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Pharmacists Have a Role to Play in Ending Human Trafficking

Human trafficking is one of the fastest growing criminal enterprises worldwide. Victims of human trafficking include children and adolescents involved in the sex trade; adults age 18 or over who are coerced or deceived into commercial sex acts; and anyone forced into different forms of labor or services, such as domestic workers held in a home or farm workers forced to labor against their will.

Each year, an estimated 1,078 Ohio children become victims, and 3,016 more are at risk. Ohio has ranked as high as fifth among all states in total reported human trafficking cases, with Toledo, OH, being identified as the fourth highest-ranking city in the nation for recruiting victims into the illegal trade.

As health care providers, pharmacists are professionals who may interact with trafficking victims who are still in captivity. The expert assessment and interview skills of health care providers contribute to their readiness to identify victims.

To assist pharmacists in identifying victims of human trafficking, the Ohio State Board of Pharmacy is proud to offer a no-cost, one-hour (0.1 CEU) pharmacy jurisprudence course. This course can be accessed by visiting *www.pharmacy.ohio.gov/humantrafficking*.

I also encourage you to visit *www.humantrafficking.ohio.gov* to learn more about Ohio's efforts to combat human trafficking. This site contains a number of resources such as fact sheets, posters, and other materials to help raise awareness of this tragic crime.

On behalf of the Board, I thank you for your efforts in raising awareness of this important issue facing our communities. Only by working together can we end human trafficking in Ohio.

Sincerely,

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

New Drug Compounding Chapter of the Ohio Administrative Code Went Into Effect May 1, 2015

On May 1, 2015, Ohio Administrative Code (OAC) Chapter 4729-16 went into effect. This new chapter consolidates many existing rules regarding drug compounding and includes the following rules.

- 4729-16-01: Provides the definitions for the chapter.
- 4729-16-02: Requires Food and Drug Administration-registered outsourcing facilities to be licensed in Ohio.
- 4729-16-03: Provides the requirements for the compounding of drugs in a pharmacy, including adherence to United States Pharmacopeia Chapters <795> and <797>. This rule replaces OAC 4729-9-21.
- 4729-16-05: Provides the requirements for drugs compounded in a fluid therapy pharmacy. This rule replaces OAC 4729-31.
- 4729-16-06: Provides the recordkeeping requirements for compounded drugs.
- 4729-16-07: Authorizes the compounding of drugs at an in-state pharmacy for direct administration by a prescriber. This rule replaces OAC 4729-9-25 and restricts this practice to in-state pharmacies only.
- 4729-16-08: Provides the requirements for drugs compounded by nonresident (out-of-state) pharmacies.
- 4729-16-09: Reflects changes to Ohio law that requires prescriber practices that were previously exempted from licensure to obtain a terminal distributor of dangerous drugs license in order to possess, have custody or control of, and distribute dangerous drugs that are compounded or used for the purpose of compounding.
- 4729-16-10: Authorizes in-state pharmacies to compound drugs in the event of a drug shortage. This requires an entity to submit notification to the Board.

As a reminder, OAC 4729-19 still applies to prescribers who compound sterile products, including, but not limited to, total parenteral nutrition solutions, parenteral analgesic drugs, parenteral antibiotics, parenteral antineoplastic agents, parenteral electrolytes, parenteral vitamins, irrigating fluids, and ophthalmic preparations.

All licensees are encouraged to review these rules in detail. These rules are available on the Board's website at *www.pharmacy.ohio.gov/LawsRules/OAC.aspx*.

Outsourcing Facilities Licensed in Ohio

The Drug Quality and Security Act, signed into law on November 27, 2013, created a new Section 503B in the Federal Food, Drug, and Cosmetic Act. Under Section 503B, a compounder can become an "outsourcing facility." These facilities are permitted to provide non-patient-specific compounded sterile drug products that must meet current Good

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FDA's New Database Simplifies Searching for Guidance Documents

Food and Drug Administration (FDA) has released a new database that houses most FDA guidance documents for regulatory professionals. The guidance documents for nearly all FDA-regulated professions and industries are available in a searchable database that allows users to enter keywords that update automatically as they are typed. Search results may also be narrowed by product, date, document type, and other terms. The database also indicates whether there is an open comment period and the deadline for submitting comments.

The database can be accessed at *www.fda.gov/RegulatoryInformation/Guidances/default.htm*.

2014-2015 Targeted Medication Safety Best Practices for Hospitals

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.*

The purpose of the Targeted Medication Safety Best Practices (TMSBP) for Hospitals is to identify, inspire, and mobilize widespread, national adoption of consensus-based best practices on specific medication safety issues that continue to cause fatal and harmful errors in patients despite repeated warnings in ISMP publications. These best practices are realistic practices, already adopted by many organizations, upon which hospitals can focus their medication safety efforts. The best practices are applicable to all types of hospitals including, but not limited to, critical access hospitals, cancer hospitals, and children's hospitals. They may also be applicable to other health care settings, as well as non-inpatient areas of hospitals and hospital systems. These best practices have been reviewed by an external expert advisory panel and approved by the ISMP Board of Trustees. Related issues of the *ISMP Medication Safety Alert!* are referenced after each best practice.

Recurrent Issue of Serious Harm

Oral methotrexate for non-oncological indications administered daily instead of weekly or twice weekly is a recurrent issue and one of the six TMSBPs.

ISMP has published this error in seven *ISMP Medication Safety Alert!* issues from 1996 to 2013. Although dosed daily for oncology purposes, it is used weekly or twice weekly to treat a variety of autoimmune diseases (eg, psoriasis, severe rheumatoid arthritis). Error reports point to inadvertent ordering and/or entering as daily instead of weekly or twice weekly, and lack of patient education/understanding of medication dosing schedule. To minimize the risk of error, **Best Practice 2** calls for hospitals to:

a) Use a weekly dosage regimen default for oral methotrexate. If overridden to daily, require a hard stop verification of an appropriate oncologic indication.
b) Provide patient education by a pharmacist for all weekly oral methotrexate discharge orders.

Question: Does the best practice of a weekly frequency default for oral methotrexate apply to a specialty cancer hospital?

Answer: The intent of this best practice is to reduce errors when methotrexate is prescribed as a weekly regimen for non-oncologic or oncologic indications. Even when used for oncologic purposes, oral methotrexate is sometimes prescribed as a weekly regimen, not daily. Thus, this best practice applies to all patient care settings, including specialty cancer hospitals.

Teaching Points (Both Verbal and Written)

- Explain the weekly dosing schedule.
- Explain that taking extra doses is dangerous.
- Have the patient repeat back the instructions.
- Provide the patient with the free ISMP high-alert medication consumer leaflet on methotrexate (found at *www.ismp.org/AHRQ/default.asp)*.

To read all of the best practices, visit *www.ismp.org/Tools/BestPractices/default.asp.*

ACPE Releases Updated Definition of CPE and Guidance on CPD

The Accreditation Council for Pharmacy Education (ACPE) has released two documents that provide guidance and support for continuing pharmacy education (CPE) and continuing professional development (CPD). The two documents, approved by the ACPE board of directors, are described below.

- The revised *Definition of Continuing Education for the Profession of Pharmacy* defines the quality of CPE required by ACPE and the competencies required for CPE activity content. The *Definition* document will assist providers of CPE in planning activities that will be applicable to the professional development of pharmacists and certified pharmacy technicians.
- The *Guidance on Continuing Professional Development (CPD) for the Profession of Pharmacy* incorporates feedback from a broad survey of the pharmacy profession that was conducted in July 2014. The *Guidance* document provides details on the learning activities that may contribute to the professional development of both pharmacists and pharmacy technicians beyond CPE, and also "provides a process for pharmacists and pharmacy technicians to meet and maintain defined competencies in areas relevant to their respective professional responsibilities."

Additional information, including links to the documents, is available in a press release on the ACPE website at *www.acpe-accredit.org/pdf/ACPEAdvancesCPE-CPDforPharmacists.pdf*.

Hospira Issues Recall for Multiple Lots of Ketorolac Tromethamine Injection Due to Potential Contamination

Hospira, Inc, of Lake Forest, IL, has issued a voluntary recall of ketorolac tromethamine injection, USP in the United States and Singapore due to potential particulate matter. The presence of particulate was confirmed through a customer report of visible floating particulate that was identified as calcium-ketorolac crystals. If in-

jected, medications contaminated with particulate matter may cause localized inflammation, allergic reaction, granuloma formation, or microembolic effects. Multiple lots are impacted by this recall and are listed in a press release posted to the FDA website at *www.fda.gov/Safety/Recalls/ucm433857.htm*. The lots were distributed from February 2013 to December 2014 in the US. To date, there have been no cases of adverse events associated with this medication. Adverse reactions may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

FDA Warns of Counterfeit Cialis Tablets Entering the US

Potentially dangerous, counterfeit versions of Cialis® 20 mg tablets were intercepted in the mail before reaching a US consumer, warns FDA. Laboratory analysis of the counterfeit product showed that it contained multiple active ingredients that could lead to adverse effects or harm if used, indicates an FDA Drug Safety Announcement. The agency reminds US consumers to only buy prescription medications from state-licensed pharmacies located in the US. FDA notes that it cannot confirm that the manufacturing, quality, storage, and handling of products ordered from unlicensed websites follow US standards because the products are from an unknown source.

To help consumers identify these counterfeit medications, FDA provides guidelines in the safety announcement. For example, these counterfeits list "AUSTR81137" on the front of the bottle and lack a National Drug Code number. Other possible identifiers include misspellings and unusual colors on the label, and a manufacturer listed as "112 Wharf Road, WEST RYDE, NSW 2114" on the side of the bottle.

To date, FDA is not aware of any adverse events associated with these counterfeit medications; however, consumers are encouraged to talk to a health care provider about their condition and options for treatment if a counterfeit product was received.

The National Association of Boards of Pharmacy® (NABP®) has reviewed more than 10,900 websites selling prescription drugs to patients in the US and found that nearly 97% are operating out of compliance with pharmacy laws and practice standards established to protect the public health. To help consumers in the US find the safest sources for purchasing medications online, NABP developed the Verified Internet Pharmacy Practice Sites® (VIPPS®) program. NABP encourages consumers to look for the VIPPS Seal and to check NABP's list of accredited sites on the AWAR$_X$E® Prescription Drug Safety Program website. In addition, consumers may soon watch for pharmacy sites using the newly launched .pharmacy Top-Level Domain; sites in the domain (with a website address ending in .pharmacy) will be reviewed by NABP and approved only if they are legitimate online pharmacies or pharmacy resources adhering to applicable pharmacy laws and best practices.

Additional details on the counterfeit Cialis are available in a Drug Safety Announcement posted to the FDA website at *www.fda.gov/Drugs/DrugSafety/ucm431071.htm*. More information on VIPPS and other NABP programs is available in the Programs section of the NABP website, *www.nabp.net*.

New FDA Drug Info Rounds Training Videos Review Drug Disposal and REMS

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 "Disposal of Unused Medicines," pharmacists discuss how consumers can safely dispose of expired or unused medications to prevent abuse or misuse and accidental poisoning.
- In "REMS," pharmacists discuss the many components of Risk Evaluation and Mitigation Strategies (REMS) and how they can help manage a drug product with known or potential serious risks.

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*.

FDA Issues New Drug Labeling Rules to Benefit Pregnant, Breastfeeding Women

FDA announced new prescription drug labeling requirements that will clarify how medications might affect women who are pregnant or breastfeeding and men and women of reproductive potential. The final "Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling Rule" removes the previously used pregnancy letter categories – A, B, C, D, and X – and places information into three main categories:

- **Pregnancy:** Labor and delivery guidelines now fall under this category, which also now includes information for pregnancy exposure registries. Such registries track data on the effects of certain approved medications on pregnant and breastfeeding women.
- **Lactation:** Previously labeled "Nursing Mothers," this category provides information such as how much drug is secreted through breast milk and the potential effects on a breastfed infant.
- **Females and Males of Reproductive Potential:** This is a new category that includes information on how a certain medication might affect pregnancy testing, contraception, and infertility.

The new labeling changes go into effect on June 30, 2015. Over-the-counter medication labels will not be affected. The new rules are available for download through the *Federal Register* at *https://s3.amazonaws.com/public-inspection.federalregister.gov/2014-28241.pdf*.

FDA Approves Zohydro ER With Abuse-Deterrent Properties

In February 2015, FDA approved a new formulation of Zohydro® ER with abuse-deterrent properties. The new formulation uses a technology that allows the drug to maintain its release properties when used as intended, according to a press release from Zogenix. The abuse-deterrent system, known as BeadTek, incorporates "pharmaceutical excipients" that create a viscous gel when the medication is crushed and dissolved in a liquid or solvent, thus making the product more difficult to abuse through methods that involve crushing, breaking, or dissolving the drug. In early 2014, Zohydro ER became the first extended-release, single-ingredient hydrocodone product to receive approval for use in the US. Approval of the drug came under criticism, with some organizations arguing that the potential for addiction, abuse, and misuse could outweigh therapeutic benefits, in part because the drug lacked abuse-deterrent properties. Zogenix indicates that transition to the new abuse-deterrent formulation will take place in second quarter 2015.

Additional information on the new formulation is provided in a press release available on the Zogenix website at *http://ir.zogenix.com/phoenix.zhtml?c=220862&p=irol-newsArticle&cat=news&id=2012326*.

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Manufacturing Practice requirements. **Pursuant to OAC 4729-16-02, an outsourcing facility is prohibited from selling compounded products in Ohio unless it holds a valid license as a wholesale distributor of dangerous drugs with an outsourcing facility classification.** To identify these properly licensed entities, the Board has posted a list of approved sites to its web page at *https://pharmacy.ohio.gov/outsourcing*. This list will be updated as new outsourcing facilities are licensed by the Board.

Sign Up for Email Updates Today!

Stay up-to-date on the latest news and guidance from the Board by signing up for email notifications. To sign up, please visit *www.pharmacy.ohio.gov/RSS/Subscription.aspx*.

Where Do I Find Board-Approved Immunization Providers?

Ohio Revised Code 4729.41 requires a pharmacist or pharmacy intern to successfully complete a course in the administration of immunizations that has been approved by the Board in order to engage in the administration of immunizations. A list of approved immunization courses can be accessed by visiting *www.pharmacy.ohio.gov/immunizations*.

Reminders From OARRS

Keep the Patient Name Fields Clean

A new patient presents you with a prescription and you run an Ohio Automated Rx Reporting System (OARRS) report. You verified the spelling of the name, the birth date, and zip code, and you know the patient is receiving controlled substances (CS) from an Ohio pharmacy, yet you still get "no patients match your search criteria." Along with reasons previously discussed in prior Board *Newsletters,* patients with additional information contained in the "name" field of the patient profile make a search difficult. While including "EZ caps," "See ID," "No CPCs," etc, as part of the name may be helpful to your pharmacy, the next pharmacy/prescriber trying to look up that patient may not be able to find the patient. To address this important patient care issue, please include **only** the name for both the first and last name fields in the patient profile. Taking the few seconds to clean up the patient names will improve the quality of data and save people time when they are trying to run an OARRS report.

OARRS Reporting and DEA Numbers

OAC 4729-37-04 outlines what prescription information must be reported by the dispensing pharmacy. One of the elements is the prescriber's Drug Enforcement Administration (DEA) number, **including the DEA suffix, if applicable.** Hospital systems often allow their residents or mid-level prescribers to use the hospital DEA number with a suffix. This suffix is used by a hospital to identify the resident or mid-level prescriber. This suffix must be included in the daily data upload.

Updated OARRS Handbook

An updated version of the OARRS handbook is posted under the Documents section of the OARRS website. The new handbook outlines some common "how to" questions. Visit *www.ohiopmp.gov* to review this helpful resource.

Annual Law Continuing Education Test Available

The Board is pleased to offer the annual Jurisprudence Quiz. This no-cost quiz can be accessed by visiting *www.pharmacy.ohio.gov/quiz*. The questions in the quiz relate to the topics covered in the February, May, August, and November 2014 *Newsletters*. The test is taken online and is graded immediately upon submission. You may pre-print the exam, but you will have only one opportunity to take and submit the test for grading. A score of 75% is needed to pass. After successful completion, you will have the ability to immediately print your certificate, and a copy of your certificate will also be emailed to you. Be sure to keep this certificate to use if you are audited. The Board is not able to upload successful completion of the exam to CPE Monitor®. **Please note: Do not mail any quizzes to the Board office. The Board will neither hand-process exams nor mail a certificate to you.**

New Guidance Documents Available

The Board has posted the following guidance documents regarding recent changes to Ohio law.

- **House Bill (HB) 326 – Diabetic Shoe Fitters *(www.pharmacy.ohio.gov/diabeticshoes)*:** Exempts the following from the requirement to be licensed by the Ohio State Board of Orthotics, Prosthetics, & Pedorthics: a licensed pharmacist, licensed pharmacist intern, registered wholesale distributor of dangerous drugs, or licensed terminal distributor of dangerous drugs who is acting within the respective scope of practice.
- **HB 367 – Buprenorphine *(www.pharmacy.ohio.gov/BuprenorphineTDDD)*:** Establishes requirements regarding CS containing buprenorphine used for the purpose of treating drug dependence or addiction.
- **HB 394 – Immunizations *(www.pharmacy.ohio.gov/HB394)*:** Modifies the authority of pharmacists and pharmacy interns to administer immunizations.

These and other guidance documents are also available on the Board's Special Topics web page at *www.pharmacy.ohio.gov/Pubs/Special.aspx*.

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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