



BE AWARE & TAKE CARE:
Talk to your pharmacist!

The Script

CALIFORNIA BOARD OF PHARMACY OCTOBER 2003

California State Board of Pharmacy wins two national awards: The CLEAR and the “Fred T. Mahaffey” Awards

California leads the nation with first quality assurance program

In September 2002, the Council on Licensure, Enforcement and Regulation (CLEAR) presented its annual award to the California State Board of Pharmacy in recognition of its new quality assurance program to prevent prescription errors. This award is bestowed specifically for a program or agency that goes well beyond usual government operation.

Additionally, the National Association of Boards of Pharmacy (NABP) presented the California State Board of Pharmacy with the prestigious “Fred T. Mahaffey Award” for 2003. This

award is given to a state pharmacy board for demonstrating a significant accomplishment in protecting the public.

The California Pharmacy Board received these awards for implementing requirements that pharmacies establish a quality assurance program to prevent prescription errors from recurring. The Board sponsored legislation requiring pharmacies to implement quality assurance programs and to provide legal protections that permit the documentation and study of medication errors without the fear that these efforts will be used against the pharmacies and pharmacists

in court. Since the implementation of the program, other states have begun similar programs.

The Board was also acknowledged by the NABP for its aggressive enforcement against pharmacies that fill Internet prescriptions for patients without a “good faith prior medical examination.”

In bestowing these awards, both the CLEAR and the NABP have acknowledged and commended the California State Board of Pharmacy for its leadership in addressing the most difficult public protection issues confronting any state pharmacy board today.

Important legislative changes pending

As we go to press with this issue of *The Script*, there are currently pending a number of legislative bills that would dramatically change Pharmacy Law if enacted. For the most part, these proposed changes are not discussed in this newsletter. Instead, the Board will publish these changes in the next issue of *The Script* (currently planned for January 2004). Among the pending law changes, that could take effect as soon as January 2004, are:

- **Senate Bill 361** contains provisions for the use of the NAPLEX exam and a new California multiple choice exam that will be available via computer administration throughout the year, replacing the Board’s California Pharmacist Licensure Examination which is currently administered twice annually.

The bill also contains changes to the qualifications of a pharmacy technician—elimination of the 1,500 hours of experience as a clerk typist as a qualifying method for registration, and acceptance of certification by the Pharmacy Technician Certification Board as one way to qualify for registration.

- **Senate Bill 151** proposes to phase-in over the next 15 months major changes to the prescribing of Schedule II-IV controlled substances, including elimination of the triplicate prescription form and the requirement for any written controlled substances prescription to be on special security paper.

In the interim before publication of the next *The Script*, watch our Web site for updates!

In This Issue

| | |
|---|------------|
| Board of Pharmacy wins two awards | Front Page |
| Important legislative changes pending | Front Page |
| President’s Message | 2 |
| Changing Your Address of Record | 3 |
| Sterile Compounding Pharmacy Q and A | 4 |
| HIPAA: Protecting the privacy | 5 |
| Dispensing Internet prescriptions | 6 |
| Open Letter to Pharmacists and Pharmacy Owners .. | 7 |
| Rx for Good Practice | 8 |
| Notice to Consumers must be displayed | 9 |
| Who can sign pharmacy intern affidavits | 11 |
| DOJ to provide CURES profiles upon request | 13 |
| Opioid Addiction Treatment | 14 |
| Pharmacy Self-Assessment Forms | 15 |
| Changes in the Board | 16 |
| Pharmacy Scholarships | 17 |
| Continuing Education credit | 17 |
| Regulation Update | 18 |
| Pharmacists Recovery Program | 19 |
| Board Members | Back Page |
| Six hours of CE | Back Page |



President's Message

By John D. Jones, R.Ph.
President, Board of Pharmacy

I am delighted to update you regarding Board activities since the last issue of *The Script*. Besides dealing with such thorny issues as the budget shortfall and changes in pharmacy practice and drug delivery, the Board has represented our state at the national level, initiated a robust outreach program, and worked with state government to improve the licensing of pharmacists. The Board is blessed to have a strong staff and executive officer to support its efforts toward progress.

The National Association of Boards of Pharmacy Fred T. Mahaffey Award

The California Board of Pharmacy was honored at the NABP annual meeting in Philadelphia in May by being the recipient of the 2003 Fred T. Mahaffey Award. This is the premier award given by the NABP, which recognizes the activities, programs and accomplishment of a pharmacy board over the past year. This award is given to only one board each year. It is especially unusual for the California board to win the award because California is an associate member of the NABP, not a full member.

Board Outreach Program

The state government's budget challenges have forced the Board to eliminate the inquiry service provided by

on-call pharmacy inspectors. Although many pharmacists found it useful to call the Board and speak directly to an inspector, the Board was compelled to redirect its inspector resources to core protection activities such as the timely investigation and resolution of consumer complaints and inspections.

The Board, understanding that its licensees want an opportunity to ask questions of their regulator, has established an outreach program for that purpose. The program is an effort to educate licensees about the Board, to review new pharmacy laws and regulations, and to discuss the perspective of the pharmacy board inspectors as they perform their enforcement duties. It not only provides an opportunity for pharmacists and other licensees to ask questions in a comfortable environment, **but also awards up to two hours of continuing education credit.** So far, the Board has presented programs at the CPhA Outlook program in Anaheim and at venues sponsored by local chapters of the CPhA and CSHP in San Diego, Garden Grove, Long Beach, Santa Rosa and Santa Barbara. The Board will consider requests from California pharmacy organizations of all types if significant attendance can be assured. Interested parties may send a written request describing the hosting organization and requested date and time, or contact Patricia Harris at (916) 445-5014.

Sunset Review Legislation and the NAPLEX

Legislation to implement the recommendations of the Joint Legislative

Committee on Sunset Review [SB 361 (Figueroa)] is moving through the California Legislature. The more significant committee provisions are:

- (1) Continue the licensing and regulation of the pharmacy profession and maintain a board structure—provisions in the bill will extend the Board's sunset date four years;
- (2) Add two public board members;
- (3) Adopt the NAPLEX;
- (4) Eliminate a requirement that all Board inspectors must be pharmacists—the Board currently uses non-pharmacist staff to perform certain investigative duties. The statutory language of section 4008 of the Business & Professions Code requires Board inspectors performing specific duties to be pharmacists. This provision will be deleted by the bill.
- (5) Change registration and program requirements for pharmacy technicians to conform with changes by the Board last year—specifically to:
 - a. Accept the Pharmacy Technician Certification Board certification as one means to qualify for pharmacy technician registration;
 - b. Accept only the associate degree in pharmacy technology and eliminate other associate degrees;

See *President's Message*—Page 10

www.pharmacy.ca.gov

Licensees' address of record go online December 1, 2003

IMPORTANT NOTE: A licensee's address of record is the address to which all licenses, permits, license renewal notifications, newsletters, other publications, and correspondence from the Board is mailed. Such addresses are considered public information and is released to those who request it. Your address of record is the address printed on your license, unless you have subsequently notified the Board of a change in your address after the license was mailed to you.

All Board licensees' addresses of record will become available to the public on the Board's Web site on December 1, 2003. This is the same information provided online by other health profession (physicians, dentists, therapists) regulatory boards, pursuant to the Information Practices Act (Civil Code section 1798 et seq.) and the Public Records Act (Government Code section 6250 et seq.).

Changing Your Address of Record

If your address of record with the Board is your residence address, and you don't wish it to be available to the public on the Board's Web site, you may change it by providing the Board with a post office box number or a personal mailbox (PMB). **However, if you change your address of record to a box number, you must also provide your residence address, which will not be available to the public.**

If you list your business address as your address of record, remember that all mailings from the Board will go to that address. For some individuals, relying on a business address for licensee renewal notifications, licenses, and other mailings from the Board may be problematic, especially for receiving personal mail. For example, if you are employed in a large hospital complex with several pharmacies, opportunities for lost mail could exist. Also, using a business address would require you to change your address of record with the Board every time you change your place of employment.

To change your address of record, please complete and fax the following form to (916) 327-6308 or mail to the Board of Pharmacy, 400 R Street, Suite 4070, Sacramento CA 95814-6237.

CHANGE OF ADDRESS (Please print)

Name: _____ License # _____
(Please include license type: RPH, TCH, INT, etc.)

Social Security Number: _____
(For purposes of identification only)

Old Address: _____

Address of Record

New address: _____

Note: If the new address of record is a PO box, PMB, or a business address, please enter residence address below. Your address of record will not be changed if no current residence address is entered.

Residence Address

Address: _____

Signature: _____ Date: _____

Telephone: _____

Sterile Compounding Pharmacy Questions and Answers

Background

Effective July 1, 2003, a pharmacy may not compound injectable sterile drug products in California unless:

1. The pharmacy is also specially licensed with the Board as a sterile compounding pharmacy, OR
2. The pharmacy has a current accreditation from the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Accreditation Commission on Healthcare (ACHC), or the Community Health Accreditation Program (CHAP).

Nevertheless, all pharmacies that compound injectable sterile drug products (whether separately licensed by the Board as a compounding pharmacy) must follow Board regulations for sterile compounding. These regulations are found in Title 16, California Code of Regulations (CCR) as Article 7, beginning with section 1751. Additionally, the Board is promulgating revised regulations for compounding injectable sterile drugs products. These regulations are expected to take effect in 2005.

If a nonresident pharmacy is shipping injectable drug products into California, this pharmacy must:

1. Be licensed as a nonresident pharmacy (application form 17A-57)
2. Comply with Board regulations for sterile drug compounding, AND
3. Be separately licensed with the Board to compound injectable sterile drug products unless the pharmacy is licensed as a hospital, home health agency or skilled nursing facility AND possesses current accreditation from the JCAHO, ACHC or CHAP.

A separate application form for nonresident pharmacies compounding injectable sterile drug

products is required (except for those identified in #3 above). This application (form 17A-50) and the form described in # 1 above may be downloaded from the Board's Web site, www.pharmacy.ca.gov.

Questions and Answers

Q Who is required to possess a sterile compounding pharmacy license?

A Pharmacies that combine/compound any products from sterile or non-sterile sources for injection. The pharmacy must be separately licensed before performing these duties (unless it possesses current JCAHO, ACHC or CHAP accreditation).

Q To whom will the sterile compounding license be issued?

A The compounding license will be issued to a licensed pharmacy owner. The compounding license is a separate license, and both licenses must be issued to the same location. This is required whether the pharmacy is located in California or elsewhere in the US.

Q Does a hospital pharmacy have to possess a sterile compounding pharmacy license?

A Yes, unless the hospital pharmacy is accredited by JCAHO, ACHC or CHAP. Hospital and community pharmacies that are accredited by these organizations do not have to be specially licensed with the Board as a sterile compounding pharmacy. However; regardless of whether specially licensed or not, any hospital or community pharmacy compounding injectable sterile products must comply with Board regulations.

Q Can a pharmacy that only occasionally compounds injectable sterile medications pursuant to a prescriber's order do so without

being separately licensed as a compounding pharmacy or meeting all the regulation requirements?

A No. Even if only one injectable sterile drug product for one patient is compounded in any year, the pharmacy first must be either licensed by the Board as a compounding pharmacy or accredited by JCAHO, ACHC or CHAP AND comply with regulation requirements beginning with CCR 1751.

Q For how long is the license issued?

A One year. However, the initial license will be issued so that it expires on the same date as the regular pharmacy license at the same location, so the initial license may be issued for less than one year. After the first renewal, both licenses will expire annually.

Q Is an inspection required for renewal of the sterile compounding license?

A Yes, an inspection is required before the issuance or renewal of any sterile compounding license for a pharmacy in California. For California pharmacies that are accredited by JCAHO, ACHC or CHAP, no separate inspection is required (because no separate compounding pharmacy license is mandated). However, the Board will review compounding procedures and compliance during routine inspections.

For pharmacies located outside California, the Board requires an inspection report from the accrediting agency for the nonresident pharmacy or from the pharmacy board in the state where the pharmacy is located to issue or renew the nonresident sterile compounding pharmacy license. This inspection report must document the pharmacy's compliance with Board requirements.

See Sterile Compounding... Page 12

HIPAA: Protecting the privacy of patients' medical records

Longstanding California state law and new federal regulations provide rights to patients to protect the privacy of their medical records. The federal authority on health information privacy arises from the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Standards for Privacy of Individually Identifiable Health Information. Several California laws protect health information privacy, including the Confidentiality of Medical Records Act, the Patient Access to Health Records Act, the Insurance Information and Privacy Protection Act, and the Information Practices Act. All laws referenced here may be found on the Office of Privacy Protection's Web site at www.privacy.ca.gov/laws.htm.

To protect patients' medical information, HIPAA imposes several requirements on healthcare providers:

1. **Notice of Privacy**—HIPAA regulates doctors, hospitals, HMOs, **pharmacies**, and other healthcare organizations that transmit personal health information electronically. HIPAA requires these entities to provide patients with a "Notice of Privacy" that explains how the patient's personal medical information will be used.
2. **Authorization**—In many instances the patient's doctor, **pharmacy**, insurance company, or other healthcare provider must obtain the patient's written permission before they can release the patient's personal health information, often referred to as PHI (protected health information). PHI is any individual health information that is under the control of the healthcare provider. It may be transmitted electronically, kept in any medium, and transmitted or kept in any other form. The patient's written permission is called an "authorization." It must state what information can be released, to

whom, for what purpose, and it must be dated. The patient may at any time retract the written authorization.

However, pharmacies may disclose a patient's PHI *without* the patient's written consent or authorization to the Board of Pharmacy or another health oversight agency for oversight activities authorized by law, including:

- audits;
 - civil, administrative, or criminal investigations;
 - inspections; licensure or disciplinary actions;
 - civil, administrative, or criminal proceedings or actions; or
 - other activities necessary for appropriate oversight of:
 - (a) the health care system;
 - (b) government benefit programs for which health information is relevant to beneficiary eligibility;
 - (c) entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards; or
 - (d) entities subject to civil rights laws for which health information is necessary for determining compliance.
3. **Accounting of Disclosures**—The patient has the right to ask for and in most cases receive from most healthcare providers information regarding who has received the patient's PHI. This is called an "accounting of disclosures" and when required, must be provided to the patient within 60 days of receipt of the request. It must include the:
 - date of disclosure;
 - name of the entity or person who received the information;
 - what information was disclosed; and
 - purpose of the disclosure.

Board inspection or audit of pharmacies' records

Pharmacies must comply with HIPAA requirements. Two circumstances under which pharmacies must provide a Board of Pharmacy inspector access to patients' PHI are:

1. If conducting an **inspection** of the pharmacy, the inspector may have access to PHI maintained by pharmacies *without* the patient's "authorization." During an inspection a Board inspector may view numerous patients' PHI, and it is the pharmacy's responsibility to keep records of all such viewings to provide the patient(s) with an "accounting of disclosure" if requested. For the pharmacist's convenience, the inspector will place any and all viewed PHI in a single location so the pharmacist may document the disclosure(s).
2. If conducting an **investigation**, the inspector may or may not provide the pharmacy with a waiver signed by the specific patient(s) giving permission to review the PHI.

NOTE: It is important that the pharmacy's legal counsel be consulted if the pharmacy personnel are unsure of the pharmacy's responsibilities related to the sharing of PHI.

The Board of Pharmacy is not enforcing activities arising from HIPAA; instead, complaints involving HIPAA privacy violations will be referred to and investigated by:

Office for Civil Rights, Region IX
U.S. Department of Health and
Human Services
40 United Nations Plaza, Room
322
San Francisco, CA 94102
Voice Phone (415) 437-8310
FAX (415) 437-8329
TDD (415) 437-8311

See *HIPAA...* Page 13

Dispensing Internet prescriptions can be very costly!

On January 1, 2001, section 4067 of the Business & Professions Code (B&PC) became effective, permitting the Board to issue citations involving potential fines of up to \$25,000 per violation for dispensing dangerous drugs or devices on the Internet without a valid prescription. One of the primary requisites for a valid prescription is a good faith examination. Section 2242 of the B&PC states that the “prescribing, dispensing, or furnishing of dangerous drugs...without a good faith examination and medical indication therefore, constitutes unprofessional conduct.” A good faith examination includes a legitimate patient/physician relationship consisting of a physical examination (at least one) and documentation on file of the patient’s medical records. The very nature of Internet prescribing negates the opportunity to physically examine a patient

Subsequently, on May 28, 2002, Governor Gray Davis announced that the California State Board of Pharmacy had issued three citations claiming fines totaling \$88.7 million against a Los Angeles pharmacy and two pharmacists for allegedly filling Internet prescriptions in violation of California law. Approximately one year later, citations claiming fines of more than \$1.3 million were issued for similar alleged violations against another pharmacy and its owner.

According to the citations, Total Remedy and Prescription Center II, located at 6064 West Olympic Boulevard in Los Angeles, and pharmacists Barry Irvin and William Charles Packer allegedly filled more than 3,500 prescriptions in violation of California

law—the law making it illegal for Internet pharmacies to fill prescriptions for Californians without a “good faith prior examination” by a California licensed doctor.

The potential fines were:

- Total Remedy and Prescription Center II: \$54,895,000;
- Pharmacist-in-Charge and 50 percent owner, Barry Irvin: \$33,140,000; and
- Pharmacist William Packer: \$697,500.

In July 2002, the Board issued a citation naming James Mark Cohen, owner and pharmacist-in-charge of the Medicine Chest Pharmacy at 925 B Street in Hayward, for allegedly filling multiple illegal Internet prescriptions. The potential fines amounted to:

- The Medicine Chest Pharmacy: \$885,000 and
- Pharmacist-in-Charge and owner, James Mark Cohen: \$420,000.

Internet companies advertising the availability of prescription drugs seek to circumvent these prescribing laws by various methods. One company offered various “lifestyle” drugs, such as Viagra for male impotence, Propecia for hair loss, and Xenical for weight loss, on the received the drug and printed material regarding the drug and its use. There was neither a “good faith prior examination” nor patient consultation.

These violations involved two cases that led to the largest potential fines authorized by section 4067. The fines were appealed and a settlement was reached

with the licensees. Total Remedy and Prescription Center II agreed to pay a fine of \$1 million, and if the fine is not paid within 90 days, the pharmacy permit will be revoked. Pharmacist Irvin agreed to the discipline of his pharmacist license, which was suspended for six months and placed on probation for three years. Additionally, he must pay a fine of \$150,000. Failure to abide by the suspension, probation and payment requirements would be basis for revocation of his license. Mr. Packer also agreed to the discipline of his pharmacist license. He was placed on probation for three years and must pay the Board \$25,000. Failure to abide by the probation and payment requirements would be basis for revocation of his license.

The settlement reached with The Medicine Chest Pharmacy resulted in a fine of \$25,000. Pharmacist Cohen agreed to pay a fine of \$195,000, and he was required to submit to the Board a letter for publication titled “Open Letter to Pharmacists and Pharmacy Owners” regarding his conduct in this matter. [That letter is published on the following page.](#)

The Board’s action in pursuing these violations in an eight-month investigation “...is sending a strong message to pharmacists that they have a duty to protect patients and fill prescriptions the safe and legal way,” said Gov. Davis. With potential fines of up to \$25,000 per prescription violation, the cost of dispensing dangerous drugs or devices for Internet prescriptions can be very costly and for pharmacists and pharmacies.

Open Letter to Pharmacists and Pharmacy Owners

The explosion of technology as an integral part of our society has presented pharmacists and pharmacies with the opportunity to fill patient prescriptions that are generated through the use of the Internet. This can seem like an enticing opportunity for increased business and revenue. It certainly seemed that way to me. I have practiced pharmacy for many years and consider myself to be a capable, conscientious and ethical pharmacist. As with many pharmacists practicing in this challenging time, my idea was to find a steady revenue stream of cash patients for my pharmacy. The Internet seemed like the ideal solution. It was not.

I want to share with you what I learned the hard way. You need to live up to your obligation as a licensed professional to keep yourself informed of the current rules regulating the practice of pharmacy. You also should think long and hard before you involve yourself or your pharmacy in Internet-generated prescriptions. The Internet is not a panacea when it comes to prescriptions and generating pharmacy income.

This is some of what I thought and then learned:

Myth 1: I can have customers from all over the United States and ship prescriptions throughout the country without any restrictions.

Truth 1: Many, if not all, states require that a pharmacy be licensed as an "out-of-state" pharmacy before it may fill and mail prescriptions to residents of that state. The failure to obtain a license or registration in that state can lead to civil penalties and other sanctions. Those sanctions can then lead to action by the California State Board of Pharmacy against your California license.

Myth 2: Prescriptions generated via the Internet are legal prescriptions as long as the physician has a current medical license and a valid DEA registration.

Truth 2: A valid medical license and DEA registration are not the only concerns. Business and Professions Code section 4067 requires a "good faith prior examination" by the physician in order to lawfully dispense or furnish dangerous drugs pursuant to prescription generated via the Internet. Further, the requirement in California Code of Regulations, title 16, section 1761, that a pharmacist not dispense drugs pursuant to an erroneous or uncertain prescription also applies to prescriptions generated via the Internet.

Myth 3: It is okay to fill Internet prescriptions for dangerous drugs or devices, so long as the Internet prescription I fill is for a California resident and was written by a California-licensed physician, because I have a California pharmacy license issued by the California State Board of Pharmacy.

Truth 3: The locations of the physician, pharmacy or pharmacist are not germane to this issue. Effective January 1, 2001, Section 4067, prohibits the dispensing or furnishing of a dangerous drug or device, thru the use of the Internet, to a resident of California unless the prescription for that drug or device was issued pursuant to a "good faith prior examination." The law authorizes the California State Board of Pharmacy to assess a fine of up to \$25,000 for each violation, e.g., each prescription filled.

Myth 4: The filling of an on-line questionnaire by a patient meets the statutory requirement of a "good faith prior examination."

Truth 4: The California State Board of Pharmacy has taken a very firm position that this is not a "good faith prior examination." The board requires that there be a face-to-face encounter between the patient and prescribing physician, at which an appropriate history is obtained, a legitimate medical purpose is established, and contraindications for the drug are

eliminated. This position is consistent with the position taken by the Medical Board of California.

Myth 5: As long as no patient is actually harmed or injured as a result of a prescription I fill, the California State Board of Pharmacy will just tell me to stop and not impose any fine or sanction.

Truth 5: The California State Board of Pharmacy has also taken a very firm position that the furnishing or dispensing of a dangerous drug or device pursuant to a prescription generated via the Internet when you either knew or reasonably should have known that there was no good faith prior examination by the prescriber is a serious violation of California law. Simply because you were lucky that no patient was actually harmed or injured, does not mean that you did not put the public's health and safety at risk. Accordingly, the California State Board of Pharmacy will do more than just tell you to stop. It will most probably impose a substantial fine.

Myth 6: If I was unaware that Section 4067 became effective on January 1, 2001, I cannot be held accountable for prescriptions I filed after that date and no fine can be imposed by the California State Board of Pharmacy.

Truth 6: Ignorance in this instance is *not* bliss, nor is it an excuse. It is the pharmacist's responsibility and obligation as a licensed professional to stay current with all new laws and regulations affecting the practice of pharmacy. Although the Board did advise me through its publication, The Script, of the existence of Section 4067, I did not become familiar with requirements of this law prior to filling prescriptions generated via the Internet. That was a big mistake. From my own experience, I can tell you that the California State Board of Pharmacy and state legislature are serious about curbing the practice of unlawfully



Rx for Good Practice

In day-to-day pharmacy practice, unusual situations sometime occur, generating questions. So to help our licensees with questions that may or may not be answered in the pharmacy law book, "Rx for Good Practice" is featured in each issue of The Script. If you have questions you would like to see answered in this column, please fax your question to The Script at (916) 327-6308. (Note: The Board's Web site contains the text of California Pharmacy Laws with an index.)

Q The first question published in this column of the March 2003 issue of *The Script* related to section 4052.5 of the Business & Professions Code (B&PC) that authorizes pharmacists to use their professional judgment and allows them to "...select a different form of medication with the same active chemical ingredients of equivalent strength..." without calling the prescriber. Does this mean that a pharmacist is allowed change a prescription for a cream (e.g., triamcinolone) to an ointment — without calling the doctor—if the cream is not in stock?

A With some exceptions, the pharmacist may make such a change "...when the change will improve the ability of the patient to comply with the prescribed drug therapy." Your professional judgment would tell you whether the substitution would improve the patient's ability to comply with the prescribed therapy rather than waiting until the product was in stock to begin treatment. The patient should, of course, be advised of the substitution.

Q Can nurse practitioners, certified nurse midwives or physician assistants have their own DEA triplicate forms and prescribe Schedule II drugs?

A Currently, existing law permits only physician assistants (not certified nurse midwives or nurse practitioners) to prescribe Schedule II drugs, and they have their own triplicate forms (B&PC 3502.1). However, there is pending legislation to provide nurse

practitioners with the authority to prescribe Schedule II drugs.

Section 4040 of the B&PC permits nurse practitioners, certified nurse midwives and physician assistants to issue drug orders for Schedule III-V controlled substances. These orders are to be treated as prescriptions and must conform to all requirements of a prescription. Additionally, to furnish or issue drug orders for controlled substances, nurse practitioners, certified midwives and physician assistants must obtain a DEA registration number.

Q Can a physician write a prescription for a patient and his/her partner? Example: "George Smith and your partner"

A Section 120582 of the Health & Safety Code (H&SC) permits a physician "...who diagnoses a sexually transmitted chlamydia infection in an individual patient may prescribe, dispense, furnish, or otherwise provide prescription antibiotic drugs to that patient's sexual partner or partners without examination of that patient's partner or partners." Additionally, a nurse practitioner, certified nurse-midwife and a physician assistant may also provide prescription antibiotic drugs to the sexual partner of a patient with a diagnosed sexually transmitted chlamydia infection without examination of the patient's sexual partner(s). Please see "New Law for

Treating Chlamydia" in the April 2001 issue of *The Script* for more information on this subject..

Q How many refills are permitted for Schedule III or IV prescriptions?

A A Schedule III or IV prescription may be refilled no more than five times in a six-month period. Furthermore, the amount of all the prescription's refills taken together may not exceed a 120-day supply. (H&SC 11200)

Q Is there a limit to the quantity of controlled substances that can be dispensed at one time (i.e., 540 Vicodin or 25 Duragesic patches)?

A Neither state nor federal law places any limits on the quantity of controlled substances that a prescriber may prescribe for a patient. However, the prescription must be for a legitimate medical purpose, with the responsibility for the proper prescribing and dispensing resting with the prescriber. Additionally, a "corresponding responsibility" rests with the pharmacist who fills the prescription. If in the pharmacist's professional judgment there is any uncertainty or he or she has any questions concerning the prescription, the prescriber must be contacted to validate the prescription. If after contacting the prescriber the pharmacist determines the prescription is not for a legitimate

Notice to Consumers must be displayed

One year ago the new "Notice to Consumers" was mailed to all pharmacies (see copy of the new notice below). The new 17" X 22" notice must be posted in the pharmacy where it is conspicuous to and can be read easily by consumers. If the poster distributed by the Board is not displayed, the pharmacy may print the exact wording of the notice on the back of customer receipts (Business & Professions Code section 4122). Pharmacies cannot produce their own posters.

Some pharmacies have not yet replaced the old Notice to Consumers (a yellow poster with green print) with the new poster. If your pharmacy did not receive the new poster, please contact the Board. If your pharmacy has special language needs, the Board's Web site, www.pharmacy.ca.gov, now has 8.5" X 11" versions of the notice available for downloading in five additional languages: Chinese, Vietnamese, Spanish, Korean, and Russian.

Notice to Consumers

Before taking any prescription medicine, talk to your pharmacist; be sure you know:

1

What is the name of the medicine and what does it do?

2

**How and when do I take it – and for how long?
What if I miss a dose?**

3

What are the possible side effects and what should I do if they occur?

4

Will the new medicine work safely with other medicines and herbal supplements I am taking?

5

What foods, drinks or activities should I avoid while taking this medicine?

Ask your pharmacist if you have additional questions.

At your request, this pharmacy will provide its current retail price of any prescription without obligation. You may request price information in person or by telephone. Ask your pharmacist if a lower cost generic drug is available to fill your prescription. Prescription prices for the same drug vary from pharmacy to pharmacy. One reason for differences in price is differences in services provided.

BE AWARE & TAKE CARE



Talk to your Pharmacist

California State Board of Pharmacy
(916) 445-5014 • www.pharmacy.ca.gov
400 R Street, Suite 4070, Sacramento, CA 95814



OSP 02 7011

President's Message

Continued from Page 2

- c. Accept graduation from a school of pharmacy; and
- d. Eliminate the equivalent experience provision for the clerk typist.

Other recommendations of the Joint Legislative Committee on Sunset Review not included in SB 361 are to:

- (6) Make all committee meetings of all boards public—a proposed legislative change to require this of all boards is being developed by the Department of Consumer Affairs. However, most Board committee meetings are already public.
- (7) Modify the citation and fine program to exclude the involvement of board members and delegate authority to the executive officer to issue citations and fines;

A note about adoption of the NAPLEX exam in California: The Board supported this change following a psychometric audit of NAPLEX by independent national experts in 2001. The pending legislation would allow pharmacists who pass the NAPLEX and

the California jurisprudence exam on or after January 2004 to become licensed in California. Pharmacists who have taken the NAPLEX before 2004 will have to retake the exam to gain licensure here.

The Board has sent three prominent California pharmacists to serve on the NABP test construction committee. Their presence ensures that the future NAPLEX exams will reflect the rigorous competency testing that is generally associated with the California Board licensing exam. Previously, the NAPLEX was used nationally to test pharmacists at the entry level of the B.S. pharmacy

degree. Now that all U.S. pharmacy colleges are graduating Pharm.D. candidates and the educational programs must all meet the American Council for Pharmaceutical Education accreditation standards, the clinical rigor of the NAPLEX will evolve to reflect that change.

The proposed change to the pharmacy licensing exam criteria, should help to contain the cost of licensing pharmacists in California, and put pharmacists on par with physicians, nurses and other health professionals, all of whom use national exams.



Open Letter...

Continued from Page 7

dispensing dangerous drugs or device through the use of the Internet. The Board ordered me to stop, but it also imposed heavy fines on me and my pharmacy.

In conclusion, believe me when I tell you that I know of what I speak. I filled Internet-generated prescriptions for California and out-of-state residents for a period of time. Both my pharmacy and pharmacist license were assessed fines by the State Board that exceeded

\$1,000,000. This does not include my own legal fees. Additionally, I was fined by another state for dispensing dangerous drugs via Internet generated prescriptions to residents of that state without being licensed there. Therefore, I advise you to look past the potential short-term financial gain and avoid the long-term mistake that I made.

The laws and regulations that govern our profession and our professional activity help and protect the patients,

residents, and customers of California. We need to take the initiative in making sure that we understand and comply with them.

We are all in this together. I write this "open letter" so you can benefit from what I have learned.

Sincerely,
James M. Cohen
Registered Pharmacist

Rx for Good Practice

Continued from Page 8

medical purpose, it should not be dispensed (H&SC 11153 and California Code of Regulations (CCR) 1761).

Q Can a maintenance medication prescription be refilled in its entirety without a doctor's authorization if (a) the doctor is unavailable after hours, or (b) the doctor has not had a chance to respond?

A Yes, if in the pharmacist's professional judgment failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being (B&PC 4064) However, the pharmacist must:

- have made every reasonable effort to contact the prescriber for authorization,
- inform the patient the prescription is being refilled pursuant to the above section,
- make an appropriate record of the refill, including the basis for proceeding with the refill, and
- inform the prescriber within a reasonable period of time of any refills dispensed pursuant to the above section.

Q My pharmacy manager tells me that since a triplicate does not have to be in the handwriting of the prescriber—only his/her signature is required—omission of the patient's address can be filled in by the pharmacist. Is that correct?

A Yes. If the patient's address is not specified on the triplicate, the pharmacist may write or type the address on the prescription provided the prescriber is notified. (H&SC 11164(a)).

Q My pharmacy manager tells me that it is legal to accept a transferred prescription in the form of a faxed label and use as a hard copy without having it being reduced to writing by the pharmacist receiving the transfer. Is that correct?

A Not necessarily. A pharmacist at the receiving pharmacy may accept a transfer prescription via a faxed prescription label from a pharmacist at the sending pharmacy and consider it the "hard copy," eliminating the need to reduce the prescription to writing. However, the label must comply with the requirements for a prescription as provided in B&PC 4040 and the prescription information and transfer process must comply with the requirements of CCR 1717(f).

Q Are there any laws regulating how soon a prescription can be refilled? I was told to follow the insurance policy of 75 percent used, regardless of whether the prescription is a controlled substance or not.

A Insurance companies may institute procedures for authorizing payments for dispensing, but such procedures do not override law. General provisions for refills are located in B&PC 4063 and 4064, H&SC 11200 and 11201, and CCR 1716.

www.pharmacy.ca.gov

Who can sign pharmacy 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, the 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.

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

Sterile Compounding Pharmacy Q and A

Continued from Page 4

Q What will inspectors look for during inspections?

A California Board of Pharmacy inspectors will determine compliance with CCR 1751. This includes the maintenance of records, existence of current written policies and procedures that reflect operational practice, quality assurance/quality control, competencies and training of staff, equipment maintenance and calibration, sterilization process and associated records, biological sampling and qualitative/quantitative analysis of end products.

Q Do out-of-state pharmacies have to obtain a pharmacy license to ship dangerous drugs into California?

A Yes. A nonresident pharmacy may ship prescription drugs or devices into California only if licensed with the Board as a nonresident pharmacy (California Business & Professions Code (B&PC) 4120).

Q Do out-of-state pharmacies have to obtain the additional sterile compounding license to ship compounded injectable sterile drug products into California?

A Yes, unless the nonresident pharmacy is licensed as a hospital, home health agency or a skilled nursing facility AND is accredited by JCAHO, ACHC or CHAP. If so, it is exempt from specialty licensure as a nonresident sterile compounding pharmacy. (However, the nonresident pharmacy must still obtain the nonresident pharmacy permit described above.)

Again, regardless of whether the nonresident pharmacy is specially licensed with the Board as a sterile compounding pharmacy or is JCAHO, ACHC or CHAP accredited and thus exempt from specialty licensure, all medications compounded for California must be prepared in accordance with Board sterile compounding regulations (CCR 1751).

Q How will the Board determine compliance of nonresident pharmacies with Board compounding requirements?

A The Board will use inspection reports from the board of pharmacy in the state where the pharmacy is located or from the accrediting agency when it last inspected the pharmacy.

Q During an inspection, what will happen if an inspector identifies noncompliance or substandard practices?

A For instances of noncompliance that do not jeopardize the health and safety of patients, the inspector will request correction and proof of correction before a permit is issued or renewed. Violations that pose an immediate threat to the health and safety of patients can result in the Board's order to cease and desist compounding until the matter is resolved through administrative means or after correction of the problem. Specific procedures are established in California B&PC 4127.3.

Q Are there additional requirements for pharmacies that compound injectable sterile drug products from a non-sterile source?

A Pending Board regulations that may take effect in January 2005 would require specialized equipment and procedures for pharmacies that perform this type of compounding. The proposed text of the regulations can be obtained from the board's Web site, www.pharmacy.ca.gov/pdfs/1751_exact.pdf.

Q Will the Board accept policies and procedures from a source that sells written sterile compounding procedures?

A Whatever source a pharmacy uses as the core of its policies and procedures, whether written by the pharmacy or obtained from another source, the procedures must be specific for the processes used by the pharmacy that compounds injectable sterile drug products. Many of the commercially available policies and procedures are written in a guideline format and need modifications to reflect the specific processes that comply with CCR 1751.



HIPAA...

Continued from Page 5

Questions and Answers regarding HIPAA

Q Who are the “authorized officers of the law” who can access patient records in a pharmacy?

A The term “authorized officers of the law” is expressly defined in the Business & Professions Code section 4017. These individuals are: (1) inspectors of the California State Board of Pharmacy, (2) inspectors of the Food and Drug Branch of the State Department of Health Services, (3) investigators of the Department of Consumer Affairs Division of Investigation, and (4) peace officers engaged in official investigations. The term “peace officers” is defined in Penal Code section 830, which essentially provides that any qualified person who comes within the provisions of Penal Code sections 830 through 832.9 (Penal Code, Title 3, Chapter 4.5) is a peace officer. For example, an investigator of the Medical Board of California is a peace officer. (Note: You can access this law by going to www.leginfo.ca.gov and selecting California law, and then selecting the Penal Code.)

Further, if an authorized officer of the law requests and takes possession of prescription records (not simply reviewing these in the pharmacy), the pharmacy should receive a receipt identifying the records. If a Board inspector should subsequently ask for the same records, the pharmacy would then be able to produce the receipt documenting the release of the records to an authorized officer of the law.

Decisions of whether to provide prescription records to an authorized officer of the law should be determined by the pharmacy’s own legal counsel.

Q Because of HIPAA, some pharmacists have been advised not to give anyone, including Board inspectors, access to a patient’s medical record without the patient’s written authorization. Is that correct?

A No. Pharmacies and pharmacists are permitted to release protected health information to the Board of Pharmacy and to certain other health oversight agencies. HIPAA also permits pharmacists to make certain disclosures to state board inspectors on their own initiative if the information disclosed constitutes evidence of criminal conduct related to (a) receipt of or payment for health care or (b) qualification for receipt of benefits, payments, or services based on a fraudulent statement or material misrepresentation of the patient’s health. Similarly, the law permits and expects pharmacists to disclose to Board officials protected health information that the pharmacist believes constitutes evidence of criminal conduct that either occurred at the pharmacy or was witnessed by an employee of the pharmacy.

Q Under HIPAA, what information can Board inspectors access?

A Inspectors may request and receive all of the information currently provided to inspectors as part of routine inspections or investigations. HIPAA’s privacy rule does not expand or change the present scope of a Board inspection or investigation.

Q If a patient wants to know who has reviewed his/her health information on file at the pharmacy, are records that are viewed by Board inspectors to be included in the accounting of disclosures?

A Yes. The “skimming” of patient files by state inspectors or investigators must be included in an accounting if requested by a patient.



DOJ to provide CURES profiles upon request

Physicians and pharmacists can now request CURES profiles for their patients from the Department of Justice as a result of legislation that became effective this year. (Health & Safety Code 11165 and 11165.1)

Under the terms of the legislation, the Department of Justice may provide these practitioners with CURES profiles for their patients upon request by the practitioner. This legislation also permits the Department of Justice to send CURES profiles to the physicians and pharmacists providing care to patients whose CURES profiles indicate the possibility of prescription drug abuse.

The Board of Pharmacy Web site, www.pharmacy.ca.gov, has the request form for pharmacists’ use when requesting CURES profiles. Download the form, follow the instructions and submit the request to the fax number listed on the form. The CURES profile will be mailed to the address of the pharmacy listed on the request form.

Physician Office-Based Opioid Addiction Treatment

In October 2000, the Drug Addiction Treatment Act of 2000 (commonly known as DATA 2000) was signed into federal law. This legislation provides significant changes in medical treatment of opioid addiction in this country. This new federal Act supersedes current California Health & Safety Code regulations.

For the first time since the enactment of the Harrison Narcotic Act of 1914, some physicians will now be allowed to treat opioid addiction as a part of their office-based practice. Physicians may treat only with opioid medications that are Schedule III-V controlled substances. These drugs must also be specifically FDA approved for treatment of opioid dependence. Schedule II drugs used to treat opioid addiction, like Methadone and LAMM, may only be prescribed and dispensed from a specialized opioid treatment program (i.e., methadone maintenance program). Methadone and LAMM may not be prescribed by a physician in an office-based setting to treat drug dependence or addiction.

Physicians, who want to treat opioid dependence in their office setting must first apply for a waiver from the Substance Abuse and Mental Health Services Administration (SAMHSA), an agency within the federal Department of Health and Human Services. To qualify for this waiver, physicians must meet at least one of six qualifiers that include various types of board certifications in addiction medicine, addiction psychiatry or completion of a training program related to treatment and management of opioid-dependent patients. The waiver allows a physician to treat only 30 patients at one time. If a physician is part of a group practice, the entire group

practice may treat only 30 patients at a time. It is also very clearly stated that the physician may not delegate this prescribing to a nurse or a physician assistant.

Once the waiver is granted by SAMHSA, that agency notifies the DEA that the physician qualifies to prescribe these medications. The DEA will then issue a DEA unique identification number (UIN) in addition to the physician's regular DEA number. The UIN authorizes the physician to prescribe FDA approved Schedule III-V drugs for opioid addiction. The identifier must be used in conjunction with the DEA registration. The identifier is identical to the DEA registration except the "A" or "B" at the beginning of the number will be replaced by an "X", the remainder of the letters and numbers will be the same as the physician's DEA registration.

This identifier is used to protect the privacy of the patient. An identifier provided on a hand written prescription or on an orally or electronically transmitted prescription is the signal to the pharmacist that this medication is being used to treat opioid dependence and the pharmacist should monitor and counsel the patient accordingly.

There are currently over 200 physicians in California who have received their waiver and UIN. To verify whether a physician has a valid waiver you may e-mail info@buprenorphine.samhsa.gov or call 1-866-BUP-CSAT. If a physician is not listed as having a waiver, contact the physician, as there is a provision for some emergency prescribing by the physician before he/she actually receives the waiver, provided the physician has

appropriately notified SAMHSA when applying for the waiver.

In October 2002, the FDA approved the first two Schedule III-V drugs for use in treatment of opioid dependence:

1. Subutex (buprenorphine hydrochloride) is a Schedule III controlled substance, a sublingual tablet available in 2mg and 8mg strengths. It is intended to be used in the beginning of addiction treatment (induction phase).

Some physicians may choose to stock Subutex in their office and dispense it themselves to the patient during the induction phase of treatment, as that phase requires close monitoring of each dose by the physician. Secondly, the physician may send a relative to obtain the prescription for their family member and return to the physician's office with the medication for administration during the induction phase of treatment. A third option allows the patient to be sent to pick up the prescription themselves. In such an instance, the patient may experience some level of withdrawal while waiting in the pharmacy for the prescription to be dispensed.

2. Suboxone (buprenorphine hydrochloride and naloxone combination) – is a Schedule III controlled substance, a sublingual tablet available in 2mg or buprenorphine/ 0.5mg naloxone and 8mg of buprenorphine/2mg of naloxone. It is intended for the maintenance phase of addiction treatment. Naloxone is added to prevent the buprenorphine tablets from being dissolved and injected.

...Opioid Addiction Treatment

Continued from Page 14

The vast majority of Suboxone prescriptions are expected to be dispensed by pharmacies for the maintenance phase of treatment.

Note: other forms of buprenorphine like Buprenex or compounded formulations are not approved for treatment of opioid addiction.

As with all new prescriptions, including those prescriptions that have not been previously dispensed to the patient with the new dosage, strength, or directions), the pharmacist must consult with the patient or the patient's agent. (California Code of Regulations 1707.2)

Since this is the first time in almost a century that physicians and pharmacists are being allowed to dispense these drugs except as a part of a federally regulated special treatment program, DATA 2000 contains an extensive risk-management plan to prevent the diversion or misuse of these two drugs. The pharmacist's role in risk-management includes:

- If the patient presents with prescriptions from more than one prescriber for the same time period, the pharmacist should refuse to fill the second prescription and notify all of the involved physicians of the duplication of orders.
- A physician or a group practice may treat only 30 patients for opioid addiction at one time. If the pharmacy receives prescriptions for more than 30 patients for a particular time period, the pharmacist should contact the physician to be certain the prescriptions are not forgeries.
- The pharmacist should remind patients who are picking up induction phase doses (Subutex) to return as directed to their doctor's office, so they can be supervised while taking the medication.

In addition to all current state and federal privacy and confidentiality of medical information regulations, the patient records are subject to 45 Code of Federal Regulation, Part 5, sections 160

and 164. To ensure the physician will be able to communicate with the pharmacist and verify the legitimacy of these prescriptions, the physician should have the patient complete a medical release allowing this communication. If the physician faxes or telephones these prescriptions to the pharmacy, it is considered a disclosure of the patient's identifying information and requires the physician to obtain a medical release.

This is an exciting step forward for addiction treatment, the patients and the practitioners. Pharmacists need to be prepared to participate effectively as a member of the health care team in this setting.

Two excellent Web Sites for information include:

www.buprenorphine.samhsa.gov
www.fda.gov

Pharmacy Self-Assessment Forms completion deadline was July 1, 2003

The Board reminds all pharmacists-in-charge (PICs) that section 1715 of the California Code of Regulations requires PICs to complete a self-assessment of their pharmacy before July 1 of each odd-numbered year.

Additionally, completion of a self-assessment is required within 30 days of a new pharmacy permit being issued or whenever there is a change of PIC.

The Board of Pharmacy will **not** be mailing forms to each pharmacy this year. The forms can be downloaded by clicking on "Forms and Publications" at the Board's Web site, www.pharmacy.ca.gov.

And please remember: **DO NOT MAIL THE COMPLETED FORM TO THE BOARD.** It must be retained in the pharmacy for three years after the assessment is completed and readily available for review.

Early next year, the Board will have a new version of the self-assessment form available from its Web site that will contain up-to-date changes in pharmacy law made throughout 2003.

Changes in the Board

Departing Members

The Board wishes to extend its best wishes and express appreciation to three departing members, Steve Litsey, Pharm.D., Donald W. Gubbins, Jr., Pharm.D., and Caleb Zia, Ed.D.

Dr. Litsey was appointed to the Board in 1998 and served as Board president from 2001-2002. During his tenure as president, Dr. Litsey oversaw implementation of a number of key legislative proposals, including:

- the quality assurance program regulations,
- the sterile injectable compounding licensure program and development of implementing regulations, and
- enactment of legislation to broaden the practice of the pharmacist from licensed facilities to anywhere the pharmacist is.

Also, while he was president, he oversaw the Board's actions to:

- pursue recommendations of the Pharmacy Manpower Task Force,
- reinstate the routine pharmacy compliance program, and
- evaluate the NAPLEX examination.

Dr. Litsey also served on the Board's Legislative, Organizational Development, and Competency Committees.

Dr. Gubbins was appointed to the Board in March 2000. During his tenure with the Board, Dr. Gubbins served as vice president from 2002 to 2003. He was involved in the Board's review of the Manpower Task Force report and assisted with the exam development and grading of the Pharmacist Licensing Examination with the Competency Committee. Additionally, Dr. Gubbins served on the Board's Licensing Committee, Enforcement Committee and the Citation and Fine Committee.

The Board's most senior member, Dr. Zia, was appointed to the Board in 1995. During his tenure with the Board, he served eight years as treasurer and assisted the Board in its conversion from one policy body into five policy committees, the structure within which we now operate. This was a fundamental change in the way the Board performed its duties.

Dr. Zia oversaw the broadening of the Board's public education program to a much more vigorous presence, including:

- the production of *Health Notes*,
- the expansion of the Board's Web site as a source of communication with licensees and the public,
- development of the new Notice to Consumers, and
- the translation of Board public education materials into languages other than English and Spanish.

Dr. Zia also served on the Board's Licensing Committee and the Communication and Public Education Committee, and he was a strong advocate for the educational training of pharmacy technicians.

The Board thanks Drs. Litsey, Gubbins, Jr. and Zia, for their dedication and countless contributions.

New Officers

Upon Dr. Zia's departure from the Board, John E. Tilley, R.Ph., was elected treasurer.

New Members

The Board welcomes two new pharmacist members, Ruth M. Conroy, Pharm.D., and Kenneth H. Schell, Pharm.D., and two new public members, James E. Acevedo and Richard L. Benson.

Dr. Conroy, a graduate of the University of the Pacific School of Pharmacy, was a pharmacy manager at Walgreens from 1985 to 1996. Since then she has been a pharmacy supervisor at Walgreens in San Francisco. Dr. Conroy serves as an associate professor of Clinical Pharmacy at the University of California, San Francisco, and has served in the same capacity at the University of the Pacific. She is a board member of the San Francisco Immunization Coalition and Pharmacy Systems Project. Dr. Conroy is a member of the American Pharmacists Association, the California Pharmacists Association and the Pharmacists' Society of San Francisco.

Dr. Schell, a graduate of the University of California, San Francisco, School of Pharmacy, has been the Clinical Operations Manager for Kaiser Permanente, San Diego, since 1999. From 1997 to 1999, he served as the Clinical Manager for Owen Healthcare, Inc. in the Scripps Health System. He was the Critical Care Pharmacist at the Children's Hospital and Health Center in San Diego and served as staff pharmacist at the same facility from 1985 to 1997. Dr. Schell has also served as the assistant clinical professor at both the Western University School of Pharmacy at Pomona and the University of California, San Francisco, School of Pharmacy. He is a member of the American Society of Hospital Pharmacists, the California Society of Hospital Pharmacists (where he was recognized as Pharmacist of the Year in 2002), the Academy of Managed Care Pharmacists and the Pediatric Pharmacy Group. He has also been recognized as a fellow of both the American and the California Society of Health-system Pharmacists. Dr. Schell also earned a bachelor degree from the University of California, San Diego.

Changes...

Continued from Page 16

Mr. Acevedo has served as the commissioner for the Port of Los Angeles since 2001 and is the owner and president of DCP, Inc. He has also served as a co-principal of GrapeVine Land Company. Mr. Acevedo previously worked for the Charles Company and served as CEO for the Community and Mission Hospitals of Huntington Park. He was also the assistant regional administrator for Greater El Monte Hospital, Woodruff Hospital, Monterey Park Hospital, Community Hospital of Huntington Park and Mission Hospital of Huntington Park. In 1990, Mr. Acevedo served as director of development at Panorama Hospital. He has been the President of the Neighborhood, Empowerment and Economic Development, Inc. He served as a commissioner of the Los Angeles City Fire Commission and the Los Angeles City Board of Zoning Appeals. He is also a board member of the World Trade Center of Los Angeles. Mr. Acevedo earned Bachelor and Master of Arts degrees from California State University, Los Angeles.

Mr. Benson, of Belmont, has been the President and CEO of the United Food and Commercial Workers Union since 1994 and has served the Union in various leadership positions since 1987. Mr. Benson serves as an Executive Committee Member of the Alameda County Central Labor Council. He was appointed by Chief Justice Ronald George to "The Task Force on the Quality of Justice" and served on the Subcommittee on Alternative Dispute Resolution and the Judicial System. Mr. Benson earned a Bachelor of Arts degree at Golden State University.

Pharmacy Scholarships

In the March 2003 issue of *The Script*, there was information detailing the establishment of the California Pharmacist Scholarship and Loan Repayment Program to be funded by voluntary \$25 contributions by pharmacists (Business & Professions Code 4409 and Health & Safety Code 128198). These contributions are devoted to a program that provides scholarships to help pay educational expenses of pharmacy students and repay qualifying education loans of pharmacists who agree to practice in medically underserved areas. License renewal notices will provide a space for noting such donations.

Subsequent to that article, inquiries were made as to whether the Board can accept a contribution that is either less or more than the \$25 specified in the code section. Donations of less than \$25 and up to \$35 will be accepted. However, amounts above the \$35 limit (original \$25 authorized by statute, plus \$10 overpayment) will be refunded to the donor. Those wishing to donate pay more than \$35 toward the program are encouraged to make that excess donation directly to the California Pharmacist Scholarship and Loan Repayment Program in the Office of Statewide Health Planning and Development, which is responsible for the loan program.

Continuing Education credit from other health professions providers approved

The Board has changed requirements to broaden the diversity of continuing education courses available to pharmacists without having to petition the Board for credit or pay an additional fee. Section 1732.2 of the California Code of Regulations (see "Regulation Update," Page 18) was recently amended to allow licensees to receive credit for courses approved for CE by the Medical Board of California, the California Board of Podiatric Medicine, the Board of Registered Nursing and the Dental Board of California. Coursework approved by these boards must meet the standards of relevance to the practice of pharmacy and educational quality.

Now pharmacists can earn CE approved by the American Council on Pharmaceutical Education or the Accreditation Evaluation Service, as well as by the other healing arts boards without petitioning the Board of Pharmacy.

Pharmacists may still petition the Board for CE credit from other providers on a form entitled "Pharmacist Petition for Continuing Education Credit from a Non-Recognized Provider." This form can be downloaded at www.pharmacy.ca.gov/pdfs2/c_e_petition_rph.pdf. Along with the completed petition, the licensee must submit a fee of \$40 per class hour of coursework to be reviewed. For example, the fee for approval of a one-hour course offered by a non-recognized provider would be \$40; for a three-hour course, \$120.

Mail all petitions and fees to:

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

Regulation Update

This article contains information relating to amendments to sections of Chapter 17, Title 16 of the California Code of Regulations. For your convenience this information is included here so that it may be saved until published in the *Pharmacy Laws*. The complete text of these sections is also available at the Board's Web site, www.pharmacy.ca.gov.

1717. Pharmaceutical Practice

The amended portion of this section is in subsection (e). The new text is underlined, and the deleted text is struckthrough:

- (e) No licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy. However, a licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services ~~is present~~. The Board may in its sole discretion waive this application of the regulation for good cause shown.

1720.1. Graduates of Foreign Pharmacy Schools

Subsection (b) was added to this section to permit foreign graduates with insufficient documentation for equivalency evaluation by the Board to be evaluated by other sources.

- (b) Each applicant for admission to the pharmacist licensure examination whose collegiate study was in a foreign country shall provide transcripts and other reference material sufficient for the board to evaluate an

applicant's collegiate equivalency pursuant to Business & Professions Code section 4200(a)(3). If the applicant cannot provide documents sufficient to determine collegiate equivalency, the board may accept the findings of a foreign credentials evaluation service. This service shall be required at the discretion of the board and may include



authentication, translation and or evaluation of such documents as deemed necessary by the board. Any costs for the review shall be paid directly to the evaluation service by the applicant.

1732.2 Coursework From Non-Recognized Providers

The amended portion of this section is in subsection (b) and has been changed to permit approval of continuing education courses obtained from other California healing professions boards without first petitioning the Board of Pharmacy.

- (a) Non recognized providers or pharmacists may petition the board to allow continuing education credit for specific coursework

which is not offered by a recognized provider, but meets the standards of relevance to pharmacy practice and educational quality, as set forth in section 1732.1(c).

- (b) Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance to pharmacy practice and has been approved for continuing education by the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California shall, upon satisfactory completion, be considered approved continuing education for pharmacists.

1745. Partial Filling of Schedule II Prescriptions

The amended portion in this section is in subsection (c)(1). The new text is underlined, and the deleted text is struckthrough:

- (c) When partially filling a prescription, all of the following conditions must be met:
- (1) The prescription must be tendered and at least partially filled within ~~seven~~ fourteen days following the date of issue;
 - (2) The pharmacist records the date and amount of each partial filling in a readily retrievable form and on the original triplicate prescription, also recording the initials of the pharmacist dispensing the prescription;
 - (3) No portion of the prescription is dispensed more than 30 days from the date of issuance of the prescription; and
 - (4) The original triplicate prescription is forwarded to the Department of Justice in conformity with Health & Safety Code section 11164(a) at the end of the month in which the prescription has been completely filled or in which the prescription has been canceled by death of the patient or otherwise, whichever comes first.

New management for Pharmacists Recovery Program

Through the state's competitive bidding process, a new contractor has been awarded oversight of the Pharmacists Recovery Program (PRP). The new contractor is Maximus, Inc.. However, the program structure will remain largely unchanged.

The PRP seeks ways to identify and rehabilitate pharmacists and interns whose competency may be impaired due to the abuse of alcohol or other drugs, or due to mental illness. The program allows these individuals to be treated and returned to the practice of pharmacy in a manner that will not endanger the public health and safety. Confidentiality is an important part of the program.

For information about the program, call 1-800-522-9198.



This newsletter is published by the

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

400 R Street, Suite 4070
Sacramento CA 95814
(916) 445-5014
Fax: (916) 327-6308
www.pharmacy.ca.gov

BOARD MEMBERS

John D. Jones, R.Ph., *President*
John E. Tilley, R.Ph., *Treasurer*

James E. Acevedo, *Public Member*
Richard L. Benson, *Public Member*
Ruth M. Conroy, *Pharm.D.*
David J. Fong, *Pharm.D.*
Stanley W. Goldenberg, *R.Ph.*
Clarence Hiura, *Pharm.D.*
William Powers, *Public Member*
Kenneth H. Schell, *Pharm.D.*
Andrea Zinder, *Public Member*

Executive Officer
Patricia Harris

Newsletter Publishing Services
Hope Tamraz, *Editor*

PRSRT STD
U.S. Postage
PAID
Permit No. 424
Sacramento, CA

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

Continuing education (CE) hours are being awarded to encourage licensees 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.

The remaining meeting date for 2003 is **October 29–30, 2003.**

Doubletree Hotel
200 Marina Boulevard
Berkeley, California
(510) 548-7920

Additional information regarding site and agendas will be posted on the Board's Web site (www.pharmacy.ca.gov) approximately 10 days prior to meetings, or you may contact the Board at (916) 445-5014, Ext. 4006.