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News

State of Ohio Board of Pharmacy

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Pharmacists Can Now Dispense Naloxone Without a Prescription

Dear Ohio Pharmacist,

Ohio is in the grips of a drug overdose epidemic. Since 1999, drug overdoses have taken the lives of more than 13,000 citizens of this state. These deaths are largely attributable to the abuse of opioids, a class of drug that includes both prescription pain relievers and heroin.

Fortunately, a safe and effective medication called naloxone (Narcan) is available to reverse an opioid overdose. When administered during an overdose, naloxone blocks the effects of opioids on the brain and restores breathing. It can be given as an injection into a muscle (via syringe or auto-injector) or as a nasal spray. According to the Centers for Disease Control and Prevention, use of naloxone administered by laypersons has resulted in over 26,000 drug overdose reversals between 1996 and 2014.

In an effort to facilitate greater access to naloxone, Governor John Kasich recently signed Ohio House Bill (HB) 4 (sponsored by Representatives Robert Sprague and Jeff Rezabek) into law. This new law authorizes a pharmacist or pharmacy intern to dispense naloxone without a prescription in accordance with a physician-approved protocol. Use of a protocol provides a convenient way for at-risk opioid users, as well as concerned family members and friends, to obtain this lifesaving medication.

To assist pharmacies that are interested in dispensing naloxone pursuant to a protocol, the State of Ohio Board of Pharmacy has developed a dedicated web page *(www.pharmacy.ohio.gov/naloxone)* that features a number of resources, including a guidance document, sample protocols, and patient educational materials. In addition, the Board is offering printed, no-cost patient educational materials to any participating pharmacy.

To help stem the tide of drug overdose, the Board encourages pharmacists to consider offering this important service in their communities. Should you have any questions regarding this new law, please do not hesitate to email the Board directly at contact@pharmacy.ohio.gov.

Together, we can all do our part to prevent drug overdose deaths in Ohio.

Sincerely,

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

Effective September 15, 2015, Pharmacists Dispensing CS Medications in Ohio Must Have an OARRS Account

Pursuant to Ohio HB 341 (130th General Assembly), all practicing Ohio pharmacists who dispense or plan to dispense controlled substance (CS) medications in the state are required to have an account with the Ohio Automated Rx Reporting System (OARRS). If you are a practicing Ohio pharmacist and you do not have an account, you can sign up by visiting *www.oarrs.pharmacy.ohio.gov.* You will be required to attest on your renewal that you have an account or that you do not need an account (ie, you do not dispense or plan to dispense CS in Ohio).

Pharmacist and Intern License Renewals for 2016

In the Board's continuing effort to provide an efficient and consistent process for renewals, you will notice changes for both pharmacists and interns. Please read the following carefully. Going forward, the Board is utilizing email and online technology to streamline the license renewal process. The pharmacist and intern renewal notices for 2016 were sent out via email in July. This email contained the user identification (ID) and password necessary to renew online. Only those licensees whose email addresses presented an issue with

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Counterfeit Botox Found in the United States, FDA Warns

On April 16, 2015, Food and Drug Administration (FDA) alerted health care providers that a counterfeit version of Botox® was found in the United States and may have been sold to doctors' offices and clinics throughout the country. The counterfeit products may be identified by a missing lot number on the vial, missing information on the carton (next to LOT, MFG, and EXP), and a displayed active ingredient as "Botulinum Toxin Type A" instead of "OnabotulinumtoxinA." The counterfeit products were sold by an unlicensed supplier who is not authorized to ship or distribute drug products in the US, according to an FDA Drug Safety Alert. The agency advises health care providers to confirm that the distributor from which they purchase Botox is authorized by Allergan, the drug's manufacturer. No adverse events related to this product have been reported to FDA.

Medical practices that purchase and administer counterfeit, illegal, and unapproved medications from unlicensed or foreign sources are putting patients' health at risk, as patients may not be getting proper treatment, warns FDA. Wholesale drug distributors must be licensed in the states where they conduct business. Suspicious Botox products may be reported to FDA's Office of Criminal Investigations. More information is available on the FDA website at *www.fda.gov/Drugs/DrugSafety/ucm443217.htm*.

One way pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws, as well as NABP's VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo an on-site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the US drug supply.

Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!

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.*

ISMP has been reflecting on the strength and resolve of many across the nation who have demonstrated an unparalleled commitment to keeping patients safe. Despite the many safety accomplishments in 2014, ISMP cannot help but mull over persistent medication safety gaffes that continue to be unresolved. ISMP would like to share seven persistent safety gaffes of 2014, in three parts, with NABP *National Pharmacy Compliance News* readers with the hope that they will join ISMP in bringing attention to these crucial issues and the compelling need for their resolution. Part one of the three-part series is below.

1) Patient Counseling: Still Only a Veiled "Offer" in Many States

The effectiveness of patient counseling in a community pharmacy to detect and prevent medication errors, and its link to improved medication adherence and positive clinical outcomes have been well documented in the literature. Yet, studies have placed patient counseling rates at only eight percent to 42%. An increase in the frequency and quality of patient counseling has been linked to state-specific regulations that require patient counseling for new prescriptions coupled with strict enforcement surveillance. States that require an "offer" to counsel have very low patient counseling rates. Patients often fail to recognize an offer to counsel when simply asked, "Do you have any questions?" or told to "Please sign here." They may not even know what to ask. This means that, with few exceptions, pharmacies in states that require only an offer to counsel will likely dispense a powerful opioid such as fentanyl transdermal patches and allow the patient or caregiver to walk out of the pharmacy without even a brief discussion about safe use and disposal. ISMP has long promoted mandatory patient counseling in community pharmacies for prescriptions for targeted high-alert medications.

For a list of high alert community medications, please visit *www.ismp.org/communityRx/tools/ambulatoryhighalert.asp.* ISMP hopes you will use this list to determine which medications require mandatory patient education in order to reduce the risk of errors and minimize harm.

2) Patients Impacted by Dispensing Errors: Callous Response From Pharmacists

When patients report dispensing errors to ISMP, they are usually more upset about the response they received when contacting the pharmacist or pharmacy manager than the actual error itself. All too often, consumers tell ISMP that pharmacy staff have responded in a callous manner when confronted with the possibility of a dispensing error, demonstrating a lack of empathy and concern for the adverse effects the patient might have experienced. While pharmacy staff may want to be more responsive to patients who report errors, they are often following corporate policies that are focused on legal concerns. As patients are continually encouraged to be active participants in their health care, they want and deserve honest disclosure of errors, and knowledge that there is an action plan to reduce the risk of it happening again.

Flurbiprofen-Containing Topical Medication May Be Dangerous to Pets, Cautions FDA

People who use topical medications containing flurbiprofen, a nonsteroidal anti-inflammatory drug (NSAID), should take care to prevent their pets from being exposed to the drug, recommended FDA in an April 2015 Safety Alert. The warning is in response to reports of cats in two separate households that became ill or died after their owners used topical medications containing flurbiprofen to treat

muscle, joint, or other pain. Two cats in one household developed kidney failure and recovered with veterinary care. Two cats in a second household developed symptoms that included reluctance to eat, lethargy, vomiting, melena, anemia, and dilute urine, and subsequently died despite veterinary care. A third cat in the second household also died after the owner stopped using the medication. Necropsies on the three cats found evidence that were consistent with NSAID toxicity. The pet owners had applied the drug to their own neck or feet, and not directly to the pet, and it is not known exactly how the cats became exposed to the medication, the Safety Alert notes.

Health care providers who prescribe or dispense topical pain medications containing flurbiprofen should advise patients with pets to take steps to prevent exposure of the pets to the medication. Additional information is available in the FDA Safety Alert available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm443386.htm*.

New FDA Drug Info Rounds Videos Available

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 "NDC Directory," pharmacists demonstrate how to use this quick, easy, online resource.
- In "FAERS," pharmacists discuss the FDA Adverse Event Reporting System (FAERS) and review three ways FAERS data is made available to the public.

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*.

Mucinex Cold, Sinus, and Flu Medications Recalled Due to Possible Labeling Error

In April 2015, RB (formerly Reckitt Benckiser) of Parsippany, NJ, issued a voluntary recall of certain lots of liquid Mucinex® due to a potential error involving the over-the-counter medications' drug facts labels. While the front label of the recalled lots correctly lists the name of the product as well as the active ingredients, some bottles may not have the correct corresponding drug facts label on the back. The recall was initiated after a confirmed report from a retailer. The recalled medications include:

- MUCINEX FAST-MAX Night-Time Cold & Flu;
- MUCINEX FAST-MAX Cold & Sinus;
- MUCINEX FAST-MAX Severe Congestion & Cough; and
- MUCINEX FAST-MAX Cold, Flu & Sore Throat.

If mislabeled, consumers who purchase these products may be unaware of the side effects and potential risks associated with active ingredients such as acetaminophen, dextromethorphan, guaifenesin, phenylephrine, and/or diphenhydramine. RB is recalling these products as a precautionary measure to ensure consumers have all relevant facts and warnings; the company asks consumers to dispose of any unused product.

Additional information about the recall, including the lot numbers and expiration dates for the recalled medications and guidelines for safe disposal, is available on the FDA website at *www.fda.gov/Safety/Recalls/ucm444028.htm*.

Pharmacists Are Performing More Patient Care Activities, National Survey Indicates

Pharmacists are performing more patient care activities in a variety of health care settings and are spending less time in traditional dispensing roles, indicates the *2014 National Pharmacist Workforce Survey*. Specifically, the report found that 60% of pharmacists provided medication therapy management, and 53% performed immunizations in 2014, indicates a press release from the American Association of Colleges of Pharmacy (AACP). The survey was created using a random sample of 5,200 individuals selected from a list of 7,000 licensed pharmacists in the US. Response rate to the survey was 48%.

Additional details, including the full results of the survey and an executive summary, are available through the Resources section of the AACP website, *www.aacp.org*.

Potentially Lethal Drug Sold Globally as Diet Supplement, Warns INTERPOL

INTERPOL has issued a global alert for a drug known as 2.4-dinitrophenol (DNP), an illicit and potentially lethal drug sold as a dieting and body building aid. The "Orange Notice" warning about DNP was published in May 2015, following the death of a woman in the United Kingdom and the serious illness of a man in France. In the 1930s, DNP was used to boost metabolism and encourage weight loss, but it was taken out of circulation due to several deaths. Sold as a plain yellow powder, capsules, or cream, DNP is often illegally manufactured and sold via the Internet; unsafe manufacturing of the drug and potential contamination may be magnifying the dangers of taking the drug, notes INTERPOL.

Additional information is available on the INTERPOL website at *www.interpol.int/News-and-media/News/2015/N2015-050*.

HHS Announces New Interactive Training on Safe Opioid Use

The Department of Health and Human Services (HHS) has announced a new, interactive training course that teaches health care providers how to talk to patients about safely using opioids to manage chronic pain. The course, "Pathways to Safer Opioid Use," also teaches implementation strategies for meeting the opioid-related recommendations from the National Action Plan for Adverse Drug Event Prevention. Adverse drug events (ADEs) are the largest contributor to hospital-related complications and account for more than 3.5 million physician office visits each year, according to HHS. The training, which is offered at no cost, includes self-guided interactive videos with decision points to help users learn how to apply health literacy strategies to help patients understand and act on information to prevent opioid-related ADEs; identify individual risk factors, opioid medications, and interactions that place individuals with chronic pain at increased risk for opioid-related ADEs; recognize the importance of a multidisciplinary team-based approach to treating patients with chronic pain; and demonstrate the ability to combine the principles of the Health Literate Care Model and the biopsychosocial model.

Additional information, including a link to the National Action Plan for Adverse Drug Event Prevention, is available on the course website at *http://health.gov/hcq/training.asp#pathways*.

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delivery will receive their renewal notification through the mail. The paper mailing will not contain the renewal application; it will provide the necessary information for a licensee to access electronic means to renew his or her license. Any licensee who receives the paper mailing will be required to update his or her contact information with the Board for future renewals. The electronic and paper renewal notification will contain directions and your user ID and password necessary for renewal. Even if you need to submit a paper renewal, you must first go online with your user ID and password and answer legal questions before you can print out a paper renewal to submit manually with your check. Electronic renewals will require the use of a credit card for payment.

All "033" pharmacists are attesting (reporting) to completion of their continuing education (CE) during this year's pharmacist renewal. All CE certificates of participation must be dated between March 1, 2012, and September 15, 2015. Carefully read the online renewal questions, as the Board must take into consideration all CE reporting situations. These questions are presented in a specific order to address each reporting situation.

Please be aware that some licensees sometimes experience the double-billing of their credit cards during the online renewal process. 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, contact the Board office and you will receive a refund.

You will be able to print your own pocket ID card once you have successfully renewed (for both online and paper submissions). Within 48 hours of your successful renewal, you will receive an email with the link to your 2016 license. All you will have to do is click on the link and open the file in Adobe Reader to print your pocket card. If you do not receive an email within 48 hours, remember to check your spam folder. If you still cannot locate the email, 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. The link to print your new card will only be accessible for 30 days, so please be sure to print it during that time frame or you will have to pay to get a duplicate license ID card.

You must renew your license by September 15, 2015, if you plan to continue practicing pharmacy in Ohio after that date. If you do not wish to renew your license or if you need additional information, please email the Board office by visiting *www.pharmacy.ohio.gov/contact.aspx*.

Yes, It Is Legal to E-Prescribe CS in Ohio

While you may have heard otherwise, it is legal to electronically prescribe (e-prescribe) CS in Ohio. The process for approval of electronic systems to send and pharmacy systems to receive CS e-prescriptions was established by Drug Enforcement Administration (DEA) regulations (Title 21 Code of Federal Regulations §1311) in 2010. Pursuant to Rules 4729-5-21 and 4729-5-30 of the Ohio Administrative Code (OAC), systems meeting DEA's requirements to send and receive e-prescriptions for both CS and non-CS are considered approved by the Board.

While it may be legal, utilization of electronic systems to transmit CS prescriptions by Ohio prescribers remains low. In fact, only 333 Ohio clinicians were e-prescribing CS as of April 2015. While prescriber usage is low, more than 80% of Ohio pharmacies can now accept CS prescriptions electronically.

In an effort to provide greater clarity regarding the e-prescribing of CS, the Board, along with the Ohio Health Information Partnership and members of the Ohio E-Prescribing Task Force, recently released a series of guidance documents for pharmacists, prescribers, and hospital systems.

These guidance documents provide additional information regarding the approval of e-prescribing systems as well as what to do when presented with an e-prescription for a CS.

The documents can be accessed on the Board's e-prescribing web page, *www.pharmacy.ohio.gov/eprescribing*. This page also provides additional information regarding the e-prescribing of non-controlled medications.

New Toolkit to Help Ohio Communities Fight Heroin, Prescription Drug Epidemic

Communities across Ohio recently received a boost in the fight against heroin and other opioid addiction with the release of the "Health Resource Toolkit for Addressing Opioid Abuse." The toolkit provides guidance on topics such as building a local coalition to prevent overdose deaths; promoting responsible prescribing practices; expanding access to Medication-Assisted Treatment; and embracing specialized docket programs to close the revolving door of addiction and crime. The resource includes technical support contacts at the state level, guidance on accessing relevant data and trend information, and a checklist for building an effective local response. Two community case studies – highlighting innovative strategies and tactics deployed in Lucas and Summit counties – are also included. The toolkit can be accessed by visiting *www.mha.ohio.gov/GCOAT*.

National Prescription Drug Take-Back Day Scheduled for September 26, 2015

DEA is planning a National Prescription Drug Take-Back Day on Saturday, September 26, 2015. For more information, including participating Ohio locations, please visit *www.pharmacy.ohio.gov/takebackday.*

Updates From OARRS

Reporting OARRS Quantities for Wholesale Transactions: There Is a Difference

Is your pharmacy selling CS medications to prescribers? To another pharmacy? These transactions must be reported to OARRS as a wholesale distribution. There is a wholesale handbook on the OARRS web page under "Documents," which outlines how these transactions must be reported. The major difference is when selling a bottle of product to another pharmacy or to a prescriber (transferring product from one DEA number to a different DEA number), the transaction is reported by number of **packages.** In these cases, you realistically will be transferring an entire bottle. OARRS staff knows the quantity of tablets based on the National Drug Code number of the package you transfer. Only selling 30 capsules out of a bottle of 100? OARRS wholesale reporting accepts fractional quantities by entering decimals.

Daily Reporting, 'Zero Reporting'

OAC 4729-37-07 is the rule for daily reporting or a daily zero report. Pharmacies must account for every single day, including days on which they are closed. Common mistakes seen are when a pharmacy has nothing to report for four days, but the only date entered as "zero" is the last of the four days. OARRS requires a "zero" for each of those four days. Every day of every week must have either data (showing a CS was dispensed) or a "zero" with no gaps or omissions.

Pharmacies are strongly encouraged to train more than one person on building and uploading OARRS data. Vacations are not an excuse for not reporting.

The handbook *(https://www.ohiopmp.gov/portal/docs.aspx)* gives step-by-step instructions on marking business days closed, zero reporting, and other helpful hints.

OARRS Corrections

When a prescription is reversed or corrected, the reversal or correction must also be reported to OARRS (OAC 4729-37-11). Depending on your pharmacy's software, corrections or deletions to pharmacy data may or may not be automatically transmitted. Check with your software vendor. All data must be submitted or corrected electronically unless prior permission for an alternate method is approved by the Board.

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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