



State of Ohio Board of Pharmacy

Published to promote compliance of pharmacy and drug law

77 S High St, Room 1702 • Columbus, OH 43215-6126 • Tel: 614/466-4143

Fax: 614/752-4836 • www.pharmacy.ohio.gov

New Ohio Law Makes Changes to Dispensing of Emergency Refills Without a Current Prescription

Dear Ohio Pharmacist,

As a pharmacist, you sometimes find yourself faced with difficult decisions. Each decision requires clear and careful thought and a robust knowledge of the rules and laws governing this profession. Therefore, the State of Ohio Board of Pharmacy strives to ensure that such laws and rules are always clearly communicated.

One decision you may face occurs when you are asked to dispense an emergency refill of a medication that no longer has a current prescription (ie, no refills left or refills have expired). Ohio Revised Code (ORC) Section 4729.281 – which was recently amended – permits a pharmacist to dispense medication, other than a Schedule II controlled substance (CS), without a written or oral prescription if all of the following conditions are met:

- (1) The pharmacy at which the pharmacist works has a record of a prescription for the drug in the name of the patient who is requesting it, but the prescription does not provide for a refill or the time permitted for providing refills has elapsed. As a reminder, refills are good for one year from the date the prescription was written on a non-controlled prescription and six months for a CS.
- (2) The pharmacist is unable to obtain authorization to refill the prescription from the health care professional who issued the prescription or another health professional responsible for the patient's care.
- (3) In the exercise of the pharmacist's professional judgment, the drug is essential to sustain the life of the patient or continue therapy for a chronic condition, and failure to dispense or sell the drug to the patient could result in harm to the health of the patient.

Upon completion of these steps, a pharmacist is permitted to dispense the following:

- ◆ Up to a 72-hour supply for any prescription drug, including Schedule III-V CS; or

- ◆ Up to a 30-day supply for a non-controlled prescription drug or, if the standard unit of dispensing for the drug exceeds a 30-day supply, the amount of the drug dispensed or sold does not exceed the standard unit of dispensing.

In order to exceed the 72-hour supply limit for non-controlled drugs, the pharmacist must determine that the patient has been on a consistent drug therapy as demonstrated by records maintained by a pharmacy. A pharmacist is not permitted to dispense up to a 30-day supply of a particular drug to the same patient more than once in any 12-month period.

The Board would like to remind all pharmacists that they are not required to dispense the full amount of an emergency refill as allowed by law and should use their professional judgment to determine the supply that is in the best interest of their patient.

For more information on emergency dispensing, please visit www.pharmacy.ohio.gov/emergency.

Understanding your role in helping patients get access to lifesaving medications is important, and I hope that reminders of this nature are beneficial to you. On behalf of the Board, I thank you for the work that you do in helping serve the needs of patients across Ohio.

Sincerely,

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

Opiate Mid-Biennium Review Announced

On April 12, 2016, the Board and Governor John Kasich's Cabinet Opiate Action Team announced new legislation aimed at addressing Ohio's opiate addiction crisis. This legislation includes new reforms to strengthen prescription drug oversight, encourage responsible treatment, and prevent drug overdoses. For more information, visit www.pharmacy.ohio.gov/MBR2016.



FDA Approves Naloxone Nasal Spray to Prevent Opioid Overdose Deaths

Food and Drug Administration (FDA) has approved Narcan® Nasal Spray (also known as naloxone), a life-saving medication that can stop or reverse the effects of an opioid overdose. Prior to this approval, naloxone was only approved in injectable forms, most commonly delivered by syringe or auto-injector, explains FDA in a news release.

Narcan Nasal Spray does not require assembly and delivers a consistent, measured dose when used as directed. This prescription product can be used on adults or children and is easily administered by anyone, even those without medical training. The drug is sprayed into one nostril while the patient is lying on his or her back, which can be repeated if necessary. However, it is important to note that it is not a substitute for immediate medical care, and the person administering Narcan Nasal Spray should seek further immediate medical attention on the patient's behalf. The use of Narcan Nasal Spray in patients who are opioid dependent may result in severe opioid withdrawal characterized by body aches, diarrhea, increased heart rate (tachycardia), fever, runny nose, sneezing, goose bumps (piloerection), sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. Narcan Nasal Spray is distributed by Adapt Pharma, Inc, of Radnor, PA. The FDA news release is available at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm473505.htm.

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.

It is a nearly impossible task to list all the risks associated with medication use that could lead to harmful medication

errors. So where do health care professionals start to improve medication safety? Most people frequently resort to playing “whack-a-mole,” addressing risks only after they pop up and become visible after an adverse event.

Listed below are two serious medication safety risks that might fall off the radar screen unless an adverse event happens to draw attention to them. Additional serious risks will be published in future issues of the National Association of Boards of Pharmacy® *National Pharmacy Compliance News*.
Patient Information – Placing Orders on the Wrong Patient's Electronic Health Record

A potentially hidden vulnerability that can lead to serious errors is placing orders on the wrong patient's electronic health record. A recent study published in the *Journal of the American Medical Informatics Association* identified and quantified close calls that would have resulted in wrong-patient errors. According to this study, about 14 wrong-patient electronic orders are placed every day in a large hospital system with approximately 1,500 beds, or about 68 wrong-patient errors per 100,000 medication orders. By this measure, one in 37 hospitalized patients will have an order placed for them that was intended for another patient.¹

These errors are sometimes due to juxtaposition but more often caused by interruptions and having more than one patient's electronic health record open.

Multiple studies have demonstrated ways to reduce these events. Requiring verification of the patient's identity has reduced errors by 16% to 30%, and requiring re-entry of the patient's identification has reduced errors by 41%.^{1,2} Prompting clinicians for an indication when certain medications are ordered without an indication on the patient's problem list has intercepted errors at a rate of 0.25 per 1,000 alerts.³ In one study, most emergency department (ED) staff (81%) felt a room number watermark on the patient's electronic health record would eliminate most wrong-patient orders in the ED.⁴

Communication About Drug Therapy – Confusing the Available Concentration as the Patient's Dose on Electronic Records

Another risk deals with how home medications appear on computer screens. For example, a physician accidentally ordered 100 units of Lantus® (insulin glargine) instead of the correct dose of six units because the list of medications used at home displayed the concentration right next to the drug name on the first line, and the patient's dose below it on the second line: “Insulin glargine (Lantus) 100 units/mL,” followed on the next line with “6 units subcutaneous daily every evening.”

Now that insulin is available in 100 units/mL, 200 units/mL, 300 units/mL, and 500 units/mL concentrations, the risk



of receiving an overdose of insulin is high if the presentation of the order lists the product's concentration before the patient's dose. ISMP's recommendation is to list the drug name, patient-specific dose, and directions for use on the first line of the electronic medication administration record and patient medication lists, and the available concentration and any directions on how to measure the patient's dose below it.

References

1. Adelman JS, Kalkut GE, Schechter CB, et al. Understanding and preventing wrong-patient electronic orders: a randomized controlled trial. *J Am Med Inform Assoc.* 2013; 20(2):305-310.
2. Green RA, Hripcsak G, Salmasian H, et al. Intercepting wrong-patient orders in computerized provider order entry system. *Ann Emerg Med.* 2015; 65(6):679-686.
3. Galanter W, Falck S, Burns M, Laragh M, Lambert BL. Indication-based prescribing prevents wrong-patient medication errors in computerized provider order entry (CPOE). *J Am Med Inform Assoc.* 2013; 20(3):477-481.
4. Yamamoto LG. Reducing emergency department charting and ordering errors with a room number watermark on the electronic medical record display. *Hawaii J Med Public Health.* 2014; 73(10):322-328.

FDA Provides Training Videos on MedWatch Resources and Breakthrough Therapy

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 January 2016 Drug Info Rounds video, "MedWatch Tips and Tools," pharmacists discuss reporting adverse events to FDA's MedWatch Safety Information and Adverse Event Reporting Program and the resources available for health care professionals to report safety information. In the December 2015 Drug Info Rounds video, "Breakthrough Therapy," pharmacists discuss the breakthrough therapy designation program, which is intended to expedite the development and review of drugs for serious or life-threatening conditions. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research (CDER), 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.

Reading Medicine Labels Helps Reduce Acetaminophen Overdoses

The Acetaminophen Awareness Coalition (AAC) reminds pharmacists and other health care providers to encourage patients to properly read medicine labels to avoid unintentional acetaminophen overdoses. The coalition also encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use.

AAC's "Know Your Dose" campaign reminds patients to take these four steps to avoid acetaminophen overdose:

- (1) Always read and follow the medicine label.
- (2) Know if their medicines contain acetaminophen.
- (3) Take only one medicine at a time that contains acetaminophen.
- (4) Ask their health care provider about any questions.

Additionally, pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website at www.knowyourdose.org.

Over-the-Counter Children's Medicine Recalled Due to Incorrect Dose Markings

In January 2016, Perrigo Company voluntarily recalled two lots of children's guaifenesin grape liquid cough medicine (100 mg/5 mL) and three lots of children's guaifenesin DM cherry liquid cough medicine (100 mg guaifenesin and 5 mg dextromethorphan HBr/5 mL) sold in 4 oz bottles. The recall was initiated because some packages contain an oral dosing cup with incorrect dose markings. The affected products were sold by distributors nationwide and distributed through retail stores. The recalled lots and store brands are available in the Perrigo press release posted on the company's website, www.perrigo.com, under "Investors." To date, the company has not received reports of overdose. Distributors and retailers that have the affected lots should stop distribution and return the product using the information provided in the press release.

Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at www.fda.gov/MedWatch.

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information, CDER, presents a series of continuing education webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Past topics have included "Introduction to FDA's MedWatch Adverse Reporting Program" and "An Overview of the FDA's Breakthrough Therapy Designation Program." Upcoming webinars, previous webinars, and presentation slides can be accessed on FDA's website at www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm.

Pharmacist Consult Agreements With Physicians

Recent changes to Ohio law regarding pharmacist consult agreements are now in effect ([ORC 4729.39](#)). The Board is in the process of adopting new rules regarding consult agreements. In the interim, it has adopted a resolution to provide licensees with guidance on implementing recent changes.

The resolution can be found by visiting www.pharmacy.ohio.gov/consult.

2016 Roundtables

Today's demands on pharmacists are great. Adding to this is the fact that drug diversion is at an all-time high, and thus the need to maintain supervision, accountability, and security over the pharmacy is critical.

Join the Board in a roundtable presentation to learn the duties of a pharmacist and the importance of this role in ensuring compliance with Ohio's laws and regulations. Registration information and a full list of presentation dates, times, and locations can be found by visiting www.pharmacy.ohio.gov/2016RP.

Some of the topics to be covered will include: Who has a right to inspect your site? What is the difference between physical and electronic security? What can you do to prevent robbery or burglary? What do terms like "supervision and control," "tamper evident," "adequate safeguards," "deter and detect," and "significant loss" mean?

A roundtable presentation qualifies for two hours (0.2 CEUs) of Board-approved jurisprudence continuing education (CE).

2016 CE Law Presentations

The Board will be holding a series of law presentations throughout the state. The presentations, approved for two hours (0.2 CEUs) of Board-approved jurisprudence CE, will provide an overview of existing laws impacting pharmacists with an emphasis on recent updates to the ORC and Ohio Administrative Code. Registration information and a full list of presentation dates, times, and locations can be found by visiting www.pharmacy.ohio.gov/2016Law.

Free CE Available

Do not forget the availability of three Board-approved home study jurisprudence programs, available at <http://pharmacy.ohio.gov/Licensing/CE.aspx>. While the Board does need your NABP e-Profile ID to access the quizzes, credit earned for these programs will not show up on CPE Monitor®, a National Association of Boards of Pharmacy® (NABP®) service. Keep your certificates if you are audited.

Updates From OARRS

OARRS Reports and 'TMI'

"Too much information" (TMI) is not limited to social media. On rare occasion (less than 1% of the number of reports generated), two people will show up on a single Ohio Automated Rx Reporting System (OARRS) report. This most often occurs when both parties have the same birth date or same street name, or when there are multiple pieces of overlapping information and the Board's computer is unable to isolate one unique patient. This is common with twins or when two people in the same household have the

same or similar names (father/son, Sr/Jr, Joan/John, Michelle/Michael). Email OARRS at info@pharmacy.ohio.gov or call the office at 614/466-4143 (option 1). Provide the name (with proper spelling) and date of birth of the patient. OARRS will separate the accounts; staff prefers this information come from the prescriber or pharmacy, not the patient, as they are not able to separate patients from interstate requests.

Until the report is separated, pharmacists and prescribers can isolate which prescription belongs to which patient. The four-digit patient ID to the left of every name in the box of names that appear to match the search criteria corresponds with the four-digit patient ID on each line item of prescription data. Cross off the names and prescription line items you do not need so that you may see what your patient receives.

Informing OARRS staff of merged reports allows them to clear it up so future reports will be unique.

Congratulations, New Pharmacists!

It is time to upgrade your OARRS account from a pharmacy delegate to a pharmacist. To do this, send (email or fax) the signed acceptable use policy for your new role (available at www.pharmacy.ohio.gov/OARRSdocuments) along with a photocopy of your pharmacist wallet license. The Board will update the account and send a confirmatory email to you once it is complete.

Registering for the Proper Type of OARRS Account

OARRS has three unique types of accounts. Health care professional/delegate accounts are individually owned accounts to look up a patient's prescription history. Pharmacy accounts are used to send dispensed prescription data to OARRS. Wholesale accounts are used to report when your pharmacy sells product to another pharmacy or to a prescriber office for office use. Every day the Board receives calls from pharmacists who are unable to link their delegates to the pharmacist's account because the delegate registered for the wrong type of account. Just because they work in a pharmacy does not translate to needing a pharmacy account. A description of what the account does is provided with each account type.

Ohio Adopts New Law on Expedited Partner Therapy

Effective March 23, 2016, Ohio physicians, advance practice registered nurses, and physician assistants are authorized to prescribe or personally furnish a drug for a sexual partner of a patient diagnosed with chlamydia, gonorrhea, or trichomoniasis without examining the sexual partner. For more information on this new law, visit www.pharmacy.ohio.gov/EPT.

Page 4 – May 2016

The *State of Ohio Board of Pharmacy News* is published by the State of Ohio Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF™) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

Steven W. Schierholt, Esq - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Deborah Zak - Communications Manager
