



BE AWARE & TAKE CARE:
Talk to your pharmacist!

The Script

CALIFORNIA BOARD OF PHARMACY JULY 2001

Expiration Dates— Compliance Guidelines

Expiration Date—*The expiration date identifies the time during which the prescription drug may be expected to meet the requirements of the Pharmacopeial monograph, provided it is kept under the prescribed storage conditions.*

Prescription medication shall not be dispensed after the expiration date on the manufacturer's container. The expiration date placed on the prescription label should be that of the effectiveness of the drug (Business and Professions Code section 4076[a][9]). **That date, in most circumstances, is the date printed on the manufacturer's container.**

Proper storage conditions of the prescription drug (Title 16 of the California Code of Regulations section 1707.2[d][3]) should be reinforced during patient consultation.

Guidelines from the United States Pharmacopeia

Beyond-Use Date—*The beyond-use date is the date after which the prescription drug may not be used.*

The beyond-use date defines an appropriate period of time during which a prescription drug may be retained by a patient after it is dispensed and takes into account such factors as the conditions under which the medication may be stored in the patient's home, the type of

packaging, the nature of the drug being dispensed, and the frequency with which the package may be opened.

For non-sterile solid and liquid pharmaceutical products repackaged into unit-dose or single-unit containers, pharmacists must affix a "beyond-use date" that is "one year or less, unless stability data or the manufacturer's labeling indicates otherwise." For all other non-sterile dosage forms, the beyond-use date is "one year or the time remaining of the expiration date."

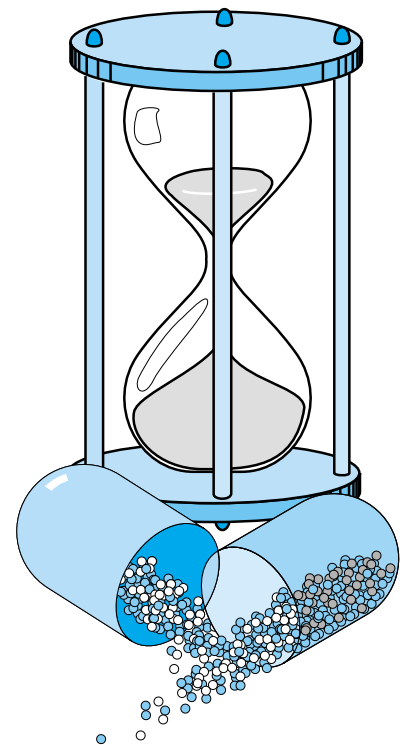
Beyond-use dates for multiple-unit containers, such as a typical prescription vial, remain as follows:

"not later than (a) the expiration date on the manufacturer's container or (b) one year from the date the drug is dispensed, whichever is earlier."

(These packaging standards appear in the first supplement to The United States Pharmacopeia, 24th Rev., and The National Formulary, 19th Ed. (USP24/NF19).)

Compliance Direction

The pharmacy is not to dispense expired drugs. During an inspection, the inspector will randomly select some filled prescriptions to compare the expiration dates to the manufacturer's container. If the expiration date on the prescription label exceeds the manufacturer's date, this is a violation.



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President's Message

By Steve Litsey, Pharm.D., FCSHP
President, Board of Pharmacy

This message of *The Script* will focus on the Board's mission and goals for serving the consumers of California by:

- Protecting their health, safety and welfare with integrity and honesty.
- Helping them attain health education, wellness and an improved quality of life.
- Ensuring high quality pharmacists' care.

The Board has five committees that work with the board staff and with consumer, pharmacy, and legislative groups to meet the mission. The committees and resulting Board activities include:

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Goals:

- To encourage the public to discuss their medication with their pharmacist.
- To emphasize the importance of compliance with their medication therapy.

The Board:

- Is revising the "Notice to Consumers." It will include questions that patients should ask and understand before taking medications, along with a Board of Pharmacy toll-free telephone number for consumers.
- Approved topics for future Health Notes include "Alternative Medicines," "Pharmacists' Care" and "Quality Assurance Programs."

LICENSING COMMITTEE

Goal:

To ensure that those entering and those continuing the practice of pharmacy meet minimum requirements for education, experience and knowledge.

The Board:

- Received a report on the January 23rd meeting of the Pharmacy Manpower Task Force—a working group to ensure patient access to pharmacists' care and prescription services. The 15-member task force collected approximately 32 proposed solutions with written documentation. These proposed solutions were discussed at the task force meeting on April 27th. A subsequent task force meeting was held on June 8th at the USC School of Pharmacy, and the next meeting is scheduled for July 24 at the San Diego Westgate Hotel.
- Recommended support for regulatory change to all utilization of automated dispensing machines at remote pharmacies.

ENFORCEMENT COMMITTEE

Goals:

- To protect the public by preventing violations.
- To effectively enforcing federal and state pharmacy laws when violations occur.

The Board:

- Adopted the proposed language of Title 16 of the California Code of Regulations section 1711 to require pharmacies to establish and maintain a quality assurance program designed to prevent medication errors. The Board has modified the proposed language and will notice the changes for a 15-day comment period.
- Approved the policy to accept e-mail or fax comments on proposed regulations only if they contain the

commenter's name and mailing address.

LEGISLATION AND REGULATION

Goals:

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

The Board:

- Supports SB 340 to allow dosage form changes by pharmacists without consulting the prescriber.
- Supports SB 1000 to extend the Controlled Utilization Review and Evaluation System (CURES) sunset date and state intent of the Legislature to eliminate the triplicate prescription requirement as soon as possible.
- Sponsored SB 1339 requiring a quality assurance program (QAP) in all pharmacies and adopted the QAP at the April 2001 Board meeting.
- Adopted a regulation expanding the cite and fine authority to cover all violations of the pharmacy law.
- Adopted revision of the Pharmacy Self-Assessment forms.
- Adopted revision of the Disciplinary Guidelines.

ORGANIZATIONAL DEVELOPMENT

Goals:

To use strategic planning, budget management and staff development activities to ensure the efficient achievement of the Board's mission and goals.

The Board:

- Approved the recommended budget change proposals for 2002/03.
- Updated the environmental scan for its 2001/02 Strategic Plan.

The Board's Strategic Plan includes a number of activities focused on improving board operations and public information. We will continue to seek additional staff resources to better serve the consumers and our licensees. Our role as board members requires no less.

Physicians and pharmacists have corresponding responsibility when writing and dispensing controlled substance prescriptions

If a physician writes a controlled substance prescription that is not for a legitimate medical purpose, the pharmacist shares a corresponding responsibility or liability with that physician if he or she fills that prescription while knowing or having objective reason to know that the prescription was not issued for a legitimate medical purpose.

A pharmacist's "objective reason to know" includes, but is not limited to, warnings or cautions or other suspicious information from a Board inspector, Board publications, the media, other pharmacy personnel, or personnel of other drug entities. These are all ways of putting a pharmacist on notice to be cautious and to use that information and his or her professional judgment to determine whether a prescription should be filled. The more the pharmacist is already on notice to be cautious, the less additional information or factors would be required to establish that he or she failed to properly consider prescriptions before filling them.

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

Questions Relating to the Patient

- Are you able to verify the true name and identity of the patient?
- Does the patient live within or outside the normal trading areas of the pharmacy? Is the distance so great that it is unlikely the patient would travel so far to fill a legitimate prescription?
- How far is the patient's residence from the prescriber's office?

- What do you know about the drug history of the patient?
- What is the patient's physical appearance and demeanor in relation to the drug being prescribed?
- When a third party picks up the prescription, what is his or her relationship to the patient? What is his or her physical appearance and demeanor?

Questions Relating to the Prescribing Physician

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

Questions Relating to the Therapeutic Appropriateness of the Prescription

- What are the abuse history and current patterns of abuse of the prescribed drug?

- If the patient's diagnosis is known, is the prescribed drug therapeutically appropriate?
- Is the frequency of refills or new prescriptions for the same drug the same as in the directions for use given by the physician?
- How do the length and quantity of the prescribed drug therapy compare to recognized and accepted prescribing practices?
- Is the physician prescribing unusual combinations of drugs or antagonistic or contraindicated drugs?

Regulatory References

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

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

Changes in the Board

The Board wishes to extend its best wishes and appreciation to two departing members, Dr. Darlene Fujimoto and Richard Mazzoni. While saying goodbye to its departing members, the Board is also pleased to welcome three new members: Stanley W. Goldenberg, R.Ph., Dr. Clarence Hiura, Pharm.D., and John E. Tilley, R.Ph.—all appointed by Governor Gray Davis.

New Members

Mr. Goldenberg, a graduate of the University of Arizona College of Pharmacy, is a licensed pharmacist who has specialized in long term care facilities and skilled nursing facilities since 1972. He presently serves as president of Pharmatech LTC, a company that provides research for a nationwide network of skilled nursing and long term care facilities, of Long Term Care Management Council and of Osteographix Medical Associates, which provides osteoporosis testing and educational services. Mr. Goldenberg has also served as president of Advanced Pharmaceutical Services, an institutional pharmacy specializing in skilled nursing facilities.

Dr. Hiura, a resident of Los Angeles, earned a Pharm.D. degree from the University of Southern California (USC) and has practiced pharmacy for more than 42 years. He presently serves as vice president and part-time pharmacist at K.C. Pharmacies. He is president of the California Pharmacy Association Board, Inc. and vice president of United Pharmacy Network, Inc. Dr. Hiura is also a member of the board of directors for QSAD, a fund development organization for the USC School of Pharmacy. Dr. Hiura was a clinical associate professor at USC and is a member of the Los Angeles Pharmacy Task Force. He is a former member of the California State Board of Pharmacy, having served from 1979 to 1986.

Mr. Tilley has practiced pharmacy for 24 years, owned three Zweber Apothecaries in Downey, California, since 1984 and owns pharmacies within 26 Stater Brothers Markets in southern California. He is a past trustee and president of the California Pharmacist Association (CPhA) and president of the California Pharmacists Political Action Committee. He is also a member of the American Pharmaceutical Association and serves on the board of directors for the American College of Apothecaries. Mr. Tilley also serves on the Executive Committee for the National Community Pharmacists Association (NCPA), where he is in the midst of a 14-year commitment that culminates in the presidency of the NCPA. In 1994 he received CPhA's Bowl of Hygeia award, an honor presented annually to California pharmacy's community practitioner of the year. Mr. Tilley has testified before joint sessions of the Senate and House Health Subcommittees on prescription coverage for Medicare, and attended meetings at the White House during the health care reform debate in 1994. He earned bachelor of science degrees from

Pharmacy Board meetings are open to the public...

... and the Board encourages all interested parties to attend. The remaining meeting date and site for 2001 is:

October 17–18, 2001
Embassy Suites
150 Anza Blvd.
Burlingame CA 94010
(650) 342-4600

Agenda with meeting times, location and other information may be obtained by contacting the Board at (916) 445-5014, Ext. 4006.

Whittier College and Idaho University College of Pharmacy.

Departing Members

The Board wishes to express its gratitude to Dr. Darlene Fujimoto, appointed by Governor Pete Wilson in December 1992, whose term ended in June of this year. While on the Board, Dr. Fujimoto served as Board president and vice president and chaired the Board's Enforcement Committee and the Southern Compliance Committee.

During her tenure, Dr. Fujimoto was involved in the Board's activities to remove triplicates as a barrier to appropriate patient care by helping to form the multiple agency task force to use the Controlled Substance Utilization and Review Evaluation System (CURES) to track Schedule II prescriptions. She sought to further optimize the use of CURES by using it for evaluating abuse

and diversion of controlled substances. She also led the Board's efforts to eliminate triplicate prescriptions.

Dr. Fujimoto was supportive and involved in the formal process of strategic planning for the Board, interacting with Board members, inspectors and office staff and elicited the public's participation in discussion and planning. While chairing the Enforcement Committee, Dr. Fujimoto emphasized and supported programs to streamline the procedures for obtaining fast resolution of disciplinary cases. She also encouraged the formation of enforcement teams as a viable structure within the Board to pursue and close cases.

Richard Mazzoni was appointed to the Board by Governor Pete Wilson in January 1998. During his membership, Mr. Mazzoni served as Board president

See Changes in the Board, Page 7

New regulations provide expanded enforcement tools for the Board

On June 22, 2001, the Office of Administrative Law approved Board of Pharmacy-sponsored amendments to sections 1775 and 1775.2, repealed 1775.1 and added 1775.15 to the California Code of Regulations. These changes expanded the scope of the existing citation and fine program and became effective on July 22, 2001. The Board will begin applying this citation and fine authority to violations that occur on or after August 1, 2001.

This authority is intended for violations that warrant stronger action than formal admonition through the compliance committee or office conference processes but do not rise to the level of formal disciplinary action. The Board also intends to use citation and fine authority in situations where neither admonishment nor discipline is likely to obtain compliance.

Prior to this change, the Board was permitted to issue citations and fines for failure to provide patient consultation, unlicensed activity, and continuing education violations. The newly approved regulations permit the issuance of a citation and fine for any violation of the Pharmacy Law (Business and Professions Code 4000 et seq.) and for any violation of Board-adopted regulations.

This regulation was pursued to provide the Board with intermediate sanctions between formal admonition and formal disciplinary action. Under the new regulations, citations and fines for virtually all pharmacy and pharmacist violations are issued by the Board's compliance committees (composed of at least two Board members appointed by the Board president). All other citations and fines may be issued by the executive officer. Please see Regulation Update, Pages 9 and 10 for text of the new and amended regulations.

Chlamydia Follow-Up

The April 2001 issue of *The Script* contained an article regarding a new law passed in 2000 allowing physicians to write a prescription (without a physical examination) for a patient's sexual partner or partners for the treatment of chlamydia. Prescriptions for the unexamined partner(s) may be written in any of the following ways.

1. The prescriber may write a separate prescription if the patient will provide the partner's name.

2. The prescriber may write a single prescription for both the patient and her partner(s) by simply adding the partner's name to the prescription and increasing the quantity appropriately.

3. The prescriber may also simply add "partner(s)" to the prescription and increasing the quantity appropriately.

The preferred option is a separate prescription for each partner; however, all three options listed above are valid prescriptions and can be filled by a pharmacist. You can obtain additional information on chlamydia and partner delivered therapy at <http://www.ucsf.edu/castd> or from the Department of Health Services STD Control Branch at (510) 540-2657.

www.pharmacy.ca.gov

The Medical Device Retailer program has been transferred to the Department of Health Services, effective July 1, 2001

Under provisions enacted by the California Legislature and signed by the Governor, the Board of Pharmacy no longer regulates medical device retailers, warehouses and exemptees as of July 1, 2001. The Department of Health Services now issues permits and regulates all these licensees.

A copy of the law can be obtained from the internet at www.leginfo.ca.gov. Select Assembly Bills for 1999-2000 and search for AB 1496. The new provisions are also printed in our lawbook and are noted with an effective date of July 1, 2001.

For firms whose licenses expired on or before June 30, 2001, the Board renewed the permits if payments were postmarked by June 30, 2001.

For licenses that expired on and after July 1, 2001, the Department of Health Services will issue the renewal permits. The Board cannot accept the renewal payment for any MDR or exemptee permit that expires after July 1. (The Department of Health Services is increasing fees substantially for these permits, and some licensees may want to renew early to save on the fees; however, this is not possible.)

Applications pending with the Board after July 1, 2001 will be transferred to the Department of Health Services for completion. Any pending applicants who have not responded to the Board's request for additional information within 60 days will be withdrawn, and these applicants will then need to apply to DHS for a permit.

No renewal notices will be mailed to Board of Pharmacy-licensed MDRs and exemptees with expiration dates of 7/1/01 or later. This process has been stopped, and the Department of Health Services will contact these licensees about how to renew their permits. Questions about this should be asked of the Department of Health Services.

MDRs and exemptees (with expiration dates before 7/1/01) who have

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

If you are an innovative, highly motivated individual who is looking for an exciting career that puts you on the front line of changes in the pharmacy practice, the Board of Pharmacy is looking for you! Applications for examination and employment as a pharmacy inspector for the Board are accepted on an ongoing basis.

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

To be considered, you must be registered as a pharmacist in California with two years' experience in the practice of pharmacy and possess a valid California driver's license. You will be required to take a civil service examination, and the examination results will determine your ranking on the civil service list. Based on that ranking and other qualifications, you may be called to appear for the Board's employment interview and writing skills evaluation. If you are a good match for this position, the Board wants you!

Inspectors from all over California are assigned to work in teams, and each inspector's duties are divided between those

performed in a home office environment (report writing and answering telephone inquiries) and those requiring travel. Travel, which includes local and statewide, is approximately 20-25 percent of the workweek.

There are plenty of perks. Inspectors are provided the use of home office equipment (telephone, cell phone, computer, printer, fax machine), a state car, business and travel expense reimbursement, a salary range of \$5,288 - \$6,005 per month, and all the health and retirement benefits of state civil service.

To obtain an application for examination and employment, you may access Board's website at www.pharmacy.ca.gov and click on What's New. Or you may contact the Board at (916) 445-5014.

Your completed application and résumé should be mailed to:

Department of Consumer Affairs
P. O. Box 980428
West Sacramento CA 95798-0428
Attention: Human Resources



renewed their permits with the Board will be regulated by the Department of Health Services after 7/1/01. However, the current plan is that they will renew their permits at the next expiration date with the Department of Health Services, and there will be no separate application process for currently licensed MDRs and exemptees.

Requests for new MDR site applications and questions should be addressed to:

Department of Health Services
Food and Drug Branch
P.O. Box 942733
Sacramento CA 94234-7320
(916) 445-2263

New DEA Telephone Numbers

For your convenience, here is a list of the latest Drug Enforcement Administration telephone numbers and the zip codes territories for each.

Los Angeles Office: (213) 621-6960

This office handles calls, inquiries, etc. from zip codes beginning with 900 through 919, 923 through 931, 934, and 962 through 966.

San Diego Office: (858) 616-4321

Zip codes beginning with 919 through 922. However, only callers in San Diego County with a 919 zip code should use this number. All other calls from zip codes beginning with 919 should go the Los Angeles office.

San Francisco Office: (888) 304-3251

This office handles calls from zip codes beginning with 932, 933, and 935 through 961.



Pharmacy Self-Assessment Update

In the April 2001 issue of *The Script*, we reported that the pharmacy self-assessment forms were undergoing changes, and those changes were expected to be approved and the new forms distributed to the pharmacies by July 1, 2001. However, changes to the forms are still under review, currently by the Department of Consumer Affairs, and the new forms cannot be provided until later this year.

Section 1715 of the California Code of Regulations requires pharmacists-in-charge (PIC) to perform a self-assessment of their pharmacy before March 31 of each odd-numbered year. In addition, completion of a self-assessment is required within 30 days of a pharmacy permit being issued or whenever there is a change of PIC. However, recent changes to pharmacy law necessitate appropriate modification to the self-assessment forms, and includes moving the biennial self-assessment completion date from March 31 to July 1 of each odd-numbered year.

So again, the question is: Since the new forms were not distributed in time for a July 1 completion, what are pharmacies supposed to do about the self-assessment requirement in the interim?

The answer is: Retain the completed March 31, 1998, self-assessment form, signed by the current PIC, until you receive the new form from the Board. If there has been a change in PIC since that date, the new PIC must have completed a new self-assessment form (the 1998 version) and have it on file in the pharmacy. When the new forms are ready, they will be mailed to every pharmacy.

If you need a copy of the current form, it is available on the Board's website (www.pharmacy.ca.gov), or you may request it from the Board.

And remember: **DO NOT MAIL THE COMPLETED FORM TO THE BOARD.** It must be retained in the pharmacy.

Changes in the Board

Continued from Page 5

and as chair of the Legislation & Regulation Committee and the Northern Compliance Committee. He participated in the crafting and passage of two milestone regulations: (1) enabling central refill, and (2) lunch breaks for pharmacists. He also held the first forum to discuss the pharmacist manpower shortage. Mr. Mazzoni was an advocate for expanding (1) the scope of practice for pharmacists, (2) technology in pharmacy and (3) the roles of other pharmacy staff to aid the pharmacist—all with the intent of providing more time for the pharmacist to interact with patients.

The Board has been truly fortunate and is grateful for its long association with such talented, creative and dedicated people.

New Officers

New Board officers were elected at the April 2001 meeting:

Steve Litsey, Pharm.D., President

John Jones, R.Ph., Vice President

Caleb Zia, Ed.D., Treasurer



Rx for Good Practice

In day-to-day pharmacy practice, unusual situations sometime occur, generating questions. So to help our licensees with questions whose answers may or may not be found in the pharmacy law book, "Rx for Good Practice" will be featured in each issue of The Script. If you have a question you would like to see answered in this column, please fax your question to The Script at (916) 327-6308 or e-mail it to the editor at hope_tamraz@dca.ca.gov.

Q Is it legal for a pharmacy to mail a prescription to a mail box or post office box?

A Under California law there are no restrictions on addresses to which prescriptions may be mailed. There was formerly a federal restriction on the mailing of narcotics, but that restriction was removed some time ago. There is, however, a restriction on the mailing of abortive drugs or devices (18 U.S.C. § 1461).

Q Can a pharmacist fill a Schedule II prescription written by an out-of-state prescriber?

A No—unless the prescription is written on a California triplicate prescription form, and out-of-state prescribers are not likely to have such forms. However, if the prescription is for a Schedule II drug and meets all requirements of section 11159.2 of the California Health & Safety Code (including the words "11159.2 exemption"), it can be dispensed if written on a regular prescription form.

Q Can a pharmacist provide a small amount of maintenance medication for a patient who presents a prescription container from another pharmacy? (Example: a patient who is on vacation from another state)

A First, call the out-of-state pharmacy to transfer the prescription, or call the prescriber for a new prescription. If unable to reach either of these, you may use your professional judgement whether to give the patient enough medication for 24 hours. Then during that 24-hour period, continue trying to reach the pharmacy or

the prescriber. Additionally, attempt to verify the prescriber's licensure through the medical board of that state or online.

Q What does the pharmacist do when a patient presents a Schedule II prescription for 60 pills, but their insurance will pay for only 30?

A The pharmacist may dispense 30 pills in a container and bill them to the insurance carrier and dispense another 30 pills to be paid for by the patient. The amount of pills may be divided in any number of ways, as long as there are separate labels for each container and the total does not exceed the amount written on the triplicate prescription.

Q Can a physician assistant or nurse practitioner sign a drug order?

A Yes, pursuant to the following: Business & Professions Code (B&PC) 4040 defines a prescription and states that if the prescription is in writing, it must be "signed by the prescriber issuing the order, or the physician assistant or nurse practitioner who issues a drug order pursuant to section 3502.1 or 2836.1." The January 2000 issue of *The Script*, page 4, addresses SB 816 (Escutia) that summarizes sections 2836.1 and 3502.1. That same section notes that section 2836.2 requires all physician assistants and nurse practitioners who are authorized to furnish or issue drug orders for controlled substances to obtain a Drug Enforcement Administration registration number.

Q When transferring a prescription from one pharmacy to another, is it OK for a pharmacy technician to simply fax a copy of the computer-generated label to another pharmacy without talking to the pharmacist on duty?

A No. Only pharmacists are permitted to transfer prescriptions from one pharmacy to another, and the procedures do not include faxing a copy of the computer label to the receiving pharmacy. For more information on the transfer of prescriptions, please see Page 6, Item #14 of your pharmacy's (community pharmacy) self-assessment form (Form 17 I-29 Rev. 9/98). Also see sections 1717 and 1717.1 of the California Code of Regulations (CCR) and 21 Code of Federal Regulations section 1306.25.

Q What type consultation documentation is required in an outpatient pharmacy setting? Is the consulting pharmacist required to initial and check (v) "consulted" box?

A There is no requirement in California statutes or regulations that consultation be documented. However, it is prudent and good practice to document that consultation was refused/declined by the patient/agent. How this is done is up to the pharmacist.

Many pharmacies have incorporated a consultation section in their 3rd party/cash receipt log. The patient signs for the receipt of the prescription, and there is usually an area for documenting the consultation (provided or declined). Again, this is at the discretion of the pharmacy.

Q What are the rules about the disposal of expired drugs or prescription drugs that are returned to the pharmacy by patients?

A The FDA Compliance Guideline recommends that a pharmacy should not accept returned medications from patients, to prevent the re-dispensing of drugs that have been out of the pharmacy's control or oversight. Such returns are considered medical waste. However, some pharmacies may choose, for good public relations, to accept returned drugs. In these instances, the medication should be placed in a "quarantined" area which is used only for out-dated products that are to be properly returned to the manufacturer or to a reverse distributor (an entity that will process medications for credit or destruction). Any medications that the reverse distributor is unable to return for credit should be processed and disposed of by a DEA-approved hazardous/medical waste disposal company. In California you may contact:

EXP Pharmaceutical Waste Management
30017 Ahern Ave
Union City CA 94587
(510) 476-0909 or 1-800-350-0397

Lastly, for the destruction of returned and expired drugs, do not consider flushing them away or mixing with water and pouring down the sink. The Safe Drinking Water and Toxic Enforcement Act of 1986 prohibits anyone from discharging or releasing a listed chemical into water or into land where such chemical would or could pass into any source of drinking water.

Q Many of my pharmacy's patients have the same name, and we attempt to distinguish between them by their birthday. Is it legal for me to refuse a telephoned prescription if the prescriber cannot provide the patient's birth date?

A As a professional committed to serving the health care needs of your patient, you may well try to determine whether there is another method of identifying the proper patient in this instance, other than the birthdate. If, however, in your professional

judgment you cannot obtain reasonable assurance that the medication will go to the right person, you may of course refuse to fill the prescription.

Q What do we do when we receive a prescription for "one bottle" or "one jar" of a drug that is manufactured in more than one size?

A This is an unclear prescription which must be verified with the prescriber. Please refer to CCR 1761 that relates to unclear or ambiguous prescriptions.

Board Passes Quality Assurance Program Regulation

On April 26, 2001, the Board adopted proposed language for a new regulation requiring all pharmacies to implement quality assurance programs designed to reduce medication errors. However, the Board will be making further changes to the proposed language in response to comments received from the public. If these subsequent changes are approved, the regulation will take effect on January 1, 2002. The current text of the regulation is posted on the Board's website, www.pharmacy.ca.gov.

Regulation Update

This article contains additions and amendments to Chapter 17, Title 16 of the California Code of Regulations. For your convenience, these sections are included here so that they may be cut out and saved until the next publication of the Pharmacy Law.

1714.5 Storage of exempt dangerous drugs and devices (New)

As provided in Section 4057 of the Business and Professions Code, the listing below shall be exempt from the provisions of Chapter 9, Division 2 of the Business and Professions Code where the sale or furnishing is made to a clinic, hospital, institution, or establishment holding a currently valid and unrevoked license or permit under Division 2 (commencing with Section 1200) of the Health and Safety Code, or Chapter 2 (commencing with Section 3300) of Division 3 of, or Part 2 (commencing with Section 6250) of Division 6, of the Welfare and Institutions Code:

- (a) dangerous devices,
- (b) hypodermic needles and syringes,
- (c) sterilized sutures,
- (d) parenteral solutions of 50 cubic centimeters or over,
 - (1) sterile water for injection,
 - (2) dextrose solutions of 10% or less,

- (3) ready-made parenteral nutritional solutions,
- (4) pre-diluted ready-to-use electrolyte containing solutions,
- (5) colloidal and low molecular weight plasma expanders,
- (6) Mannitol,
- (7) sodium chloride solutions of 5% or less,
- (8) alcohol (ethanol) solutions of 10% or less in dextrose infusions,
- (e) sterile water U.S.P.,
- (f) sterile normal saline solution,
- (g) medicinal gases,
- (h) inhalation anesthetics,
- (i) laboratory chemicals,
- (j) non-controlled topical anesthetics,
- (k) injectable local anesthetics when in sealed, pre-packaged kits,
- (l) topical stains and dyes,
- (m) diagnostic agents and contrast medium for X-ray examination,
- (n) medicated dressings,
- (o) irrigation solutions, and
- (p) ophthalmic irrigation solutions.

1775. Citations and Fines (Amended)

(a) A committee of the board may issue citations containing orders of abatement and fines for any violation of the Pharmacy Law or regulations adopted

See Regulations Update, Page 10

Regulation Update

Continued from Page 9

pursuant thereto. For the purposes of this article, "committee of the board" means a committee of board members appointed by the board president to consider investigations of alleged violations.

(b) Each citation shall be in writing and shall describe with particularity the nature and facts of the violation, including a reference to the statute or regulations alleged to have been violated. The citation shall be served upon the individual personally or by certified mail.

(c) A citation must inform the cited person or entity that if he/she or it desires a hearing to contest the finding of a violation, that hearing shall be requested by written notice to the board within 30 days of the issuance of the citation. If a hearing is not requested pursuant to this article, payment of any fine shall not constitute an admission of the violation charged.

(d) A committee of the board shall meet periodically in both the northern and southern portions of the state for the purpose of reviewing alleged violations, including notices of violation issued by the board inspectors, and issuing citations to licensees of the board. A person or entity shall appear, upon request of the board, before a committee of the board. The request to appear shall include a summary of alleged violations to be reviewed at that hearing. Persons or entities may reschedule their appearance before a committee of the board to review an alleged violation once. A committee of the board may issue a citation and impose a fine, and/or an order of abatement in the absence of a person or entity who fails to appear a second time. Citations shall be issued within 60 days of the committee meeting where the determination to issue the citation was made.

Section 1775.1 (Repealed)

1775.15 Executive Officer, Citations (New)

- (a) The executive officer may issue citations for violations of the following :
- (1) Article 8 of the Pharmacy Law

(Commencing with Business and Professions Code Section 4130) and any regulations relating to medical device retailers.

- (2) Article 9 of the Pharmacy Law (Commencing with Business and Professions Code Section 4140) and any regulations relating to hypodermic needles and syringes.
 - (3) Article 11 of the Pharmacy Law (Commencing with Business and Professions Code Section 4160) and any regulations relating to wholesalers and manufacturers.
 - (4) Article 13 of the Pharmacy Law (Commencing with Business and Professions Code Section 4180) and any regulations relating to nonprofit or free clinics.
 - (5) Article 14 of the Pharmacy Law (Commencing with Business and Professions Code Section 4190) and any regulations relating to surgical clinics.
 - (6) Article 15 of the Pharmacy Law (Commencing with Business and Professions Code Section 4196) and any regulations relating to veterinary food-animal drug retailers.
 - (7) Article 17 of the Pharmacy Law (Commencing with Business and Professions Code Section 4230) and any regulations relating to continuing education.
 - (8) Section 1708.2 of Title 16 of the California Code of Regulations.
- (b) The executive officer may also issue citations, in accordance with Section 148 of the Business and Professions Code, against any person (as defined in Section 302 of the Code) who is performing or who has performed services for which licensure is required under the Pharmacy Law or regulations adopted pursuant thereto. Each citation issued under this section shall contain an order of abatement. The sanction authorized under this section shall be separate from and in addition to any other

civil or criminal remedies.

- (c) In addition to the formal appeals process contained in Business and Professions Code Section 125.9 (b)(4) and Section 1775.4 (a) of Title 16 of the California Code of Regulations, an intermediate appeal of any citation issued by the executive officer shall be heard by a committee of the board where the appellant appears in person before the committee. Requests for a hearing by a committee of the board must be submitted within 14 days of receipt of the citation. A committee of the board may either affirm, modify (but not increase) or dismiss the citation, including any administrative fine or order of abatement.

1775.2. Amount of Fines and Factors Considered (Amended)

In no event shall a fine issued pursuant to Section 1775 exceed \$2,500.

In his/her or its discretion, the executive officer or a committee of the board may issue a citation with an order of abatement without levying a fine.

In assessing the amount of an administrative fine, the executive officer or a committee of the board shall give due consideration to the following factors:

- (a) The gravity of the violation.
- (b) The good or bad faith of the cited person or entity.
- (c) The history of previous violations.
- (d) Evidence that the violation was or was not willful.
- (e) The extent to which the cited person or entity has cooperated with the board's investigation.
- (f) The extent to which the cited person or entity has mitigated or attempted to mitigate any damage or injury caused by the violation.
- (g) Other matters as may be appropriate.
- (h) The number of violations found in the investigation.

Disciplinary Actions by the Board

CAUTION: The California Board of Pharmacy has approximately 62,378 registered individuals: pharmacists, pharmacy interns, pharmacy technicians and exemptees—many of whom share the same names. All disciplinary action information is taken from court documents and may not include middle initials, etc., so when reviewing the Board's disciplinary actions, please read carefully for names, cities and license/registration numbers.

PHARMACISTS/PHARMACIES

JAHANGIR NOORVASH, RPH
31001, Los Angeles CA and
CENTURY CITY MEDICAL PLAZA
PHARMACY, PHY 36965,
Los Angeles CA

Violation: Clearly excessive furnishing of controlled substances.

Action: RPH—Revoked, stayed; four years' probation; 60 days' suspension; pass law examination; no new ownership; share payment of \$13,662.25 in costs with PHY. PHY—Revoked, stayed; four years' probation; 30 days' suspension;

share payment of \$13,662.25 in costs with RPH.

Effective: November 4, 1999

STEPHEN RAYMOND BAJON, RPH
25384, New Orleans LA

Violation: Being convicted of a crime substantially related to the practice of pharmacy—forging, altering or issuing a prescription for narcotic drugs and filling the prescription.

Action: Revoked, stayed; suspended until return to California; payment of \$3,000 in costs.

Effective: January 26, 2001

GOHARSHAD BANI, RPH 46777,
Las Vegas NV

Violation: License being revoked by the Arizona Board of Pharmacy for charging insurers for prescriptions that were not dispensed; while acting PIC, closing the pharmacy without providing the required notice.

Action: Revoked.

Effective: January 12, 2001

LEONARD ROBERT MASTRO, JR.,
RPH 26375, Claremont CA and
BOB MASTRO PHARMACY, PHY
38126, La Verne CA

Violation: For purposes of settlement only, respondent admitted to billing for brand/preferred products while dispensing generic drugs; failing to maintain accurate record of acquisition and disposition of dangerous drugs.

Action: RPH—Revoked, stayed; three years' probation; 120 days' suspension; pass law examination; payment of \$7,000 in costs. PHY—revoked.

Effective: January 26, 2001

TECHNICIANS

SHARIF GAMAL CLARK, TCH 2447,
Los Angeles CA

Violation: Being convicted of driving under the influence of alcohol on more than one occasion; being in possession of controlled substance; driving a vehicle with a suspended license; providing perjured information about convictions to the Board.

Action: Revoked.

Effective: January 12, 2001

LORNA MILLER, TCH 781,
Sacramento CA

Violation: Diverting controlled substances for her own use from the pharmacy where she was employed.

Action: Revoked.

Effective: January 12, 2001

APRIL SUNSHINE BLACKHURST,
TCH 15433, Bakersfield CA

Violation: Being convicted of driving and causing an accident while under the influence of alcohol.

Action: Revoked.

Effective: January 12, 2001

Explanation of Disciplinary Language

1. *Revoked* means the license is canceled, voided, annulled, rescinded. The right to practice or operate a Board of Pharmacy-licensed business is ended.

2. *Revoked, stayed; 60 days' suspension; three years' probation*—“Stayed” means the revocation is postponed or put off. Professional practice or operation may continue so long as the licensee complies with specified probationary terms and conditions, which in this example includes 60 days' actual suspension from practice or operation. Violation of probation may result in the lifting of the stay and the implementation of the stayed revocation.

3. *Stipulation* indicates a form of negotiation where the case is settled prior to hearing (similar to an “out-of-court settlement” in civil court).

4. *Voluntary Surrender of License*—The licensee returns his or her license to the Board, subject to specific conditions of surrender and acceptance by the Board.

5. *Effective* indicates the date the disciplinary decision goes into operation.

6. *Statement of Issues* refers to the initial or accusatory pleading (filed by the Board) which initiates the administrative procedure for denial of licensure to an applicant.

7. *Letter of Reprimand (or Reproof)* is a public document reprimanding a licensee for violations of Pharmacy Law.

8. *Writ of Mandate* indicates that the respondent has requested review of the Board's decision by the superior court.

This newsletter is published by the
California State Board of Pharmacy
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Storage of Exempt Dangerous Drugs and Devices

Section 1714.5 of Title 16 of the California Code of Regulations was added to establish a list of dangerous drugs and dangerous devices that may be stored outside a pharmacy in hospitals and clinics. Please see Regulation Update on Page 9 for the text of this new regulation, and it is also available on the Board's website (www.pharmacy.ca.gov). This new regulation took effect May 9, 2001.

www.pharmacy.ca.gov