



BE AWARE & TAKE CARE:
Talk to your pharmacist!

The Script

CALIFORNIA BOARD OF PHARMACY OCTOBER 2001

Pharmacists' Care Enhanced

The Board of Pharmacy is pleased to announce that Governor Gray Davis recently signed Assembly Bill 826 (Cohn), which will allow pharmacists to perform clinical functions outside of a pharmacy or other licensed health facility. This bill was sponsored by the Board and reflects one of its long-standing priorities to permit pharmacists to consult practitioners, as well as patients, in other than pharmacy settings.

AB 826 also permits pharmacists in outpatient care settings to initiate drug therapy for patients (prior law only allowed the adjustment of drug therapy in outpatient settings). However, as with existing law, initiation of drug therapy is permitted only when appropriate protocols are in place. The bill also requires that the pharmacist notify the prescriber within 24 hours of initiating a drug regimen under this new authority.

Expanding this type of collaborative practice to additional practice settings will allow greater flexibility in providing quality pharmacists' care to patients. Collaborative practice makes the best use of the skills of each of the members of the health care team and grants freedom to provide care to the patient in the

manner that best serves the patient's needs.

Before AB 826, pharmacists were permitted to perform a variety of healthcare functions in collaborative practice with physicians and other healthcare providers. The rules governing such practice are specified in protocols developed collaboratively by prescribers, pharmacists, and other health care professionals involved in providing patient care. These functions include (1) adjusting an existing drug regimen (altering dose, frequency, route of administration, etc.) and (2) initiating a drug regimen (commencing a new course of drug therapy).

The change of settings where a pharmacist may provide the above services is particularly important, given the increasing complexity of drug therapy being provided outside of hospitals and clinics. The participation of pharmacists in providing drug therapy has been shown in numerous studies to improve patient outcomes and reduce the cost of health care.

The most commonly recognized role of pharmacists is that of dispensing medications, an activity that takes place

in thousands of pharmacies every day. However, pharmacists provide patient care in clinical settings, too. But unlike most healthcare professionals, pharmacists are generally required to practice in a pharmacy or other licensed setting, such as a hospital or skilled nursing facility. For example, current law does not permit pharmacists to provide clinical or consulting services in a doctor's office or medical office building because these structures are not licensed by the state.

Because of the enactment of AB 826, California law has been clarified and strengthened to assure pharmacists can practice pharmacy wherever the pharmacist is, not just when he or she is located within a licensed facility or pharmacy. Examples include but are not restricted to:

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Talk About Prescriptions Month

October was designated "Talk About Prescriptions Month," by the National Council on Patient Information and Education. In keeping with that theme, this issue of *The Script* includes information that will help pharmacists reduce prescription errors and offer ways to educate consumers on the importance of prescription medication compliance.



President's Message

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

This message of *The Script* will focus largely on two issues currently being addressed by the Board: California use of the North American Pharmacist Licensure Examination (NAPLEX) and the amended regulation language for the establishment of Quality Assurance Programs in pharmacies to help prevent medication errors.

NAPLEX

At the recommendation of the Board of Pharmacy Licensing Committee, an audit of the NAPLEX was conducted under the direction of Norman R. Hertz, Ph.D., Chief Officer of Examinations for California. After completing an audit that evaluated the NAPLEX in terms of standards pertaining to job analysis, test development, cutscores, test administration, and score reporting, the audit team concluded that the NAPLEX is a valid measure of competencies essential for entry-level pharmacist practice and meets relevant psychometric standards. The Board then approved a recommendation from the Licensing Committee to support use of the NAPLEX as the California pharmacist licensing examination—contingent, however, on several conditions.

The Board's conditions include the requirement that the National Association of Boards of Pharmacy (NABP) perform a job analysis within two years and every

five years thereafter and incorporate California's 1999 job analysis in its next job analysis. The Board further requires the NABP to administer a California-specific Multi-State Pharmacy Jurisprudence Examination (MPJE) using the NABP computer-based testing program.

The Board wishes to retain its Competency Committee (subject matter experts) for the development and maintenance of the MPJE question bank, to write questions for the NAPLEX, and to participate on the NAPLEX Review Committee (NRC). The Board would also require the placement of at least 8 members from the Competency Committee on the NAPLEX Review Committee and Cutscore-Setting Committee. The Board also would retain its own examination consultant to provide questions for the MPJE and NAPLEX examinations. Lastly, California must be allowed to use the "direct processing" option where an applicant submits his/her examination application directly to NABP, and NABP sends the examination results directly to the candidate.

The NABP will respond to the audit recommendations and provide documentation to the Board's Competency Committee for review and recommendation to the Licensing Committee.

If the above conditions are met, legislation then must be introduced and passed to authorize the acceptance of the NAPLEX and California's MPJE after June 1, 2002. This means that applicants

who take the California licensure exam prior to and including the June 2002 examination will be subject to the pre-existing testing requirements.

Legislation is also required to authorize the transfer of a pharmacist license from another state, based on specified conditions which include the passage of the NAPLEX and California's MPJE after June 1, 2002. And legislation must be passed adjusting the application fee for pharmacist licensure accordingly.

Quality Assurance Program

The Board is pursuing a Quality Assurance Program (QAP) regulation to support each pharmacy's procedures for managing quality related to the prevention of medication errors. In response to the comments received concerning the initially proposed regulation language, revised language has been put out for a 15-day comment period and posted on the Board's web site.

Other Issues

At the Board's request, routine pharmacy inspections by Board inspectors were renewed on July 1, 2001, with an emphasis on education and prevention of violations. The Board is also supporting the introduction and passage of proposed legislation increasing the standards for pharmacies engaged in sterile compounding.

The Board of Pharmacy website at www.pharmacy.ca.gov is a valuable source of information. Topics include Licensure Verification, Licensee Information, Application Info, What's New, Forms & Publications, Legislation & Regulations, Frequently Asked Questions and more. I encourage you to visit the website.

www.pharmacy.ca.gov

Let's take that EXTRA STEP!

The Institute for Safe Medication Practices has generously given their permission for the Board to reprint the following information, which was taken from the ISMP MEDICATION SAFETY ALERT! Volume 6, Issue 14, July 11, 2001.

Patient safety is all about taking that extra step.

Problem: We're often reminded of medication errors that have been prevented by healthcare practitioners who are diligent enough to fully investigate situations that "just don't seem right," even after there's been an initial confirmation by an authoritative source.

Taking this "extra step" can often prevent patient harm. Such a case was reported last week. A patient with several medical conditions, including glaucoma and diabetes, was admitted to a hospital with medication orders that included "glucose control solution one-drop to left eye twice a day." Since this substance is actually used to verify proper functioning of glucose monitoring devices, the pharmacist questioned the nurse and prescriber, both of whom stated "that's what the patient uses at home." **The pharmacist then took the time to question the patient directly.** Indeed, the patient said that he'd been instilling glucose control solution into his left eye at home and thought this was the correct way to use the medication, based upon instructions from his local physician. **The pharmacist, still not satisfied, telephoned the original prescriber** who indicated that, actually, timolol ophthalmic solution was to be used for the patient's glaucoma. The pharmacist later discovered that the diabetic patient, having very poor eyesight, had interchanged the glucose control solution with the timolol (both products are available in small dropper containers with yellow caps and black lettering).

Safe Practices Recommendation:

When pharmacists question the appropriateness of a prescription, they may receive responses such as:

- "That is what the doctor ordered."
- "The attending told me to order it that way."
- "The patient (or Mom) says that's how they take it at home."
- "It was published in recent literature (journal reference cited)."
- "This is a special case."
- "The patient's been titrated up to that dose."
- "The patient is on a protocol."
- "The dose is from the patient's old chart."
- "It's on the list of meds the patient gave me."
- "We always give it that way."

Don't allow such responses to dissuade you from performing additional follow up.

You might wish to post this list in the pharmacy (adding any other inappropriate answers to the list when they come up) as a reminder not to allow off-putting responses to keep you from taking that extra step.

When medication orders do not seem quite right, pharmacists, nurses, and physicians must take that "extra step" to verify an order before a medication is prescribed, dispensed, or administered to a patient. In the example cited above, the pharmacist did not just take the word of the physician, nurse, or patient, all of whom said that the prescription was accurate. During orientation of new staff, and continuing education of current staff, we must instill the thought that the "reasons" cited above are unacceptable responses if an order is questioned. Practitioners must have the support of colleagues and management to pursue

questionable medication orders until there is absolute satisfaction that the order is appropriate.

One of the most important methods for preventing medication errors is for organizations to be proactive by seeking and using knowledge from other organizations that have already experienced problems. Additionally, to make a significant impact on error prevention efforts, administrative staff and an interdisciplinary committee at each practice site should review a description of the problem, make recommendations for safe medication practices, and then take the necessary action to minimize errors.

I. Look-alike/sound-alike drug names, ambiguous or look-alike labeling and packaging

* BREVIBLOC (esmolol) premixed infusion bags

Problem: The foil outer-wrap lists the drug's identity on one side only. When the bag is turned over, its appearance is identical to the Baxter dopamine premixed bag, which is also in a foil wrap and labeled on one side only. Further, like certain other Baxter premixed products, the plastic IV bags of Brevibloc are printed in black type with red type for the drug name and strength.

Recommendation: Do not store the premixed product in patient care areas. Use the special medication labels that Baxter includes in the shipping cartons. The premixed solution should be used only if pharmacy dispenses the product for each patient after affixing the special labels to both sides of the plastic bag.

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Let's take...

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* COLAZAL (balsalazide) and CLOZARIL (clozapine)

Problem: Orders for COLAZAL (balsalazide), a drug used to treat mild to moderate ulcerative colitis, could easily be confused with the antipsychotic CLOZARIL (clozapine). Colazal is available as a 750 mg tablet taken three times daily. Clozaril is available in 25 mg and 100 mg tablet strengths, but dosing can range as high as 900 mg a day, which can overlap with the tablet strength of Colazal. Also, orders for Clozaril 75 mg, written improperly with a terminal zero (75.0 mg) increase the chance of a mix-up.

Recommendation: A mix-up between these drugs could be dangerous, making it critical to communicate the medication's purpose on all prescriptions for either drug. We also recommend installing alerts in your computer and

applying auxiliary labels to the drug containers.

* Glass bottles of D5W and premixed nitroglycerin bottles

Problem: An emergency department nurse erroneously hung a bottle of plain D5W instead of premixed nitroglycerin. Both solutions are available from several manufacturers in 500 mL glass bottles. D5W is on hand to prepare admixtures of drugs such as CORDARONE (amiodarone) that are incompatible or less stable in plastic (PVC) bags. While Cordarone use is increasing in the ED and ICU, most glass bottles that nurses handle are premixed nitroglycerin, making it easy to confuse it with D5W.

Recommendation: Educate staff about the potential problem, reinforcing the importance of reading labels. A change in supplier for one of these items would decrease appearance similarities. For the

same reason, purchasing premixed nitroglycerin in 250 mL bottles and D5W in 500 mL bottles would also help. Pharmacy should prepare and send them to patient care areas when possible to ensure an added check.

* ANZEMET (dolasetron mesylate) injection ampuls

Problem: The font size used for the name and strength of the drug on the ampul label was recently decreased by more than half and the color was changed from black on white to a light green on white. These changes make the new label nearly impossible to read. Also, the glass ampul itself has gone from fully scored (easily opened) to a "One Point Cut," which fractures if it isn't opened precisely as instructed.

Recommendations: Abbott Laboratories, who co-markets the drug with Aventis, has asked their sales force

New Pharmacy Self-Assessment Forms on the Way

On September 22, the Board's regulation requiring a biennial self-assessment of California pharmacies by the pharmacist-in-charge was amended to:

- * require a self assessment by the PIC in July of every odd-number year, and
- * within 30 days of a new PIC or the opening of a new pharmacy.

(Formerly the self-assessment was required to be completed in March of every odd-numbered year.)

The Board will soon be mailing to all

California pharmacies the new self-assessment form (the form is dated 1/01). Because the regulation requiring the biennial self-assessment took effect in September but requires the self assessment be completed in July, the Board asks that the PICs complete the 2001 self-assessment form as soon as they can.

During inspections in November and thereafter, the Board will reivew the new form for completion. (Please do not mail completed forms to the Board).

San Diego DEA Telephone Number CORRECTION

In the July issue of *The Script*, DEA telephone numbers were published. Unfortunately, the number for the San Diego office was incorrect. The correct number is (858) 616-4542, and their toll-free number is (800) 284-1152.

Please keep this number with your other DEA numbers.



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to provide customers with information about the proper way to open the ampul. Aventis is promising an improved label. If problems aren't satisfactorily resolved, an alternative 5-HT₃-receptor antagonist might be considered.

*** OCCLUSAL-HP and OCUFLOX (ofloxacin)**

Problem: A physician prescribing via computer chose OCCLUSAL-HP (17% salicylic acid, topical) from an alphabetical product list and sent the prescription to a hospital outpatient pharmacy with directions to "use daily as directed." The patient was being treated for "pinkeye" and the physician intended to select the ophthalmic antibiotic, OCUFLOX (ofloxacin).

Recommendation: It is essential that pharmacists have information about the purpose of each prescription in order to properly advise patients and protect them from potential harm. Patient counseling can also help in detecting errors.

II. Dangerous abbreviations, confusing dose designations, and other unsafe ways of communicating orders

*** Verbal orders confused as dosing range**

Problem: A prescriber's telephone order for XANAX (alprazolam) 0.125 mg prn was misheard by a nurse as "Xanax .1 to 5 mg" and transcribed as a dose range of "Xanax .1 - 5 mg prn."

Recommendation: Use computerized screening of orders to prevent excessive medication doses. Place limitations on verbal orders and be sure staff is aware of this potential problem. When intended, dose ranges should always be associated with specific clinical parameters.

*** Errors due to misinterpreting dangerous dose expressions and abbreviations**

Problem: Misinterpretation of "naked" decimal points and other dangerous dose expressions and abbreviations continue to harm patients. A 9-month-old baby girl died after the baby's physician prescribed morphine ".5 mg IV" and the unit secretary transcribed the order by hand onto a medication administration record (MAR) as "5 mg." An experienced nurse followed the directions on the MAR and gave the baby 5 mg of IV morphine initially and another 5 mg dose two hours later, leading to the fatality.

Recommendation: A link to a table of dangerous abbreviations and dose expressions most often associated with misinterpretation and patient harm (as reported to the USP-ISMP Medication Errors Reporting Program) is available on our web site with the May 2, 2001 issue of this newsletter. Please use this

list to establish and enforce a list of abbreviations and dose expressions that should never be used. The Joint Commission on Accreditation of Healthcare Organizations has agreed to publish an issue of Sentinel Event Alert regarding dangerous abbreviations and dose designations.

III. Other troublesome items

*** Fentanyl transdermal systems:** Prescribers trying to manage patients with acute pain have occasionally recommended fentanyl transdermal systems to opiate-naive patients, which could lead to tragic outcomes. Even when patients are opiate tolerant, incorrect conversion from an oral opiate to fentanyl patches, difficulty titrating doses, combined oral-topical therapy, and variability in absorption have led to opiate overdoses. Dosing should not exceed 25 mcg/hr in opiate-

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Medication Safety Self Assessment Quality Assurance Program

The Institute for Safe Medication Practices (ISMP) provides the nation's community pharmacies with the *ISMP Medication Safety Self Assessment™ for Community/Ambulatory Pharmacies*. This comprehensive tool is designed to help pharmacists, pharmacy technicians, managers, and owners assess the safety of medication practices in their pharmacy, identify opportunities for improvement, and compare their experiences with the aggregate experiences of demographically similar community pharmacies around the nation.

The Board of Pharmacy encourages community/ambulatory pharmacies to participate in this program as part of their ongoing quality improvement activities, and hopes that they will submit their findings anonymously to ISMP so that a national baseline of community pharmacy efforts to enhance medication safety can be established.

Confidentiality is a priority and ISMP has taken all available precautions to protect the data and to assure that your responses cannot be traced to an individual or specific company.

Information about this important program is available at www.ismp.org.

Questions and Answers for Pharmacists about the treatment for Anthrax

by:

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California Poison Control System, UCSF School of Pharmacy

Stuart E. Heard, Pharm.D., Executive Director

Q What is anthrax and how is it transmitted?

A Anthrax is a disease caused by an infection from the spore-forming bacterium *Bacillus anthracis*. It most commonly occurs in animals (sheep, goats, cattle), but can occur in humans if exposed to infected animals or the spores of the bacteria. This has been considered one of the agents or weapons for a bioterrorist attack. Direct contact to the spores through contaminated powders in mail has become the main concern for human infections since the terrorist attacks on the United States. The inhaled form of Anthrax is the most deadly and initial symptoms are similar to having a common cold. Anthrax can also cause a less serious skin infection if abraded or cut skin is exposed to the spores. Fortunately, it takes a dose of at least 8,000 spores to infect a human with inhalation, the disease is not contagious (It is not transmitted from person to person), and is treatable if antibiotics given early after

exposure. Therefore, the people at greatest risk are those who directly handle and inhale contaminated powders.

Q What is the approved treatment for Anthrax?

A Anthrax can be treated by any of three types of antibiotics. These include fluoroquinolones (ciprofloxacin-Cipro®), tetracyclines, and penicillins. Patients who have inhaled the spores must be treated before they have symptoms of the disease for the best prognosis. Ciprofloxacin has been widely publicized for the prevention of pulmonary disease, due in part to the Centers for Disease Control and Prevention recommendations. Consequently, significant public demand for ciprofloxacin has created the potential for depleting pharmacy stocks.

Q Should patients ask their physicians to write a prescription for ciprofloxacin or other antibiotics to treat Anthrax?

A No. The widespread prescribing of these antibiotics could lead to the development of drug-resistant bacteria and reduce the effectiveness of these antibiotics to treat other serious infections. Considering that the recommended duration of Anthrax prophylaxis is 60 days, this potential for development of resistance is great. In addition, the antibiotics used to treat Anthrax may be associated with serious side effects and significant drug interactions.

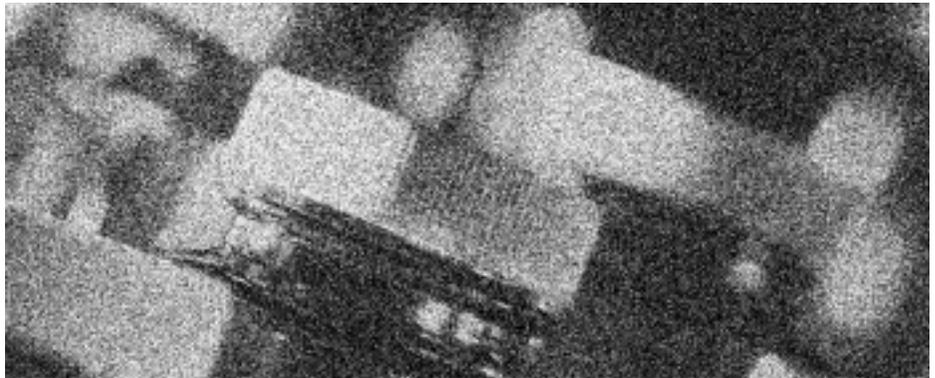
Q If we have a major attack with Anthrax, how can we obtain enough antibiotics to respond?

A The government has created the National Pharmaceutical Stockpile Program. They can ship large stockpiles of antibiotics to any area of the country within 12 hours following notification of an attack.

Q Where can I get more information on Bioterrorism?

A There are several local, state and federal governmental agencies and other private groups that provide updated information on the internet. Two useful links for pharmacists include:

www.bt.cdc.gov (The CDC Bioterrorism Preparedness and Response Program—includes link to the National Pharmaceutical Stockpile Program and the Health Alert Network that serves as an early warning system and share guidelines on how to respond to a threat—e.g., receiving a suspicious package or unknown powder) and www.hopkins-biodefense.org (The Johns Hopkins University Center for Civilian Biodefense Studies—includes link to the *JAMA* Consensus Statements on Medical Management of bioterrorism agents).



Pharmacists' Care

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- * Adjusting the dosages, forms, or combinations of drugs for patients with complex drug therapies to maximize the benefit and reduce undesirable side-effects of drug therapy;
- * Reviewing the medications prescribed for a patient to identify drugs that duplicate effects, cause dangerous interaction effects, and/or eliminating unnecessary drugs;
- * Educating patients about how, when, and under what circumstances (with food, without food, etc.) to take their drugs; and
- * Conducting compliance programs to ensure that patients adhere to the drug regimen that has been prescribed.

Asthma, high blood pressure, diabetes, AIDS, and pain are examples of chronic conditions with complex drug therapy for which clinical pharmacists provide services.

AB 826 becomes effective January 1, 2002, and the exact language of the new law will be published in the January 2002 issue of *The Script*.

Drug Expiration Dates Revisited

The Board received many inquires and requests for clarification of the July issue of *The Script* article on drug expiration dates. The following information is taken directly from the Fourth Supplement, USP 24-NF 19:

...The expiration date limits the time during which the article may be dispensed or used. Where an expiration date is stated only in terms of the month and the year, it is a representation that the intended expiration date is the last day of the stated month. The beyond-use date is the date after which an article must not be used. The dispenser shall place on the label of the prescription container a suitable beyond-use date to limit the patient's use of the article based on any information supplied by the manufacturer and the *General Notices and Requirements* of this pharmacopeia. The beyond-use date placed on the label shall not be later than the expiration date on the manufacturer's container.

...For nonsterile solid and liquid dosage forms that are packaged in single-unit and unit-dose containers, the beyond-use date shall be one year or less, unless stability data or the manufacturer's labeling indicates otherwise. For all other types of nonsterile dosage forms, the beyond-use date is one year or the time remaining of the expiration date, whichever is less.



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.

Occasionally, our answers to your questions generate more questions and require subsequent clarification. One of those dealt with the question:

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?

A The answer to that question is: No. Only pharmacists are permitted to transfer prescriptions from one pharmacy to another. Unfortunately, in the July issue of *The Script*, the editor also added that procedures in the references cited did not include "faxing a copy of the computer label to the receiving pharmacy." If you checked out all those references, you noted that none of them say that you can fax a label to the receiving pharmacy, nor does it say you cannot. So the answer given in the July newsletter should not be interpreted as meaning that you cannot fax the label to the receiving pharmacy. If you do fax a label, remember that the label must be in compliance with all the requirements of CCR 1717(f).

Another question In the July 2001 issue of *The Script* that provoked additional information was:

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

A In addition to our previous answer, we'd like to include the following information related to **controlled substances**. Title 21 of the Code of Federal Regulations Part 1307.21 directs anyone wishing to dispose of controlled substances to request assistance from the nearest DEA Special Agent in Charge. While the previous article listed the only DEA-approved California reverse distributor, your DEA agent can provide an extensive list of out-of-state companies that may be contacted for pharmaceutical waste disposal.

Q Is it still a requirement that the physician MUST hand-write all Schedule III, IV and V prescriptions?

A Please refer to the January 2001 issue of *The Script*, page 8. There you will find a chart indicating the items to be handwritten by the prescriber of a Schedule III or IV prescription:

- * The date
- * Prescriber's signature
- * Patient's name
- * Drug's name, quantity
- * Quantity and directions for use

Schedule V prescriptions require that only the prescriber's signature and the date be hand-written (Health & Safety Code 11164[b]).

Q Can a pharmacist fill a Schedule III-V prescription that was faxed to the pharmacy from a doctor's office?

A Yes, and the fax must contain a telephone number with which to verify that the prescription came from the prescriber (Business & Professions Code 4040[c]).

Q Is it a California requirement to record the DEA number of the pharmacy transferring a prescription for a non-controlled drug?

A No. California regulations (California Code of Regulations 1717[f]) do not require the recording of DEA registration numbers when transferring prescriptions for non-controlled drugs nor do federal regulations.

Recording the DEA numbers of both the transferring and receiving pharmacy is required when transferring Schedules III, IV, and V prescriptions (21 CFR 1306.25[a][1][ii] and [b][v]).

Regulation Update

Q Can physicians prescribe drugs, including controlled substances, for themselves or their family members, and are those prescriptions restricted by the physician's scope of practice?

A A physician **cannot** write a controlled substance prescription for himself (H&SC 11170). He or she must refer to another physician for CS prescriptions and should refer to another physician for other dangerous drug prescriptions. The other physician would be responsible for the prescription record keeping.

A physician can write prescriptions for family members **only** if there is a physician/patient relationship, if the prescription is for a legitimate medical purpose, a good faith examination performed, and appropriate records kept. Additionally, prescriptions always must be within the prescriber's scope of practice.

However, in cases where a physician prescribes a controlled substance for a family member in an emergency situation, the prescription should be for no more than just enough to last until the family member is able to see his or her regular physician for subsequent care.

Always refer to the Standard of Practice, and your own professional judgment.

This article contains additions to Division 17, Title 16, of the California Code of Regulations. For your convenience, these regulations can be cut out and saved until their publication in the next issue of the Pharmacy Law.

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

(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in (a), the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

- (1) A new pharmacy permit has been issued, or
- (2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.

(c) The components of this assessment shall be on Form 171-29 (Rev 1/01) entitled "Community Pharmacy and Practice Self-Assessment (Including Hospital Pharmacy That Dispenses Prescriptions)" or Form 171-30 (Rev 1/01) entitled "Hospital Inpatient Pharmacy and Practice Self-Assessment" which are hereby incorporated by reference to evaluate compliance with federal and state laws and regulations regarding: facility condition and security, drug stock, posting of certificates and notices,

pharmacist-in-charge obligations, intern pharmacist activities, pharmacy technician activities, general pharmacy practice, corresponding responsibility for filling controlled substances provisions, prescription labeling and dispensing, refill authorization, prescription transfers, confidentiality of prescriptions, record keeping requirements for all dangerous drugs, record keeping requirements for controlled substances, automated dispensing devices, repackaging for use by the pharmacy, compounding unapproved drugs for future use or prescriber office use, electronic transmission of prescriptions.

(d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed.

1717.3. Preprinted, Multiple Checkoff Prescription Blanks

(a) No person shall dispense a controlled substance pursuant to a preprinted, multiple checkoff prescription blank.

(b) A person may dispense a dangerous drug, that is not a controlled substance, pursuant to a preprinted, multiple checkoff prescription blank and may dispense more than one dangerous drug, that is not a controlled substance, pursuant to such a blank if the prescriber has indicated on the blank the number of dangerous drugs he or she has prescribed.

(c) "Preprinted, multiple checkoff prescription blank," as used in this section means any form listing more than one dangerous drug where the intent is that a mark next to the name of a drug i.e., a "checkoff," indicates a prescription order for that drug.

Let's take...

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naive patients. Fentanyl patches are best reserved for opiate-tolerant patients with chronic pain. Base the initial dose on the total daily dose, route, potency, and characteristics of the drug the patient has been taking previously, narcotic tolerance, and the patient's general condition. New prescriptions should be accompanied by a dose calculation sheet and verified by a pharmacist.

* **Bowel prep drugs pose problems in renal patients:**

Serious consequences to renal patients may go unrecognized when doses for some bowel preparations are too high. Fleet products such as Fleet enemas and Fleet Phosphosoda contain more than 160 mM of phosphate per dose. Magnesium, in magnesium citrate solution and milk of magnesia, can accumulate in a patient with renal dysfunction. These items often are maintained in floor stock and treated with impunity. Special precautions are needed to alert nurses to contraindications for renal patients. Information on electrolyte content of each product should be listed clearly on floor stock items along with a warning that the product may cause problems for patients with renal impairment. Restricted access may be necessary to limit removal of doses from automated dispensing systems prior to a pharmacist's clinical review of the order. During order entry, computer systems should warn practitioners about electrolyte content when these agents are about to be used for patients with decreased renal function.

* **Errors of Omission:** Medication errors are hard to detect, but some that occur during the prescribing phase may be especially elusive and elicit controversy as to whether they are truly an error or an acceptable difference in professional judgment.

Errors of omission are less obvious when prescribers fail to order medications for which there are evidence-based studies documenting significant reduction in morbidity or mortality. Pharmacists can play a pivotal role in the application of evidence-based knowledge by actively reviewing applicable research, disseminating the information to the medical staff, and establishing clinical monitoring functions for selected outcomes. Daily pharmacists' interactions with prescribers (for inpatients) should be face-to-face to assist in the selection of appropriate drug therapy, including those prescribed at discharge. Pharmacists should document interventions and share aggregate results with prescribers to generate ideas for improvement.

Safety Briefs

* There is a developing nomenclature issue with LANTUS (insulin glargine [rDNA origin]) a new insulin product approved for use in both type 1 and type 2 diabetes mellitus. Lantus was approved last year but was marketed in May of this year by Aventis. Lantus is administered subcutaneously once daily at bedtime. Unlike other insulins, it maintains a relatively constant blood level over 24 hours with no pronounced peak. In ISMP's May 3, 2000 issue, they expressed concern that oral or written orders for Lantus may be mistaken as "Lente" insulin, which has a more rapid effect and shorter duration of activity. Last week ISMP received its first error report. A diabetes educator suggested Lantus as a good alternative for a difficult-to-control diabetic patient. The primary physician, unfamiliar with Lantus, prescribed Lente insulin instead. The patient was not harmed. A special advisory to prescribers should be considered.

* Wrong time errors are also possible

as Lantus is given at bedtime, not in the morning like other insulins. If the drug is simply ordered "daily," those administering the drug may assume it should be given in the morning. Keep in mind too that prescribers have been known to designate the type of insulin by using the associated one-letter-abbreviation currently appearing on insulin vials. For example, 16 units of Lente insulin is sometimes written as "L - 16 units." Since Lantus also begins with an "L," it's possible that mix-ups with Lente insulin may occur in this way. One hospital has decided to place stickers on the Lantus vial to warn nurses about the differences.

* ISMP first reported the potential for confusion between SERZONE (nefazodone), an antidepressant, and SEROQUEL (quetiapine), used for psychotic disorders, in their November 5, 1997 issue. Since then, reporters have informed USP and ISMP of 17 actual errors where a patient received one drug for the other. There are several confounding similarities. The names look quite similar when poorly handwritten. They have the same SER- prefix, so the drugs may be stored near one another or appear together on a computer monitor during order entry. Both drugs share 100 mg and 200 mg strengths and both are packaged in containers holding 60 tablets. Also, both are used in mental health, and have dose ranges and administration frequencies that often overlap. There are some reports of sedation or dizziness when Seroquel was dispensed instead of Serzone and decompensation of mental status when Serzone was given instead of Seroquel.

Further, there are many potentially dangerous drug interactions with Serzone. There are reports of serious, sometimes fatal, reactions when patients receiving monoamine oxidase inhibitors are given drugs with pharmacologic

properties similar to nefazodone. In vitro, nefazodone inhibits the cytochrome P450 3A4 isoenzyme and increases in plasma concentrations have been seen with co-administered drugs metabolized by this enzyme. If either of these drugs is used or may be used in the future at your practice site, we recommend that you take steps to prevent the possibility of medication errors. This can be achieved by educating staff and patients, adjustments in drug storage and computer mnemonics, use of reminders in the computer system and name alerts affixed to drug containers.

* *Hospital Pharmacy* included an article that demonstrates vincristine sulfate stability when diluted in the range of 20-50 mL and packaged in plastic syringes or IV bags (Trissel et al. *Hosp Pharm* 2001;36:740-5). Hopefully this will serve as a deterrent to inadvertent intrathecal injection since intrathecal doses of drugs are usually prepared in volumes less than 10 mL.

* In ISMP's July 28, 1999 and July 26, 2000 issues, they cautioned that poorly handwritten orders for AVANDIA (rosiglitazone maleate), an antidiabetic agent, can look like COUMADIN (warfarin). The opposite mix-up also could occur. Graphics of the misread prescriptions appear in ISMP's website at www.ismp.org. Although it is difficult to imagine that the two names might look alike when handwritten, the graphics make the possibility of confusion very clear. Complicating the issue is that both are available in 2 mg and 4 mg strengths, both are tablets, and, with either drug, patients are usually directed to take one tablet daily. These similarities increase the likelihood that patients will experience a dangerous mix-up. In a case just reported by a consumer given Coumadin by mistake, a severe intestinal bleeding episode resulted, requiring bowel resection. Since

accidental administration of either drug could pose a great danger to any patient, physicians, nurses, pharmacists and patients must be alerted to the possibility of medication errors. Prescribers should always include the medication's purpose on prescriptions and pharmacists and nurses should clarify the drug's purpose prior to dispensing and administration. We also recommend that reminders be added to pharmacy containers and computer system alerts. FDA and the manufacturers are aware of the problem.

* ISMP has been given a "heads up" to look at current procedures for securing needle disposal boxes in patient care areas. According to a reporter, there have been several arrests made in the Kansas City, KS area involving suspects stealing entire boxes of used syringes. One suspect had more than 100 boxes from which he'd been extracting leftover opiates. More than 10 hospitals have been involved.

Report medication errors to the USP Medication Errors Reporting Program (USP MERP). Call 1-800-23 ERROR (233 7767).

Unless otherwise indicated, error reports referenced in this publication were received through the USP MERP, operated in cooperation with ISMP.

*E-MAIL: ismpinfo@ismp.org.
www.ismp.org. HOTLINE: 1-800 FAIL SAFE (324 5723).*

Preceptors, be careful when completing Intern Hours Affidavits!

Increasingly, interns attempting to become licensed as pharmacists are faced with charges of unlicensed activity because their preceptors enter the wrong beginning dates on the intern's hours affidavit indicating that the intern was working **before** his/her permit was issued. The resolution of such problems delays the intern's registration as a pharmacist, frustrating both the intern and the employer waiting to hire him or her. Pharmacists who act as preceptors must review the issue dates on each intern's permit, and must not allow them to work as an intern before that date.

The bottom line is all licenses and registrations must be carefully checked for issue dates before hiring. Performing the duties of a pharmacist, a pharmacy intern, or a pharmacy technician before a license or registration is issued or after it has expired constitutes unlicensed activity and may be subject to disciplinary action by the Board.

C.U.R.E.S. Update

Schedule II Reporting Procedure

Be sure that you are using the correct California Board of Pharmacy license number for your pharmacy when transmitting Schedule II controlled substance triplicate prescription information to Atlantic Associates. If your pharmacy has changed its license number due to a change of location or ownership since the Controlled Utilization Review and Evaluation System (C.U.R.E.S.) was implemented in 1998, please update your software to reflect the new license number. The correct license number is essential for accurate reporting.

Disciplinary Actions by the Board

CAUTION: The California Board of Pharmacy has approximately 63,000 registered individuals: pharmacists, pharmacy interns, pharmacy technicians, and exemptees?some of whom share the same names. All disciplinary action information is taken from court documents which 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

ZINA FRAYMAN (Non-licensed pharmacy owner), Mission Hills, CA and SHELL PHARMACY, PHY 41869, Van Nuys, CA and LANARK PHARMACY, PHY 41260, Van Nuys, CA

Violation: For purposes of settlement only, respondents admitted to failing to maintain all records for inspection and a complete, current and accurate inventory of dangerous drugs; remaining closed for over 120 days; and failing to report a

change of ownership to the Board.

Action: Both licenses revoked; prior to reinstatement of revoked permit or as a precondition for issuance of any permit related to Ms. Frayman, costs of \$12,000 must be paid in full.

Effective: March 28, 2000

FRANK A. LEVANT, RPH 15637, Los Angeles, CA

Violation: No admissions or findings of liability.

Action: Public reproof; payment of \$500 in costs.

Effective: September 21, 2000

MARCEL DIENNET, President (Unlicensed) and THE DIENNET PHARMACY, PHY 41054, Beverly Hills, CA

Violation: Being convicted of a crime substantially related to the practice of pharmacy (unlawful importing of controlled substances).

Action: Revoked, stayed; three years'

probation; no new ownership; payment of \$4,500 in costs.

Effective: December 15, 2000

ATOOR SAMO, RPH 38900, Arroyo Grande, CA

Violation: Respondent contested the charges and allegations contained in the accusation but stipulated that, if proven, said charges and allegations would be cause for discipline against the license.

Action: Public reprimand.

Effective: December 15, 2000

ROBERT JOHN KELLY, RPH 29622, Huntington Beach, CA and R.J.'S PHARMACY, PHY 38185, Costa Mesa, CA

Violation: For purposes of settlement only, respondent admitted that an audit of the pharmacy proved that excessive amounts of controlled substances were dispensed to a single patient and overages of dangerous drugs found; failed to maintain accurate acquisition and disposition records; numerous prescription errors; filled illegitimate prescriptions, some of which were altered or photocopied.

Action: RPH—Revoked, stayed; three years' probation; 60 days' suspension payment of \$16,000 in costs. PHY—Revoked.

Effective: February 11, 2001

PALM DRIVE HOSPITAL PHARMACY, HSP 41951, Sebastopol, CA

Violation: For purposes of settlement only, respondent admitted that the complainant could establish a factual basis for the charges in the accusation and gave up its right to contest the charges; failing to accurately account for all controlled substances and to maintain effective controls against theft and diversion of dangerous drugs and controlled substances.

Action: Public reprimand; payment of \$3,500 in costs.

Effective: February 11, 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, 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 revocation that was stayed.

3. **Stipulation** indicates that the case is negotiated and 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 commences the administrative procedure for denial of licensure to an applicant.

7. **Letter of Reprimand (or Reproof)** is a public document reproofing 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.

**EMILIE JOAN PAPPAS, RPH 30224,
Santa Rosa, CA**

Violation: For purposes of settlement only, respondent agreed that at a hearing the complainant could establish a factual basis for the charges in the accusation and gave up her right to contest the charges; failing to accurately account for all controlled substances and to maintain effective controls against theft and diversion of dangerous drugs and controlled substances.

Action: Public reprimand.

Effective: February 11, 2001

TECHNICIANS**POLINA BRAILOVSHAIA,
TCH 20757, Los Angeles, CA**

Violation: Being convicted of a crime substantially related to the qualifications of a technician (mail fraud).

Action: Revoked; payment of \$4,000 in costs; cannot petition for reinstatement for three years and until costs are paid in full.

Effective: December 4, 1999

**DONNA VIRGINIA BARKLEY,
TCH 17775, Lucerne Valley, CA**

Violation: Being convicted of a crime substantially related to the qualifications, duties, and function of a pharmacy technician (Self use and possession of controlled substances).

Action: Revoked.

Effective: October 22, 2000

**MICHAEL JEFFREY BORN,
TCH 6929, Foster City, CA**

Violation: Admitting to multiple convictions for crimes substantially related to the qualifications, duties, and function of a pharmacy technician (DUI).

Action: Revoked, stayed; three years' probation; suspended until certified by the Pharmacy Technician Certification Board; payment of \$1,600 in costs.

Effective: December 15, 2000

**CHRISTOPHER J. RADTKE,
TCH 5370, Petaluma, CA**

Violation: Diverting large quantities of dangerous drugs and controlled substances from the pharmacy where he was employed for his own use and for his wife, without prescriptions.

Action: Revoked.

Effective: February 11, 2001

STATEMENT OF ISSUES**FABBIA DASARO, (Pharmacy
technician applicant), San Pedro,
CA**

Violation: Being convicted of a crime substantially related to the qualifications, duties, and function of a pharmacy technician.

Action: Application denied.

Effective: February 11, 2001

Help is Waiting: Make the Call!

If you have a problem with drugs, alcohol or mental illness, or live or work with a pharmacist who does, call the Pharmacists Recovery Program toll-free at **(800) 522-9198**. The purpose of the PRP is to identify and evaluate the nature and severity of the chemical dependency and/or mental illness, develop a treatment plan contract, monitor participation and provide encouragement and support. In the quickest, least stressful manner possible, the individual receives the proper help to face the problem, deal with it and, if possible, return to the profession as a contributing member.

The California Board of Pharmacy contracts with Managed Health Network, Inc. to provide assessment, referral, and monitoring services for the Pharmacists Recovery Program. The MHN has a network of professionals throughout California who specialize in the treatment of alcohol or other drug abuse and mental illness problems.

The program serves two purposes: (1) as a diversion program to which the Board may refer licensees, where appropriate, instead of, or in addition to, other means of disciplinary action, and (2) as a "confidential source of treatment for pharmacists who, on a strictly voluntary basis and without knowledge of the Board, desire to avail themselves of its services." (Business & Professions Code 4362) Additional information regarding this program can be found in B&PC 4370.

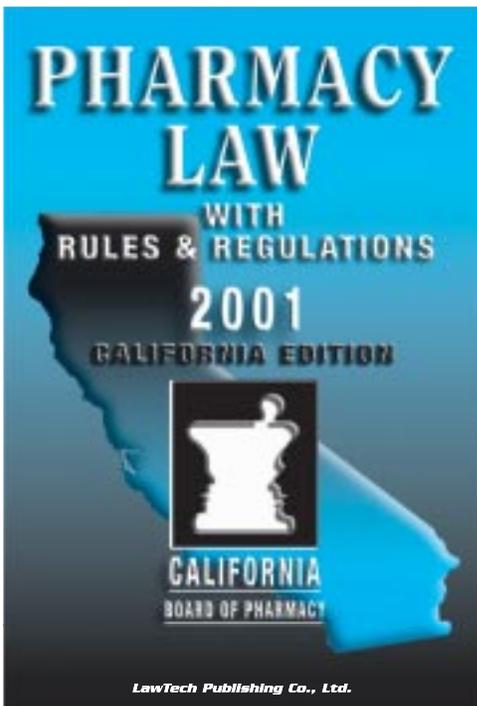
Calls to the PRP for information are confidential. So make that call! Help is waiting!

Disciplinary Guidelines Revised

The Board of Pharmacy has revised its Disciplinary Guidelines, and the updated version will be added to the Board's website, www.pharmacy.ca.gov. These guidelines are to be followed in Board of Pharmacy discipline actions and become effective November 3, 2001.

The guidelines define and explain disciplinary language and categories and are produced for those involved in and affected by the disciplinary process: the general public, attorneys from the Office of the Attorney General and the Office of Administrative Hearings.

www.pharmacy.ca.gov



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CHANGE OF ADDRESS FORM
Please fax to (916) 327-6308, or 322-3561, 323-5743
Or mail to the California State Board of Pharmacy at the above address.

Please Print Clearly

| | |
|---|-------------------|
| Licensee Name: | |
| License, Permit, or Registration Number (Please include prefix - RPH, INT, TCH) | |
| Present address of record: <hr style="border: 0; border-top: 1px solid black; margin: 10px 0;"/> <hr style="border: 0; border-top: 1px solid black; margin: 10px 0;"/> | |
| Please change my address of record to: (May be post office box, personal mail box, business address, etc.). This address is accessible to the public via written request. All Board mailings—license renewal applications, license renewals, newsletters, notices, etc.—will go to this address. <hr style="border: 0; border-top: 1px solid black; margin: 10px 0;"/> <hr style="border: 0; border-top: 1px solid black; margin: 10px 0;"/> | |
| Confidential residence street address (must be listed if the address of record is not your residence address): <hr style="border: 0; border-top: 1px solid black; margin: 10px 0;"/> <hr style="border: 0; border-top: 1px solid black; margin: 10px 0;"/> | |
| Social Security Number (for purposes of identification only) | Telephone number: |
| Signature of licensee: | Date: |

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Pharmacy Board meetings are open to the public...

... and the Board encourages all interested parties to attend. The first meeting date and site for 2002 is:

January 23–24, 2002
Furama Hotel
8601 Lincoln Boulevard
Los Angeles, California
(310) 670-8111

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