December 2014

West Virginia Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

2310 Kanawha Blvd E • Charleston, WV 25311 • *www.wvbop.com*

Pharmacy Compounding of OTCs: an Oxymoron

Pharmacy compounding continues to be a hot topic. This is, of course, due to the still new federal Compounding Quality Act, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act). As is widely known, pharmacy drug compounding is the combination of active and inactive ingredients only when done for a specific prescription order for a specific individual patient, or in limited quantities in anticipation of the receipt of valid prescription orders based on past history of receiving such orders. Over-the-counter drugs (OTCs) are those that can be sold without a prescription. So, can a pharmacy compound OTCs and sell them on the front end? Simply put, no.

According to Webster's Ninth *New Collegiate Dictionary,* copyright 1983, the definition of "oxymoron" is "a combination of contradictory or incongruous words. . ." Since pharmacies can only compound for specific prescriptions, the idea of compounding OTCs that are sold without a prescription is directly contradictory to and incongruent with the FD&C Act compounding laws. This would be manufacturing of OTCs, which requires full compliance with federal laws for current Good Manufacturing Practices. So, although you might have the best recipe for diaper paste or the best remedy for a skin irritation, unless you have gotten it approved through the Food and Drug Administration (FDA) process for manufacture as an OTC, and unless you do it in a properly licensed manufacturing facility under FDA requirements, if you decide to whip up a batch and sell it as an OTC, you are engaged in illegal manufacturing.

CSMP Reminders

In the continuing efforts to achieve compliance with the West Virginia Controlled Substance Monitoring Program (CSMP) reporting and use requirements, please take note of the following reminders:

1. Each user must have his or her own access (master account holders and delegates). In pharmacies, the master account is assigned to the pharmacist-in-charge (PIC). The PIC can then assign any pharmacist, pharmacy technician (including technician trainees), and/or pharmacy intern as a delegate. If it is a prescriber's office, the same holds true: the prescriber is listed as the master, and any employee of the prescriber can be made a delegate. This allows each access of the CSMP to be tracked by individual user for purposes of the audit trail. Remember, West Virginia Code §60A-9-5(e) requires all practitioners who prescribe or dispense controlled substances (CS) to have access to the CSMP, whether they use delegates or not.
2. The individual access is attached to the user, not the prescriber's office or pharmacy, since the CSMP can be accessed from any computer attached to the Internet. If you are making a move, please contact the West Virginia Board of Pharmacy office so it can update the access and keep it current. If you are the master and a delegate has left your employ, please go into your account and deactivate him or her as your delegate. This way, the former delegate cannot continue to access the CSMP through you as his or her master, and any potential inappropriate access by that delegate will not be connected back to you as the supervisory account holder.
3. If you have difficulty accessing the CSMP because the system rejects your user password twice, go through the password reset process. You will simply be directed to answer security questions, and will be able to reset your password. If you do not do this and try a third time with the wrong password, the system will lock you out and you will have to contact the Board office to get the access unlocked. The Board will be happy to help you in either case.
4. Required reporting of dispensings of Schedule II through IV CS must be done within 24 hours of the dispensing (48 hours if you are a mail-order pharmacy). This applies to all dispensers, whether a pharmacy or a dispensing practitioner. The Board has some pharmacies already reporting dispensings in "real time" at the point of sale. You may check with your programmer/vendor to see if this is possible for you. The more automated and in-the-background the process, the less likely you will be to get behind on your reporting. The Board has been pushing for quite some time for cooperative compliance. However, it has noticed a number of entities getting behind, and some not reporting at all for some time.

continued on page 4

DEA Reschedules Hydrocodone Combination Products as Schedule II

Drug Enforcement Administration (DEA) has published its final rule rescheduling hydrocodone combination products from Schedule III to Schedule II in the *Federal Register.* The change imposes Schedule II regulatory controls and sanctions on anyone handling hydrocodone combination products, effective October 6, 2014. DEA first published the proposed rules in March 2014 in response to a Food and Drug Administration (FDA) recommendation. DEA received almost 600 public comments regarding the proposed rules after they were published, with a small majority of the commenters supporting the change, DEA notes in a press release, which is available at *www.justice.gov/dea/divisions/hq/2014/hq082114.shtml.*

The announcement is available on the *Federal Register* website at *https://federalregister.gov/articles/2014/08/22/2014-19922/schedules-of-controlled-substances-rescheduling-of-hydrocodone-combination-products-from-schedule.*

The mL-Only Standard for Liquid Dosing Gathers Steam

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. *E-mail: ismpinfo@ismp.org.*

ISMP first reported on the confusion of teaspoonfuls and milliliters (mL) in its newsletter in 2000, and in 2009, issued a call for practitioners to move to sole use of the metric system for measuring over-the-counter and prescription oral liquid doses, but mix-ups have continued to result in the serious injury of children and adults. Use of the metric system alone when prescribing, dispensing, and administering medications would prevent mix-ups because there would only be one method used to communicate and measure doses.

The health care industry is beginning to acknowledge the risk of confusion when using non-metric measurements, especially with oral liquid medications. The National Council for Prescription Drug Programs (NCPDP) just released a white paper entitled *NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications,* which is available at *www.ismp.org/sc?id=337.* The white paper supports mL as the standard unit of liquid measure used on prescription container labels for oral liquid medications. It also calls for dosing devices with numeric graduations, and for units that correspond to the container labeling to be easily and universally available, such as including a device each time oral liquid prescription medications are dispensed. NCPDP also reiterates that dose amounts should always use leading zeroes before the decimal point for amounts less than one, and should not use trailing zeroes after a decimal point on labels for oral liquid medications.

The white paper comes as welcome news and is well-aligned with the *ISMP 2014-15 Targeted Medication Safety Best Practices for Hospitals,* Best Practice 5, which calls for organizations to use oral liquid dosing devices (oral syringes/cups/droppers) that only display the metric scale. The white paper also comes at a time when the Centers for Disease Control and Prevention, ISMP, the Consumer Healthcare Products Association, the United States FDA, the US Metric Association, and the American Academy of Pediatrics have initiatives in place that will help guide health care organizations to commit to metric measurements.

ISMP recommends the following actions to help prevent errors:

- Use only metric units, not teaspoon or other non-metric measurements, for all patient instructions, including those listed in prescribing and pharmacy computer systems. This should cover directions incorporated into computer system mnemonics, speed codes, or any defaults used to generate prescriptions and prescription labels.
- Take steps to ensure patients have an appropriate device to measure oral liquid volumes in milliliters.
- Coach patients on how to use and clean measuring devices; use the "teach back" approach and ask patients or caregivers to demonstrate their understanding.

DEA Classifies Tramadol a Controlled Substance

Under a final rule published in the *Federal Register*, the pain reliever tramadol is now classified as a Schedule IV controlled substance. As of August 18, 2014, DEA requires manufacturers to print the "C-IV" designation on all labels that contain 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl) cyclohexanol (tramadol), including its salts, isomers, and salts of isomers. The agency notes that every "DEA registrant who possesses any quantity of tramadol on the effective date of this final rule must take an inventory of all stocks of tramadol on hand as of August 18, 2014, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11 (a) and (d)." In addition, all "prescriptions for tramadol

or products containing tramadol must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR part 1306 and subpart C of 21 CFR part 1311 as of August 18, 2014."

The announcement is available on the *Federal Register* website at *www.federalregister.gov/articles/2014/07/02/2014-15548/schedules-of-controlled-substances-placement-of-tramadol-into-schedule-iv*.

FDA Lowers Recommended Starting Dose for Lunesta Due to Risk of Morning Impairment

FDA has lowered the recommended starting dose of the sleep drug Lunesta® (eszopiclone) from 2 mg to 1 mg. Patients who are currently taking 2 mg and 3 mg doses of eszopiclone should contact their health care provider to ask for instructions on how to continue to take their medication safely at a dose that is best for them, FDA advises. The dose change came after findings from a study of 91 healthy adults found that the medication was associated with impairment to driving skills, memory, and coordination for as long as 11 hours after the drug is taken, FDA notes.

More information is available in an FDA news release at *www.fda.gov/newsevents/newsroom/pressannouncements/ucm397453.htm*.

Lidocaine Should Not Be Used to Treat Teething Pain in Children, FDA Warns

FDA is recommending that prescription oral viscous lidocaine 2% solution should not be used to treat infants and children with teething pain, and is now requiring a new boxed warning to be added to the drug label to highlight this information. Oral viscous lidocaine solution is not approved to treat teething pain, and use in infants and young children can cause serious harm, including death, indicates FDA in a June 2014 Safety Announcement. FDA advises health care providers not to prescribe or recommend this product for teething pain. FDA is also requiring the "Warnings" and "Dosage and Administration" sections of the drug label to describe the risk of severe adverse events and to include additional instructions for dosing when the drug is prescribed for approved uses.

In 2014, FDA reviewed 22 case reports of serious adverse reactions, including deaths, in infants and young children who were either given lidocaine for treatment of mouth pain, or who accidentally ingested the medication.

More information is available in the safety announcement on FDA's website at *www.fda.gov/Drugs/DrugSafety/ucm402240.htm*.

FDA Reiterates Warning Against Using NuVision Pharmacy Products

Health care providers should not use or distribute compounded drugs marketed as sterile produced by Downing Labs, LLC, of Dallas, TX, also known as NuVision Pharmacy, warns FDA. Inspection results issued on July 16, 2014, indicate that FDA observed unsanitary conditions resulting in a lack of sterility assurance of sterile drug products produced by the company, which may put patients at risk, FDA notes in the safety announcement. "The inspection revealed sterility failures in 19 lots of drug products intended to be sterile, endotoxin failures in three lots of drug products, and inadequate or no investigation of these failures," states FDA in the announcement.

In 2013, the agency issued several similar warnings following NuVision's refusal to recall all sterile products. In April 2013, NuVision recalled methylcobalamin injection and lyophilized injection products, citing concerns about sterility in the wake of adverse event reports. Health care providers and consumers may report adverse events or quality problems associated with NuVision products to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Additional information is available in the safety announcement, available on FDA's website at *www.fda.gov/Drugs/DrugSafety/ucm405940.htm*.

JCPP Releases New Patient-Care Document to Promote Consistency

The Joint Commission of Pharmacy Practitioners (JCPP) has released a resource document aimed at promoting consistency in the pharmacists' process of patient care service delivery. "Pharmacists' Patient Care Process" was developed by examining key source documents on pharmaceutical care and medication therapy management. The document describes the process in five parts: collect, assess, plan, implement, and follow-up.

JCPP brings together the chief executive officers and elected officers of national pharmacy associations, including the National Association of Boards of Pharmacy®, to create a forum for discussion and opportunity for collaborative work on issues and priorities of pharmacy practice.

The document can be downloaded online at *www.pharmacist.com/sites/default/files/JCPP_Pharmacists_Patient_Care_Process.pdf*.

CPE Credit Offered for FDA Course on Misleading Prescription Drug Promotion

To raise awareness about the risks associated with false or misleading prescription medication marketing, FDA, in partnership with Medscape, is offering an online, one-hour continuing education course through its Bad Ad Program. Pharmacists may receive continuing pharmacy education (CPE) credit by taking this course. Learning objectives, faculty information, and other information is available on the course's website at *www.sigmatech.com/BadAd*. There is no registration fee for the course. Upon completion, pharmacists will receive one Accreditation Council for Pharmacy Education-accredited CPE hour (0.1 continuing education unit).

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

WEST VIRGINIA BOARD OF PHARMACY

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

continued from page 1

Some blame their software; however, it is the pharmacy and its pharmacists that are ultimately responsible. To this point, the Complaint Committee recently recommended discipline against a pharmacy or two for failure to report, which came up in investigations of other issues. If compliance by other licensees continues to be a problem, Board staff will be required to refer these issues to the Complaint Committee as well, friendly phone call or e-mail reminders notwithstanding. Thank you for your efforts to be on time with your reporting. As the Board says repeatedly, the CSMP is only as good as the data that are uploaded into it.

Inspector's Corner: Is Your Dispensing Software Up to Speed?

If you are planning to open a new pharmacy, or thinking of buying a new computer system for your prescription department, be certain that it meets all legal requirements and is adaptable to changes in those requirements (for example, Drug Enforcement Administration (DEA) requirements for electronic prescribing of CS). As inspectors look at new pharmacies and perform regular inspections, the software system in place touches on many areas they are looking at, including proper dispensing records. Of course, the dispensing software plays a vital part in today's practice to ensure that prescriptions are lawful, and to prevent errors, create proper labels and inserts, and other such things. Many pharmacies, from the single independent to the major pharmacy corporations, purchase or create systems that may not always be current on changes in law or adaptable to new laws, rules, or other legal requirements.

Software is generally not written by pharmacists, and even if it is, it may not keep required data in legally acceptable or adaptable form. If there is an error, it is doubtful that a claims auditor or investigator will be very sympathetic to an excuse that the computer did not work right when deciding to refuse a reimbursement or looking at possible administrative or criminal behavior. In the end, it is the pharmacy and its pharmacists who are responsible for compliance.

A recent example is the change of scheduling of hydrocodone combination products (HCPs) to Schedule II CS. Nearly everyone could handle that. However, once changed to Schedule II, how did you handle refills as allowed for previously written prescriptions? What about the fact that the federal guidance says that up to five refills of the pre-October 6, 2014 HCP prescriptions could be honored, but West Virginia law limits HCPs to no more than two refills? What about the West Virginia limit of these dispensings to no more than a 30-day supply at one time, versus the federal law that does not have any limit on the amount a single prescription can call for? These types of issues merit a conversation with your programmers or vendors to ensure that your pharmacy is compliant.

'Red Flags' Training Video for Pharmacists Available Through AWAR$_X$E

The National Association of Boards of Pharmacy® worked with several industry stakeholders to produce a training video to help make pharmacists more aware of certain "red flag" behaviors of patients engaged in drug diversion. Please take 10 minutes to watch the video available at *http://vimeo.com/95912158* via the Pharmacists page of the AWAR$_X$E® Prescription Drug Safety website, *www.AWARErx.org*. The Board's home page *(www.wvbop.com)* also has a version of this article with the link.

All pharmacy personnel need to be vigilant to help curb prescription drug misuse, abuse, and diversion; both DEA and West Virginia law clearly state that a pharmacist has a concurrent duty with the prescriber to make sure that the prescriptions he or she fills are valid and legal prescriptions. Interns and technicians spotting issues of potential diversion at the pharmacy should alert the pharmacist on duty to handle the situation. Thank you for viewing the video and keeping focused on this issue.

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.

West Virginia Board of Pharmacy
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Deborah Zak - Communications Manager