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

What Do I Need for Electronic Prescriptions for Controlled Substances?

By Mikayla Fick, 2016 PharmD Candidate, and Mark Hardy, PharmD, RPh, Executive Director

Drug Enforcement Administration (DEA) issued a rule change in 2010 allowing for electronic prescriptions for controlled substances (EPCS). North Dakota Administrative Code (NDAC) also allows for computer transmission of all prescriptions, including controlled substances (CS) in Schedules II-V. However, both require specific electronic signatures. These electronic signatures are obtained by the prescriber via application to DEA. However, that is not the only requirement for receiving and dispensing controlled prescriptions. Pharmacies also have a responsibility to make sure their software is capable of monitoring the prescription, any changes made to it, and the verification of the prescriber's signature. All of this can be done by a third-party provider, who will also perform annual audits of authorized prescribers to ensure that only those granted access to the system are doing so. Thus, it is a process to ensure that all the appropriate bases are covered before allowing transmission of CS prescriptions.

The prescriber will be using two-factor authentication. This is similar to automated teller machine (ATM) requirements. The individual trying to use the ATM needs to know an identification number and have a bank card in order to access any information. The same will be true for transmitting a CS prescription. This is to create a more secure network and avoid unauthorized individuals from accessing the system. Since there is no handwritten or verbal communication that may help identify if an imposter is present, two-factor authentication will help deter diversion instead. To obtain both factors of the authentication, there is a process involving a credential service provider or a certification authority that meets specific requirements.

After prescribers obtain authorization to send CS via electronic prescription, the third-party provider audits them. The audit on authorized prescribers must be conducted annually by a qualified individual. In this case, a qualified individual is one who would also be qualified to conduct specific audits, such as SysTrust, WebTrust, or SAS 70 Audit. This requirement may slow the process as they obtain these accreditations if they do not already have them. The third-party providers also look at the software of each pharmacy to make sure they meet all the requirements set forth to properly import, store, and display the information, as well as verify prescribers. Both of these are major steps and take time to process.

While the third-party provider is doing most of the work for the pharmacy to ensure that its software is capable and up to date, the pharmacy may help set controls to limit access to prescription information so that it cannot be changed. After EPCS are capable of being received, a pharmacy still maintains all the same responsibilities required of written or oral CS prescriptions. This includes making sure all information is present on the prescription and the medication is appropriate for the patient.

Being able to utilize EPCS is a process. There are many factors involved to ensure that the appropriate people have access to the system and that pharmacies have the ability to verify this information. A lot of the process relies on the individual prescriber and the third-party providers. However, pharmacies will still ultimately hold the key to ensuring the right medication is reaching the right patient.

Currently, there are a few prescribers and pharmacies authorized to transmit and receive EPCS in North Dakota. The North Dakota State Board of Pharmacy envisions many more being approved in the next year, which has prompted many questions to the Board office. As always, it is important to verify the integrity of a CS prescription with the prescriber should there be any questions or concerns.

Should you have any questions, feel free to contact the Board office.

Findings of July CE Audit of Licensed Pharmacists

- 57 pharmacists randomly audited
- 14 pharmacists were asked to provide more information
- 10 pharmacists did not have adequate continuing education (CE) hours

Those not in compliance received administrative fines and will be receiving disciplinary actions according to NDAC 61-03-04-02.

Next, the Board will be randomly auditing pharmacy technicians for the previous license years.

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*.

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

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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 North Dakota 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**
2014 Fourth	667	131
2015 First	901	305
2015 Second	917	342

Report Requests by Quarter	
Quarter	**Pharmacy Queries Requested**
2014 Fourth	23,505
2015 First	17,383
2015 Second	19,405

The Board will expect to see further increases in utilization for our profession 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 account:

1. Visit *https://northdakota.pmpaware.net/identities/new.*
2. Enter your email address and password (it must contain at least eight characters, upper and lower case letters, and punctuation or symbols) and then click Register.
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 on the Update User Roles and Continue button.
4. Fill in the online form. If you are a pharmacy technician, please select 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 the Finish button.
5. You will receive two emails: one with an email verification link you must click, and the other contains an agreement that requires a notary signature and needs to be uploaded or faxed back 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 contact 701/328-9537 or call the 24-hour support line at 855/563-4767.

Board Considers New, Revised Administrative Rules

The Board will be looking at having a rule hearing to discuss changes and additions to the administrative rules. The proposed changes have been discussed at length by the Board during previous Board meetings. The code sections below are those currently determined to be modified and/or created. Full details of the proposed rules are found on the Board's website, *www.nodakpharmacy.com.* The Board welcomes input by any and all, so please feel free to provide comments on the changes.

- Chapter 61-02-01-19 – Pharmacy Quality Improvement
- Chapter 61-02-01-03 – Pharmaceutical Compounding Standards
- Chapter 61-03-01 – Licensure of Pharmacists (terminology)
- Chapter 61-04-08 – Limited Prescriptive Practices
- Chapter 61-04-10 – CLIA Waived Laboratory Tests Rule
- Chapter 61-04-12 – Prescriptive Authority for Naloxone

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
Deborah Zak - Communications Manager