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News



State of Ohio Board of Pharmacy

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State Announces New Overdose Prevention Campaign

Dear Ohio Pharmacist,

In May of this year, the Ohio Department of Health and the Ohio Department of Mental Health and Addiction Services launched a targeted campaign to raise overdose death awareness in the 15 Ohio counties that accounted for 80% of Ohio's fentanyl-related drug overdose deaths in 2014. Those counties are Butler, Clark, Clermont, Cuyahoga, Franklin, Hamilton, Lorain, Lucas, Marion, Montgomery, Ross, Scioto, Stark, Summit, and Warren.

Fentanyl, a synthetic opioid that is estimated to be 30 to 50 times more potent than heroin, is becoming more and more prevalent across Ohio. A total of 503 fentanyl-related deaths occurred in the state during 2014, up from 84 in 2013. The campaign looks to prevent those numbers from further increasing by teaching people to look for signs of abuse and encouraging them to obtain the opioid overdose reversal drug, naloxone.

The campaign will be disseminated through billboards, a radio spot, and mobile and digital ads. Anyone interested in the campaign can also visit www.odh.ohio.gov/stopoverdoses, where there is opioid abuse information as well as explanations on how to obtain naloxone without a prescription at participating pharmacies.

But none of these campaign tools can have as much impact on a patient as you can, especially if you are operating in the specific counties mentioned previously. The State of Ohio Board of Pharmacy would like to remind you that your professional guidance can be of great significance to your patients. As a trusted pharmacist, you can help strengthen this campaign by helping to educate your patients and provide them information on how to obtain naloxone.

As a reminder, information on naloxone dispensing by a pharmacist without a prescription can be accessed at www.pharmacy.ohio.gov/naloxone.

On behalf of the Board, I want to once again thank you for the vital work you do every single day. With your help, we can continue to keep the citizens of Ohio informed about opioid abuse. The more we do, the better chance we have at saving lives.

Sincerely,

Steven W. Schierholt, Esq
Executive Director
State of Ohio Board of Pharmacy

Reporting Gabapentin Products to OARRS – Effective December 1, 2016

Effective December 1, 2016, the following entities are required to submit the specified dispensing, personal furnishing, or wholesale sale information on all products containing gabapentin to the Ohio Automated Rx Reporting System (OARRS):

- ◆ All pharmacies located outside this state and licensed as a terminal distributor of dangerous drugs that dispense gabapentin to outpatients residing in this state.
- ◆ All pharmacies located within this state and licensed as a terminal distributor of dangerous drugs that dispense gabapentin to all outpatients.
- ◆ All wholesalers licensed as a wholesale distributor of dangerous drugs that sell gabapentin at wholesale shall report those drug transactions.
- ◆ All pharmacies licensed as a terminal distributor of dangerous drugs that sell gabapentin at wholesale shall report those drug transactions.
- ◆ All prescribers, except veterinarians, located within this state who personally furnish gabapentin to outpatients, including samples.

For more information, visit www.pharmacy.ohio.gov/gabapentin.



FDA Calls for Review of Opioids Policy, Announces Action Plan

As part of a broad national campaign to address opioid abuse, dependence, and overdose, Food and Drug Administration (FDA) Deputy Commissioner for Medical Products and Tobacco, Dr Robert Califf, along with other FDA leaders, developed a comprehensive action plan to reassess the agency's approach to opioid medications. The objective of the plan is to "focus on policies aimed at reversing the epidemic, while providing patients in pain access to effective relief," indicates the FDA news release. FDA's plan is to:

- ◆ Re-examine the risk-benefit paradigm for opioids and ensure that the agency considers their wider public health effects;
- ◆ Convene an expert advisory committee before approving any new drug application for an opioid that does not have abuse-deterrent properties;
- ◆ Assemble and consult with the Pediatric Advisory Committee regarding a framework for pediatric opioid labeling before any new labeling is approved;
- ◆ Develop changes to immediate-release (IR) opioid labeling, including additional warnings and safety information that incorporate elements similar to the extended-release/long-acting (ER/LA) opioid analgesics labeling that is currently required;
- ◆ Update Risk Evaluation and Mitigation Strategy requirements for opioids after considering advisory committee recommendations and review of existing requirements;
- ◆ Expand access to, and encourage the development of, abuse-deterrent formulations of opioid products;
- ◆ Improve access to naloxone and medication-assisted treatment options for patients with opioid use disorders; and
- ◆ Support better pain management options, including alternative treatments.

FDA will also seek guidance from outside experts in the fields of pain management and drug abuse. The National Academies of Sciences, Engineering, and Medicine has been asked by FDA to help develop a framework for opioid review, approval, and monitoring that balances individual need for pain control with considerations of the broader public health consequences of opioid misuse and abuse. The news release is available on FDA's website at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm.

More Selected Medication Safety Risks to Manage in 2016



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.

Manufacturer Drug Labeling, Packaging, Nomenclature – Per Liter Electrolyte Content on Various Sizes of Manufacturers' IV Bags

The way electrolyte concentrations are expressed on intravenous (IV) bags in volumes less than or greater than one liter has tripped up many practitioners over the years. Concentrations are listed per liter, not per container volume. For example, a 250 mL 0.9% sodium chloride injection container label lists the sodium chloride content as 154 mEq/1,000 mL, rather than 38.5 mEq/250 mL. Commercially available parenteral nutrition products available in containers greater than one liter also express the electrolyte ingredients "per liter."

An error occurred while a pharmacist was preparing a bag of 3% sodium chloride after the pharmacy unexpectedly ran out of the commercially available bags. The pharmacist mistakenly set the proportion up as $154 \text{ mEq}/0.9\% = x/3\%$ and calculated that he needed 513 mEq of sodium chloride, when he actually only needed 256-257 mEq of sodium chloride for a 500 mL bag ($77 \text{ mEq}/0.9\% = x/3\%$).

For single- and multiple-dose injectables, the United States Pharmacopeial Convention (USP) requires the strength per total volume as the primary, prominent display on the label, followed in close proximity by the strength per mL enclosed in parentheses. This should apply to large volume parenterals as well. Until it does, pharmacists who calculate electrolyte quantities should seek out an independent double check. Sufficient quantities of commercially available products should be used whenever possible. For products that routinely require admixture, an instruction sheet should be available to guide the process.

Patient Education – Discharging Patients Who Do Not Understand Their Discharge Medications

Despite the importance of teaching patients about the medications to take after discharge, studies suggest health care providers are not successfully preparing patients for the transition home. Between 30% and 70% of patients make a medication error in the immediate weeks following hospitalization,¹⁻⁵ and the Centers for Medicare & Medicaid Services reports an average national hospital readmission rate of 17.5% to 19.5%.⁶ The discharge process is often rushed and interrupted, making it difficult to ensure patients know what medications to take, the correct doses, and how to take them after discharge. Immediately prior to discharge is not an ideal time for education either, as patients may be overwhelmed with the amount of information being provided at once.

Medication errors that occur during the first few weeks after discharge from the hospital can cause significant harm. In fact, one study showed that almost a quarter of all post-discharge errors were considered serious or life-threatening, and that



most of these errors happened within the first 14 days after discharge.⁵ The highest predictors of post-discharge errors included low health literacy and low subjective numeracy (self-reported measure of the ability to perform mathematical tasks and the preference for numerical versus prose information (ie, ordinary words)).⁴

Perhaps this risk is best addressed with a redesigned discharge process that facilitates the most effective means of teaching patients about their medications, initiating education earlier in the hospital stay, and providing post-discharge support.

References

1. Coleman EA, Smith JD, Raha D, Min SJ. Posthospital medication discrepancies: prevalence and contributing factors. *Arch Intern Med.* 2005;165(16):1842-1847.
2. Mesteig M, Helbostad JL, Sletvold O, Røstad T, Saltvedt I. Unwanted incidents during transition of geriatric patients from hospital to home: a prospective observational study. *BMC Health Serv Res.* 2010;10:1.
3. Lalonde L, Lampron AM, Vanier MC, Levasseur P, Khaddag R, Chaar N. Effectiveness of a medication discharge plan for transitions of care from hospital to outpatient settings. *Am J Health Syst Pharm.* 2008;65(15):1451-1457.
4. Mixon AS, Myers AP, Leak CL, et al. Characteristics associated with postdischarge medication errors. *Mayo Clin Proc.* 2014;89(8):1042-1051.
5. Kanaan AO, Donovan JL, Duchin NP, et al. Adverse drug events after hospital discharge in older adults: types, severity, and involvement of Beers criteria medications. *J Am Geriatr Soc.* 2013;61(11):1894-1899.
6. American Hospital Association. Rethinking the hospital readmissions reduction program. *TrendWatch.* March 2015.

USP Publishes Chapter on Handling Hazardous Drugs in Health Care Settings

A new general chapter, <800> *Hazardous Drugs—Handling in Healthcare Settings*, has been published as part of a suite of health care quality standards included in the *United States Pharmacopeia – National Formulary (USP–NF)* by USP to help prevent and/or limit hazardous drug exposures in health care. The standard applies to all health care personnel, such as physicians, nurses, veterinarians, pharmacists, and technicians, and all health care facilities where hazardous drugs are handled or manipulated, including their storage and distribution. Health care facilities have more than two years to conform to the new requirements and have until July 1, 2018, to implement the new standard, indicates a USP press release, which is available at www.usp.org in the News section. General Chapter <800> is available in both the First Supplement to *USP 39–NF 34* and the *USP Compounding Compendium*.

FDA Provides Training Video on Keeping Medications Safe in Emergency Situations

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. In the February 2016 Drug Info Rounds video, “Emergency Preparedness – Keeping Medications Safe,”

pharmacists discuss educating patients about having a plan in place for emergency medication and medical supplies and the resources available for pharmacists to use when advising their patients. 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. All Drug Info Rounds videos can be viewed on the FDA website at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.

FDA Requires Class-Wide Labeling Changes for IR Opioid Analgesics

FDA is requiring class-wide safety labeling changes for IR opioid pain medications, which will include a new boxed warning about the serious risks of misuse, abuse, addiction, overdose, and death. The announcement is part of the agency’s effort to educate prescribers and patients about the potential risks related to opioid use. FDA is also requiring several safety labeling changes across all prescription opioid products to include additional information on the risk of these medications. The new requirements are part of a plan to reassess the agency’s approach to opioid medications. The plan is focused on reversing the epidemic of abuse and overdose while still providing patients in pain access to effective relief, indicates the FDA news release at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery.

Further, FDA is requiring updated labeling for all opioids (both IR and ER/LA products) to include safety information about potentially harmful drug interactions with other medicines that can result in a serious central nervous system condition called serotonin syndrome. In addition, updated labeling will include information about opioid effects on the endocrine system, including a rare but serious disorder of the adrenal glands (adrenal insufficiency) and decreased sex hormone levels (androgen deficiency). More information about these risks is available in FDA’s Drug Safety Communication announcement, available at www.fda.gov/Drugs/DrugSafety/ucm489676.htm.

FDA Issues Alert Regarding All Unexpired Sterile Drug Products Produced by Medaus Pharmacy

On April 1, 2016, FDA alerted health care providers and patients not to use products marketed as sterile from Medaus Pharmacy in Birmingham, AL. Insanitary conditions, including poor sterile production practices, were identified by FDA investigators during a recent inspection at Medaus’ facility. The affected products were distributed nationwide and internationally. The alert applies to all unexpired drug products that are intended to be sterile. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from Medaus, and not administer them, indicates the FDA Safety Alert, available at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsForHumanMedicalProducts/ucm493871.htm.

New and Updated Rules – First and Second Quarter 2016

The Board has adopted a number of rule changes in the first and second quarter of 2016. To assist licensees in maintaining compliance with these requirements, a complete list of the changes along with implementation dates can be accessed at www.pharmacy.ohio.gov/2016rules. Some highlights include the following:

- ◆ Changes to the Board’s responsible person (RP) rule (Ohio Administrative Code (OAC) 4729-5-11), including new requirements for wholesalers and reduction in the notification time when there is a change of RP.
- ◆ Personal furnishing requirements for prescribers licensed as terminal distributors of dangerous drugs (OAC 4729-5-17).
- ◆ A new central fill pharmacy rule (OAC 4729-5-28).
- ◆ Updates to the security and control requirements for terminal distributors of dangerous drugs (OAC 4729-9-11).

Roundtable and Law Presentations at the University of Toledo

The Board has added dates in northwest Ohio to its schedule of roundtables and law presentations.

For more information on the roundtables, including registration information, visit www.pharmacy.ohio.gov/roundtables.

For more information on the law presentations, including registration information, visit www.pharmacy.ohio.gov/2016law.

Zika Resources Available

Mosquito season runs from May through October, and bites from infected mosquitoes can transmit serious diseases such as the Zika virus or West Nile virus. While the primary mosquito that transmits the Zika virus is found in the tropics and southern United States and not known to be established in Ohio, it does have a “cousin” that is found in parts of Ohio and may potentially transmit the virus.

West Nile virus can also be a serious public health issue. The mosquito that carries the virus is established in Ohio, and cases occur each year with potential seasonal flare-ups under certain weather conditions. The mosquitoes that transmit the Zika virus primarily bite during the day, while those that transmit the West Nile virus primarily bite at dusk and dawn.

As health care providers, pharmacists should be aware of the risks associated with mosquito-related diseases and such risks should be communicated to your patients. While patients might think that mosquito bites are simply an annoyance, the Board urges you to remind your patients who are around active mosquitoes to wear light-colored clothing, long pants, long-sleeved shirts,

shoes, and socks. Use of Environmental Protection Agency-registered mosquito repellent and following the label directions is also recommended.

You can find additional information on how to stay safe from mosquito bites this summer by visiting www.pharmacy.ohio.gov/zika.

Ohio Medical Marijuana Control Program

In early September, House Bill 523 goes into effect, legalizing medical marijuana in Ohio. The Board is responsible for implementing rules on the registration of medical marijuana patients and the licensure of medical marijuana dispensaries. The Board is in the process of developing rules to implement this new law and is committed to keeping the public up to date throughout the process. Those who are interested can sign up to receive email updates from the Board by visiting www.pharmacy.ohio.gov/medical.

Controlled Substance Diet Drug Regulations

The Board continues to get questions about diet drugs. The State of Ohio Medical Board Rule [4731-11-04](#) governs the use of controlled substances (CS) to assist in weight **reduction**. This rule still has the requirements of the face-to-face meeting with the physician, the 12-week limit on duration of therapy, and the seven-day gap restrictions.

Medical Board Rule [4731-11-04.1](#) governs the use of CS for **chronic weight management**. The key differences in this rule are:

- (1) The physician shall meet face to face with the patient for the initial visit and at least every 30 days during the first three months of treatment. Following the initial visit and two follow-up visits, the treatment may be continued under one of the following means:
 - (a) The physician may authorize refills for the CS anorexiant up to five times within six months after the initial prescription date;
 - (b) The treatment may be provided by a physician assistant in compliance with this rule, the supervisory plan or policies of the health care facility, and the physician assistant formulary adopted by the Medical Board.
- (2) There is no 12-week maximum length of therapy for weight loss medications that are Food and Drug Administration-approved for chronic weight management.
- (3) There is no seven-day gap limitation on medications for chronic weight management.

Rule 4731-11-03 of the OAC permits the prescribing of CS stimulants for the treatment of moderate to severe binge eating disorder (BED). BED is considered to be a separate, distinct diagnosis.

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As always, pharmacists are required to request an OARRS report when required, to use corresponding responsibility regarding the validity of the prescription, and to exercise professional judgment.

Supplying Stock Medications to Prescribers or Another Pharmacy

A prescriber wants to purchase product from the pharmacy to be used in his or her office. A pharmacy wants to purchase a bottle of medication from another pharmacy, either within the same chain or to another chain. This is permitted, but how should the pharmacy accomplish this?

For Schedule II CS, the **only** legal way is for the purchaser (prescriber or other pharmacy) to complete his or her own Drug Enforcement Administration (DEA) Form 222 and give it to the selling pharmacy, much like how a pharmacy completes a DEA Form 222 for its wholesaler (back before the Controlled Substance Ordering System). The selling pharmacy must comply with all rules regarding processing the DEA Form 222.

For all other dangerous drugs, both controlled and non-controlled, the pharmacy may sell product to the prescriber or other pharmacy by using an itemized invoice detailing precisely how much and what medications are being sold. Such transactions must be done in accordance with Rule 4729-9-10 of the OAC.

Under no circumstance should you fill a prescription labeled with “office use” as the patient. Prescriptions and the prescription numbering sequences are for unique, individual patients. Prescription numbers are **not** to be used as an office accounting system.

Do not forget the OARRS component of this transaction. Remember that all sales of CS (and gabapentin after December 1, 2016) from your pharmacy DEA registration to another DEA registrant (either a pharmacy or a prescriber) must be reported as a wholesale transaction in OARRS. This will require the pharmacy to establish an OARRS wholesale account. A “wholesale handbook” is posted on the OARRS website under the Documents tab.

Reporting Buprenorphine Prescriptions to OARRS

The following is a frequently asked question (FAQ) regarding reporting buprenorphine prescriptions to OARRS.

Q: When reporting buprenorphine prescriptions to OARRS, which identifier should be reported: the prescriber’s regular DEA number or his or her “X” number?

A: When reporting buprenorphine prescribed for the purpose of treating addiction, report the “X” number. When reporting buprenorphine prescribed for the treatment of pain, report the regular DEA number.

Compliance FAQs

Below are two common FAQs about compliance with prescription regulations.

Q: Does the body mass index (BMI) have to be written on a diet drug prescription?

A: No. While BMI is useful clinical information for the pharmacist, it is not required to be written on the prescription per OAC 4729-5-30.

Q: Can I accept an electronic signature for a printed prescription?

A: No. All printed prescriptions must have the manual signature of the prescriber in wet ink.

Acute Pain Guidelines Training Module

In its ongoing efforts to combat prescription drug abuse and save lives, the Governor’s Cabinet Opiate Action Team recently released the *Ohio Guideline for the Management of Acute Pain Outside of Emergency Departments*.

You may have recently received an email from the Opiate Action Team encouraging you to watch a short training module on the new guidelines. **While this training is not mandatory, the module is strongly encouraged.**

For those who did not receive the email link, you may access the training video by visiting <http://ohiorxguidelines.com>.

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