September 2014

News

West Virginia Board of Pharmacy

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New Board Officers Elected for 2014-2015 Fiscal Year

The West Virginia Board of Pharmacy elected its new officers for the July 1, 2014 through June 30, 2015 fiscal year: Carl K. Hedrick, Jr, RPh, as president, formerly vice president; Charles Woolcock, a public member and prior secretary for many years, as vice president; and Rebekah Heavener, RPh, as secretary. Outgoing President Lydia Main, RPh, congratulated the new officers. She and Past Presidents Sam Kapourales, RPh, and George Karos, RPh, continue on the Board, along with Public Member Martin Castleberry.

Substances Containing Butalbital Have Long Been Schedule III; What About Fioricet and Fiorinal?

Since House Bill (HB) 4208 passed in the 2014 Regular Legislative Session, the Board has received several inquiries regarding Fioricet® versus Fiorinal® (both containing butalbital). An example of the questions is: "According to HB 4208, are Fioricet and Fiorinal now Schedule III controlled substances? Are all products containing any butalbital now included as Schedule III drugs?" The answer is, yes, all are included, but this is not a new requirement; in fact, this has long been the case. Per HB 4208, West Virginia Code §60A-2-208(c) now states that Schedule III includes "any material, compound, mixture or preparation which contains any quantity of . . . Butalbital (including, but not limited to, Fioricet)." However, for years prior (the Board looked back as far as 1991, so it was put in even before), West Virginia Code §60A-2-208(c)(3) has included the following in Schedule III: "any substance which contains any quantity of a derivative of barbituric acid or any salt of barbituric acid." Given that established language, anything containing butalbital, a derivative of barbituric acid, or a salt of barbituric acid, has long been a Schedule III substance here.

So, if this has long been in the West Virginia Code, why did the legislature add the language, "Butalbital (including, but not limited to Fioricet)"? It became evident from dealing with state-level criminal cases that a clarification would be helpful due to a difference in how the federal law treats Fiorinal and Fioricet. Fiorinal is butalbital, aspirin, and caffeine. Fioricet is butalbital, acetaminophen, and caffeine. Due to the federal law, when combining certain controlled substances (CS) with non-controlled aspirin or acetaminophen in certain ratios or amounts in the final drug product, Fiorinal is a federally Scheduled III CS, but Fioricet is not federally scheduled. This different treatment in the federal schedules sometimes caused confusion in West Virginia state cases under the state law involving one or the other, despite the fact that they both contain butalbital. So, this additional language in HB 4208 was simply a clarification of the state law. In any event, Board staff has been informing those asking about the new language that the Board is not seeking out those who have not treated Fioricet as a CS under state law all along; it is simply seeking compliance with the Schedule III CS requirements going forward from the effective date, June 6, 2014 (including any necessary initial and ongoing inventories).

Board Receives Public Comment, Makes Changes to Proposed Pharmacy Technician Rules

The June *Newsletter* discussed proposed changes to the pharmacy technician (PT) rules due to the Pharmacy Practice Act revisions for PTs, effective July 1, 2014 (ie, must complete a PT education and training program and pass a national certification exam). West Virginia Code, Section 30-5-11 requires PT training and education to be done through either a learning institution or an on-the-job training program. The proposed revisions to Title 15, Series 7 would have shortened the on-the-job training period to 960 hours within nine months, with three more months to pass the Pharmacy Technician Certification Exam or the Exam for the Certification of Pharmacy Technicians. However, after receiving a presentation from pharmacy stakeholders at its June Board meeting, and reviewing written public comments to the proposed revisions at its July Board meeting, the Board revised the rule to allow 15 months to obtain the 960 hours (still with three months to pass a national exam). However, offsetting the additional time, the Board also voted to require individuals to file a pharmacy technician trainee (PTT) application, including the results of a criminal background check. If approved, he or she can begin as a PTT in a training program. Also notable, the Board voted to clarify that currently approved training programs remain approved for use under the new rules, as the required topics are unchanged.

National Pharmacy

(Applicability of the contents of articles in the National Pharmacy Comp
and can only be ascertained by examini

New Educational Video for Pharmacists Addresses Prescription Drug Abuse

The National Association of Boards of Pharmacy® (NABP®) and the Anti-Diversion Industry Working Group (ADIWG), a consortium of pharmaceutical manufacturers and distributors of controlled substances (CS), have released an educational video for pharmacists to help them identify the warning signs of prescription drug abuse and diversion when dispensing CS prescriptions. The video, entitled "Red Flags," encourages pharmacists to help combat this national problem by exercising their professional judgment to ensure that the prescriptions they dispense were written for a legitimate medical purpose, and to act upon any unusual behavior they observe.

Drug Enforcement Administration and various state pharmacy boards have described "red flags" as circumstances surrounding the presentation of a CS prescription that should raise reasonable suspicion about the validity of that prescription. The video highlights a number of these potential warning signs, some of which are not easy to spot, by weaving personal narratives with interactions between pharmacists and customers.

The video is available in the Pharmacists section of the AWAR$_X$E® Prescription Drug Safety website at *www.AWARERX.ORG/pharmacists*.

Root Causes: A Roadmap to Action

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 Error Reporting Program Report online at* www.ismp.org. *E-mail: ismpinfo@ismp.org.*

Errors are almost never caused by the failure of a **single** element in the system. More often, there are **multiple** underlying system failures that lead to an error, many of which can be identified when the involved health care providers take the time to uncover them.

Consider the following error: A doctor sent a hand-written order for car**bam**azepine 400 mg twice daily for an adult patient with a history of seizures.

The pharmacist entered the medication into the profile of a four-year-old child with the same last name as the adult patient for whom the medication had been prescribed.

The pharmacist failed to notice that the patient was a child, as age was not in a prominent location on the order entry screen. The nurse failed to recognize that the dose was too high and administered 400 mg of car**bam**azepine to the child. She also never thought to question why the pharmacy would send oral tablets for a four-year-old child, considering that the drug is available in chewable tablets and as a liquid suspension.

The nurse **assumed** that the child was receiving the medication because he had a history of seizures. However, the nurse did not check the patient's medical record. In fact, the child did **not** have a history of seizures.

The parents had a very limited understanding of English, so they were unable to intervene to correct the erroneous seizure history.

The error was finally detected after the child became lethargic and developed nausea and vomiting. At the time of discovery, the child's car**bam**azepine level was 18 mcg/mL; levels greater than 12 in pediatric patients are supratherapeutic.[i]

It may be discouraging to see how many things go wrong when a medication error reaches a patient. However, a thorough root cause analysis (RCA) can uncover the latent failures and produce an action plan to avoid future errors.

ISMP, through a generous grant from the National Association of Boards of Pharmacy Foundation™, has developed the *Root Cause Analysis Workbook for Community/Ambulatory Pharmacy.* The workbook is designed to assist community pharmacy personnel in completing RCA for a sentinel event that may have occurred in their pharmacy. The RCA workbook uses a specific set of steps and associated tools to identify the primary causes of the **sentinel event.**

The goal of the RCA is to create an action plan framework, including risk-reduction strategies, communication and implementation strategies, and measurement of effectiveness.

RCA for **sentinel events** is required in the Center for Pharmacy Practice Accreditation's standards developed by NABP, American Pharmacists Association, and American Society of Health-System Pharmacists Association, as well as by several boards of pharmacy in conjunction with their continuous quality improvement regulations.

This ISMP RCA workbook is suitable for use in community pharmacy, mail-order pharmacy, or other ambulatory pharmacy practice settings that need to investigate a **sentinel event.** For more information and to access the **free** workbook, visit *www.ismp.org/tools/rca/.*

[i] *http://pediatrics.aappublications.org/content/113/2/406.abstract*

FDA Withdraws Approval of Some High Dose Acetaminophen Products

Food and Drug Administration (FDA) is withdrawing approval of 108 abbreviated new drug applications (ANDAs) for prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit. For the 108 ANDAs, the manufacturers asked to withdraw their applications, as announced in the March 27, 2014 *Federal Register* notice. A second *Federal Register* notice addresses the applications of six manufacturers who have discontinued marketing their products, but who have not withdrawn their applications. The notice also announces FDA's intention to begin the process of withdrawing approval of those applications.

In light of these announcements, and to protect patients from inadvertent acetaminophen overdose, NABP advises that pharmacies no longer dispense combination drugs containing more than 325 mg of acetaminophen per dosage unit. NABP also advises that pharmacists consult with prescribers to discuss alternative products with lower acetaminophen doses.

FDA asked manufacturers to voluntarily withdraw these products from the market to reduce the risk of severe liver injury from inadvertent acetaminophen overdose. In January 2014, FDA recommended that providers consider prescribing acetaminophen products containing 325 mg or less per dose. The original announcement may be found in the Drug Safety and Availability section of FDA's website at *www.fda.gov/Drugs/DrugSafety*.

NCPDP Recommends Standardized Metric Measurements on Oral Liquid Medication Labels

The National Council for Prescription Drug Programs (NCPDP) has issued new recommendations and guidance for standardizing the dosing designation used on prescription container labels of oral liquid medications dispensed by community pharmacies in order to reduce dosing errors. NCPDP notes that such errors have been "a source of concern for many years," and that dosing errors involving young children are of particular concern because they may be more susceptible to harm from measurement errors and overdoses. The paper outlines the following recommendations for the dosing designation on prescription container labels for oral liquid medications:

- The millimeter (mL) should be used as a standard unit of measurement.
- Dose amounts should always use leading zeros before decimal points for amounts less than one and should not use trailing zeros after a decimal point.
- Dosing devices with numeric graduations and units corresponding to the container label should be made easily and universally available. For example, a device should be included with each dispensed medication.

The white paper was developed following a meeting with stakeholders representing 27 participants, including NABP. In addition to its general recommendations, the white paper also issued calls to action for relevant stakeholders, including government agencies, standards organizations, pharmacists and pharmacy technicians, pharmacy leadership, and health care associations. The white paper, *NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications,* is available for download from the NCPDP website at *http://ncpdp.org/Education/Whitepaper*.

USP Proposes New General Chapter Addressing Compounding of Hazardous Drugs

In an effort to protect health care providers and personnel who handle hazardous drugs, United States Pharmacopeial Convention (USP) has proposed new General Chapter <800> Hazardous Drugs–Handling in Healthcare Settings. The new proposed chapter addresses standards that apply to all personnel who compound hazardous drug preparations and all places where hazardous drugs are prepared, stored, transported, and administered. The new chapter also covers standards for receiving, storing, compounding, dispensing, administering, and disposing of nonsterile and sterile products and preparations. The proposed chapter applies to all personnel who are involved in handling hazardous drugs, including health care providers and staff, occupational health and safety specialists, and human resources. General Chapter <800> was published in the May/June issue of *Pharmacopeial Forum,* and may currently be viewed on the USP website at *www.usp.org/usp-nf*. Comments were accepted until July 31, 2014.

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2014 License Renewal Period Ending; Rules Proposed to Change Process Beginning 2015

For pharmacists and PTs due for their biannual license/registration renewals, your grace period is at its end. The grace period for pharmacy, mail order, manufacturer, wholesale drug distributor and/or CS handling licenses/permits ended August 1. Pharmacists and PTs had until August 30; after that, the Board will send a notification to those who failed to renew, giving 30 days from the date of receipt of the notice before you will be considered lapsed and have to do reinstatement. Even if you never received a renewal application, and even if you do not get a notice after August 30, if you have not renewed, your license is expired and you cannot practice until you get it reinstated. It is your responsibility to obtain a renewal application and get it in to the Board.

In an effort to streamline the process and drive timely renewals, the Board has proposed modifications to the rules for renewals in 2015. These changes will do away with sending certified mailers to individuals who fail to renew, and will modify the reinstatement process to charge the current reinstatement fee as a late fee, and to only require testing as part of a reinstatement process for those who fail to renew within one year of letting their license lapse. While this puts a little more responsibility on the individual to remember to renew, since the last-chance certified mail notifications will no longer be sent by the Board, it also relaxes the reinstatement process to allow payment of a late fee and not require reinstatement testing unless you let your license go for a whole year. Again, this will not be implemented until 2015, and only if the legislature approves the changes.

CSMP Data Being Mined and Used; Data Entry Accuracy More Important Than Ever

The West Virginia Controlled Substances Monitoring Program (CSMP) receives data on over 5 million dispensings of CS in/into the state every year. Prescribers, dispensers, law enforcement, and various agencies with access to the data make use of it in making treatment decisions and in investigations. Recently, the CSMP Advisory Committee set parameters for the Board to look for outlying patients (doctor shoppers, etc) in the system and send unsolicited information about them to their prescribers (as well as to look for other outliers). So, in December 2013 and January 2014, Board staff sent over 2,200 individual letters to prescribers informing them of specific patients of theirs who had CS dispensings from 14 or more prescribers in the prior 12-month period (one patient had dispensings from 30 different prescribers, so 30 different letters were required for that one patient alone). Again, in July 2014, Board staff sent over 3,000 letters to prescribers concerning specific patients of theirs who had dispensings in the prior 12 months from 12 or more different prescribers. Not all of those patients are involved in illegal conduct or doctor shopping, but the letters make the prescribers aware and encourage them to review the CSMP patient reports for themselves. Although the Board has not sent these communications to the dispensing pharmacies, it goes without saying that this tool is also available to them to help carry out the concurrent duty to prevent diversion and ensure that the prescriptions being filled are valid.

Unfortunately, while the Board has received good feedback from many of the prescribers, it has also been informed that many of the patients were not theirs, and that the dispensing pharmacy had made a data entry error for the prescriber's Drug Enforcement Administration number. Accuracy of the dispensing information is extremely important, given that this data is widely used to make prescribing decisions and in many criminal and administrative cases. Please take efforts to ensure your reported dispensing information is correct. If you make an error, you can now make corrections in the CSMP directly. Click "data submission," then click "correction request," and follow through with the correction process. Better data will result in better decisions.

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
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