September 2012

News

Wyoming State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

Wyoming State Board of Pharmacy • 1712 Carey Ave, Suite 200 • Cheyenne, WY 82002
http://pharmacyboard.state.wy.us

Faxing of Scheduled Prescriptions

Prescriptions for Schedules III, IV, and V controlled substances may be transmitted by fax (Chapter 2, Section 20, Rules and Regulations, Wyoming Pharmacy Act). The prescriber must sign the controlled substance prescription "in the same manner as the practitioner would sign a check or legal document. The use of electronic or digital signatures or signature stamps are not allowed, unless electronic prescriptions are used . . ." (Chapter 6, Section 5, Rules and Regulations, Wyoming Controlled Substances Act). A pharmacist can contact the prescriber and document the validity of the prescription, thus making it an "oral prescription" if the prescriber uses an electronic signature. Several prescribing software and dispensing software systems have been accredited for electronic (computer-to-computer) transmission under the new federal and state regulations. Contact your software company to determine if accreditation for electronic prescriptions for controlled substances is in process. Prescribers may need to be reminded that tramadol is a Schedule IV controlled substance in Wyoming.

Are Prescription Refills Allowed When the Prescriber Has Moved Away?

Chapter 2, Section 14, Rules and Regulations, Wyoming Pharmacy Act states:

> Upon learning that a patient/practitioner relationship has been terminated for reasons other than discharge of the patient by the practitioner, a pharmacist utilizing his/her professional judgment may honor a patient's request for remaining medication refills, for a period not exceeding twelve (12) months.

The key is to keep the best interest of the patient in mind and determine if he or she needs to be referred immediately to another practitioner.

Rules Revision Clarification from 2011: Chapter 7 (Computer Regulations) Repealed

At the June 2012 Wyoming State Board of Pharmacy meeting, the members discussed the regulation from the repealed chapter that required a log book or file with the pharmacist "attesting to the fact that the prescription information entered into the computer that day has been reviewed and is correct . . ." and a printout of each day's prescription information that was to be signed and dated. The Board members agreed that this regulation is outdated and does **not** need to be done.

Technician Licensing in Wyoming

The Board inspectors continue to find unlicensed technicians working in Wyoming pharmacies. When a technician-in-training has passed the Pharmacy Technician Certification Exam (PTCE) he or she must apply to be a registered pharmacy technician before the technician-in-training permit expires. This can take four to eight weeks depending on receipt of the background check, as well as review of other documents. Passing the PTCE is necessary to become licensed as a pharmacy technician but **certification by the Pharmacy Technician Certification Board (PTCB) is not a license.** The following is the current process for technician licensure:

Technician-in-Training Permit: Chapter 10, Section 9, Rules, Wyoming Pharmacy Act

- Request a packet and apply within 10 calendar days of starting on-the-job training
- Permit will be issued within two weeks of review in the Board office (usually)
- Permit is valid for two years, non-renewable
- Sponsoring pharmacy is location specific; if changed, the permit must be revised using the transfer form from the Board office
- No compounding by a technician-in-training is allowed
- Wear a name badge that reads "Pharmacy Technician-in-Training" in pharmacy areas
- Answer the telephone as "Pharmacy Technician-in-Training" while on duty
- Post the permit in the pharmacy
- Pharmacists and pharmacy technicians "shall participate in training"

Pharmacy Technician Registration: Chapter 10, Section 10, Rules, Wyoming Pharmacy Act

- Request an application packet including fingerprint cards to be mailed to applicant
- Provide current certification of the PTCB
- Wear a name badge that reads "Pharmacy Technician" in pharmacy areas
- Answer the telephone as "Pharmacy Technician" while on duty
- Complete six hours of continuing education annually
- Notify the Board of changes in employment or mailing address within 30 days
- Perform compounding after competency is certified by the pharmacist-in-charge (PIC)
- Renew license annually by December 31

PIC Responsibilities for Pharmacy Technicians and Technicians-in-Training

- Ensure that permits and licenses are current and posted
- Ensure that only a pharmacist or intern receives a new verbal prescription

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FDA Warned Medical Practices About Counterfeits in US and Risks to Patients

In April 2012, Food and Drug Administration (FDA) sent letters to medical practices in several states requesting that they stop administering drugs purchased from any foreign or unlicensed source. FDA's letters were sent in response to the discovery that the medical practices purchased medications from foreign or unlicensed suppliers that sold illegal prescription medications. FDA has advised that these medical practices are putting patients at risk of exposure to medications that may be counterfeit, contaminated, improperly stored and transported, ineffective, and dangerous.

In an FDA statement, the agency urges the health care community "to examine their purchasing practices to ensure that they buy directly from the manufacturer or from licensed wholesale drug distributors in the United States." Further, FDA reminds health care providers, pharmacies, and wholesalers/distributors that they are valuable partners in protecting consumers from the threat of unsafe or ineffective products that may be stolen, counterfeit, contaminated, or improperly stored and transported. FDA advises that the receipt of suspicious or unsolicited offers from unknown suppliers should be questioned, and extra caution should be taken when considering such offers.

FDA notes that the "Verify Wholesale Drug Distributor Licenses" FDA Web page, available at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm,* may be used to verify that a wholesale drug distributor is licensed in the state(s) where it is conducting business.

The FDA warning letters were sent following two incidences of counterfeit injectable cancer drugs found in US medical practices, one in February 2012, involving counterfeit Avastin® 400 mg/16 mL, and another in April 2012, involving a counterfeit version of Roche's Altuzan® 400 mg/16 ml (bevacizumab).

More information and a list of the medical practices that were sent warning letters are available on the FDA Web site at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm299920.htm.*

Rethink the Vial

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

Recently, ISMP has been receiving many reports from consumers who report the pharmacy "shorted them" on a variety of opioid prescriptions. They report that when they call the pharmacy to complain about the missing number of tablets or capsules the pharmacy staff insists the proper quantity was dispensed. ISMP also receives reports from pharmacists reporting this same situation. The concern is that pharmacy personnel may be diverting the medication, the patient may be seeking more medication than what was prescribed, or some of the medication may be taken by someone else in the patient's home.

In the US, we dispense almost all oral solid drugs as loose tablets or capsules in a plastic vial that is labeled for the patient. This manner of dispensing makes diversion of a few tablets or capsules relatively easy. However, in many other countries, unit-dose and unit-of-use packaging is widely used.

It seems to reason that if unit-of-use, manufacturer-sealed containers or individual unit-dose packages of medications were used in the US for these drugs, diversion and/or speculation of diversion could be reduced. Manufacturers could produce unit-dose or unit-of-use packages, in numbered strips for ease of inventory and dispensing. Patients could be asked to sign for and agree to the amount dispensed at the point-of-sale. The numbered packaging would also help patients at home know if they had taken their medication or possibly alert them to diversion within their home. Of course, prescribers would need to prescribe quantities available in patient compliance packs or in multiples of that packaging, and insurance companies would have to pay for this specialized packaging.

Unit-of-use packs would provide other safety benefits. For example, patients would be able to verify the drug name on the label for each dose, which would add a redundancy in checking the pharmacy label to what was actually dispensed. Also, the manufacturer could print and attach the patient information sheet and/or medication guide to the package the patient receives, eliminating extra work in the pharmacy to print and supply these mandated education sheets to the patient.

It is evident that further steps must be taken to reduce and minimize abuse of prescription drugs. It is critical that education be provided to patients, caregivers, and health care providers to increase awareness about the dangers of prescription drug abuse and about ways to appropriately prescribe, dispense, store, and dispose of prescription medications. Development and deployment of consumer-friendly and environmentally responsible prescription drug disposal programs may also help to limit diversion (as well as reduce the risk of accidental ingestion) of drugs by family members and friends. FDA must continue its efforts to require new concepts for risk evaluation and mitigation strategies and provider education for opioid drugs. For more information on understanding prescription drug abuse, and to request *Parents' Guide to Understanding Prescription Drug Abuse* brochures for distribution to your patients, visit *www.SafeguardMyMeds.org.*

Counterfeit Vicodin ES Sold Via Rogue Internet Drug Outlet, Abbott Reports

In March 2012, Abbott warned consumers and health care providers about counterfeit Vicodin® ES purchased via the Internet. Abbott reports that the counterfeit product drug and package do not match that of Abbott's FDA-approved Vicodin ES (hydrocodone bitartrate and acetaminophen). Descriptions and images of the counterfeit product and authentic Vicodin ES are shown in a consumer alert posted on the Abbott Web site at *www.abbott.com/vicodin-consumer-alert.htm.* Abbott advises that anyone who has the counterfeit ver-

sion should stop taking the product. Further, consumers who suspect a product to be counterfeit or have questions about the legitimacy of Vicodin ES are encouraged to make a report to FDA Office of Criminal Investigations (OCI) by calling 800/551-3989 or by completing the online form on the OCI Web site at *www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm.*

PSM LEADER's Guide Offers Tips for Protecting Patients from Counterfeits

The Partnership for Safe Medicines (PSM) released a guide to assist health care providers in protecting patients from counterfeit drugs and recognizing the signs that may indicate use of counterfeits. Three versions of the *LEADER's Guide* – including one for nurses, one for doctors, and another specific to pharmacists – are available for download from the PSM Web site at *www.safemedicines.org/resources-for-healthcare-professionals.html*. Each guide provides tips specific to these health care provider roles and includes guidance for safe sourcing of medications, evaluating suspect medications, educating patients about counterfeit drugs and the risks of ordering drugs online, and reporting suspected counterfeit drugs.

FDA Urges Providers to Help Prevent Children's Accidental Exposure to Fentanyl Patches

FDA issued a safety alert reminding patients, caregivers, and health care providers to appropriately store, use, and dispose of fentanyl patches to prevent children's accidental exposure to the medication, which is potentially life-threatening. FDA recently evaluated a series of 26 cases of pediatric accidental exposures to fentanyl patches reported over the past 15 years, and determined that 10 of the cases resulted in death, and 12 in hospitalization. In addition, 16 of the 26 cases occurred in children two years old or younger.

FDA warns that young children may be at risk for accidental exposure when fentanyl patches are discarded in trash receptacles, or when children find lost or improperly stored patches. Young children can be harmed when they place the patches in their mouths or stick the patches to their skin. In addition, young children are at risk of exposure when being held by someone wearing a partially detached patch that can then transfer to the child. Exposure of young children to a fentanyl patch can lead to serious adverse events and even death, due to the amount of fentanyl present in the patches. FDA stresses that harm can even occur with used patches because they may still contain a considerable amount of fentanyl.

To prevent accidental exposure, FDA advises that patients securely store needed fentanyl patches out of children's reach and sight. When applying a patch, FDA also recommends that patients consider covering the fentanyl patch with an adhesive film to make sure the patch does not come off. Finally, FDA recommends checking throughout the day to make sure that the patch is still in place.

Further, FDA advises that used or unneeded patches are properly disposed. FDA recommends that the adhesive side of the patch should be folded together and then the patch should be flushed down the toilet. FDA notes that the agency "recognizes that there are environmental concerns about flushing medicines down the toilet. However, FDA believes that the risk associated with accidental exposure to this strong narcotic medicine outweighs any potential risk associated with disposal by flushing. When the patches are no longer needed, disposing by flushing completely eliminates the risk of harm to people in the home."

FDA urges health care providers to educate patients and their caregivers about the appropriate use and disposal of fentanyl patches. FDA's consumer Web page provides detailed information for patients and caregivers and is available at *www.fda.gov/ForConsumers/ConsumerUpdates/ucm300803.htm.* Providers, patients, and caregivers are also encouraged to review the fentanyl patch product label for instructions. The FDA safety alert is available at *www.fda.gov/Drugs/DrugSafety/ucm300747.htm.* Additional consumer information about safe medication use and storage, and the importance of proper disposal of unneeded medications, is available on the AWAR$_X$E® Web site at *www.awarerx.org/informedSiteMap.php.*

Providers Asked to Advise Patients of Acetaminophen Safe Use Steps

With a world of conditions and hundreds of medicines, the Acetaminophen Awareness Coalition asks pharmacists and other health care providers to educate patients and caregivers about the proper use of medications containing acetaminophen. As the most common drug ingredient in America, acetaminophen can be found in over 600 medicines, including many prescription and over-the-counter medicines. The coalition notes that when used as directed, acetaminophen is safe and effective. The coalition asks providers to advise patients that there is a daily dosage limit for acetaminophen and that taking more than directed is an overdose and can lead to liver damage.

The coalition calls on health care providers to participate in the Know Your Dose campaign, by reminding all patients and caregivers to (1) always read and follow the labels on their medicines; (2) know if a medicine contains acetaminophen; and (3) never take or administer two medicines that contain acetaminophen at the same time. Additional medication safety tips for consumers and more information about the Know Your Dose campaign are available on the "OTC Medication Use" page of the AWAR$_X$E Web site at *www.awarerx.org/OTCMedUse.php.* The AWAR$_X$E consumer protection program and the National Association of Boards of Pharmacy® (NABP®) are part of the Acetaminophen Awareness Coalition.

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- Ensure that only pharmacists or interns obtain any needed clarifications
- Ensure that only pharmacists or interns perform "Prospective Drug Review" (Chapter 9)
- Ensure that only pharmacists or interns perform consultations with prescribers or staff
- Ensure that only pharmacists or interns make the offer to counsel and perform counseling
- Ensure that no prescription product leaves the pharmacy until a pharmacist is present and authorizes the release
- Ensure that a retail pharmacy may not remain open when no supervising pharmacist is in the building
- Ensure that the ratio of pharmacy technicians and technicians-in-training to pharmacists is no more than three to one
- Certify competency of all staff, including compounding

Wyoming Statute 33-24-101 of the Wyoming Pharmacy Act defines "unprofessional conduct" as "Employing directly or indirectly any student, any unlicensed pharmacy technician or any unlicensed pharmacist to practice pharmacy . . ." Pharmacists and technicians have been held accountable by the Board when the statutes or regulations have not been followed. Wyoming Statute 33-24-113(d) states:

> The board may deny, suspend, revoke or refuse to renew a license issued under this section, may issue a letter of admonition . . . and may assess an administrative penalty . . . on any of the following grounds: . . . (x) Allowing a person who is not licensed by the board to perform duties as a pharmacist, pharmacy technician or pharmacy technician in training.

The Board is reviewing draft rule changes for technician responsibilities and ratios, which will be posted on the Board Web site for public comment this fall.

Disciplinary Actions

Note: All fines are payable to the county treasurer where the action occurred for the credit of the public school fund in that county pursuant to Wyoming Statute §33-24-113(f).

E.G. Pharmacist License #2569. Pharmacy had expired products, missing information on labels, dirty equipment, no certificate of authenticity on chemicals, and domperidone had been compounded and dispensed (non-Food and Drug Administration approved). Suspension ordered then stayed if cited problems on inspection are acceptable, a written improvement plan is sent to the Board, and a fine of $2,000 is paid.

K.K. Pharmacist License #2564. Administrative penalty of $200 for failing to complete 12 hours of continuing education in 2011.

A.S. Pharmacy Technician License #1845T. License revoked due to noncompliance with Board order to be monitored by Wyoming Professional Assistance Program (WPAP).

K.M. Pharmacist License #2051. License suspended 30 days, additional continuing education required due to dispensing unauthorized prescriptions to self (non-controlled substances).

C.B. Pharmacist License #2317. Pharmacist with a Board order for monitoring from another state, license conditioned to comply with monitoring by WPAP.

Perpetual Inventories

Be sure to record annual inventory as one line in the perpetual inventory. It is also a good idea to initial the actual count at each quarterly perpetual inventory. Use another line if you have to reconcile and record the reason. Examples: "Filed Drug Enforcement Administration form 106," "broken tablets," etc.

What a Pharmacist Can *Change on a Schedule II Prescription*

After consultation/approval of the prescribing practitioner, the pharmacist is permitted to change the following: drug strength, drug quantity, directions for use, dosage form. The pharmacist is permitted to change the patient's address with proper verification without consulting the prescribing practitioner. Any change made by the pharmacist shall be documented and shall include the date, name of person consulted, and initials of the pharmacist.

Days Supply

Be careful in calculating and entering the "days supply" in your dispensing software. If the number is wrong, the patient may have their third party payor deny the next refill or new prescription. An inhaler or bottle of insulin should not be a "one-day" supply. Prescribers are concerned about early refills and the "days supply" is one way for pharmacies to assist them in monitoring patient compliance.

The *Wyoming State Board of Pharmacy News* is published by the Wyoming State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

Mary K. Walker, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Larissa Doucette - Communications Manager

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National Association of Boards of Pharmacy Foundation, Inc
1600 Feehanville Drive
Mount Prospect, IL 60056

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