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A Change in Leadership – Time for a New Chapter

It is with sadness that I inform you that I will be leaving the Ohio State Board of Pharmacy as of September 1, 2014. I want everyone to know that it has been an honor and a privilege to serve as your executive director. I am so proud of the work this agency has accomplished, goals achieved, and the culture change that has occurred during my tenure; however, it is time for a new chapter for me. In review of my time here, I am in awe of what our team has accomplished. Some of these accomplishments include information technology-centric strategies designed to streamline and simplify internal and external Board processes; Ohio Automated Rx Reporting System (OARRS) improvements designed to simplify use and make this tool more effective in combatting the opioid epidemic; assistance with many statutes and creation of rules; as well as compliance efforts addressing complex pharmacy issues, such as the New England Compounding Center compounding tragedy and illicit synthetic drugs. And last but not least, attempting to make this agency a better place to be and to serve, as I truly believe culture drives everything, ultimately dictating the service provided to the citizens of this state. I am glad to say that we have a culture of professionalism and service unparalleled in state government. These accomplishments would not have occurred without the support and drive from our incredible leadership team, office staff, field agents, and compliance specialists. Ohio is so fortunate to have these employees that make this one of the best boards of pharmacy in the country. I hope you will view the Board's new annual report, to be posted on its website *(www.pharmacy.ohio.gov)* prior to August 15, which will highlight agency statistics as well as what these employees have accomplished by department. I wish the very best for the next executive director and will always hold in deepest regard my time with this agency and relationships made over the years. I am so thankful for the opportunities afforded me while in this role, and can only say thank you.

Kyle Parker, MBA, RPh
Executive Director, Ohio State Board of Pharmacy

Regulatory Updates

Tramadol Now a Schedule IV Controlled Substance per DEA

Effective August 18, 2014, tramadol and products containing tramadol will be classified as Schedule IV controlled substances (CS) pursuant to a rule adopted by the United States Drug Enforcement Administration (DEA). **Please note: This DEA rule takes effect prior to a recent Ohio Board rule that would have made tramadol a Schedule IV CS effective September 1, 2014.** To assist with the implementation of this rule, the Board has developed a guidance document, which can be accessed at *http://pharmacy.ohio.gov/deatramadol,* addressing the conversion issues of this scheduling change.

Senate Bill 230 Signed into Law June 17, 2014; Effective September 17, 2014

This law prohibits a pharmacist or pharmacy intern from dispensing non-self-injectable cancer drugs by delivering the drugs directly or causing the drugs to be delivered directly to a patient's home unless that patient is:

(1) a resident of a nursing home, residential care facility, rehabilitation facility, or similar institutional facility or heath care facility; or

(2) a hospice patient or client of a home health agency.

As a floor amendment to this bill, it also removed the requirement that the executive director of the Board be a licensed pharmacist in good standing, thereby allowing a non-pharmacist to serve as the executive director. This changed the Board's 130-year tradition since the Board's creation in 1884.

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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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MMR Vaccination Update

Effective June 9, 2014, licensed pharmacists are permitted to administer the measles, mumps, and rubella (MMR) vaccine to individuals 18 years and older pursuant to Amended Emergency Rule 4729-5-38.

Pharmacists should be advised that the following criteria must be met in order to provide the vaccine:

- The individual receiving the vaccination must be 18 years or older (Ohio Revised Code (ORC) 4729.41).
- The pharmacist must be able to document meeting the training criteria required by Rule 4729-5-36 of the ORC.
- The vaccine must be included on the physician-established protocol required by Rule 4729-5-37.

Time to Renew Your Pharmacist License and Print Your Own Pocket Card

The pharmacist renewal notices were sent out on July 15, 2014, utilizing e-mail again this year. You will once again access your renewal password and user ID from the Board website by visiting *www.pharmacy.ohio.gov* and clicking on the link entitled "R.Ph./Intern License Renewal - Click here to retrieve your username and password online license renewal." If you are unable to renew online, you must submit a written, e-mailed (Emily.Maggard@bop.ohio.gov), or faxed request for a printed renewal application. You will not be able to utilize a credit card for payment if you renew with a printed renewal application. Interns will follow the same process.

All "032" pharmacists are "attesting" (reporting) to completion of their continuing education (CE) during this year's pharmacist license renewal. All CE certificates of participation must be dated between March 1, 2011 and September 15, 2014, unless this is the pharmacist's first-ever (newly licensed by exam) CE reporting year. Please carefully read the online renewal question titles and questions, as the Board must take into account all CE reporting situations. These questions are presented in a specific order to address each reporting situation.

The only real problem that may occur during the online renewal process is double-billing of credit cards. This is a result of hitting the "back" button after submitting final information. Every time you hit the back button, your credit card is charged. If you accidentally get charged more than once, the Board tries to catch it and credit your account. However, if a double billing appears on your statement, let the Board office know and the Board will get it refunded.

New this year: You will be able to print your own pocket ID card once you have successfully renewed (online or paper)! Within 48 hours of your successful renewal, you will receive an e-mail with a link to your 2015 license. All you will have to do is click on the link and open the file in Adobe Reader to print your pocket card; it is as easy as that! Please be sure to print your license before the expiration date given in the e-mail. If you do not receive the e-mail within 48 hours, **please check your spam folder.** If you still cannot locate the e-mail, please contact the Board office utilizing the "Contact the Board" selection along the left side of the website. Be sure to select "General Licensing Information" as your subject line.

Again, you need to renew your license by September 15, 2014, if you plan to continue practicing pharmacy in Ohio after that date. If you do not wish to renew your license, please notify the Board office immediately via e-mail. The Board truly appreciates all of the pharmacists and pharmacy interns who utilize the online renewal process.

Compliance Update: FAQs

Is this a valid prescription? Ohio Administrative Code (OAC) 4729-5-30 addresses "Manner of issuance of a prescription." See below some of the frequent questions the Board receives, along with the response listed with alphabetical letters and numbers referring to this specific section of Rule 4729-5-30.

The prescriber faxed a prescription to us. Do they have to keep a copy of the prescription in the patient's records? Yes.

> 4729-5-30(E) Original written prescriptions authorized and signed by a prescriber may be transmitted by the prescriber or the prescriber's agent by facsimile machine to a pharmacy pursuant to the following:
>
> (1) The facsimile of the prescription must include the full name of the prescriber and if applicable the full name of the prescriber's agent transmitting the prescription to the pharmacy.
>
> (2) The original prescription signed by the prescriber from which the facsimile is produced shall not be issued to the patient. **The original prescription signed by the prescriber must remain with the patient's records at the prescriber's office or the institutional facility where it was issued.**

Can a Schedule II prescription be sent to the pharmacy via traditional fax? Yes, under certain circumstances listed below.

> 4729-5-30(E)(3) Prescriptions for schedule II controlled substances may not be transmitted by facsimile **except** for:

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(a) A resident of a long term care facility pursuant to rule 4729-17-09 of the Ohio Administrative Code.

(b) A narcotic substance issued for a patient enrolled in a hospice. **The original prescription must indicate that the patient is a hospice patient.** The facsimile transmission must also meet the other requirements of this rule.

(c) A compounded sterile product prescription for a narcotic substance pursuant to rule 4729-19-02 of the Ohio Administrative Code.

(4) A facsimile of a prescription received by a pharmacy in any manner other than transmission directly from the prescriber or the prescriber's agent shall not be considered a valid prescription.

Questions on prescribing? The Board receives many prescribing questions. Though glad to help, rules about prescribing come from the prescriber's respective licensing board, and many times questions need to be redirected to them. The State Medical Board of Ohio *(www.med.ohio.gov)* has several links to frequently addressed areas, including prescribing of diet drugs, prescribing for self and family members, and the physician assistant formulary. Physician assistants fall under the authority of the medical board. The Ohio Board of Nursing is responsible for advance practice nurses. Its rules and prescribing formulary are found at *www.nursing.ohio.gov/Practice.htm#AdvancedPractice.* Of course, the pharmacist continues to have a corresponding responsibility when filling these prescriptions.

Attention All In-State CE Providers

Per OAC 4729-7-05(C), all in-state CE providers must renew their provider status every three years. All current providers should have received information (provider number and password) to allow online renewing/updating of their status as an in-state provider of CE programs. Additionally, program notifications are now submitted online as well, thus reducing the need to fax the information to the Board. It is still the responsibility of the provider to keep a list of participants for any particular program. Providers, be sure to renew online now so your account does not lapse.

OARRS Goes to Daily Reporting (Even When There Is Nothing to Report)

Effective May 22, 2014, pharmacies and prescribers who personally furnish reportable medications (including samples) to their patients must report those transactions on a daily basis. On days for which there is no dispensing of a reportable medication, the pharmacy is required to enter a "zero report." Every day must be accounted for. The OARRS website *(www.ohiopmp.gov)* has a guidance document posted to assist pharmacies on how to mark their locations as being closed on a weekend so an automatic zero report is generated for them.

Important! Many pharmacies have been sending a report that does not contain any dispensing information and understandably think this is a zero report. It is not. **An empty report does not register in OARRS as a zero report.** The pharmacy must still manually enter the zero report. This issue often pops up when a low-volume store that did not dispense any reportable medications that day is batched with the rest of the stores in the same chain. The software vendor sweeps all stores and reports what it collects. Watch for this and pay attention to the OARRS compliance reminders that are e-mailed on a daily basis.

Disciplinary Actions

Anyone having a question regarding the license status of a particular practitioner, nurse, pharmacist, pharmacy intern, or dangerous drug distributor in Ohio should contact the appropriate licensing board. The professional licensing agency websites listed below may include disciplinary actions for their respective licensees.

State Dental Board.....614/466-2580
www.dental.ohio.gov

State Medical Board.....614/466-3934
www.med.ohio.gov

State Nursing Board.....614/466-3947
www.nursing.ohio.gov

State Optometry Board.....614/466-5115
www.optometry.ohio.gov

State Pharmacy Board.....614/466-4143
www.pharmacy.ohio.gov

State Veterinary Medical Board.....614/644-5281
www.ovmlb.ohio.gov

Drug Enforcement Administration.....800/882-9539
www.deadiversion.usdoj.gov

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