June 2016

North Dakota State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

1906 E Broadway Ave • Bismarck, ND 58501-4700 • Phone: 701/328-9535
Fax: 701/328-9536 • *www.nodakpharmacy.com*

Pharmacist Prescribing of Naloxone

The North Dakota State Board of Pharmacy finalized rules (North Dakota Administrative Code (NDAC) 61-04-12) implementing the authority given by Senate Bill 2104, which granted prescriptive privileges for naloxone to pharmacists in North Dakota. This important measure will be one of the tools the profession of pharmacy can utilize to help save lives from the illicit and prescription drug abuse issues currently affecting so many.

The process for a pharmacist to prescribe naloxone is available on the Board's website along with information that can be provided to patients and patients' loved ones. The process is very straightforward and involves reviewing the context of the rule, completing one of the educational programs, and informing the Board of your intentions to prescribe this lifesaving drug. The Board will make the locations to which pharmacists are prescribing naloxone available to the public for their information. Please strongly consider providing this service in your pharmacy location.

Continuous Quality Improvement Program Required for Pharmacies

The Board finalized the rules that will require that a continuous quality improvement (CQI) program be utilized within each pharmacy in the state (NDAC 61-02-09). CQI programs are becoming a standard of practice for a pharmacy to ensure tracking of errors or quality-related events. This assures the public that a pharmacy is continuously looking at their processes to ensure that improvements can be made to minimize and learn from these situations. The Board has previously required these processes in hospital pharmacies and telepharmacies.

The Board wanted to make sure that the information collected is used as a learning tool and not as a method for punitive action. Thus included in the rule is the protection from discovery from a third party of any information collected by the CQI. The Board will monitor through its inspectors to ensure pharmacies are participating in a CQI process and that reports are monitored on a regular basis with staff.

CLIA-Waived Tests Revised and Expanded

The Board enacted rules (NDAC 61-04-10) in 1999 allowing pharmacies to provide Clinical Laboratory Improvement Amendments (CLIA)-waived tests to the public. The list was limited to cholesterol tests, blood glucose, and hemoglobin A1c. The Board finalized rules, which are now effective, that revise the standards to provide CLIA-waived tests to the current practice standards.

Also included in the rule is an expansion of the CLIA-waived tests a pharmacist may provide to the public. This expanded list includes tests such as rapid influenza, rapid strep, nicotine, thyroid-stimulating hormone, urine drug tests, and many others. The Board heard from pharmacists and employers looking for this expansion of services. The Board is hopeful that this authority will get utilized by pharmacists in the changing health care model. The expansion of CLIA-waived tests along with the expanded collaborative agreement rules and laws should provide opportunities to work with your local health care institution to assist in an interprofessional model of care for the benefit of your patients. The Board looks forward to stories on how this expanded authority is utilized.

EPCS Reminder

Drug Enforcement Administration (DEA) issued a rule change in 2010 allowing for electronic prescriptions for controlled substances (EPCS). North Dakota law also allows for electronic prescription transmission of all prescriptions, including controlled substances (CS). The DEA rule requires providers and pharmacies to have a certification in place for their electronic prescribing/dispensing system. This certification ensures safeguards are in place for authorized prescriptions to be received and transmitted. For pharmacies, much of this work is done by your dispensing software systems. The Board continues to see a rapid escalation in the number of providers and pharmacies that are approved to transmit EPCS. If you are not accepting EPCS, the Board encourages you to work with your vendor to make the adjustment, as this adds a tremendous amount of efficiency to both the pharmacy and the provider. As always, it is important to verify the integrity of a CS prescription when a red flag presents itself and work with the provider should there be any questions or concerns.

Update on Registration With the North Dakota PDMP

The number of pharmacy registrants and requests made by pharmacy registrants has increased quite substantially during the past year. Below you will see charts showing the increase. The Board is proud of the increase in utilization of the Prescription Drug Monitoring Program (PDMP), which is continuing to prove to be the most powerful patient care tool to prevent and deter prescription drug abuse.

Registrants by Quarter		
Quarter	**Pharmacist**	**Pharmacy Technician**
2015 Third	951	432
2015 Fourth	968	457
2016 First	979	498

Report Requests by Quarter	
Quarter	**Pharmacy Queries Requested**
2015 Third	20,701
2015 Fourth	15,421
2016 First	21,531

continued on page 4

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*.

National Association of Boards of Pharmacy Foundation
1600 Feehanville Drive
Mount Prospect, IL 60056

NORTH DAKOTA STATE BOARD OF PHARMACY

Presorted Standard
U.S. Postage
PAID
Chicago, Illinois
Permit No. 5744

continued from page 1

The Board expects to see further increases in utilization for the profession of pharmacy due to the implementation of the administrative rules for pharmacies to utilize the PDMP. If you have not created an account for direct access to the PDMP, if applicable, you should follow the steps below to receive online access and ensure that you utilize it in your practice.

To create your North Dakota PDMP account:

1. Visit *https://northdakota.pmpaware.net/identities/new.*
2. Enter your email address and password (must contain at least eight characters, upper and lower case letters, and punctuation or symbols) and then click Save and Continue.
3. Select your role. For example, click the arrow next to Healthcare Professional, then select the box next to Pharmacy Technician or Pharmacist, and then click Save and Continue.
4. Fill in the online form. If you are a pharmacy technician, please scroll down to the "I am a delegate for…" box and enter the email address of your pharmacist-in-charge or any other pharmacist you work with who already has an account (from any location). Click Submit Your Registration.
5. You will receive two emails: one with an email verification link that you must click on, and the other with an agreement that requires a notary signature and needs to be uploaded or faxed to 701/328-9536.

The administrator will review your application and, if everything is in order, will approve it. You can then visit *https://www.nodakpharmacy.com/pdfs/AWARxErequest.pdf* for one-page instructions for pulling the best results when you make a request.

If you have questions or need assistance, please call 701/328-9537 or call the 24-hour support line at 855/563-4767.

Evidence That Pilots Are Increasingly Using Over-the-Counter, Prescription, and Illicit Drugs

The National Transportation Safety Board (NTSB) recently analyzed toxicology tests from 6,677 pilots who died in a total of 6,597 aviation accidents between 1990 and 2012. The results demonstrate a significant increase in the use of a variety of potentially impairing drugs.

The study found significantly increasing trends in pilots' use of all drugs, potentially impairing drugs (those with a United States Food and Drug Administration warning about sedation or behavior changes in routine use), CS, and illicit drugs (those defined as Schedule I by DEA). The final report, *Drug Use Trends in Aviation: Assessing the Risk of Pilot Impairment,* is available on the NTSB's Safety Studies web page at *www.ntsb.gov/safety/safety-studies/pages/safetystudies.aspx* under report number SS-14/01.

In this study, the pilot was considered to be positive for a drug if it could be qualitatively or quantitatively identified in blood or tissue; drugs identified only in urine or used as part of resuscitative efforts were excluded.

Overall, 98% of the study pilots were male and 96% were flying privately rather than for commercial purposes. The average age of study pilots increased from 46 to 57 years over the study period.

Over the course of the study, the following was found for fatally injured pilots:

- The proportion of pilots testing positive for at least one drug increased from 10% to 40%.
- More than 20% of all pilots from 2008 to 2012 were positive for a potentially impairing drug, and 6% of all pilots were positive for more than one potentially impairing drug.
- Overall, the most common potentially impairing drug pilots had used was diphenhydramine, a sedating antihistamine (the active ingredient in many Benadryl® and Unisom® products).
- During the most recent five years studied, 8% of all pilots tested positive for CS; hydrocodone and diazepam each accounted for 20% of the positive findings.
- The percentage of pilots testing positive for marijuana use increased to about 3% during the study period, mostly in the last 10 years.

The large increase in the proportion of fatally injured pilots with evidence of potentially impairing drugs suggests an increasing risk of impairment in general aviation. Aviation is the only transportation mode in which a fatally injured operator (pilot) routinely undergoes extensive toxicology testing; no similar testing is routinely performed for fatally injured operators of boats, trains, trucks, or cars. Given the general increase in drug use in the population, it is likely that there has been a similar trend in drug use among operators across all modes of transportation.

These results highlight the importance of routine discussions between health care providers and pharmacists and their patients about the potential risks that drugs and medical conditions can create when patients are operating a vehicle in any mode of transportation.

The *North Dakota State Board of Pharmacy News* is published by the North Dakota State 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.

Mark J. Hardy, PharmD - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Amy Suhajda - Communications Manager