allows NDs to furnish or order Schedule III - V drugs under a standardized procedure or protocol and supervision of an MD. It also provides that the MD and ND develop a formulary for the supervised ND. Additionally, NDs may only order or furnish Schedule III controlled substances in accordance with a *patient-specific* protocol approved by the treating or supervising physician. As they do with other prescribers, pharmacists may request a copy of the standardized procedure used by a supervised ND and relating to controlled substances.

Q. As a pharmacist, may I fill an ND's prescription for Armour Thyroid before a formulary has been developed under standardized procedures or protocol with an MD?

A. Yes. Confusion may exist here because section 3640.5 of the Business & Professions Code states that a naturopathic doctor may furnish or order prescription drugs if there is a standardized procedure or protocol developed and approved by the supervising physician and surgeon. However, section 3640.7 states, "Notwithstanding the requirements of Section 3640.5 or any other provision of this chapter, a naturopathic doctor may independently prescribe epinephrine to treat anaphylaxis and natural and synthetic hormones." Armour Thyroid is a natural hormone, so neither a formulary nor protocol with a physician is required.

Q. Does the law permit NDs to independently prescribe hormones that are scheduled drugs, such as testosterone?

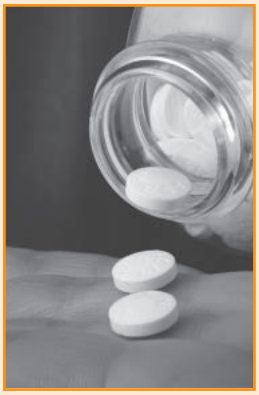
A. Legal opinions from the Board of Pharmacy and the Bureau of Naturopathic Medicine concluded that NDs may prescribe hormones that are scheduled drugs, but they must have a DEA number and a furnishing number issued by the Bureau of Naturopathic Medicine (BNM) to do so. Such legal opinions are expressions of the views of the Department of Consumer Affairs Legal Affairs Division. While they may be entitled to some weight, the opinions are not binding in any court.

Q. What certification is provided to an ND from the Bureau of Naturopathic Medicine that demonstrates their competence to prescribe?

A. The BNM provides a furnishing number to licensees who meet the requirements to furnish or order drugs. The furnishing number is preceded by the letters "NDF" (e.g., NDF-704).

Q. If a pharmacist has questions about filling a prescription from an ND, where can he/she obtain help and information?

A. The regulations dealing with the prescribing authority of NDs can be found in the Business and Professions Code sections 3640-3645. To review these provisions, you may access the Bureau of Naturopathic Medicine's Web site, *www.naturopathic@ca.gov*, and click on Laws/Regulations. Any questions should be directed to the Bureau of Naturopathic Medicine at 916-445-8692.



Can Retired Physicians Prescribe?

The January 2005 issue of *The Script* included an article advising that physicians with retired status licenses cannot practice medicine or write prescriptions. However, the article failed to note that a retired physician who holds a **"Voluntary Service"** license and provides ***voluntary, unpaid service*** is still permitted to practice medicine and write prescriptions.

Pharmacists with questions about the license status of a physician should contact the Medical Board of California at (916) 263-2382 or visit *www.medbd.ca.gov*.

Changes in the Board of Pharmacy

The Board welcomes new Public Member Marian Balay to the Board of Pharmacy. It also extends its best wishes and appreciation to departing Public Member James E. Acevedo and Pharmacist Member John E. Tilley.

New Member

On March 31, 2005, Governor Arnold Schwarzenegger appointed Marian Balay of Fullerton to the Board of Pharmacy as a public member. Ms. Balay's background is centered in the law profession, and since 1991, she has worked as a paralegal for American Suzuki Motor Corporation, focusing on product liability litigation. Prior to that time, Ms. Balay worked at Baker & Botts, a Texas law firm.

Departing Members

In February of this year, Public Member James E. Acevedo submitted his letter of resignation from the Board to Governor Schwarzenegger, citing family commitments and a work schedule that no longer permitted him to continue as a board member. However, Mr. Acevedo assured the Governor that it had been a difficult decision to make because his association and participation with the Board had been very rewarding.

Pharmacist Board Member John E. Tilley's appointment to the Board expired in June 2004, and he continued to serve on the Board until July 1, 2005, completing a year of grace. He served on the Licensing Committee and chaired the Organization and Development Committee. Under Mr. Tilley's leadership, the Board created the 50-year pharmacist recognition program. A member since June 2001, Mr. Tilley's many contributions to the Board were valuable, and he will be missed.

Reappointments

Andrea Zinder, a public member since May 1999, was reappointed to the Board by Speaker of the Assembly Fabian Nuñez. Ms. Zinder's term will expire June 1, 2008.

Pharmacist Member Stanley W. Goldenberg, R.Ph., was reappointed to the Board for a second term by Governor Arnold Schwarzenegger. Mr. Goldenberg's term will expire June 1, 2008.

New Officers

At the April 2005 Board meeting, Mr. Goldenberg was elected to a second term as Board president. Public Member William Powers was elected vice president. At the July 2005 Board meeting, Pharmacist Member Kenneth Schell was elected treasurer.

Changes to Prescription Medication Container Labels

On January 1, 2006, a new element must be added to labels on prescription containers dispensed from outpatient pharmacies. 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. 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.*"

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.

This requirement appears in the Business and Professions Code section 4076(a)(11)(A).

Preprinted Prescriber Prescription Requirements and Exceptions

Preprinted Prescriber Prescription Requirements

On January 1, 2005, California implemented new security requirements for controlled substance prescription forms. The new security prescription forms must contain all required security features and be printed by a Board-approved security printer. The forms also must contain the prescriber's preprinted information, specifically:

- Name,
- License category (e.g., MD, DDS) and license number,
- Federal controlled substance registration number, and
- Address and phone number are required, and the Board recommends that this information also be preprinted. However, locum tenens physicians or physicians that substitute at various facilities may stamp or handwrite this information on the form at the time the prescription is written.

In a medical group or clinic having one or more physician, multiple prescribers or multiple addresses with check boxes are allowed on the controlled substance prescription forms. (*See Health and Safety Code [H&SC] section 11162.1[a][9] and 11164.*) However, a new physician (whose name is not yet included on the prescription form) to the group office is not allowed to write or stamp his/her name on the preprinted prescription form. New prescription forms that include the new preprinted name must be ordered, or the new physician would have to order his/her own preprinted prescription forms.

Preprinted Forms for Licensed Health Care Facilities

There are different requirements for the security prescription forms used by licensed health care facilities. A "licensed health care facility" is a facility licensed pursuant to H&SC, commencing with section 1250 (e.g., an inpatient acute care hospital, acute psychiatric hospital, skilled nursing facility, or intermediate care facility). Licensed health care facilities using the institution style forms must have a "**designated prescriber**" who orders forms, receives delivery, distributes the forms to authorized prescribers within the facility, and records the authorized prescriber's name, federal controlled substance registration number, license number, and quantity of forms issued to each prescriber.

The institution prescription forms must be ordered from an approved printer and contain all of the required security features. Preprinted information must include:

- Facility's name and address,
- Department of Health Services license number, and
- Designated prescriber's name and address, licensure category and number, and federal controlled substance registration number.

A blank area is provided for the actual prescriber within the facility to write or stamp the:

- Prescriber's name,
- Licensure category and license number, and
- Federal controlled substance registration number.

The facility must maintain the records for three years. Institution style forms may be filled at any pharmacy.

It is important to note that a prescription written on an institutional style form is not valid without the actual prescriber information filled in on the form. (*See H&SC 11162.1[c].*)

Exceptions: Computer-Generated Prescriptions Using Institution Style Controlled Substance Prescription Forms

There are other specific provisions unique to prescriptions written in licensed health care facilities. Licensed health care facilities that computer-generate the prescription portion on the institution style forms to print on a shared laser or dot matrix printer are provided the following exceptions: (*See newly added H&SC 11162.1[c][4][B].*)

- Computer-generated institution style forms do not require the quantity check-off boxes that are required on all other security prescription forms;
- The facility's designated prescriber is not required to maintain a record of the prescribers to whom the institution style computer-generated prescription forms are distributed within the facility; and
- The computer software can generate the actual prescriber's name, licensure category, federal controlled substance registration number, and state license number on the form, as well as the date the prescription is written, to print on the laser or dot matrix institution form.

Note: These exceptions for institution forms do not apply to laser or dot matrix style controlled substance prescription forms used by a single prescriber, group practice or any outpatient setting.

Free Hotline for Reporting Illegal Prescription Sales and Suspicious Internet Pharmacies

1-877-RxAbuse

In December 2004, the United States Drug Enforcement Administration (DEA) launched a toll-free international hotline (1-877-RxAbuse) for reporting the illegal sale and abuse of pharmaceutical drugs. People in the United States and Mexico—with one simple call—now have an anonymous, safe and free way to report suspected illegal pharmaceutical distribution anytime of the day, 365 days per year.

Abuse of certain prescription drugs controlled substances such as painkillers and performance enhancing steroids—has become an increasingly widespread problem in the United States, leading to dangerous addiction and sometimes fatalities. The 2003 National Survey on Drug Abuse and Health reports 6.3 million persons currently use prescription medications non-medically. Another alarming statistic, provided by the Drug Abuse Warning Network, is that since 1995 the number of drug abuse-related emergency room visits involving pain relievers such as Vicodin®, Percocet®, OxyContin® and Darvon® increased 153% (from 42,857 to 108,320). Preliminary data from the Attitude Tracking Study of the Partnership for a Drug-Free America suggests that **many adolescents do not even consider pharmaceutical drug abuse risky, and one out of every 10 high school seniors now reports abusing powerful painkillers**.

While all illegal pharmaceutical sales should be reported, the DEA is particularly interested in hearing from families whose loved ones have suffered or died of an overdose of pharmaceuticals obtained over the Internet. Illegal prescription sales and rogue pharmacies operating on the Internet can be reported online at *www.dea.gov* by clicking on a link and completing the electronic form.

The information collected through the hotline and online reporting will assist the DEA in bringing drug dealers to justice and preventing the tragedies that come from prescription drug abuse.

The above information was obtained from the DEA Web site.

Environment for Compounding Sterile Injectable Products

In the January 2005 issue of *The Script*, a new statute (Business and Professions Code section 4127.7) concerning the compounding of sterile injectables was included under "Changes in Pharmacy Law for 2005" on page 8. However, several words were omitted from the synopsis of the statute, which may cause confusion.

For clarification, please see the statute's exact language below:

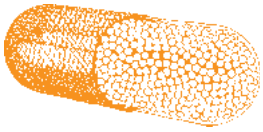
"On and after July 1, 2005, a pharmacy shall compound sterile injectable products from one or more nonsterile ingredients in one of the following environments:

(a) An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom with a positive air pressure differential relative to adjacent areas;

(b) An ISO class 5 cleanroom;

(c) A barrier isolator that provides an ISO class 5 environment for compounding."

Update on Mid-Level Practitioner Registration for Pharmacists



Effective January 1, 2005, a licensed health care facility pharmacist who is authorized to write or issue prescriptions for a Schedule II-V controlled substance, pursuant to a protocol with a physician, must now apply for personal registration as a new Mid-Level Practitioner (MLP) with the Drug Enforcement Administration (DEA). If the protocol does not include controlled substance therapy, the pharmacist is not required to obtain DEA registration.

You may apply online (www.deadiversion.usdoj.gov) for DEA registration as a new MLP (DEA Form 224). The DEA strongly advises that to expedite your application and prevent delay, you must include on the application the business name with which you are associated and any suite, room number, floor, etc. (for example, "Kaiser Permanente, Inpatient Pharmacy, 123 Elm St. R, 456". Also, be sure to check off "MLP"—not "Pharmacy"—on the application.

Please direct any registration questions to the DEA at:

Los Angeles area: ..... (213) 621-6960
San Diego area: ..... (858) 616-4542
San Francisco area: ..... (888) 304-3251

Answers to Questions about Pharmacists Prescribing Controlled Substances

Q. Do pharmacists who are prescribing need a different type of prescription form?

A. No. Pharmacists will use the same prescription form as other prescribers and MLPs. The prescriptions must comply with Business and Professions Code section 4040 (prescription content requirements) and Health and Safety Code section 11162.1 (controlled substances prescription forms requirements).

Q. I am a pharmacist with a DEA-issued license and will be prescribing under protocol with more than one physician. Do all of the physicians' names have to be preprinted on my prescription forms?

A. No. There is no requirement for the supervising physician's name to be preprinted or written on the prescription form.

Q. How can the dispensing pharmacist recognize that the prescriber on a prescription is a MLP?

A. Mid-Level Practitioner DEA registration numbers begin with the letter **M**, followed by the first letter of the registrant's last name and seven numbers (e.g., John Smith, MS1234567).

Revisiting the Necessity for Pharmacist to Check Automated/ Robotic Dispensing

The January 2005 issue of *The Script* included an article about whether a pharmacist is required to check every medication dispensed by an automated dispensing system (a robotic apparatus into which medications are deposited and that uses bar code technology to automate the storage, dispensing, returning and restocking of medications). Readers were informed that there is neither a law requiring a pharmacist to check each dose dispensed by the system to assure the right medication is dispensed to the right patient, nor a law absolving the pharmacist from checking. However, the following questions on this subject have been asked:

Q. If an inpatient pharmacy elects to do random quality checking of robot-dispensed doses, are they in compliance with current Board of Pharmacy regulations?

A. As stated, there is no statute or regulation requiring a pharmacist to check doses dispensed by an automated drug delivery system.

Q. Will Board of Pharmacy inspectors require pharmacists to check 100 percent of the medications dispensed by an automated dispensing system?

A. The law does not require the pharmacist to check any of the medications dispensed by an automated dispensing system; however, **the pharmacist is responsible for any errors that occur—the same way the pharmacist is responsible for any erroneous prescription dispensed from any type delivery system, personal or automated.** The law is violated only when a prescription is dispensed erroneously.

The bottom line here is that it is the responsibility of the dispensing pharmacist and pharmacy to ensure 100 percent accuracy of the dispensing. Licensees electing to save costs or time by reducing their level of error checking do so at their own risk.

If the Board chooses to enforce a particular process for checking or not checking automated dispensing, new statutes or regulations would be required.

Requests for Pharmacy Records by Medical Board Investigators

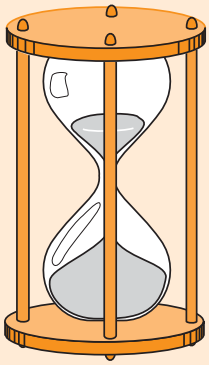
The Board has become aware that occasionally pharmacists have declined to release prescription records when requested by a Medical Board of California investigator engaged in an official investigation. The pharmacists cite their belief that such records cannot be released without an investigative subpoena, for to do so would result in a citation for violation of pharmacy law—which is not true.

Medical Board investigators are authorized officers of the law (Business and Professions Code [B&PC] section 160), as are Board of Pharmacy inspectors (B&PC 4008), and when engaged in an official investigation are authorized to request and receive prescription records from a pharmacy without a subpoena.

If the pharmacist releases the documents, the investigator must provide the pharmacist with a receipt identifying the records specifically and to whom they were released (Health and Safety Code section 11195). The receipt would provide any subsequent inspection with information of the records' whereabouts. However, failure to comply with an investigator's request is a misdemeanor (B&PC 4033).

Questions relating to the release of pharmacy records should be referred to your pharmacy's legal counsel.

Time Limits Change on Partially Filled Schedule II Prescriptions



Occasionally, pharmacists have questions regarding the different time limits imposed for the complete dispensing of a partially filled Schedule II prescription. Time limits for partially filling Schedule II prescriptions are:

1. For inpatients of a skilled nursing facility or terminally ill patients

Schedule II prescriptions may be partially filled *if the prescription is for an inpatient of a skilled nursing facility or for a "terminally ill" patient*. Effective October 7, 2005, section 1745 of the California Code of Regulations will require that a Schedule II prescription must be presented and at least partially filled within **60 days** (previously 14 days) following the date of issue, and no portion of the prescription can be dispensed more than **60 days** (previously 30 days) from the prescription issuance date. No matter how many times the prescription is partially filled, the total amount dispensed must not exceed the amount written on the prescription.

2. Inadequate pharmacy stock

If the pharmacist is unable to supply the full quantity called for in a written or emergency oral Schedule II prescription and partially fills the prescription, there is no change in the time limit allowed for dispensing the remaining amount. The remaining portion of the prescription may be filled within 72 hours of the first partial filling. However, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist must notify the prescriber, and no further quantity may be supplied beyond the 72 hours without a new prescription. Again, the total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. (*See Code of Federal Regulations section 1306.13*.)

Board Honors

Continued from Page 1

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.

The following list includes the names of all pharmacists still on active status who received their license on or before July 15, 1955.

Ackerman, Morris H	No Hollywood, CA
Adler, Harold I	Laguna Woods, CA
Aikenhead, John J	Paso Robles, CA
Alexander, Donald M	Rolling Hills Estates, CA
Alexander, Joseph S	Los Angeles, CA
Alford, Jack M	Lomita, CA
Allphin, Dorothy M	Phoenix, AZ
Altmiller, William A	Bakersfield, CA
Anderson, Walter C	Sacramento, CA
Applebaum, Jack	Burbank, CA
Arnesen, Trygve T	Gonzales, CA
Asche, Robert F	Fresno, CA
Avera, Jr, B W	Long Beach, CA
Ayres, George W	Arcata, CA
Bailey, John T	Camarillo, CA
Balazs, Karl Richard	Temecula, CA
Ball, Dudley J	Los Angeles, CA
Barberian, Richard G	Burlingame, CA
Bardovi, Milton	Northridge, CA
Barekman, James C	Sonoma, CA
Barrack, Sr, Alfred Thomas	La Mesa, CA
Barsamian, Antranik	Patterson, CA
Barton, Jr, James W	Bakersfield, CA
Beckerman, Joseph H	Camarillo, CA
Beebe, John W	Aptos, CA
Belasco, Melvin	Encino, CA
Bennett, George T	Carson City, NV
Berger, Edward B	Bell Canyon, CA
Berris, Benjamin	Rancho Palos Verdes, CA
Bertolozzi, Rudolph C	S San Francisco, CA
Beyeler, Seth F	Bakersfield, CA
Bigler, Donald L	Apple Valley, CA
Bilz, Jack B	El Cajon, CA
Bitondo, Dorothy D	Lakeside, CA
Black, Kenneth E	Mendocino, CA
Block, Robert J	Sherman Oaks, CA
Bloomer, Helen E	Paradise, CA
Bogard, Col, Dorr E	Placerville, CA
Bohrer, Ivan L	Las Vegas, NV
Bottemiller, Freddie L	Bayside, CA
Botts, Madison R	Camarillo, CA
Bowen, Luther R	Orange, CA
Boyajian, Harry M	La Jolla, CA
Braun, Jr, CArl H	Grover Beach, CA
Brazill, Joseph W	Forestville, CA
Brehany, Jr, James J	Costa Mesa, CA
Bridgeforth, Neodros V	Los Angeles, CA
Broidy, Earl Jay	Tarzana, CA
Bronfeld, Martin O	Rancho Mirage, CA
Brooner, Charles A	Shell Beach, CA
Broude, Leonard	Sherman Oaks, CA
Brown, Harry R	Avalon, CA
Brown, Robert A	Cambria, CA
Bunter, Martha L	Santa Cruz, CA
Callagy, Michael A	Sonoma, CA
Cannon, Jr, Roy B	San Diego, CA
Caramelli, Samuel V	Los Osos, CA
Carmichael, Robert E	San Diego, CA
Caro, Jr, Ralph	Los Gatos, CA
Carusa, Stephen A	Campbell, CA
Cerullo, Joseph Pat	Rocklin, CA
Chacon, Andrew	Bakersfield, CA
Chen, Anna May	Berkeley, CA
Chersky, Joseph	Beverly Hills, CA
Chew, Leland R	Oakland, CA
Choisser, Donald Cuthbert	San Antonio, TX
Clark, James G	Palm Springs, CA
Clevinger, Nathan T	Chandler, AZ
Clifford, Benton W	Oxnard, CA
Coar, Richard O	Kingston, WA
Cohen, Sol	Los Angeles, CA
Cole, Jack Robert	Tucson, AZ
Cole, Ronald C	Bakersfield, CA
Collins, Robert J	Alhambra, CA
Coppi, Milton W	Gustine, CA
Corn, Charles	Los Angeles, CA
Cornwell, James K	La Canada, CA
Corrales, Manuel	Ventura, CA
Cortese, Frank V	Albany, CA
Cramer, Robert Hewitt	La Jolla, CA
Cunningham, Eugene F	Fallbrook, CA
Curtis, Jr, Herman C	National City, CA
Davis, Arthur	Oakland, CA
Davis, Darrell B	Kent, WA
Davis, George E	Apache, OK
Debenedetti, Donald J	Vallejo, CA
Demetro, Alexander F	San Jose, CA
Desmond, John F	Reno, NV
Dessel, Jr, Frank W	Seal Beach, CA

Deveraux, Wayne Leon	Red Bluff, CA
Di Domenico, Raymond	Colfax, CA
Dion, Robert E	Arcadia, CA
Odlese, Jr, Joseph W	Santa Barbara, CA
Donovan, Daniel P	Novato, CA
Doria, John J	Escondido, CA
Dowdy, Jr, Haydon F	Long Beach, CA
Downes, Yale J	Moraga, CA
Drake, Jr, Jesse N	Los Angeles, CA
Dreike, Ralph A	Mountain View, CA
Duarte, Roy Anthony	Fremont, CA
Dunn, Derald W	Turlock, CA
Edwards, Leland Bert	Hemet, CA
Egan, Joan Marie	San Jose, CA
Epstein, Seymore L	Pasadena, CA
Fadich, Burton John	San Pedro, CA
Faucher, Louis Henry	Imperial Beach, CA
Faulkner, John Gilmer	Corona, CA
Fernandez, Albert A	Sunnyvale, CA
Findley, John M	San Diego, CA
Fink, Charles W	Auburn, CA
Fischer, Walter C	Santa Ana, CA
Flanigan, Elmer C	Bakersfield, CA
Fong, Arthur C	San Francisco, CA
Fong, Lois L	Walnut, CA
Fong, Tong Ruby	Berkeley, CA
Fox, Logan Lewis	Auberry, CA
Franklin, Richard A	Los Angeles, CA
Franscioni, John Virgil	Soledad, CA
Franusich, Paul N	Elk Grove, CA
Freeman, Burton	Mill Valley, CA
Freilich, Stanley	Woodland Hills, CA
Frey, Jr, Arthur W	La Habra, CA
Fujii, Kiyo	Los Angeles, CA
Fujikawa, Hiroshi	Lodi, CA
Fuller, Wayland C	San Francisco, CA
Fung, David	Fresno, CA
Fung, Herbert Jung	Fresno, CA

See **Board Honors**, Page 18

Board Honors

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Funk, Jerry Harry	Warner Springs, CA
Furukawa, CAlvin A	Carlsbad, CA
Gale, Murray J	Ladera Ranch, CA
Galli, Robert R	Lafayette, CA
Galloway, Jr, Albert J	La Mesa, CA
Gantt, Robert A	Los Angeles, CA
Garfield, Marvin	Calabasas, CA
Garich, Lee Frank	Escondido, CA
Gee, Benjamin M	Los Angeles, CA
Gee, Hing	Alameda, CA
Genis, George C	Fairfax, CA
Gennai, Vivian J F	San Francisco, CA
Gibson, Robert D	Petaluma, CA
Giddings, Jr, Paul	Las Vegas, NV
Gile, Ralph L	Fairfield, CA
Gill, De Voe Charles	San Diego, CA
Gills, Floyd M	Long Beach, CA
Ginsburg, Myron S	Sonoita, AZ
Golish, George T	Castro Valley, CA
Gong, Yin Mina	Sunnyvale, CA
Gordon, Seymour S	Las Vegas, NV
Gostanian, Ben	Fresno, CA
Green, Albert	Los Angeles, CA
Green, Arthur W	Bakersfield, CA
Green, Walter T	Middletown, CA
Greenberg, Roland M	North Hills, CA
Greenberg, Stanley B	Los Angeles, CA
Greenstein, Marvin	Beverly Hills, CA
Greer, Mary C	Thousand Oaks, CA
Greer, Milton L	Moreno Valley, CA
Gregory, Norris	Los Altos, CA
Grow, Robert E	Tustin, CA
Guerra, Reynoldo	Corcoran, CA
Gutierrez, Eliseo	Covina, CA
Haley, Don J	Los Alamitos, CA
Hall, Richard A	Crystal Lake, IL
Hanke, Karl A	Woodland, CA
Harder, George L	Sacramento, CA
Harris, Kenneth H	Kentfield, CA
Hartley, Daniel B	Palm Desert, CA
Hausman, Russill C	Sacramento, CA
Henderson, Stuart B	Arcadia, CA
Henesian, Jack G	Sunnyvale, CA
Hepps, Richard N	Los Angeles, CA
Heryford, James E	Marysville, CA
Hicks, Jr, Frank E	Weaverville, CA
Hirsch, James M	Sherman Oaks, CA
Hirsch, Warren W	San Francisco, CA
Hoffman, Joe M	Oxnard, CA
Homler, Joseph R	Los Angeles, CA
Hoppe, James M	Ontario, CA
Hori, Meito	Fullerton, CA
Horwitz, Daniel	Fountain Valley, CA
Howey, Mary N	Los Angeles, CA
Hunter, Richard E	Arcadia, CA
Ichiuji, Harry	Los Gatos, CA
Ignoffo, Salvador A	Millbrae, CA
Ikemiya, Toshiko	Reedley, CA
Iknoian, Richard	Fresno, CA
Imsland, Albert H	Sacramento, CA
Ishibashi, Yasuko	Culver City, CA
Israel, Benjamin Samuel	Los Angeles, CA
Ito, Ikuko	Los Angeles, CA
Ivans, Nicholas J	Avenal, CA
Iwata, Toshiko	Albany, CA
Jacob, Daniel J	Tucson, AZ
Jeha, Robert G	Walnut Creek, CA
Jelden, Lowell W	Glendora, CA
Jensen, Lenard A	Yuba City, CA
Johnson, Donald H	Walnut Creek, CA
Johnson, Harry B	Watsonville, CA
Josephs, Arthur B	Los Angeles, CA
Jue, Wellman	Hanford, CA
Kaempf, Edward J	Portland, OR
Kamada, James K	Manhattan Beach, CA
Kanai, Masao	San Pedro, CA
Kandarian, Albert A	Fowler, CA
Keneley, Jr, Frank T	Laguna Beach, CA
Kenny, Jr, John R	Annapolis, MD
Ketscher, Fred E	Reedley, CA
Kiefer, Richard	Temecula, CA
Kikawa, Yoshiteru G	Monterey Park, CA
King, Clara Eng	Monterey Park, CA
King, James L	Fresno, CA
Kirkpatrick, David V	Tucson, AZ
Klonoff, Fae	Los Altos, CA
Kobayashi, Akira	Camarillo, CA
Koch, Elmer G	Fresno, CA
Korobkin, Sydney B	Los Angeles, CA
Korr, Irving	Oakland, CA
Kotler, Willard B	Las Vegas, NV
Kovacs, Sanford H	Woodland Hills, CA
Krainert, Jr, John	Benicia, CA
Krause, Jean R	Palm Springs, CA
Krichman, Myron David	Mission Viejo, CA
Kuluris, Bill E	Orange, CA
Kunde, James F	Redwood City, CA
Kurihara, Rokuro	Glendale, CA
Kurilich, Jr, John	San Leandro, CA
Kyffin, Theodore E	Thousand Oaks, CA

Lachman, Richard G	Corona, CA
Lamers, M Joan	San Francisco, CA
Lange, Alfred G	Vallejo, CA
Lange, Greta	Vallejo, CA
Larson, Melford A	Manteca, CA
Larson, Phillip S	Upland, CA
Lassoff, Harold R	Santa Monica, CA
Laurell, Norman L	Van Nuys, CA
Lazare, Raymond Irwin	Manhattan Beach, CA
Leiter, Lionel	Palm Desert, CA
Leon, Manuel L	Port Hueneme, CA
Levant, Frank A	Los Angeles, CA
Levin, Harold	Lincoln, CA
Levine, Martin	Granada Hills, CA
Levine, Norman P	Santa Monica, CA
Levy, Ernest	Ojai, CA
Lewis, Walter G	Covina, CA
Limon, Kathryn B	Morro Bay, CA
Lipson, Henry P	Sherman Oaks, CA
Liss, Joseph M	Anaheim, CA
Lobdell, Marvin G	Visalia, CA
Loken, Richard S	Prescott, AZ
Louie, William F	San Mateo, CA
Louie, William L	Firebaugh, CA
Lowenthal, Theodore S	Cedarhurst, NV
Lucid, Daniel D	Dinuba, CA
Luebkeman, Donald R	Castro Valley, CA
Lynche, Sylvester J	Culver City, CA
Maddux, Marjorie E	Chico, CA
Magid, Morris J	Los Angeles, CA
Maher, Daniel J	Hollister, CA
Mancuso, Joseph S	Los Angeles, CA
Margolies, Marvin H	Encino, CA
Martin, Donald B	Fresno, CA
Matsumoto, Kazuko	Long Beach, CA
Mayeda, John T	Monterey Park, CA
Mayer, Frederick S	San Rafael, CA
Mc Craney, Bruce L	Palm Desert, CA

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Mc Dermed, Elaine M	Carmel, CA
Mc Dermott, Jr, Wm Earl	Pittsburg, CA
Mc Elmoyl, John W	Greenfield, CA
Mc Lain, Monte P	Murrieta, CA
Means, Jack C	Portland, OR
Melton, Curtis	Corona, CA
Miller, Alan S	Moraga, CA
Miller, Kenneth D	Covina, CA
Mizutani, Mitsuo J	Anaheim, CA
Mohorovich, Stephan	Stockton, CA
Molles, Victor J	Merced, CA
Moon, Winnie N	San Francisco, CA
Moore, James G	Kentfield, CA
Morales, Herman F	Tucson, AZ
Morford, ORmond R	Folsom, CA
Morgan, Lila M	Marina Del Rey, CA
Morita, Asayo S	San Jose, CA
Morris, John A	San Jose, CA
Morris, Richard L	San Clemente, CA
Morrison, John A	Novato, CA
Morrison, Jr, George T	Oakdale, CA
Motta, Louis J	Escondido, CA
Murphy, Howard J	Larkspur, CA
Murray, Jr, George E	San Jose, CA
Nagase, Gene T	San Francisco, CA
Nahin, Edward S	Bishop, CA
Nakamura, Frank F	Marysville, CA
Nash, Stuart D	Alpine, UT
Navarro, Manuel	Scottsdale, AZ
Neggo, Ilse Anna	N Hollywood, CA
Newkirk, Russell L	So Lake Tahoe, CA
Newman, Harvey F	Santa Monica, CA
Nigro, Nelly A	Los Angeles, CA
Nishikawa, George J	Sacramento, CA
Nishimura, Roy Shiro	San Leandro, CA
Novatt, Bernard	Ventura, CA
Obata, Betty M	Parlier, CA
Okamoto, Shizuo Harold	San Francisco, CA
Olson, Edwin J	Brainerd, MN
Ostarello, John F	Carmel, CA
Palm, Jack E	Santa Rosa, CA
Pantages, George J	Las Vegas, NV
Paper, Simon	San Mateo, CA
Parry, Everett C	Arcadia, CA
Patrick, Raymond H	Camarillo, CA
Pattee, Jewett S	Long Beach, CA
Perlman, Samuel	Del Mar, CA
Peters, John E	Arvin, CA
Peterson, William D	Sunny Valley, OR
Peterson, William W	San Rafael, CA
Phipps, Frederick W	Cypress, TX
Plagmann, Lawrence L	Burlingame, CA
Plaskoff, Stanley	Beverly Hills, CA
Poer, Gordon L	Placerville, CA
Pong, George Yee	San Mateo, CA
Posin, Edwin M	Incline Village, NV
Potashnick, Julian I	Oakland, CA
Poulos, Theodore	Manteca, CA
Principe, Louis G	Lakeside, CA
Puritz, Jacob J	Culver City, CA
Purlia, Sam L	Alpine, CA
Quesenberry, Marion P	Santa Cruz, CA
Quinn, Myles John	Walnut Creek, CA
Quon, Frances Do	Santa Clara, CA
Ramirez, Eddie M	Los Angeles, CA
Ratto, Peter G	Alameda, CA
Ratzlaff, William B	Santa Rosa, CA
Renge, Nobuo	Fresno, CA
Renzi, Lawrence G	Bakersfield, CA
Richardson, James J	Calimesa, CA
Richey, Wilbur A	Mesa, AZ
Riley, Jr, C A	Paradise, CA
Rivers, John D	Pleasanton, CA
Rollins, Rex R	Yountville, CA
Rose, William Allan	Modesto, CA
Rosen, Arthur A	Los Angeles, CA
Rosen, Milton	Los Osos, CA
Sallus, B Irwin	Palos Verdes Estates, CA
Sanders, George W	Pasadena, CA
Sandler, Donald H	Palm Desert, CA
Saner, John V	Long Beach, CA
Santos, Harold J	Modesto, CA
Schafer, Henry N	Anaheim, CA
Schechter, Aaron	Long Beach, CA
Schell, Jr, W O	Glendora, CA
Schierholt, Harold F	Hemet, CA
Schloss, Daryl J	Santa Rosa, CA
Schneier, Edward L	Tarzana, CA
Schniepp, Glen P	San Diego, CA
Scholnick, Herbert	San Diego, CA
Schulz, Mary C	San Rafael, CA
Schutkin, James J	Milwaukee, WI
Schuur, Martin	Long Beach, CA
Sclar, Leon	Los Angeles, CA
Seid, Ruth	Los Angeles, CA
Serbin, Arnold L	Phoenix, AZ
Sheridan, Sidney O	Covina, CA
Shilton, Thomas E	Ventura, CA
Shimasaki, Fred F	Hayward, CA
Shinoda, Frank J	Stockton, CA

Simmons, Sidney M	N Hollywood, CA
Singerman, Sam	Los Angeles, CA
Siskin, William A	San Carlos, CA
Sitkoff, Irwin L	Los Angeles, CA
Smith, Jr, Arthur	Lompoc, CA
Smith, Jr, Glenn E	Riverdale, CA
Sogliuzzo, Frank	San Pedro, CA
Sokolik, Martin L	Van Nuys, CA
Somers, Robert W	Encino, CA
Speck, Billy Bob	El Sobrante, CA
Sprugasci, Irving A	San Jose, CA
Stamper, Adrian L	Alta Loma, CA
Stapleton, Kenneth E	Lodi, CA
Statti, Alfonse	Morgan Hill, CA
Stein, Maxwell M	Santa Rosa, CA
Stern, Leon Paul	La Mirada, CA
Strange, Roger W	Ceres, CA
Sturzenegger, Jake D	Fallbrook, CA
Sweet, Irving	Northridge, CA
Switzer, Jack B	Covina, CA
Tainter, George W	Pacific Grove, CA
Tanaka, Takuji	Port Hueneme, CA
Tarlton, Richard E	Los Alamitos, CA
Tharaldsen, Shirley S	Paso Robles, CA
Thompson, James B	Beaumont, CA
Tobenkin, Myron L	Walnut Creek, CA
Tobias, Leo A	Bakersfield, CA
Tom, William K	San Francisco, CA
Tomomatsu, Kiyoko	Van Nuys, CA
Topham, Albert F	Oakhurst, CA
Trager, D David	Simi Valley, CA
Tribulato, Angelo P	San Jose, CA
Tucker, Jr, W T	Three Rivers, CA
Urrutia, Daniel C C	Glendale, CA
Vernon, Gregge C	Fremont, CA
Vidulich, John N	San Pedro, CA
Wakley, Clive	Redding, CA
Walike, Edward A	Woodland Hills, CA

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Know Your Employees

Did you know that last year the Board issued 99 citations and 86 fines for unlicensed activity? Unlicensed activity means working without a current active license and includes licenses in delinquent status for failure to renew timely. A pharmacist's license can be delinquent also for failure to fulfill the continuing education requirements for renewal.

The Board encourages all employers to take the following steps to assure that all pharmacy licensees (pharmacists, interns and pharmacy technicians) are working with current active licenses:

- Before hiring new employees, verify that the name listed on their identification is the same as the name listed on their pocket or wall license.
- Check the board's Web site to confirm that the license is current and active.
- Remember that pocket licenses can be inaccurate or altered, so examine them carefully.
- Conduct an annual verification of each licensee's registration status.

NABP Evaluation

Continued from Page 3

information about the answer or related material can be obtained.

Upon completion of the PSAM, pharmacists will receive a Record of Completion, which may be used to satisfy CE requirements for license renewal in 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*, contact NABP at (847) 391-4406, or via e-mail at *custserv@nabp.net*.

Board Honors

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Wallet, George L	Fresno, CA
Walton, Harold	Pebble Beach, CA
Waring, Annette F	Williams, CA
Waring, Jr, Albert	Williams, CA
Wasserman, Paul Meyer	Beverly Hills, CA
Watanabe, Mitsuo H	Coalinga, CA
Weiner, Sydney	Los Angeles, CA
Weinstein, Eugene	Miami, FL
Weintraub, Harry	W Los Angeles, CA
Weiss, Alvin C	Sherman Oaks, CA
Weiss, Don E	La Quinta, CA
Weiss, Henry A	Los Angeles, CA
Weller, Kenneth V	Houston, TX
Wiedmann, Merton L	Shafter, CA
Wiedmann, Patricia S	Shafter, CA
Williams, James M	Newport Beach, CA
Williams, Julian M	Avery, CA
Williamson, Harold E	Iowa City, IA
Wilson, David C	Solvang, CA
Wisner, Robert S	Jackson, CA
Wiswell, Donald R	Bandon, OR
Witz, Gordon A	Oceanside, CA
Wolfred, Morris	Beverly Hills, CA
Wong, Yukiye D	San Jose, CA
Woodward, Kenneth D	La Quinta, CA
Worthy, Jr, Parker A	Arcadia, CA
Wright, James R	Woodland, CA
Wright, Kermit M	Clovis, CA
Yarchover, Bernard	Tarzana, CA
Yaskiel, Jack I	Camarillo, CA
Yee, Richard D M	Daly City, CA
York, James B	Bakersfield, CA
Young, John S	San Leandro, CA
Young, Saul	Los Angeles, CA
Zanger, Mary T	Hollister, CA

Surety Bonds

Continued from Page 9

- Any applicant for initial licensure or license renewal as a wholesaler or nonresident wholesaler must submit a surety bond of $100,000 made payable to the Pharmacy Board Contingency Fund. In lieu of the bond, applicants may submit other equivalent means of security acceptable to the Board (e.g., an irrevocable letter of credit or a trust account or financial institution deposit, payable to the Pharmacy Board Contingency Fund).
- The Board may accept a surety bond of $25,000 if the annual gross receipts for the previous tax year are $10 million or less;
- A licensee who has posted a $25,000 bond but has been disciplined by any state or federal agency or issued an administrative fine under California Pharmacy Law may be required to submit a $100,000 surety bond;
- A single surety bond or other means of security is required and covers all licensed sites under common ownership;
- **Exception**: Licensed manufacturers who are licensed as wholesalers or nonresident wholesalers in California are exempt from these requirements.

The Board is developing the necessary forms that will be required to verify that the wholesaler or nonresident wholesaler has complied with the surety bond, irrevocable letter of credit or trust fund account deposit requirement. These forms will be available in early Fall 2005 and will be mailed to all licensees and pending applicants.

The exact language for the B&PC sections cited above can be found at the Board's Web site, *www.pharmacy.ca.gov*, under "Pharmacy Law and Regulation."

A Word of Appreciation

The Board of Pharmacy wishes to thank RPh Wai-Kuan (Nicole) Chan Of Kaiser Permanente in Livermore and Malia Cong and Richard Meza of Prescription Solutions in Costa Mesa for their help with a Board public education brochure to be published in several languages. We are truly grateful for their assistance.

President's Message

Continued from Page 2

- **PDPs (Medicare Prescription Drug Plans):** Beginning in 2006, everyone with Medicare will be able to enroll in plans that cover prescription drug costs. The standard benefit includes:
  - A premium of about $25 per month, in addition to the current premium for the Part B benefit;
  - A $250 annual deductible;
  - Coverage of 75% of drug costs between $250 and $2,250;
  - No coverage for drug costs between $2,250 and $5,100 (known as the "doughnut hole";
  - After reaching the $5,100 threshold ($3,600 in out-of-pocket spending), beneficiaries reach a "catastrophic" level of coverage and will only be required to pay the greater of a copayment ($2 for generic drugs or $5 for brand name drugs) or coinsurance of 5 percent.
- **MTMS (Medication Therapy Management Services):** This is a distinct group of services that optimize therapeutic outcomes for individual patients. Such services are independent of, but can occur in conjunction with, the provision of a medication product. Medication Therapy Management en-compasses a broad range of professional activities and responsibilities within pharmacists', or other qualified health care providers', scope of practice.
  A program that provides coverage for MTMS includes:
  - Patient-specific and individualized services provided directly by a pharmacist to the patient;
  - Face-to-face interaction with the patient and the pharmacist as the preferred method of delivery;
  - Opportunities for pharmacists and other qualified health care providers to identify patients who should receive medication therapy management services;
  - Payment for MTMS consistent with contemporary provider payment rates that are based on the time, clinical intensity, and resources required; and
  - Processes to improve continuity of care, outcomes, and outcome measures.

The Licensing Committee has taken the challenge of insuring that MTM can occur within and outside of California. This may require redefining pharmacy so that the Board will have enforcement options to respond to all adverse events. Again, this one of the issues that crosses state lines and is being addressed by the NABP also.

I encourage you to attend these meetings.

2. **Pharmacists' obligation vs. right to dispense:**

Does a pharmacist, when presented with a valid prescription for a drug that is to be used in a treatment that is in conflict with personal beliefs, have the right to refuse to dispense the drug (e.g., emergency contraception, assisted suicide)? This has become a state and federal legislative question. Two bills were introduced in California on this issue and would require pharmacists who will not dispense specific medications to advise the pharmacy managers in advance, and the pharmacy must have a referral policy to aid the patients in getting the prescription filled: Senate Bill 644 (Ortiz) and Assembly Bill 21 (Levine).

3. **Counterfeit drugs and drug pedigree:**

The increased counterfeiting of medicines and sophisticated methods used to introduce counterfeit medicines into the legitimate drug distribution system of the U.S. are being addressed in California and nationally. To combat these problems, wholesalers or pharmacies will be prohibited from selling, trading, transferring or receiving a dangerous drug at wholesale without an electronic pedigree recording each change of ownership of a dangerous drug—from manufacture to final dispensing to a patient. Implementation of these requirements in California can begin as early as 2007.

4. **Drug importation/reimportation:**

Drug prices in foreign countries are often below U.S. prices because of their government's subsidies or price controls. The reimportation of these lower priced drugs back into the U.S. might be seen as a way to provide lower cost drugs to consumers. The safety of imported drugs continues to be an issue nationally, as some states or cities enact programs to import or make it easier for patients to buy medication from outside the U.S.

5. **Internet drugs:**

A growing problem is that individuals can buy drugs without a valid prescription from Internet entities that are not licensed pharmacies. These entities provide dangerous drugs without a physical examination or ongoing health monitoring.

6. **Refill prescriptions from self-serving delivery systems:**

New technology is continuously being developed for use in pharmacies. When deciding whether new pharmacy

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Questions

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dating, and recording of all of the required information. Direct entry of orally transmitted information is probably not "electronic transmission," exempting the pharmacy from keeping hard copies per B&PC 4070 (dangerous drugs) or H&SC 11164.5 (controlled substances). In other words, direct entry does not eliminate any of the hard copy requirements.

Q. When a prescription is sent electronically from the prescriber's or hospital's computer to the pharmacy's computer, what is required by B&PC 4070, H&SC 11164(b)(1) and/or other statutes and regulations?

A. This question has been answered already by the foregoing general discussions. As a general rule, a hard copy of these prescriptions must be printed out, the required signatures affixed, the required information collected, and the hard copies retained. A hard copy of electronically transmitted dangerous drug/device prescriptions need not be produced/retained when all the conditions of B&PC 4070 are met, and a hard copy of an electronically transmitted controlled substance prescription need not be produced/retained when permission is given and all of the conditions of H&SC11164.5 are met.

Emergency Room Dispensing

Q. Do the laws for emergency room dispensing permit a prescriber to dispense a starter pack to an emergency room patient if the hospital or a nearby pharmacy is open?

A. B&PC 4068 states that a prescriber may dispense a dangerous drug, including a controlled substance, to an emergency room patient **only** if the hospital outpatient pharmacy is closed and there is no pharmacist available in the hospital; the dangerous drug is acquired by the hospital pharmacy; and the dispensing information is recorded and provided to the pharmacy for retention when the pharmacy reopens. The prescriber must determine that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued and reasonably believes that a pharmacy outside the hospital is not available or accessible at the time of dispensing to the patient. The quantity of drugs dispensed are limited to that amount necessary to maintain uninterrupted therapy during the period when pharmacy services outside the hospital are not readily available or accessible, but shall not exceed a **72-hour supply**. The prescriber must ensure that the drug label contains all required information and he or she will be responsible for any error or omission related to the dispensed drugs.

Pharmacy law does not define or reference a "starter pack," but the hospital pharmacy may prepackage the 72-hour supply of medication to be placed in a Pyxis or other medication "safe" for dispensing to an emergency room patient **only** when there is no pharmacist available to provide outpatient services.

President's Message

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technology can be accommodated by current law, the Board considers how the new technology can better serve California consumers while maintaining patient safety.

Self-serving delivery systems are similar to ATM vending machines from which patients who have requested this service can obtain refill prescriptions by inserting a credit card. This system gives patients access to refill prescriptions when the pharmacy is opened or closed. Consultation can still be provided on all prescriptions dispensed from a delivery machine, but the consumer must seek it: however, those drugs that require counseling on refills (e.g., Coumadin, Flagyl, etc.) can still be kept outside the machine, based on the professional judgment of the pharmacist.

The Board of Pharmacy respects and expects the pharmacist's professional judgment.

This summer, a contingent of Board members, the Board's executive and assistant executive officers, and supervising inspectors received a "hands on" presentation by the manufacturer of self-service delivery system. The focus of the meeting was patient safety, HIPPA confidentiality issues, and the actual operational policy and procedures for the systems.

The Board is now moving toward establishing regulations related to the use of such systems. Regulation is necessary because the only enforcement option the Board has presently is to remove the waiver, while a regulation carries all available enforcement options to answer any adverse events.

The opportunities for you to interact with the Board of Pharmacy and influence your future can occur at our committee meetings and the public Board meetings.

Go to our Web site, *www.pharmacy.ca.gov*, for meeting dates. To be included in the agenda, write to the Board at least 30 days prior to the meeting, or **show up** and **speak up**. An organized presentation should include your topic and how it would protect the public or advance the profession to better serve the public.

With the total involvement of professionals, consumers, students and stakeholders, the Board can create a dynamic environment for pharmacy in the 21st Century—all working together for the people of California.

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Board of Pharmacy Wins Fifth National Award in Eight Years!

For the third time in eight years, the California Board of Pharmacy received the prestigious National Association of Boards of Pharmacy Fred T. Mahaffey Award. Such awards are bestowed especially for a program or an agency that goes well beyond usual government operation. The 2005 award recognizes the Board's successful sponsorship of legislation requiring an electronic pedigree for prescription drugs, tracking ownership of all dangerous drugs, from the manufacturer to wholesaler(s) to the pharmacy that finally dispenses the drug.

In 1997, the Board won the Fred T. Mahaffey Award for its outstanding leadership in developing, producing and disseminating public education material promoting consumers' understanding of the pharmacist to patient consultation about medication. In 2003, the award was again presented to the Board for implementing quality assurance requirements in pharmacies to prevent prescription errors. Both of these awards were presented to the Board before it became a full member of NABP in 2004.

Additional national awards earned by the Board include the 1999 Paul G. Rogers/NCPIE Medication Communicators Award by the National Council for Patient Information and Education in Washington, D.C., in recognition of the Board's quality assurance program to prevent prescription errors and the Council on Licensure, Enforcement and Regulation (CLEAR) annual award in 2002 for the Board's "ingenuity in creating partnerships with the media, profession, and industry for the successful implementation of a highly visible consumer education program with minimal costs to the Board."

The Board is very proud of its ongoing accomplishments!

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