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West Virginia Board of Pharmacy News

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Review of Prescription Drug Overdose Deaths Ongoing; Drug Combinations a Problem

West Virginia Code §60A-9-5(b) requires the West Virginia Controlled Substance Monitoring Program (CSMP) Database Review Committee to, among other things, review notices of drug overdose deaths provided by the West Virginia Office of the Chief Medical Examiner (OCME) and determine on a case-by-case basis whether a practitioner who prescribed or dispensed a controlled substance (CS) resulting in or contributing to the drug overdose may have breached professional or occupational standards or committed a criminal act when prescribing the CS at issue to the decedent. The CSMP Database Review Committee has examined the notices from the OCME, as well as the corresponding CSMP reports from the West Virginia Board of Pharmacy, for hundreds of decedents from drug overdose, and found that most involved large numbers of opioids, as well as frequent multiple drug combinations, particularly opioids and benzodiazepines.

It seems impossible to attend a continuing education course, seminar, or other educational training on substance abuse without hearing of the "trinity," "holy trinity," or "Houston cocktail" as street slang for the drug combinations of an opioid, a benzodiazepine, and a muscle relaxant. It is worth repeating here what the slang means: the trinity or Houston cocktail would be hydrocodone, alprazolam, and carisoprodol; the holy trinity would substitute oxycodone for the hydrocodone. Any time you see a patient getting all three, you should be more vigilant in determining if these are for a legitimate medical purpose. However, as seen by the OCME data, many of the deaths are occurring with just the opioid and the benzodiazepine, meaning that you need to have heightened awareness any time you see the combination in your patient's profile.

In an effort to inform prescribers who are encountered when reviewing these cases, and to hopefully reduce the number of these unfortunate outcomes, the Board – on behalf of the CSMP Database Review Committee – has sent letters asking that they review their practices regarding the prescribing of these CS, especially if it involves combining multiple drug types. The letters also encourage regular utilization of the CSMP database to obtain an accurate list of drugs the patients are currently receiving. Of course, these communications go to the dispensers as well. One of the common fallouts is that some prescribers are cutting patients off, and pharmacies are refusing to fill certain prescriptions. This is posited by some to be one contributing factor in driving these "patients" to buy drugs on the street, including diverted prescription drugs and heroin, and contributing to the increase in heroin overdoses, hepatitis and HIV from needle sharing, and other related issues. As such, if you suspect one of your patients is misusing prescription drugs, it is critical to your patient's safety that you alert his or her prescriber who can make referrals to drug addiction management programs when possible, or that you attempt to make those referrals yourself.

New PT and PTT Applications and Background Check Process Being Refined

In the efforts to implement the new rules requiring an approved application and background check for a new pharmacy technician trainee (PTT) prior to beginning work, and the new changes and background check requirement for full registration as a newly registered pharmacy technician (PT), Board staff have been working with the West Virginia State Police (WVSP) and its process for obtaining the criminal history record checks. West Virginia Code of State Rules §15-7-3 and §15-7-4.3 are specific about the type of background check required: it must be one that is an electronic fingerprint-based criminal history record check. While the Board initially thought it could accept copies of background checks run by employers, the Board learned that this would not work because of certain confidentiality laws, contractual issues between the employers and their background companies, and other issues. As such, the Board is not able to accept background checks performed by the employer. Only background checks provided through the WVSP process, obtained at this time through IdentoGO (WVSP's contracted agent), will be accepted. (Note: Out-of-state applicants must go through their home state police department process for the records, but have them submitted directly to the Board.) Applicants are responsible for all fees and costs associated with the required background checks.

continued on page 4

Counterfeit Botox Found in the United States, FDA Warns

On April 16, 2015, Food and Drug Administration (FDA) alerted health care providers that a counterfeit version of Botox® was found in the United States and may have been sold to doctors' offices and clinics throughout the country. The counterfeit products may be identified by a missing lot number on the vial, missing information on the carton (next to LOT, MFG, and EXP), and a displayed active ingredient as "Botulinum Toxin Type A" instead of "OnabotulinumtoxinA." The counterfeit products were sold by an unlicensed supplier who is not authorized to ship or distribute drug products in the US, according to an FDA Drug Safety Alert. The agency advises health care providers to confirm that the distributor from which they purchase Botox is authorized by Allergan, the drug's manufacturer. No adverse events related to this product have been reported to FDA.

Medical practices that purchase and administer counterfeit, illegal, and unapproved medications from unlicensed or foreign sources are putting patients' health at risk, as patients may not be getting proper treatment, warns FDA. Wholesale drug distributors must be licensed in the states where they conduct business. Suspicious Botox products may be reported to FDA's Office of Criminal Investigations. More information is available on the FDA website at *www.fda.gov/Drugs/DrugSafety/ucm443217.htm*.

One way 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. Wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws, as well as NABP's VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo an on-site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the US drug supply.

Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization 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 provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

ISMP has been reflecting on the strength and resolve of many across the nation who have demonstrated an unparalleled commitment to keeping patients safe. Despite the many safety accomplishments in 2014, ISMP cannot help but mull over persistent medication safety gaffes that continue to be unresolved. ISMP would like to share seven persistent safety gaffes of 2014, in three parts, with NABP *National Pharmacy Compliance News* readers with the hope that they will join ISMP in bringing attention to these crucial issues and the compelling need for their resolution. Part one of the three-part series is below.

1) Patient Counseling: Still Only a Veiled "Offer" in Many States

The effectiveness of patient counseling in a community pharmacy to detect and prevent medication errors, and its link to improved medication adherence and positive clinical outcomes have been well documented in the literature. Yet, studies have placed patient counseling rates at only eight percent to 42%. An increase in the frequency and quality of patient counseling has been linked to state-specific regulations that require patient counseling for new prescriptions coupled with strict enforcement surveillance. States that require an "offer" to counsel have very low patient counseling rates. Patients often fail to recognize an offer to counsel when simply asked, "Do you have any questions?" or told to "Please sign here." They may not even know what to ask. This means that, with few exceptions, pharmacies in states that require only an offer to counsel will likely dispense a powerful opioid such as fentanyl transdermal patches and allow the patient or caregiver to walk out of the pharmacy without even a brief discussion about safe use and disposal. ISMP has long promoted mandatory patient counseling in community pharmacies for prescriptions for targeted high-alert medications.

For a list of high alert community medications, please visit *www.ismp.org/communityRx/tools/ambulatoryhighalert.asp.* ISMP hopes you will use this list to determine which medications require mandatory patient education in order to reduce the risk of errors and minimize harm.

2) Patients Impacted by Dispensing Errors: Callous Response From Pharmacists

When patients report dispensing errors to ISMP, they are usually more upset about the response they received when contacting the pharmacist or pharmacy manager than the actual error itself. All too often, consumers tell ISMP that pharmacy staff have responded in a callous manner when confronted with the possibility of a dispensing error, demonstrating a lack of empathy and concern for the adverse effects the patient might have experienced. While pharmacy staff may want to be more responsive to patients who report errors, they are often following corporate policies that are focused on legal concerns. As patients are continually encouraged to be active participants in their health care, they want and deserve honest disclosure of errors, and knowledge that there is an action plan to reduce the risk of it happening again.

Flurbiprofen-Containing Topical Medication May Be Dangerous to Pets, Cautions FDA

People who use topical medications containing flurbiprofen, a nonsteroidal anti-inflammatory drug (NSAID), should take care to prevent their pets from being exposed to the drug, recommended FDA in an April 2015 Safety Alert. The warning is in response to reports of cats in two separate households that became ill or died after their owners used topical medications containing flurbiprofen to treat

muscle, joint, or other pain. Two cats in one household developed kidney failure and recovered with veterinary care. Two cats in a second household developed symptoms that included reluctance to eat, lethargy, vomiting, melena, anemia, and dilute urine, and subsequently died despite veterinary care. A third cat in the second household also died after the owner stopped using the medication. Necropsies on the three cats found evidence that were consistent with NSAID toxicity. The pet owners had applied the drug to their own neck or feet, and not directly to the pet, and it is not known exactly how the cats became exposed to the medication, the Safety Alert notes.

Health care providers who prescribe or dispense topical pain medications containing flurbiprofen should advise patients with pets to take steps to prevent exposure of the pets to the medication. Additional information is available in the FDA Safety Alert available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm443386.htm*.

New FDA Drug Info Rounds Videos Available

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. The latest Drug Info Rounds videos are as follows.

- In "NDC Directory," pharmacists demonstrate how to use this quick, easy, online resource.
- In "FAERS," pharmacists discuss the FDA Adverse Event Reporting System (FAERS) and review three ways FAERS data is made available to the public.

Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. These videos and previous Drug Info Rounds resources are available on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm*.

Mucinex Cold, Sinus, and Flu Medications Recalled Due to Possible Labeling Error

In April 2015, RB (formerly Reckitt Benckiser) of Parsippany, NJ, issued a voluntary recall of certain lots of liquid Mucinex® due to a potential error involving the over-the-counter medications' drug facts labels. While the front label of the recalled lots correctly lists the name of the product as well as the active ingredients, some bottles may not have the correct corresponding drug facts label on the back. The recall was initiated after a confirmed report from a retailer. The recalled medications include:

- MUCINEX FAST-MAX Night-Time Cold & Flu;
- MUCINEX FAST-MAX Cold & Sinus;
- MUCINEX FAST-MAX Severe Congestion & Cough; and
- MUCINEX FAST-MAX Cold, Flu & Sore Throat.

If mislabeled, consumers who purchase these products may be unaware of the side effects and potential risks associated with active ingredients such as acetaminophen, dextromethorphan, guaifenesin, phenylephrine, and/or diphenhydramine. RB is recalling these products as a precautionary measure to ensure consumers have all relevant facts and warnings; the company asks consumers to dispose of any unused product.

Additional information about the recall, including the lot numbers and expiration dates for the recalled medications and guidelines for safe disposal, is available on the FDA website at *www.fda.gov/Safety/Recalls/ucm444028.htm*.

Pharmacists Are Performing More Patient Care Activities, National Survey Indicates

Pharmacists are performing more patient care activities in a variety of health care settings and are spending less time in traditional dispensing roles, indicates the *2014 National Pharmacist Workforce Survey*. Specifically, the report found that 60% of pharmacists provided medication therapy management, and 53% performed immunizations in 2014, indicates a press release from the American Association of Colleges of Pharmacy (AACP). The survey was created using a random sample of 5,200 individuals selected from a list of 7,000 licensed pharmacists in the US. Response rate to the survey was 48%.

Additional details, including the full results of the survey and an executive summary, are available through the Resources section of the AACP website, *www.aacp.org*.

Potentially Lethal Drug Sold Globally as Diet Supplement, Warns INTERPOL

INTERPOL has issued a global alert for a drug known as 2.4-dinitrophenol (DNP), an illicit and potentially lethal drug sold as a dieting and body building aid. The "Orange Notice" warning about DNP was published in May 2015, following the death of a woman in the United Kingdom and the serious illness of a man in France. In the 1930s, DNP was used to boost metabolism and encourage weight loss, but it was taken out of circulation due to several deaths. Sold as a plain yellow powder, capsules, or cream, DNP is often illegally manufactured and sold via the Internet; unsafe manufacturing of the drug and potential contamination may be magnifying the dangers of taking the drug, notes INTERPOL.

Additional information is available on the INTERPOL website at *www.interpol.int/News-and-media/News/2015/N2015-050*.

HHS Announces New Interactive Training on Safe Opioid Use

The Department of Health and Human Services (HHS) has announced a new, interactive training course that teaches health care providers how to talk to patients about safely using opioids to manage chronic pain. The course, "Pathways to Safer Opioid Use," also teaches implementation strategies for meeting the opioid-related recommendations from the National Action Plan for Adverse Drug Event Prevention. Adverse drug events (ADEs) are the largest contributor to hospital-related complications and account for more than 3.5 million physician office visits each year, according to HHS. The training, which is offered at no cost, includes self-guided interactive videos with decision points to help users learn how to apply health literacy strategies to help patients understand and act on information to prevent opioid-related ADEs; identify individual risk factors, opioid medications, and interactions that place individuals with chronic pain at increased risk for opioid-related ADEs; recognize the importance of a multidisciplinary team-based approach to treating patients with chronic pain; and demonstrate the ability to combine the principles of the Health Literate Care Model and the biopsychosocial model.

Additional information, including a link to the National Action Plan for Adverse Drug Event Prevention, is available on the course website at *http://health.gov/hcq/training.asp#pathways*.

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continued from page 1

To get the background check, the applicant must visit the IdentoGO website at *www.identogo.com,* or contact IdentoGO at 1-855/766-7746, and follow its instructions. At this time, the site is up and running, but can only process the state portion of the background checks. The Board will accept state-only records at this time until the federal portion is available. (This will increase the fee, so those of you getting in early before the federal portion is activated can save a few dollars.) Upon entering the website, the applicant will select West Virginia on the map, and then click "Make a New Appointment." Next, select "WV Board of Pharmacy" from the drop-down box to indicate that the check is being done for and sent to the Board, and then click "Continue." On the Services page, you will choose the background checks being done, which, as stated above, will only list "WV Board of Pharmacy State only," as federal will be added in the future when it becomes available to the Board. Next, it will require you to enter your personal information. Then, you will select an appointment location and date/time (a complete list of West Virginia fingerprinting sites is available on the IdentoGO website, with 22 of them currently spread throughout the state). Finally, you will review your details and make the final submission. You can make payment online at time of application with IdentoGO, or wait and pay at the fingerprinting site in person.

At the fingerprinting appointment, you will be assigned a Transaction Control Number (TCN). Please make careful note of it, as this number is required to be placed on your PT or PTT application as proof of submitting for the background check and for Board-tracking of results. Please do not submit the application until this process is completed. Any applications received by the Board that do not indicate the required TCN will be immediately returned.

Once the electronic fingerprints are obtained, IdentoGO can often process the background check within 72 hours, sometimes faster. So, except for the unusual case, once the process is fully up and running, IdentoGO will likely have the results ready to send to the Board by the time the application arrives in the mail. The goal is that there will be very little or no lag time. Obviously, things change, and processes can often be improved. However, the Board is encouraged by the progress made already, and hopes to make this as easy as possible under the new scheme.

Preprinted Materials and Compounding, Certain Restrictions Apply

Pharmacies engaged in compounding obviously desire to get the word out about their capabilities, so they often put out materials to prescribers and others, listing what they frequently compound. To be compliant, a couple of rules need to be remembered. West Virginia Code of State Rules §15-1-19.10 states: "Prescription order forms – No pharmacist or pharmacy shall provide any practitioner with prescription order forms imprinted with any reference to a pharmacy or pharmacist." This means your listing of compounds in your advertisement cannot be in the form of a prescription order form if it contains any reference to the pharmacy, including name, contact information, website, or other such things. If it is not in a form that would be used as a prescription order form, then that information can be included.

Next, state law restricts CS orders to having only one drug per prescription blank. Further, West Virginia Code of State Rules §15-1-21.1.3 prohibits preprinted CS prescriptions. So, if your advertisement lists multiple compounds, and any CS is included, then the advertisement cannot be in the form of a prescription order form, as this provides the prescriber the opportunity to select a controlled and a non-controlled, or multiple CS on the same prescription order blank, and would constitute a preprinted CS prescription. This may also violate the rules, as only an agent of the prescriber can fill in the CS being prescribed for the prescriber's final review and signature, and the pharmacy is not the prescriber's agent. The Board hopes this helps as you advertise your services.

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™ (NABPF™) 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 NABPF or the Board unless expressly so stated.

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