June 2018

# North Dakota State Board of Pharmacy News

*Published to promote compliance of pharmacy and drug law*

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## Growth of the Drug Disposal Program

The North Dakota State Board of Pharmacy has sponsored a drug disposal program since 2016. The Board currently has over 110 pharmacies participating in the program, and that number continues to increase. In working with the North Dakota Pharmacists Association (NDPhA), the Board identified a need for the public to have access to a safe and easy avenue to dispose of controlled substances (CS). When Drug Enforcement Administration (DEA) allowed for pharmacies to become drug disposal sites, the Board was called upon to develop the opportunity for North Dakota pharmacies to provide this service to their patients.

The Board recently moved its drug disposal program to Sharps Compliance, Inc's MedSafe system. The Board hopes those pharmacies that are participating find this to be a great service to the public. It is the Board's intention to continue to provide this service, free of charge, to pharmacies across the state of North Dakota that are willing to participate in this opportunity.

The federal Government Accountability Office recently released a report, *Preventing Drug Abuse: Low Participation by Pharmacies and Other Entities as Voluntary Collectors of Unused Prescription Drugs.* The report shows that, because of the drug disposal program the Board is offering, North Dakota has 32% of its pharmacies participating in a drug disposal program, which beats the national average of just 2.49%. North Dakota is also the only state with over 75% of its population living within five miles of a DEA-authorized prescription drug take-back location.

Thank you to those participating in offering this service to the public. Through your efforts, the program has collected and safely destroyed nearly two tons of unused medications. Any eligible pharmacy not currently set up through the program can do so by reaching out to the Board office for information.

## Free Prescription Opioid Bag Stuffers Developed for Distribution to Patients

The Board has partnered with the North Dakota Department of Human Services and NDPhA to develop and distribute free bag stuffers that can be utilized when dispensing opioid prescriptions. The abuse and misuse of opiates is a huge public health concern for the nation and North Dakota alike. As health care practitioners, pharmacists are on the frontline of day-to-day interactions with patients and provide a crucial step in educating through consultation the potential dangers associated with CS. This bag stuffer is meant to be a tool for you to utilize in your practice. The Department of Human Services, through grant funding, is able to ship more to your pharmacy upon request at no cost. Ordering these can be done through the North Dakota Prevention Resource & Media Center website at *www.prevention.nd.gov,* under "Free Materials." There may even be other materials of interest to your practice that can be obtained from the website as well. Please consider providing information like this to your patients as one small but meaningful step to help educate patients and their loved ones about opioid medications.

## USP Chapter <800> and Board Task Force

The recent big news in the practice of pharmacy was the decision by the United States Pharmacopeial Convention to delay the implementation of United States Pharmacopeia (USP) Chapter <800> Hazardous Drugs—Handling in Healthcare Settings until December 2019. This delay in implementation will provide ample time for state boards and pharmacies to determine a response to this new chapter. USP Chapter <800> will affect not only pharmacies across the state, but also health care facilities.

USP Chapter <800> provides guidance for personal handling of hazardous drugs (HDs), including the use of personal protection equipment and proper communication, training, transport, package labeling, and disposal. It also offers specifications for the building environment

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# National Pharmacy Compliance News

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NABPF
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## FDA Requires Labeling Update on Opioid-Containing Cough and Cold Medicines

In January 2018, Food and Drug Administration (FDA) announced that the agency is requiring safety labeling changes to limit the use of prescription opioid cough and cold medicines containing codeine or hydrocodone in children younger than 18 years old because the serious risks of these medicines outweigh their potential benefits in this population. After safety labeling changes are made, these products will no longer be indicated for use to treat cough in any pediatric population and will be labeled for use only in adults aged 18 years and older. In addition, labeling for the medications will be updated with additional safety information for adult use. This update will include an expanded Boxed Warning notifying consumers about the risks of misuse, abuse, addiction, overdose and death, and slowed or difficult breathing that can result from exposure to codeine or hydrocodone. Additional information is available in FDA's news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592109.htm.*

## Latest NDTA Shows Opioids Pose Significant Impact to Public Health

Drug Enforcement Administration (DEA) indicates a significant shift in the overall drug threat reported by law enforcement over the last 10 years with opioids (including controlled prescription drugs, fentanyl and other synthetic opioids, and heroin) reaching epidemic levels and impacting significant portions of the United States. According to the *2017 National Drug Threat Assessment (NDTA)* report, every year since 2001, controlled prescription drugs, specifically opioid analgesics, have been linked to the largest number of overdose deaths of any illicit drug class, outpacing those for cocaine and heroin combined.

From 2007 to 2010, responses to the National Drug Threat Survey indicate cocaine was the greatest national drug threat, followed by a significant decline as the heroin threat increased between 2010 and 2016, eventually becoming the greatest national drug threat in 2015.

Illicit fentanyl and other synthetic opioids, primarily sourced from China and Mexico and shipped directly to the US or trafficked overland via Mexico and Canada, are contributing factors in the current synthetic opioid overdose epidemic. Traffickers in the US usually mix fentanyl into heroin products and sometimes other illicit drugs or press it into counterfeit prescription pills, often without users' awareness, which leads to overdose incidents, notes the *2017 NDTA.* To access the *2017 NDTA,* visit *www.dea.gov/divisions/hq/2017/hq102317.shtml.*

## FDA Recognizes Eight European Drug Regulatory Authorities Capable of Conducting Inspections

FDA has determined it will recognize eight European drug regulatory authorities as capable of conducting inspections of manufacturing facilities that meet FDA requirements. The eight regulatory authorities found to be capable are those located in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom. This achievement marks an important milestone to successful implementation and operationalization of the amended Pharmaceutical Annex to the 1998 US-European Union (EU) Mutual Recognition Agreement, which enables US and EU regulators to utilize each other's good manufacturing practice inspections of pharmaceutical manufacturing facilities. "By partnering with these countries, we can create greater efficiencies and better fulfill our public health goals, relying on the expertise of our colleagues and refocusing our resources on inspections in higher risk countries," said FDA Commissioner Scott Gottlieb, MD, in a news release located at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm583057.htm.*

## Incorrect Use of Insulin Pens at Home Can Cause Severe Hyperglycemia

The National Coordinating Council for Medication Error Reporting and Prevention has issued an alert on the incorrect use of insulin pens at home causing severe hyperglycemia in patients, including one reported fatality. The Institute for Safe Medication Practices National Medication Errors Reporting Program has received several reports of patients who failed to remove the inner cover of standard insulin pen needles prior to administering insulin. In the latest such event, a patient with type 1 diabetes did not know to remove the standard needle cover and was unaware she was using the pen incorrectly and had not been receiving any of the insulin doses; the patient developed diabetic ketoacidosis as a result and died.

Since insulin pens may differ between pens with automatic needle retraction devices and those with standard needle covers that require manual removal before administering insulin, it is imperative that removal of

needle covers be explained to patients who are issued standard insulin pens during their diabetes education. Pharmacists should verify that a patient understands the appropriate administration technique whenever pens and insulin needles are dispensed, notes the alert, which can be viewed at *www.nccmerp.org/sites/default/files/nan-20171012.pdf.*

## FDA Advises on Opioid Addiction Medications and Benzodiazepines

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found at *www.fda.gov/Drugs/DrugSafety/ucm575307.htm.*

## Only About 3% of Pharmacies and Other Entities Voluntarily Maintain a Prescription Drug Disposal Bin, GAO Reports

In response to the US Senate Judiciary Committee's request to review DEA's requirements for authorized collectors of prescription drugs and participation rates, the US Government Accountability Office (GAO) found that only about 3% of pharmacies and other entities eligible to collect unused prescription drugs for disposal have volunteered to do so. As of April 2017, 2,233 of the 89,550 eligible entities had registered with DEA to use disposal bins to collect unused prescription drugs. The majority of the authorized collectors were pharmacies, followed by hospitals or clinics. Factors that affected voluntary participation in maintaining disposal bins for the public included cost, uncertainty of proper implementation, and participation in other drug disposal efforts.

GAO found that participation rates varied by state. Connecticut, Missouri, and Maine had the lowest participation rates as of April 2017. North Dakota had the highest participation rate, followed by Alaska. The report, *Preventing Drug Abuse: Low Participation by Pharmacies and Other Entities as Voluntary Collectors of Unused Prescription Drugs,* is located on the GAO website at *www.gao.gov/products/GAO-18-25.*

## One in Five Drivers Uses a Prescription Drug That Can Impair Driving Despite Receiving Warnings

A new study that analyzes data from the National Roadside Survey of Alcohol and Drug Use, 2013-2014, found that one in five drivers has taken prescription drugs that could impair driving despite having been warned about the risks. The authors of the study, "Receipt of Warnings Regarding Potentially Impairing Prescription Medications and Associated Risk Perceptions in a National Sample of U.S. Drivers," indicate that of the 7,405 random drivers who completed the prescription drug portion of the survey, almost 20% reported recent use (within the past two days) of a potentially impairing prescription drug.

Compared to people who were prescribed antidepressants (62.6%) and stimulants (57.7%), those who were prescribed sedatives (85.8%) and narcotics (85.1%) were most likely to report receiving warnings about the potential of these drugs to affect driving from their health care provider, pharmacy staff, or medication label.

Several European countries have introduced color-coded categories (ie, no, minor, moderate, and major influence on driving) to drug labeling to increase patient safety. Beyond labeling, the authors of the study note it is important that health care providers consistently communicate with patients about their medications' driving-related risks. The study was published online in the *Journal of Studies on Alcohol and Drugs* on October 31, 2017, and can be found at *https://doi.org/10.15288/jsad.2017.78.805.*

## PTCB CPhT Program Earns Accreditation From the American National Standards Institute

The Pharmacy Technician Certification Board's (PTCB's) Certified Pharmacy Technician (CPhT) Program has earned accreditation from the American National Standards Institute (ANSI) Personnel Certification Accreditation Program through December 2022. ANSI is the first personnel certification accreditation body in the US to meet internationally accepted practices for accreditation. "We were the first pharmacy technician certification program to receive accreditation by the National Commission for Certifying Agencies (NCCA) in 2006, and now we are the first and only program to achieve ANSI accreditation," said PTCB Executive Director and Chief Executive Officer William Schimmel in a news release. More details are available in PTCB's December 18, 2017 news release, which can be found in the News Room section of *www.ptcb.org.*

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for handling HDs. For many pharmacy locations that are not compounding, the USP Chapter <800> standard may not require modification of their space. However, pharmacies that do conduct HD compounding may need to make extensive changes to come into compliance with the standard.

The Board has been talking about USP Chapter <800> standards, including whether the Board is going to adopt the standard or modify existing or current Board rules to address the new standards relative to HDs. At a minimum, there are certainly improvements that can be made in our profession relative to notification and educating staff and employees about the dangers of HDs and how to correctly limit exposure to them.

For many health-system pharmacies, the modification of space must be completed to accommodate USP Chapter <800> standards, as it will be the enforceable standard of both The Joint Commission and Centers for Medicare & Medicaid Services accreditation. As things progress, compliance will certainly involve education and setting policies and procedures for how these HDs will be safely handled to minimize risk, according to where a drug falls on the National Institute for Occupational Safety and Health list of antineoplastic drugs and HDs.

The Board encourages you to take the time to educate yourself on what implementation of USP Chapter <800> will mean to your practice and practice site. Please keep the Board informed on what you feel is the appropriate path moving forward in developing an approach to ensure limited exposure to these potentially harmful substances. The Board has created a task force of volunteers from multiple practice locations to assist the Board with the pros and cons of USP Chapter <800> and to determine what the right path is for our profession in response to these new standards. As always, please feel free to contact the Board with your thoughts and suggestions on USP Chapter <800>.

## *Transfer of CS Between Pharmacies*

The Board still receives reports of "borrowing" Schedule II substances between pharmacies to deal with shortages. The desire is to circumvent the legal process of filling out a DEA Form 222 and replace the Schedule II inventory when a later shipment is received. Violation of this could produce a $10,000 fine from DEA for each separate incident.

If you run short of a Schedule II substance, get out your 222 forms and buy the CS from the other pharmacy in the proper manner. If you run short of a Schedule III, IV, or V product, the selling pharmacy should create an invoice and give a copy of it to the buying pharmacy; both pharmacies must keep a copy with their other invoices, verifying disbursement or receipt of CS. The same process would apply when looking to provide CS inventory to other practitioners (eg, dentists, physicians, veterinarians).

## *Pharmacists Are Encouraged to Sign Up for a Direct Account*

The North Dakota Health Information Network (NDHIN) Direct went live in March 2012. NDHIN Direct provides a secure, encrypted method of exchanging protected health information such as prescriptions, lab reports, consults, and other clinical information between providers, payers, health departments, etc.

NDHIN Direct is easy to use and is a web-based application, so no additional hardware is required. There are no limits to the number of users who can be enrolled for an NDHIN Direct email account. NDHIN Direct is offered free of charge to all who participate in the NDHIN. There are over 320 authorized users from 67 different facilities currently using NDHIN Direct, and the numbers continue to grow. You can view a list of current participants by visiting *www.ndhin.org/providers/participating-providers.*

NDHIN Direct offers many benefits to pharmacies. These benefits include providing a solution to the current process of mailing, scanning, and/or faxing health information, thus making the process faster, less expensive, and more secure.

You can sign up today by visiting *www.ndhin.org/services/ndhin-enrollment.* Or, for more information on NDHIN Direct, visit *www.ndhin.org/services/ndhin-direct* or send an email to ndhin@nd.gov.



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