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News

West Virginia Board of Pharmacy

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Pharmacy Interns May Not Yet Give Immunizations

The West Virginia Board of Pharmacy office has fielded a number of inquiries about when pharmacy interns may begin giving immunizations. Although the statute was amended to allow for interns to be permitted to administer them, the statute makes it clear that all immunizations by a pharmacist are subject to the rules. The same is true for interns; until joint rules are passed to govern how and when an intern may give an immunization, they cannot do any. In short, the current rules only govern pharmacists, and must be modified to include interns.

The Board, with the assistance of practicing pharmacists and the three schools of pharmacy in the state, drafted amendments to the current rules to incorporate interns, including requirements for their training and credentialing. These were forwarded to the boards of medicine and osteopathic medicine for their review. The West Virginia Board of Medicine has asked for an amendment that would require the intern be under the "personal supervision" of the supervising immunizing pharmacist, rather than "direct supervision." This would require the pharmacist to be physically present with the intern when the immunization is actually administered by the intern. The West Virginia Board of Osteopathic Medicine will review the proposal at its December meeting. If approved by all three boards, the Board will file them and post them for public comment. After the public comment period, the boards will all have to respond to the comments, make any agreed changes, and, if approved again by the boards, file them with the Legislative Rule-Making and Review Committee to seek approval by the legislature. This is a long process, so it will be some time before any joint rules are finalized for an intern to administer any immunizations.

Registering Your Delegates in the CSMP

When the Controlled Substance Automated Prescription Program, the new version of the West Virginia Controlled Substances Monitoring Program (CSMP), was rolled out earlier this year, many of you experienced bugs and glitches with the registration process. Most of those registration issues have been ironed out now. However, due to the problems master account holders experienced when trying to assign their delegates, the Board assumes that many working pharmacies are simply sharing a username and password. Since the system keeps track of who looks at what records, it is important that each individual user has his or her own username and password. The system requires the pharmacist-in-charge (PIC) of the pharmacy to be the master, and to assign delegates at the PIC's discretion to the other pharmacists and/or pharmacy technicians in the pharmacy. So, now that the bugs are worked out, if you are a master, please make sure you revisit your delegate selections and make sure your delegates are registered and using their own username and password to access the system.

Compounding Pharmacies: Be Careful With Your Advertising Practices

On several different occasions over the past few years, the Board office has been made aware of some compounding pharmacies that are violating certain rules with regard to their advertising practices. The usual situation is when the pharmacy sends information to its target prescriber-community detailing products the pharmacy can dispense for their patients. Often it is in the form of a flyer, leaflet, or maybe even a fax form, imprinted with the pharmacy's information (name, address, contact information, etc), and a list of the compounded products available. However, the list is often made with check boxes, and then blank lines for the prescriber to be able to fill in a patient's information, instructions, and a line for the prescriber to sign and provide his or her information. In other words, what starts as a flyer is turned into a prescription form.

This flyer-turned-prescription-form raises a couple of issues. First, some of the substances may be controlled substances (CS), in which case, it is a pre-printed CS prescription. Second, West Virginia Code of State Rules §15-1-19.10 states, "Prescription order forms — No pharmacist shall provide any practitioner with prescription order forms imprinted with any reference to a pharmacy or pharmacist." One purpose of this rule is to preserve the patient's free choice of pharmacy. When a prescriber issues a prescription, it is the patient's choice what

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Enteric-Coated Aspirin Recalled for Potential Acetaminophen Mix-Up

In June 2013, Advance Pharmaceutical Inc initiated a voluntary recall of Rugby Laboratories label enteric-coated aspirin tablets, 81 mg (Lot 13A026; expiration date: January 2015) due to a complaint that a bottle labeled with this product name actually contained acetaminophen 500 mg tablets. This over-the-counter (OTC) product is packaged in bottles of 120 tablets with National Drug Code 0536-3086-41 and Universal Product Code 3 0536-3086-41 9. The affected lot was distributed nationwide by Rugby Laboratories to wholesalers and retailers. The manufacturer warns that inadvertently taking acetaminophen, 500 mg, instead of enteric coated aspirin, 81 mg, according to the directions on the label, can lead to an acetaminophen overdose and potential severe liver damage. The manufacturer indicates that consumers who take the dosage as indicated on the defective product labeling may be ingesting up to 24,000 mg of acetaminophen, which is about six times the maximum recommended daily dose of acetaminophen (4,000 mg).

Consumers who have bottles from the affected lot should stop using the product and return it to the pharmacy or store where it was purchased and should contact a health care provider if they are experiencing any problems that may be related to using the product. Food and Drug Administration (FDA) notes that any adverse reactions related to the use of the product should be reported to FDA's MedWatch Program. More information about this recall is available on the FDA Web site at *www.fda.gov/Safety/Recalls/ucm357909*.

Barcoding Technology for Community Pharmacy

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.*

Barcoding technology is well-established in industries outside of the health care sector and is now being used within health care to enhance efficiency and safety, and in pharmaceutical wholesale operations to improve supply chain inventory and efficiency. Numerous studies prove the effectiveness and cost benefits of using barcoding technology during the drug dispensing process. About 75% of wrong drug or wrong dose errors are captured and corrected using barcode technology[1] and there is sufficient evidence that barcode scanning is becoming the standard of practice in pharmacies.

Although barcoding technology is mature with abundant evidence regarding its effectiveness, a 2006[2] study showed that only half (53.5%) of United States community pharmacies utilize a barcode scanner for verification/identification of medications. The study also revealed significantly lower adoption in independent pharmacies (11.5%) compared to chain pharmacies (62.6%).

According to a survey conducted by ISMP in 2009, the most frequently reported reasons for implementing barcode scanning for product verification included a desire to improve the accuracy and safety of the dispensing process, the ease with which the technology fits with pharmacy workflow, improvement of staff efficiency and inventory control, and a belief that the technology was necessary to stay in business. The most common reasons for **not** implementing barcode scanning for product verification, other than cost, included uncertainty regarding the "right" vendor product, satisfaction with the current system (without barcode product verification), and perceptions that the technology would reduce staff efficiency.

ISMP has developed a tool, Assessing Barcode Verification System Readiness in Community Pharmacies, to help address the reasons why barcode scanning has not been implemented and to facilitate the adoption of this technology in an estimated 27,327 community pharmacies that do not currently utilize it for product verification.

Given the resource commitment to purchase barcoding systems and the potential for technology to have a profound effect upon the work environment, this tool will help community pharmacy managers and owners better understand the issues related to barcode product verification systems. It will also help managers assess the pharmacy's readiness for the technology, prepare for the selection of a system, and implement the technology effectively.

Barcode scanning to verify prescription products prior to dispensing improves the safety and quality of pharmacy care provided to patients and increases efficiency during the provision of pharmacy services. Although technology should not be seen as a panacea, it can be a useful tool when used appropriately and combined with other patient safety strategies.[3] Does your pharmacy use barcode technology for product verification? If not, please access this free tool, at *www.ismp.org/AHRQ/Default.asp?link=sa.*

[1]*Cochran GL, Jones KJ, Brockman J, Skinner A, et al. "Errors prevented by and associated with barcode medication systems." Joint Comm J Qual Pt Safety. 2007;33(5):293-301.*

Ukens C. "New study sheds light on medication errors." Drug Topics. 2002;146(21):33.

[2]*Skrepnek GH, Armstrong EP, Malone DC, Abarca J, et al. "Workload and availability of technology in metropolitan community pharmacies." J Amer Pham Assoc. 2006; 46(2):154-160.*

[3]*American Hospital Association, Health Research and Educational Trust, Institute for Safe Medication Practices. "Pathways for medication safety: assessing bedside bar-coding readiness." 2002. Accessed on October 15, 2010 at:* www.ismp.org/selfassessments/PathwaySection3.pdf.

ISMP Launches Medication Safety Alert! Newsletter Tailored for LTCFs

ISMP has launched a new *ISMP Medication Safety Alert!* publication, *Long-Term Care Advise-ERR,* as a means to provide medication error prevention information tailored to assist staff and providers in long-term care facilities (LTCFs).

With *ISMP Medication Safety Alert!* publications making a significant impact on preventing medication errors, ISMP is now providing this new resource tailored to LTCFs. ISMP notes that medication errors reported to ISMP Medication Errors Reporting Program include reports from LTCFs. More information and a link to subscribe to this new publication are available in the Newsletters section of the ISMP Web site at *www.ismp.org/newsletters/longtermcare.*

FDA Warns of Rare Skin Reactions in Patients Taking Acetaminophen

FDA has issued a consumer update that warns of rare but serious skin reactions that may occur in patients taking acetaminophen. These complications include three serious skin reactions: Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP). SJS and TEN can both be fatal, and usually require hospitalization. Patients suffering from AGEP commonly recover within a few weeks after they stop taking the medication that caused the reaction.

Symptoms of these conditions include skin rashes, blisters, and widespread damage to the surface of the skin. Patients taking acetaminophen or other compounds that contain acetaminophen should be advised to stop taking the medication if they experience such symptoms and should consult their health care providers or seek an emergency department immediately.

FDA emphasizes that this information should be viewed within the context of millions of patients who, over generations, have used and benefited from acetaminophen and stresses that severe allergic skin reactions are an extremely rare condition. Further, the agency notes that many medications can cause allergic reactions, and skin allergy warnings have already been added to the drug labels of other categories of OTC analgesics including ibuprofen and naproxen. "This new information is not intended to worry consumers or health care professionals, nor is it meant to encourage them to use other medications," said Sharon Hertz, MD, deputy director of FDA's Division of Anesthesia, Analgesia, and Addiction Products. "However, it is extremely important that people recognize and react quickly to the initial symptoms of these rare but serious side effects, which are potentially fatal." The full consumer update is available on the FDA Web site at *www.fda.gov/ForConsumers/ConsumerUpdates/ucm363010.htm.*

Reminder to Purchase Drugs Only from Licensed Wholesalers, Including VAWD-Accredited Wholesale Distributors

To ensure that patients are receiving safe, FDA-approved medications, pharmacists and other health care providers should purchase prescription drugs either directly from the manufacturer or from wholesale drug distributors licensed in the US as advised by FDA. The agency provides a list of state agencies for assistance in verifying licensure at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm*.

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws and NABP's VAWD criteria. NABP has recently revised the VAWD criteria to allow virtual manufacturers and virtual wholesale distributors – a growing segment of the pharmaceutical wholesale industry – to qualify for VAWD, as well as to implement other changes aimed to help to ensure that the drug supply chain remains secure.

The revised VAWD criteria responds to changing business models and helps safeguard drugs in distribution at a time when there is an increased risk of counterfeit and substandard drugs entering the legitimate US drug supply chain. In particular, the criteria have been revised to provide stronger assurance that drugs diverted from pharmacies and unlawful sources are prevented from entering into the supply chain.

For a listing of VAWD-accredited facilities, please visit *www.nabp.net/programs/accreditation/vawd.*

Voluntary Recall of Unexpired Sterile Products After Reports of Adverse Events

FDA has announced a voluntary recall of all lots of unexpired sterile products produced by Specialty Compounding, LLC, in Cedar Park, TX. FDA received reports of 15 adverse events at two hospitals (Corpus Christi Medical Center Doctors Regional and Corpus Christi Medical Center Bay Area) potentially related to the use of these sterile products. Affected patients received an intravenous infusion of calcium gluconate supplied by the company.

Patients who were administered the injectable drug products are at risk of life-threatening infections. The recall applies to all unexpired sterile compounded medications dispensed by the company, including all strengths and dosage forms. Recalled products were distributed directly to hospitals and physicians' offices in Texas, and to patients located nationwide (with the exception of North Carolina). No calcium gluconate was shipped outside the state of Texas. Health care providers and patients should stop using all recalled products and return them to Specialty Compounding.

Veterinarians Not Eligible for NPIs, CMS Clarifies

Centers for Medicare and Medicaid Services (CMS) has become aware of cases in which veterinarians are told, incorrectly, that they must provide a National Provider Identifier (NPI) number for prescriptions they have written to be dispensed. The agency has issued a clarification, stressing that veterinarians do not meet the regulatory definition of "health care provider," and thus may not obtain NPI numbers. The clarification also states that "Any entity that insists veterinarians obtain an NPI [is] attempting to require veterinarians to obtain NPIs fraudulently." CMS also notes that "if a veterinarian fulfills the definition of 'health care provider' in a profession other than furnishing veterinary services," such as if they are also a nurse practitioner, "the veterinarian would be eligible for an NPI but would select a Nurse Practitioner code (not a Veterinarian code) from the Healthcare Provider Taxonomy Code Set when applying for an NPI."

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

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pharmacy fills it. Obviously, a prescriber can make a recommendation, and there is nothing inappropriate about advertising to the prescribers; however, these fliers cannot be made as prescription forms if the pharmacy's information is on them.

Next, it has been questioned whether compounding pharmacies can provide samples to prescribers to give to their patients, as many drug manufacturers do. The idea is that a patient can try something to see if it might be effective before having to pay for a prescription and other such benefits of providing samples to prescribers. However, the law is abundantly clear that compounding is only to be done for a specific patient with a specific prescription, or in anticipation of prescription orders expected to be received based upon routine and regular prescribing patterns; also, the Board is exercising discretion in compounding small amounts for prescribers' office use. All other compounding would be manufacturing. This goes for samples.

Simply, a sample is not for a specific patient, is not prepared in anticipation of routine prescribing amounts, and is not for use by a prescriber for an in-office procedure. It would be manufacturing and then marketing of the products, governed as such by the Prescription Drug Marketing Act and Food and Drug Administration laws. As such, unless the law on the federal landscape is changed, and a compounding pharmacy complies with it, provision of samples of compounded drugs as samples is prohibited by the laws of West Virginia.

CSMP Advisory Committee Recommendations Accepted by the Board

The CSMP Advisory Committee has issued some recommendations for the West Virginia CSMP. The Board took action on them at its September meeting, and made one of its own also regarding pseudoephedrine. Following are several of them, all of which will be presented to the legislature.

(a) The committee recommended tramadol be made a Schedule IV CS. Alternatively, it recommended that if tramadol is not made a CS, then it should be required to be reported to the CSMP as a drug of concern. The Board approved.

(b) The committee recommended pseudoephedrine products be made prescription-only. The Board agreed and approved. In addition, the Board passed a motion as an alternative position in the event that the legislature chooses not to make it prescription-only, that over-the-counter sales of pseudoephedrine should be limited to no more than one box of 3.6 grams or less per month, and to lower the annual limit to 24 grams per year.

(c) The committee recommended that the CSMP be expanded to track Schedule V drugs. This is a national recommendation and 29 states already do this. The Board agreed.

(d) The committee recommended the Board implement two new rules clarifying that a prescriber or dispenser may run a patient profile report prior to accepting that individual as a patient once that patient has requested to come under the practitioner's care (as a new patient, by referral, etc), and that it is permissible for a prescriber or dispenser to access the patient profile of the mother for purposes of treating a newborn child or child being breastfed. The Board approved.

(e) The committee recommended that West Virginia Code §60A-9-4a be clarified that the person whose identity must be verified under that provision is the person picking up a CS prescription at the pharmacy, whether on his or her own behalf as the patient, or on behalf of another person. The Board agreed.

These recommendations will be communicated to the legislature for the upcoming 2014 session.

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

Deborah Zak - Communications Manager