Board encourages voluntary medication error reporting

Medication errors account for almost 33 percent of the complaints received and investigated by the Board during the last three years. Reduction of such errors is one of the Board’s primary goals. Among the ways that medication errors can be reduced is for health professionals to learn from the mistakes of others, and the Board strongly encourages the profession to report errors on a confidential basis to programs such as the United States Pharmacopeial (USP) Practitioner’s Reporting Network, FDA’s MEDW A TCH program (for reports of adverse drug reactions), and the Institute of Safe Medication Practices (ISMP)—see box at right. These organizations pool and analyze medication error information obtained from all types of healthcare practitioners, manufacturers, and consumers and alert the profession to error trends.

Medication or prescription errors, usually single acts and the result of human mistakes, can occur at any point along the drug therapy course, from prescribing through transcribing, dispensing, administering, and monitoring. Examples of dispensing prescription errors include the following:

- The wrong drug (inappropriate for the patient’s condition) is ordered by the prescriber.
- Incorrect information is entered on the label of the prescription container.

The United States Pharmacopeial (USP) Practitioner’s Reporting Network provides a form for the confidential reporting of medication errors to the Medication Errors Reporting Program. The form and other information about the program can be obtained by calling 800-23-ERROR (800-233-7767) or contacting:

Diane D. Cousins, R.Ph.
USP PRN
12601 Twinbrook Parkway
Rockville MD 20852-1790

Medication errors reported to the USP are shared with the Institute of Safe Medication Practices (ISMP), which analyzes the errors to identify or predict error trends. Information regarding such trends and corrective actions by product manufacturers to improve product labeling is highlighted in the ISMP newsletter (ISMP Medication Safety Alert), which is published every two weeks. Errors may be reported to ISMP at (800) FAIL SAFE. The Internet address for ISMP is ismpinfo@ismp.org, or you may visit the website at www.ismp.org.

Another important monitoring role of pharmacists in providing quality care is to report adverse drug actions (ADRs) to the FDA’s MED WATCH program (800-FDA-1088). If you believe that the ADR you are reporting to the FDA would have significant educational value for others, also contact ISMP (800-FAIL SAFE).
President’s Message
by Thomas S. Nelson, R.Ph.
President, California Board of Pharmacy

During the last five years, much has been written, televised, and reported about the increase in prescription errors. Much has also been written on the reasons for errors, with staffing and workload issues and the hectic pharmacy environment (due in part to managed care restrictions) often being cited as causes. Some authors have even called into question the very competence of today’s practicing pharmacist. Because of the Board’s concern for and responsibility to protect the public, it has focused this issue of The Script primarily on medication errors and what can be done to prevent them.

The Board encourages pharmacies that discover a medication error to make every effort to prevent similar errors in the future and is considering a regulation requiring pharmacies to have a quality assurance program (QAP) in place to address such errors. Each pharmacy would determine the causes of its particular errors, then develop (and follow) procedures designed to prevent recurrences.

The QAP would address dispensing errors (e.g., dispensing the wrong drug with a look-alike name), as well as incidents of prescriptions being filled correctly as written but for a drug or dose that is inappropriate for a particular patient. This is the type of error that pharmacists can avoid by using their experience, knowledge, and professional judgment when reviewing the patient profiles and performing the most important function of prescription dispensing—the drug utilization review (DUR).

Too often at the Northern and Southern Compliance Committee meetings (where pharmacists are required to answer complaints before the Board), we hear that during the prescription filling process, there is little, if any, mention of the DUR or profile review. And equally often the pharmacist relies on the computer system to flag all interactions, overlaps, duplications, cross-allergies, harmful doses, and other potential problems. While today’s computers are a huge aid in prescription dispensing, I cannot think of one computer system to which I would abdicate my clinical judgment as a pharmacist. However, more and more pharmacists seem to be doing just that—relying on computers rather than on their education and expertise, and not rearranging their work flow to allow for proper DUR and profile review.

An aggressive consultation program for new prescriptions can prevent many dispensing errors. The pharmacist must discuss every new prescription with the patient, read the directions typed on the label, and open each container to assure that its contents match the container label.

Following these guidelines and instituting a meaningful QAP in every pharmacy will protect the public health and safety, while assuring that the pharmacy profession will continue to flourish into the next millennium.

Nametags required for pharmacists and interns
As of January 1, 1999, section 680 of the Business and Professions Code requires health care practitioners, including registered pharmacists and pharmacy interns, to wear nametags while working. The nametags must contain the practitioner’s name and license status and be printed in at least 18-point type. Practitioners may opt not to wear nametags if their licenses are prominently displayed in their practice area or office. However, nametags are necessary for those who are required to move from area to area while performing their duties.

Pharmacy technicians already are required to wear nametags under section 1793.7 of the California Code of Regulations, as are pharmacy technician trainees under section 4115.5 of the Business and Professions Code.
Fee reductions begin July 1, 1999

We are pleased to announce that beginning July 1, 1999, many Board fees are being reduced. The reductions affect licensing applications, original and renewal licenses (except those for pharmacy technicians) and will return fees to the amounts charged prior to June 30, 1995. For example, the renewal fee for pharmacist licenses that expires on July 31, 1999, will be $115 instead of $150. The renewal fee for a pharmacy license that expires on July 1, 1999, will be $175 instead of $250. Delinquent fees will also revert to the previous amounts. However, those whose licenses expire on or before June 30, 1999, will not be able to take advantage of the reduced rates until their next renewal.

In 1992, money was borrowed from the Board’s Contingent Fund to help satisfy a statewide budget deficit. Loss of these funds forced the Board to raise fees in July 1995 to meet its operational demands. With the repayment of this borrowed money, the Board is able to reduce fees to their previous levels with the exception of fees for pharmacy technicians. The cost of processing pharmacy technician applications for registration is significantly higher than the presently assessed fee of $50. Consequently, the pharmacy technician registration fees will not be reduced.

Error Reporting
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• A prescription is dispensed with the wrong drug or wrong dosage.
• A drug is dispensed that is contraindicated if taken with another drug.
• A prescription is filled using a drug whose expiration date has passed.

Other consistent problems contributing to prescription errors are the absence or presence of leading/trailing zeroes (computerized placeholders which are zeroes before and after the decimal point), misinterpreted abbreviations, and incomplete medication orders. Also, errors can be caused by poor communication, similarities in product names, ambiguities in directions for use or medical abbreviations, unclear labeling, or poor pharmacy procedures or techniques.

According to written comments received by the Board, some pharmacists feel that their workload-the number of prescriptions to be filled without sufficient staffing-may also cause prescription errors. Consequently, the Board, when mediating a prescription error complaint, documents the number of prescriptions filled (new prescriptions and refills) and the staffing of the pharmacy on the day of the error. If it is determined that workload factors contributed to a medication error, the pharmacy owner and the pharmacist-in-charge may be charged with violating the law. Repeated errors or serious breaches in pharmacy practices may trigger referral to the Office of the Attorney General for formal disciplinary action.

Because of concern for the growing number of medication errors, the Board is working on legislation to conduct a study of the frequency and types of medication errors in California pharmacies and to report its findings and recommendations for improving patient safety.

The Board also is considering a regulation requiring each pharmacy to have policies and procedures for recording and analyzing medication error incidents and for taking appropriate and reasonable actions to prevent future incidents of the same type. Having a quality assurance program that includes the evaluation of errors is an important method recommended by experts for the prevention of those errors. However, the Board has found that many errors would have been prevented if the pharmacist had consulted with the patient.

These programs work only because thoughtful practitioners report incidents, confident that the purpose of reporting, recording, and tracking medication errors is not to assign blame, but to aid in understanding why the errors occurred and take preventive and corrective action to preclude recurrence.
Automated drug delivery systems
OK for skilled nursing facilities

Senate Bill 1606 (Lewis, Chapter 778) amended section 1261.5 and added section 1261.6 to the Health & Safety Code. Beginning July 1, 1999, section 1261.6 will permit skilled nursing facilities and intermediate care facilities licensed by the Department of Health Services to use automated drug delivery machines (Pyxis and similar machines by other manufacturers). Currently, only hospitals use such dispensing machines to store drugs in nonpharmacy areas of the hospital because automated systems provide security and accountability of the drugs stored and dispensed from the machines.

The section also requires that transaction information for drugs dispensed from such machines be available for three years. Access to the drugs in the machines is limited to specific persons who are authorized by law to administer drugs.

Facilities using such machines must have policies and procedures for the disposition and security of stored drugs and for assuring drug potency and purity. Drugs may be removed from the machine (1) when ordered by a prescriber for administration to a patient before the next scheduled pharmacy delivery (the amount of drugs to be sufficient until the next scheduled pharmacy delivery or 72 hours-whichever is less), only after a pharmacist’s review of the order and patient’s profile, (2) drugs ordered for a patient on an as-needed basis where the use and retrieval is subject to review by a pharmacist, (3) drugs designated by the facility as emergency drugs or acute onset drugs, where the retrieval must be reviewed by a pharmacist within 48 hours.

The machines must be stocked by a pharmacist if done at the facility, or if removable drawers are used, the drawers may be removed for stocking outside the facility if: (1) the task is done by a pharmacist or by a pharmacy technician or an intern under the direct supervision of a pharmacist, (2) the drawers are transported between the facility and pharmacy in a tamper-evident container and (3) written policies and procedures exist to ensure proper placement of the drawers in the machine.

Review of the drugs in the machines must be done by the pharmacy on a monthly basis for security, accountability and cleanliness. Drugs dispensed from the machine would be exempt from patient-specific labeling requirements if unit dose or unit of use packaging is used and the facility has the information required on the label readily available.

Subsection (b) was added to section 1261.5 (also effective July 1, 1999) to provide that limitations on the number and quantity of oral dosage or suppository form drugs provided by a pharmacy to a health facility for storage in a secured emergency supplies container does not apply to an automated drug delivery system when a pharmacist controls access to the drugs.

The exact language of the two sections is entered below so they may be kept in the pharmacy, as these sections of the Health & Safety Code are not included in the pharmacy lawbook.

Section 1261.6 (New)

(a) For purposes of this section and Section 1261.5, an “automated drug delivery system” means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

(b) Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law. These records shall be maintained in the facility for minimum of three years.

(c) Individualized and specific access to automated drug delivery systems shall be limited to facility and contract personnel authorized by law to administer drugs.

(d) (1) The facility and the pharmacy shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. Policies and procedures shall define access to the automated drug delivery system and limits to access to equipment and drugs.

(2) All policies and procedures shall be maintained at the location where the automated drug delivery system is being used.

(e) Drugs removed from the automated drug delivery system shall be limited to the following:

(1) A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drugs shall be retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber’s order and the patient’s profile for potential contraindications and adverse drug reactions.

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Automated drug delivery
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(2) Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist.

(3) Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from an automated drug delivery system pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility. Within 48 hours after retrieval under this paragraph, the case shall be reviewed by a pharmacist.

(f) The stocking of an automated drug delivery system shall be performed by a pharmacist. If the automated drug delivery system utilizes removable pockets or drawers, or similar technology, the stocking system may be done outside of the facility and be delivered to the facility if all of the following conditions are met:

(1) The task of placing drugs into the removable pockets or drawers is performed by a pharmacist or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

(2) The removable pockets or drawers are transported between the pharmacy and the facility in a secure tamper-evident container.

(3) The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the pockets or drawers are properly placed into the automated drug delivery system.

(g) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review, which shall be conducted on a monthly basis, by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

(h) Drugs dispensed from an automated drug delivery system that meets the requirements of this section shall not be subject to the labeling requirements of Section 4076 of the Business and Professions Code or Section 111480 of this code if the drugs to be placed into the automated drug delivery system are in unit dose packaging or unit of use and if the information required by Section 4076 of the Business and Professions Code and Section 111480 of this code is readily available at the time of drug administration.

(i) This section shall become operative July 1, 1999.

Section 1261.5 is amended to read:

Section 1261.5

(a) The number of oral dosage form or suppository form drugs provided by a pharmacy to a health facility licensed pursuant to subdivision (c), (d), or both (c) and (d), of Section 1250 for storage in a secured emergency supplies container, pursuant to Section 4035 of the Business and Professions Code, shall be limited to 24. The State Department of Health Services may limit the number of doses of each drug available to not more than four doses of any separate drug dosage form in each emergency supply.

(b) Any limitations established pursuant to subdivision (a) on the number and quantity of oral dosage or suppository form drugs provided by a pharmacy to a health facility licensed pursuant to subdivision (c), (d), or both (c) and (d) of Section 1250 for storage in a secured emergency supplies container shall not apply to an automated drug delivery system, as defined in Section 1261.6, when a pharmacist controls access to the drugs. This subdivision shall become operative July 1, 1999.
More Answers to Pharmacy Self-Assessment Questions

When the pharmacy self-assessment forms were mailed to California pharmacies earlier this year, the January 1999 issue of The Script was also enclosed. That publication contained information and answers to questions about the pharmacy self-assessment program. Below are answers to additional questions:

Q. What type self-assessment form do I complete for a drug room or a clinic?
A. Pharmacy self-assessments are not required for drug rooms or clinics.

Q. What type self-assessment form do I complete for a skilled nursing/closed door pharmacy?
A. Community/out-patient assessments are required for skilled nursing/closed door pharmacies.

Q. What do I do with the assessment after it is completed?
A. Each assessment is to remain accessible in the pharmacy for three years from the date of its completion. Do not mail the completed form to the Board unless you are specifically directed to do so.

Q. What do I do if I haven’t received the form, and it was to be completed by March 31, 1999?
A. If you have not yet received the form, fax your request to the Board at (916) 327-6308. Please include the name of your pharmacy, license number, address, and type of practice. Your fax will be retained at the Board as a record that you did not receive the assessment in the first mailing, affecting your ability to complete it by March 31. The form(s) will be mailed to you with other important information.

Q. My pharmacy will be hiring a new pharmacist-in-charge (PIC) shortly. Will he or she be required to complete the self-assessment, even though it was just done by the previous PIC?
A. Yes, the PIC must complete a new assessment form within 30 days of being designated as PIC. (The pharmacy self-assessment form contains valuable regulatory information and should be considered an educational tool.)

Q. I found several references in the assessment to the 21 CFR and 22 CCR 70263, 70269, etc., but could not find these sections in my 1998 pharmacy law book. What are these referenced sections, and where can I locate them?
A. The “21 CFR” refers to Title 21 of the Code of Federal Regulations, part 1300 onward. It is published each year by the U.S. Government Printing Office and contains all regulations of the Controlled Substances Act as administered by the Drug Enforcement Administration. It is available in law libraries or may be purchased at bookstores offering federal legal publications or by mail from the U.S. Government Printing Office.

The “22 CCR” refers to various sections of Title 22 California Code of Regulations, commonly known as Title 22. This reference section is available in law libraries or most hospital administrators’ offices.

CURES
Compliant pharmacies received rebates of $70,200

Last year when the Controlled Utilization Review and Evaluation System (CURES) was implemented, the Board of Pharmacy offered a one-time license renewal fee reduction incentive to those pharmacies that were in compliance with the program mandate by July 18, 1998. The Board is happy to announce that 2,300 pharmacies received rebates for a total of $70,200 in reduced fees.
Be a leader-
Be a Pharmacy Inspector for the Board

Have you ever wondered what the pharmacy practice will be like in the coming millennium? 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, you can help lead the way into the future as a pharmacy inspector for the Board of Pharmacy.

The Board has inspector vacancies statewide 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.

There are plenty of perks. Inspectors, under general direction, work from home offices where they are provided equipment (telephone, cell phone, computer, printer, fax machine), their own business car, business and travel expense reimbursement, a salary range of $4,337 - $4,924, and all the health and retirement benefits of state civil service.

Applications for appointment to this state civil service classification are now being accepted on an ongoing basis. To obtain an application, you may access the Internet at http://www.spb.ca.gov/jobgen/app.htm, and for general information, http://www.sbp.ca.gov/bullback.htm. 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

Computers may miss potential medication problems

While pharmacy computer systems have become common and essential professional tools to increase staff efficiency and support effective drug therapy monitoring, studies show that these systems need serious improvement. Pharmacists must not rely on computers alone when making professional judgments.

In the February 10, 1999, issue of the ISMP Medication Safety Alert! the editor referred to a cover story published in US News and World Report (August 26, 1996) entitled, “Danger at the Drugstore.” The article concluded that pharmacy computer systems are of limited reliability when used to detect and correct prescription errors-most notably, serious drug interactions. Additionally, the Institute for Safe Medication Practices (ISMP) found that many of their respondents’ computer systems performed poorly when tested on their ability to detect serious or fatal errors. The really disturbing news is that only four out of 307 systems detected all unsafe orders presented in the field tests.

For more information relating to the field study performances of specific computer vendors, you may request the February 10, 1999, Volume 4, Issue 3, issue of the ISMP Medication Safety Alert! by contacting ISMP at (800) FAIL SAF or E-mail: ismpinfo@ismp.org.

Pharmacy Board meetings are open to the public

In accordance with its strategic plan, the Board has formed committees to address issues related to meeting the plan’s objectives. To share the various committee goals, activities, and accomplishments with the public, a portion of each Board meeting will be devoted to one of the committees and open for public comment.

◆ The May 19-20, 1999, Board (and Licensing Committee) meeting will be held in San Diego.
◆ On July 28-29, 1999, the Board (and Enforcement Committee) meeting will be held in Burlingame.

All interested parties are encouraged to participate in these meetings. If you cannot present your comments in person, your written comments will be reviewed if received at the Board office at least seven days prior to the meeting. Agendas with meeting times and locations may be obtained by calling the Board at (916) 445-5014.
Statewide diabetes screening and consultation events a great success

By Scott Ayers, Events Coordinator
UCSF School of Pharmacy

For what we hope will be the first of many collaborative projects, the American Pharmaceutical Association/Academy of Students of Pharmacy from the four California pharmacy schools and the State Board of Pharmacy cosponsored a statewide effort to provide the community with free screenings and consultations for diabetes on January 23, 1999. Pharmacy students at the University of California, San Francisco; University of the Pacific; University of Southern California; and Western University organized and hosted the events at five different sites throughout the state.

Diabetes is the seventh leading cause of death in the U.S. More than 16 million Americans have type 2 diabetes; however, nearly one-third of these individuals are unaware they have the disease. Type 2 is the most common form of the disease and accounts for 90-95 percent of diabetics. Early signs of type 2 diabetes include extreme fatigue, frequent urination, unusual thirst, and blurred vision. Since some of these symptoms are individually fairly common, they may be easily overlooked and treatment delayed for years. If left untreated, serious complications can arise, such as blindness, kidney failure, heart disease, stroke, and circulatory problems that may be severe enough to require amputation. Alternatively, early detection and proper treatment may prevent such complications.

“Talk with Your Pharmacist About Diabetes” day was designed to educate the community about the detection and early treatment of diabetes. The students first obtained a brief health history from each attendee to determine whether he or she was in a high-risk diabetes group. Then the individual’s blood glucose level was tested. With the results of the risk group questionnaire, blood glucose levels, and answers to specific questions, the students provided an action plan to each individual, i.e., referral to a physician if indicated or tips for maintaining low glucose levels.

Licensed pharmacists, and representatives from Lifescan and the American Diabetes Association were on hand to answer any questions about diabetes. State Board of Pharmacy representatives also attended and provided information on the importance of communicating with pharmacists.

The event received great media coverage, thanks to the California Pharmacists Association and Fleishman-Hillard, Inc. Stations KTLA-TV (Los Angeles) and KCRA-TV (Sacramento/Stockton) promoted the events in advance and in subsequent news segments. Also, KCBS-AM (San Francisco) aired a live radio interview during the event, prompting many individuals to get checked. Based on media estimates, the event’s promotion reached more than 577,000 viewers/listeners.

Everyone was very pleased with the success of the combined events: 654 individuals were screened, and 85 were referred to their physicians. Hundreds of thousands of others were alerted to the dangers of undiagnosed diabetes and encouraged to talk to their physicians or pharmacists about diabetes and seek medical treatment if needed. Plans for a second annual diabetes screening day are already under way, and students are looking forward to an even bigger and more successful event next year.

We would like to acknowledge and thank everyone who worked so hard to make this event the success it was. Thank you, all!

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DEA Award for Pharmacy Inspector Judith Nurse

Pharmacy Inspector Judith Nurse was recently awarded a Certificate of Appreciation by the Drug Enforcement Administration (DEA) for her outstanding contributions to drug law enforcement. Inspector Nurse holds the lead position in the Board’s Drug Diversion/Fraud Team, and has worked closely with the DEA to suppress international chemical and pharmaceutical diversion along the California/Mexico border.

An innovative leader, Inspector Nurse was central in identifying and locating counterfeiters of U.S. brand pharmaceuticals in Tijuana, Mexico. Because Inspector Nurse identified Mexican import permits as a means to verify and suppress diversion, permit verification is now a protocol nationwide and has become key evidence in federal prosecutions.

Her contributions to drug law enforcement and to the Board of Pharmacy are outstanding, and this award is truly deserved. Thank you, Judi, for your hard work! We are proud of you!

Hundreds of licenses cancelled for nonrenewal!

In the July 1998 issue of The Script, it was noted that section 4402(e) of the Business and Professions Code authorizes the cancellation of all licenses (except pharmacists’ licenses) if they are not renewed within 60 days of their expiration dates. Section 4402(a) authorizes the cancellation of pharmacists’ licenses if they are not renewed within three years of their expiration dates. As a result of these statutes, several hundred pharmacy technician and pharmacist licenses have been cancelled. Licenses cancelled under these statutes cannot be renewed or reissued—new applications must be filed with the Board.

Please contact the Board if you have questions regarding your own licensure or the licensure of those you supervise.

PICs’ Names Added to Pharmacy Licenses

Beginning July 1, 1999, each pharmacy permit printed by the Board will include the name of the pharmacy’s pharmacist-in-charge (PIC). With this new procedure, a fee of $100 will be required with all changes of PIC because it is considered a change in the permit.

Section 4101(a) of the Business and Professions Code requires pharmacists to report to the Board within 30 days of their termination as PIC of a pharmacy. Additionally, the pharmacy must file a “Change of Pharmacist-in-Charge” form with the Board within 30 days of designating a new PIC, pursuant to section 4113(a). If you anticipate a PIC change, you may obtain the appropriate form by contacting the Board.

Thank you, all!

UCSF-Scott Ayers, AphA/ASP Committee Chair and Event Coordinator Walgreens Pharmacy #3185 in San Francisco

Faculty Support: Dean Mary Ann Koda Kimble; Assistant Dean Bob Day; Associate Dean for External Affairs Lorie Rice; Mitra Assemi, PharmD; Betty Dong, PharmD; and Lisa Kroon, PharmD
Board Member: Marilyn S. Shreve, RPh
Student Support: 25 individuals

USC-Manisha Malavia, AphA/ASP Committee Chair Via Verde Prescription Shoppe in San Dimas and Mike Rudolph, PharmD and the Pasadena Senior Center in Pasadena and Cynthia Vaughn, Event Coordinator

Pharmacists (Observers/Counselors/Trainers): Michael Wincor, PharmD; May Mak, CDE, PharmD; Melissa Egan, PharmD; Manesh Bhakta, PharmD; Scott Evans, PharmD; Tracy Newman, PharmD; Sunny Park, CDE, PharmD; and Rick Reggio, PharmD
Board Members: Holly Strom, RPh and Steve Litsey, PharmD
California Pharmacists Association: Paul Drogichen, PharmD
Lifescan: Diane Schaffer
Student Support: 89 individuals

UOP-Eric Gupta, AphA/ASP Committee Chair Walgreens Pharmacy #2680 in Stockton

Pharmacists: Dan Padilla, RPh and Bruce Uch, PharmD
Board Member: Tom Nelson, RPh
Student Support: 56 individuals

Western University of Health Sciences-Ragie Aboulhosn, AphA/ASP Committee Chair Sav-On Drug #3038 in Buena Park

Pharmacist: Tim Lopez, PharmD
Faculty Support: Arlane An, PharmD and Joanne Yasuda, PharmD
Student Support: 40 individuals
More About Health & Safety Code Section 11159.2

Section 11159.2 of the Health & Safety Code became effective January 1, 1999, allowing physicians to use nontriplicate prescription forms containing the notation “11159.2 exemption” when prescribing Schedule II controlled substances that are intended only for terminally ill patients. The January 1999 issue of The Script described in detail the requirements for such prescriptions. However, as these prescriptions appear in pharmacies, new questions arise:

Q. Can a prescription for a Schedule II controlled substance with the notation “11159.2 exemption” be refilled?
A. No. Prescriptions for Schedule II controlled substances may not be refilled, pursuant to H&SC 11200(c).

Q. Under section 11159.2, how many Schedule II drugs can be prescribed on one prescription?
A. Because the BNE triplicate contains the restriction, “For One Prescription Only,” the same restriction would apply to an exempt prescription.

Q. Can an exempt prescription contain a Schedule II drug and a Schedule III, IV, or V on the same document?
A. Again, there may be only one drug listed on the exempt prescription—a Schedule II controlled substance.

Q. Does an exempt prescription have to be in the physician’s handwriting?
A. The prescription must be in the prescriber’s handwriting (pursuant to section 11164 regarding all Schedule II prescriptions). However, the notation “11159.2 exemption” may be written or preprinted on the prescription.

Q. If the exemption notation is not on the prescription, and the pharmacist knows it is for a terminally ill patient, can the pharmacist enter the notation on the prescription?
A. No. The pharmacist may neither enter the notation, nor fill the prescription if the notation is missing. The prescription must be returned to the prescriber for correction.

Q. Can a pharmacist fill a prescription with a technically incorrect notation (e.g., “1159.2 exemption,” “terminally ill,” “nontriplicate,” etc.)?
A. The prescription may be filled if the pharmacist (1) has personal knowledge of the patient’s terminal illness and (2) returns the prescription to the prescriber for correction within 72 hours.

Q. Can the physician leave anything blank on the exempt prescription?
A. A physician must meet all requirements for a Schedule II controlled substance prescription, pursuant to H&SC section 11164. However, if the physician fails to enter the patient’s address, the pharmacist may enter it on the prescription or maintain that information in a readily accessible form in the pharmacy.

Q. How long is an exempt prescription good?
A. H&SC section 11166 directs that a prescription for a Schedule II controlled substance cannot be filled 14 or more days after the date written on the prescription by the prescriber.

Q. Can a pharmacist dispense an exempt prescription for a Schedule II controlled substance telephoned to the pharmacy by the prescriber?
A. No. A pharmacist cannot dispense a telephoned prescription for a Schedule II controlled substance intended to be an exempt prescription without the original prescription that complies with section 11159.2 requirements. An oral prescription for a Schedule II drug would be processed under triplicate procedures.
Case Files: Medication Errors

Medication errors can be greatly reduced by following basic safety precautions, providing proper patient consultation, and conferring with the prescriber when there is uncertainty about the prescription. The following cases, taken from Board files, illustrate what can occur when these precautions are not taken.

Case 1: A pharmacy received an orally transmitted prescription for Procanbid 1000mg with instructions for the patient to take one and one-half tablets twice a day. As law requires, a pharmacist received the oral order; however, the pharmacist did not question it. Another pharmacist-the filling pharmacist-reviewed the prescription and realized that the tablet was a long-acting product and should not be broken in half. The filling pharmacist could not contact the prescriber and incorrectly dispensed the prescription with the long-acting product as written (error #1). During consultation, the pharmacist instructed the patient to contact her physician for clarification of the dosage.

After leaving the pharmacy, the patient realized that the medication given to her in the hospital had been two different tablets, one gray and one blue. She called the pharmacist back and was told to return to the pharmacy, where she was subsequently given four 500mg Procanbid tablets in an unlabeled container (error #2). The pharmacist made no record of furnishing the patient with the four tablets (error #3).

The filling pharmacist contacted the prescriber the following day, and the patient returned to the pharmacy a third time to pick up the correct prescription.

On the date of the error, 73 prescriptions were filled: 49 new and 24 refills. Staffing in the pharmacy consisted of one pharmacist (no clerks or technicians).

The case resulted in the following violations:

- California Code of Regulations 1761: The pharmacy and pharmacist filled an uncertain and erroneous prescription prior to conferring with the prescriber.
- Business and Professions Code 4076: The pharmacy and pharmacist dispensed medication to a patient in an unlabeled container.
- Business and Professions Code 4081: The pharmacy and pharmacist furnished the four 500mg tablets without maintaining an accurate record of their dispensing.

NOTE: Furnishing drugs without a prescription in reasonable quantities is allowed under Business and Professions Code 4062. However, a record containing the date; name and address of the person to whom the drug has been furnished; and the name, strength, and quantity of the drug furnished shall be maintained.

Case 2: A patient complained that her prescription for Toradol 10mg was incorrectly dispensed with Inderal 10mg, causing her to ingest the wrong medication for two days before a visit to her physician caught the error (error #1).

The Board inspector learned that the complainant had been in a car accident and was given the prescription for pain by her doctor. After taking the medication as directed for two days, she began to feel very disoriented; her arms, legs, and feet “tingled”; and she was still in pain. The complainant returned to her doctor, who prescribed Soma for additional pain relief. When the complainant asked her doctor if it was okay to take Soma with Inderal, the doctor realized that Inderal had been dispensed rather than Toradol.

After learning of the error, the pharmacy provided the correct medication to the patient at no charge and further offered to refund her money for the incorrectly filled drug. But because of the pharmacist’s “casual” attitude about the error, the complainant reported the incident to the Board and further noted that she had not received consultation from the pharmacist (error #2).

Later, during a subsequent inspection of the pharmacy, a Board inspector observed patients picking up their prescriptions, and for approximately 20 minutes saw no patient consultation being given. The inspector reviewed the original prescription and found that the writing on the prescription looked more like “Inodal 10mg,” rather than Inderal or Toradol. The inspector discussed the error with the filling pharmacist and admonished the pharmacist to always carefully compare the label typed by technicians or clerks with the actual prescription. Additionally, the pharmacist-in-charge was admonished to ensure that patient consultation is provided to all patients with new prescriptions and upon request. Had the complainant received consultation, the error would have been discovered before the drug was dispensed to the patient.

On the date of the error, 186 prescriptions were filled: 105 new and 81 refills. Staffing was unknown.

This case resulted in the following violations:

- California Code of Regulations 1716 and 1761: The pharmacist filled an erroneous and uncertain prescription with the incorrect medication without conferring with the prescriber.
- California Code of Regulations 1707.2 (b)(1)(A): The pharmacy and its pharmacists did not consult with a patient when the prescription drug had not previously been dispensed to the patient.
Has your name or address changed?

Section 4100 of the Business and Professions Code requires licensees to report a name or address change to the Board within 30 days of the change. Such changes must be in writing.

When notifying the Board of a change in your name, please include the following:

- A copy of legal documentation (marriage license, divorce decree, or legal name change) of your name change or
- Copies of your driver license and Social Security card (both reflecting the new name).

For address changes, please include your full name, license number, old address, and new address. Your “address of record” is accessible to the public, pursuant to the Information Practices Act and the Public Records Act. If you choose to use a post office box as your address of record, section 1704 of the Business and Professions Code requires you to also provide your residence address.

Please mail or fax all change information to:

California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento CA 95814
FAX: (916) 327-6308