September 2012

West Virginia Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

106 Capitol St • Suite 100 • Charleston, WV 25301 • *www.wvbop.com*

Board of Pharmacy Regulations Regarding Pharmacy Interns

Guest Article by David Bowyer, Experiential Director, University of Charleston School of Pharmacy, Charleston, WV

With the advent of a third school of pharmacy in the state of West Virginia, more pharmacies will be approached by students seeking internships. It is important for the pharmacists to know and understand the laws and rules relating to pharmacy internships before hiring that student. There are a couple of things the pharmacist needs to do in order to ensure the student they hire gets credit toward licensure for the hours he or she works prior to graduation. One important distinction to make pharmacists aware of is that this article is addressing student interns working in a pharmacy outside of their educational requirements. Such interns are hired by the store or are volunteering their time. These circumstances are different from the student intern rotations (placements and hours) being completed by students through their school of pharmacy as part of their educational requirements through their introductory or advanced pharmacy practice experiences. Rotations are assigned by the school and the student cannot be paid for these rotations.

Student interns are required to accrue at least 700 hours of experience outside of their educational requirements prior to applying for licensure in West Virginia. In order for those hours to count toward this requirement, the student must be licensed. According to Section 30-5-3(c) of the West Virginia State Code:

> It is the duty of a pharmacist or employer who employs an intern to license the intern with the board within ninety days after employment. The board shall furnish proper forms for this purpose and shall issue a certificate to the intern upon licensure.

At the University of Charleston, we provide all of our incoming students with the application for initial license as a registered intern. After a student is licensed by the West Virginia Board of Pharmacy, he or she must notify the Board within 10 days of employment as an intern. If they do not notify the Board of the date of starting work, those hours may not be counted toward licensure.

Once the intern has started working for the pharmacy, the hours the intern works must be submitted to the Board of Pharmacy. This is done by the completion of the internship affidavit form. Your intern may download this form from the Board of Pharmacy Web site. The hours should be recorded on a weekly basis but the form does not need to be submitted until it is full or the intern no longer works at the pharmacy. The form must be signed by the supervising pharmacist (and notarized) and documentation of the hours worked must be kept at the pharmacy. This documentation may be payroll records or other records if the intern is not being paid. If the intern is working at the pharmacy on an irregular basis (for example, semester breaks and summers), it is my recommendation to the student that he or she completes and submits this form each time he or she ceases to work for a period of time. If an intern is terminated from the pharmacy, the pharmacist should make sure that he or she completes a final intern affidavit for the intern and notify the Board of Pharmacy that the intern is no longer employed.

A couple of other notes regarding interns and their work in the pharmacy are good to keep in mind. First, according to Section 30-5-3(b) of the code, a licensed intern may compound and dispense prescriptions or prescription refills under the direct supervision of a pharmacist. Also, according to Section 15-1-4.1, the principal purpose of serving an internship is for the intern to acquire practical experience under the direct supervision and instruction of a licensed pharmacist preceptor in the providing of pharmaceutical care including the compounding and dispensing of prescriptions. Schools of pharmacy encourage preceptors to allow the students to participate in all aspects of pharmacy practice (including counseling), but keep in mind that these are still student pharmacists and this is a learning experience. The ultimate responsibility for the welfare of the patient rests with the pharmacist. Pharmacists who employ interns take on the added roles of teacher and mentor and should be prepared for this.

continued on page 4

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.

continued from page 1

The second thing to remember is that, in order to be an intern, a student must be enrolled in (or a graduate of) an approved college of pharmacy. In the unfortunate circumstance of a student being dismissed from the pharmacy program at the University of Charleston, the Board of Pharmacy is notified, but the employer is not. It is the responsibility of the employer to ensure that the intern remains enrolled in school and is making satisfactory progress toward graduation. The schools are not allowed to disclose this information to the employers but you should regulary ask the student about his or her status. Intern licenses expire each year on June 30. This is always a good time to check on the student's progress. The intern must provide a copy of his or her license so it may be displayed in the pharmacy. If the Board has been notified by the school of the student's dismissal, a license will not be reissued.

Having student interns can be a fun and rewarding experience for pharmacists. Students provide a wealth of up-to-date knowledge to pharmacies and can keep us all young. It is also good to give back to the profession by training the future generation of pharmacists. By remembering these simple steps in the process of employing an intern, you will be helping a future colleague advance in the profession and fulfill their requirements for licensure upon graduation.

More on Reporting to Controlled Substances Monitoring Program Database: What About That Government-Issued Photo ID Stuff?

In the last issue, the Board reminded the readership that Senate Bill 437 put in place the requirement for reporting dispensings of Schedule II-IV controlled substance prescriptions to the Controlled Substances Monitoring Program (CSMP) within 24 hours, and that the Board had promulgated emergency rules on the subject. One of the questions that continues to come up is what to do about the requirements for government-issued photo identification. West Virginia Code §60A-3-308(d)(2)(B), §60A-10-5(d), and the similar federal law have long contained the requirement for presenting a photo ID for distribution or dispensing of pseudoephedrine products. The same IDs appropriate for that law were incorporated into the emergency rules for the CSMP requirements. What are they? Driver's licenses, non-driver IDs, military IDs, and passports are the most common. The Board is working to try to better define the examples beyond that. For the CSMP, West Virginia Code §60A-9-4a, a new insert into the law, says that prior to dispensing any Schedule II-IV controlled substance, the pharmacist or pharmacy must "verify the full legal name, address, and date of birth of the person receiving or otherwise acquiring the controlled substance by requiring the presentation of the government-issued photo identification card." Likewise, West Virginia Code §60A-9-5 requires reporting to the CSMP this information for the patient, and for anyone who picks up the prescription on behalf of the patient.

What if the ID is expired? What if they do not have one? The Board needs to clarify the rules going forward. An expired ID is better than none. If they do not have one, strict compliance with §60A-9-4a says do not dispense. The rules for reporting to the CSMP for §60A-9-5 say to do the best you can with the information available to you. Until the Board can work through these questions, pharmacists must use professional judgment to take care of the patient, but also avoid diversion. Documentation will help if questions arise after-the-fact.

The *West Virginia Board of Pharmacy News* is published by the West Virginia 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.

West Virginia Board of Pharmacy

Carmen A. Catizone, MS, RPh, DPh - National News Editor
& Executive Editor

Larissa Doucette - Communications Manager

WEST VIRGINIA BOARD OF PHARMACY

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

Presorted Standard
U.S. Postage
PAID
Chicago, Illinois
Permit No. 5744