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North Dakota State Board of Pharmacy News

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Board of Pharmacy Website – A Wealth of Information

The North Dakota State Board of Pharmacy would like to encourage you to utilize its website as a resource. The website is the main source of linkage to the North Dakota Prescription Drug Monitoring Program (PDMP), ONE Rx, and the Prescription Drug Repository Program. On the Board's website you are going to find multiple guidance documents that will assist you with practice-related questions and concerns. Also, license and registration verification for both individuals licensed/registered with the Board and businesses able to conduct activities governed by the Board, are available on the Board website under Verify License. There is information on how to contact the Board office along with many resources and links that may be helpful for your location. We encourage you to explore the Board's website, *www.nodakpharmacy.com*.

Update on the ONE Rx Program – Is Your Pharmacy Participating?

The ONE Rx team at the North Dakota State University launched the opioid and naloxone education project in North Dakota on October 1, 2018. Since its launch, 131 North Dakota pharmacists have completed the three-hour ONE Rx training either in person or online. This free training can be accessed on the Board website, by clicking on the ONE Rx tab. Forty-eight pharmacies have enrolled to be ONE Rx pharmacies, which requires screening all patients receiving opioids for both opioid misuse risk and accidental overdose. The program provides all participating pharmacies access to the REDCap online data entry system, which allows pharmacies to track patient care measures, such as naloxone dispensed, patients counseled about medication take back, and counseling about opioid misuse disorder. As of November 6, 2018, 155 patients have been screened across North Dakota. Of these patients, 7.1% had an opioid risk tool score of eight or higher, indicating elevated risk of opioid misuse disorder, 16.6% had red flags for misuse, and 29% were at risk for an accidental overdose. This led to 78.1% of patients learning about the medication take back program, and 5.8% were dispensed naloxone after learning of the risk. The average time spent on each patient was only five minutes. This program is easily woven into normal workflow, with minimal disruption of work time, and maximally focused patient counseling and support, which is based on individualized patient information.

It should be noted that ONE Rx has a recognition program of bronze, silver, and gold level pharmacies. Bronze level pharmacies earn a $500 incentive payment upon training half of their pharmacists in ONE Rx and screening 25 patients. Gold level results in an additional $500 incentive payment, and is earned after 75% of pharmacists are trained, a take back program is put in place, and 100 patients are screened.

Through ONE Rx, North Dakota is taking the lead in opioid misuse prevention and patient care delivered by community pharmacies. The Board encourages pharmacies to participate in this outstanding project to make an impact in your communities.

North Dakota PDMP to Offer NarxCare Through Its Platform

The Board is pleased to announce an upcoming enhancement to the PDMP. This is initially funded through a Centers for Disease Control and Prevention opioid response grant received through the North Dakota Department of Health.

In December, all approved PDMP users will have access to an advanced analytics and patient support tool called NarxCare. In addition to the existing PDMP functionality, NarxCare will aggregate and analyze prescription information from providers and pharmacies and present visual and interactive information, as well as

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National Pharmacy Compliance News

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The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

SAMHSA Publishes Guidance for Treating OUD

To help broaden health care professionals' understanding of medications that can be used to treat Americans with opioid use disorder (OUD), the Substance Abuse and Mental Health Services Administration (SAMHSA) offers guidance on clinical best practices in the February 2018 publication titled *Treatment Improvement Protocol 63, Medications for Opioid Use Disorder.* The publication reviews the use of the three Food and Drug Administration (FDA)-approved medications used to treat OUD – methadone, naltrexone, and buprenorphine – and other strategies and services needed to support recovery for people with OUD.

Additionally, in February 2018, SAMHSA released the publication *Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants,* which offers standard approaches for health care professionals. This publication provides evidence-based treatment options, including pharmacotherapy with methadone, buprenorphine, and buprenorphine/naloxone, for pregnant women with OUD. The clinical guidance also helps health care professionals and patients determine the most clinically appropriate action for a particular situation and informs individualized treatment decisions. Both publications can be found in the Publications section of SAMHSA's website at *www.samhsa.gov*.

FDA Issues Final Guidance Policy on Outsourcing Facilities

In May 2018, FDA issued a new policy designed to address any ambiguity around how to define the physical features and operations of outsourcing facilities. According to FDA Commissioner Scott Gottlieb, MD, the policy in the final guidance, *Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act,* will help to:

- ensure that compounded drugs are made under appropriate quality standards;
- provide transparency to patients and health care providers about the standards under which the compounded drugs that they purchase are made; and
- respond to stakeholder feedback requesting guidance on the meaning of "facility" under section 503B.

In the guidance, FDA explains that a section 503A establishment compounding drugs pursuant to patient-specific prescriptions may be located near or in the same building as the outsourcing facility provided that they are completely separate. As explained in the guidance, the boundaries between the section 503A establishment and outsourcing facility should be clear and may include permanent physical barriers, such as walls or locked doors, and the two operations should not share rooms, equipment, supplies, or pass-through openings (eg, they may not subdivide a room with temporary barriers such as curtains). The guidance further explains that the labeling should clearly identify the compounder who produced the drug. Lastly, the guidance reminds industry and stakeholders that all drug products compounded in an outsourcing facility are regulated under section 503B and are subject to current good manufacturing practice requirements, even if those drug products are compounded pursuant to patient-specific prescriptions. Additional information can be located at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm607339.htm.*

EU-US Mutual Recognition Agreement Now Operational Between FDA and 12 Member States

In January 2018, FDA confirmed the capability of four more European Union (EU) member states – Czech Republic, Greece, Hungary, and Romania – to carry out good manufacturing practice inspections at a level equivalent to the United States. With the addition of the four EU member states, FDA can now rely on inspection results from 12 EU member states. The mutual recognition agreement between the EU and US to recognize inspections of manufacturing sites for human medicines conducted in their respective territories is progressing as planned, with plans for the agreement to be operational in all EU member states by July 15, 2019, indicates a European Medicines Agency (EMA) press release. In 2017, FDA determined the agency will recognize eight European drug regulatory authorities in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom as capable of conducting

inspections of manufacturing facilities that meet FDA requirements. The EMA news release, "Four more EU Member States benefit from EU-US mutual recognition agreement for inspections," can be found in the News and Events section at *www.ema.europa.eu.*

US Surgeon General Advisory Urges More Individuals to Carry Naloxone

In an April 2018 advisory, US Surgeon General Jerome M. Adams, MD, MPH, emphasizes the importance of more individuals knowing how to use naloxone and keeping it within reach. Surgeon General Adams recommends that family, friends, and those who are personally at risk for an opioid overdose keep the drug on hand. As stated in the advisory, expanding the awareness and availability of naloxone is a key part of the public health response to the opioid epidemic. The Surgeon General advisory on naloxone is part of the Trump Administration's ongoing effort to respond to the sharp increase among drug overdose deaths, notes a US Department of Health and Human Services (HHS) news release. HHS also has a website, *www.hhs.gov/opioids,* with resources and information for individuals who want to fight the opioid crisis in their communities or find help for someone in need. The advisory and news release can be found at *www.surgeongeneral.gov*.

Expanding Pharmacists' Scope of Practice Linked to Improved Cardiovascular Outcomes

Elevating pharmacy involvement in patient care and using a team-based care model are among the effective strategies for preventing cardiovascular disease that were identified in a new guide developed by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention (DHDSP). The guide, *Best Practices for Cardiovascular Disease Prevention Programs: A Guide to Effective Health Care System Interventions and Community Programs Linked to Clinical Services,* describes the scientific evidence behind each strategy, including collaborative drug therapy management, enabled by a collaborative practice agreement, and medication therapy management. To be included in the guide, strategies had to be supported by multiple high-quality research studies that demonstrated evidence of effectiveness in controlling blood pressure or cholesterol levels. More details about the best practice strategies along with resources and tools for implementing the strategies identified by CDC's DHDSP can be found at *www.cdc.gov/dhdsp/pubs/guides/best-practices/index.htm.*

Pharmacists Are Critical to Drug Supply Chain Integrity, States FIP

Medicines are specialized commodities and, if they are not managed rationally or appropriately, they are equivalent to a dangerous substance, indicates the International Pharmaceutical Federation (FIP). In a May 2018 report, *Pharmacists in the supply chain: The role of the medicines expert in ensuring quality and availability,* FIP provides a global picture of the role of pharmacists in supply chains, the tasks currently undertaken by pharmacists in different countries, and pharmacists' unique competencies. Based on reviews of literature, survey data, and case studies from nine countries, pharmacists were identified as having expertise that is critical to supply chain integrity. According to FIP, pharmacists and those who are involved in the planning, procurement, manufacture, storage, and distribution of medicines must:

- ♦ consider how to most effectively use the skills of the staff and personnel available;
- ♦ provide and seek training where needed; and
- ♦ keep their systems and role descriptions under review in order to adapt to changing circumstances.

FIP's report and news release can be located at *www.fip.org/news_publications.*

Emergency Department Visits for Opioid Overdoses Rose 30%

From July 2016 through September 2017, reports of emergency department (ED) visits for opioid overdoses – including prescription pain medications, heroin, and illicitly manufactured fentanyl – rose 30% in all parts of the US, according to a CDC report. The Midwest saw opioid overdoses increase 70% during this time period. According to the March 9, 2018 *Morbidity and Mortality Weekly Report*, coordinated action between EDs, health departments, mental health and treatment providers, community-based organizations, and law enforcement can prevent opioid overdose and death. People who have had an overdose are more likely to have another; thus, being seen in the ED is an opportunity for action. EDs can provide naloxone, link patients to treatment and referral services, and provide health departments with critical data on overdoses. The CDC report, "Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses — United States, July 2016–September 2017," can be accessed at *http://dx.doi.org/10.15585/mmwr.mm6709e1.*

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advanced analytic insights, machine learning risk scores, and more. This will help physicians, pharmacists, and care teams provide better patient safety and outcomes up front, for every patient, every time. NarxCare also provides tools and resources that support patients' needs and connects them to treatment, when appropriate.

With this enhancement, health care providers will have access to all the features and functions of NarxCare with a consistent look and feel for users who access the solution through the PDMP web portal. It also enables delivery of NarxCare within electronic health records and pharmacy management systems for those prescribers and dispensers in North Dakota who choose to access NarxCare through their health care information technology system via Appriss Health's PMP Gateway solution.

Additional NarxCare information and training materials will be made available through the PDMP. Instructional videos on how to navigate NarxCare and how to interpret the NarxCare report will be available for viewing.

EPCS: The Forwarding and Transferring Process

The Board has received questions and requests for further clarification on the terminology of forwarding versus transferring. The Board consulted directly with Drug Enforcement Administration (DEA) and was provided guidance relative to the process of forwarding and transferring electronically prescribed controlled substances (EPCS) when the patient prefers to use a different pharmacy than where the original electronic prescription was sent by the prescriber.

In communicating with DEA, as well as other entities, the Board wants to make sure that you understand that the **forwarding** of an EPCS prescription is meant to be a secure electronic process to send a prescription from one pharmacy to another. It is important to note that currently there are no valid **forwarding** processes that exist between pharmacy software systems. It is anticipated that in the next year the National Council for Prescription Drug Programs' standards will be updated to allow for this type of transmission between pharmacies. Until such time, there is not a legal way to transfer an **unfilled** EPCS prescription that has been placed **on hold** or **profiled** within a pharmacy software system.

Once the original EPCS prescription has been filled and dispensed, any remaining refills are able to be transferred directly between two licensed pharmacists **(cannot be delegated to other staff)** on a one-time basis. The original fill of the EPCS prescription cannot be transferred from pharmacy to pharmacy, and at this time a new prescription would need to be requested from the prescribing practitioner, when applicable.

As pharmacists acquire the forwarding ability for EPCS prescriptions in the future, it appears this capability will be extended to prescriptions in Schedule II-V. The Board anticipates this functionality to help better serve patients will be available in the next year.

Should you have any questions or need further clarification, do not hesitate to contact the Board office.

SUPPORT Act Passed to Address the Opioid Crisis

On October 24, 2018, President Donald J. Trump signed into law HR 6, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, also referred to as the SUPPORT for Patients and Communities Act. HR 6 addresses the opioid crisis by reducing access to, and the supply of, opioids and by expanding access to prevention, treatment, and recovery services.

HR 6 covers a broad range of areas related to the opioid epidemic and contains provisions that will or may affect state boards of pharmacy, pharmacies, and pharmacists.

Several SUPPORT Act provisions that will affect boards of pharmacy relate to PDMPs. Specifically, the Act requires the federal government to annually support states for the purpose of improving the efficiency and use of PDMPs, including establishing, implementing, maintaining, and improving a PDMP. States receiving support:

- are required to demonstrate that they have enacted legislation or regulations to implement a PDMP and permit the imposition of appropriate penalties for the unauthorized use and disclosure of information maintained by the PDMP;
- are encouraged to develop PDMPs that are real time and facilitate integration into provider workflow;
- shall establish a program to notify practitioners and dispensers of information that will help identify and prevent unlawful diversion or misuse of controlled substances (CS);
- shall report on the interoperability with other state PDMPs and federal agencies, where appropriate; and
- will allow prescribers, dispensers, and their delegates to use the PDMP as permitted by state law as well as educate them on the benefits of the use of PDMPs.

SUPPORT Act provisions affecting pharmacies and pharmacists include the following:

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- In the Medicare program, new rules will be imposed requiring e-prescribing for CS as well as electronic prior authorization.
- Medicare prescription drug plans will be able to suspend payments to pharmacies pending investigations of credible allegations of fraud by pharmacies.
- Pharmacies will be able to dispense implantable or injectable CS directly to providers, rather than requiring patients to pick them up from a pharmacy.
- The federal government is required to develop guidance and training on when pharmacists can decline to fill a prescription for CS due to suspicion of fraud or diversion.
- The Department of Justice (DOJ) Prescription Interdiction & Litigation Task Force will help fight the prescription opioid crisis by expanding the DOJ Opioid Fraud and Abuse Detection Unit's efforts to prosecute corrupt or criminally negligent doctors, pharmacists, and distributors.

Further, under Title III, Subtitle B, Chapter 4 of HR 6, the Special Registration for Telemedicine Clarification Act of 2018 establishes a deadline for DEA to promulgate regulations for the special registration of practitioners to practice telemedicine.

2019 Legislative Session

The 2019 legislative session is right around the corner. It certainly will be another busy session on a budgetary basis for the state, and more tough decisions will need to be made. As always, there will most likely be multiple pieces of legislation items brought before the legislature that will involve pharmacy either directly or indirectly.

In the lead up to the legislative session, the Board encourages you to contact your legislators about issues and/or concerns that you may have in your practice. Of course, the legislative body may not be able to address each issue that we may be dealing with. However, it is important that they be made aware of not only the challenges that pharmacy is facing but also the successes that our profession has created. Our profession continues to be looked at for solutions to issues in health care delivery across the state. It is important that you, as constituents, educate legislators on your professional perspective of the issues and your experiences.

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.

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