June 2019

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*

Gabapentin Added as a Schedule V Substance in the North Dakota Controlled Substance Act

The North Dakota State Board of Pharmacy requested the legislature to add gabapentin (Neurontin®) as a Schedule V drug in the state of North Dakota. The North Dakota Legislature passed House Bill (HB) 1113 and Governor Doug Burgum signed the legislation. The law became effective on April 10, 2019. Your pharmacy should have received communication from the Board's office about the change and about the need to inventory the substance and to treat prescriptions for gabapentin as Schedule V substances moving forward. It is important to note that since gabapentin is a state controlled substance (CS) and not a federal CS, federal requirements related to electronic prescribing would not need to be followed.

The Board heard increasing reports on the concerning activities around gabapentin. Although the rationale for abuse is unknown, reports describe misuse due to the effects of euphoria, improved sociability, a marijuana-like "high," relaxation, and a sense of calm. Concerning activities include obtaining high doses and utilizing multiple practitioners and pharmacies. Please be aware of this increasing trend, and when available, monitor patients through the North Dakota Prescription Drug Monitoring Program when appropriate.

Board Holds Rule Hearing at the NDPhA Convention

The Board held a rule hearing on April 6, 2019, at the North Dakota Pharmacists Association (NDPhA) convention to obtain comments on proposed changes to 18 sections of the North Dakota Administrative Code (NDAC) relating to the practice of pharmacy and CS. Many of the rules would be considered a modernization of practices and will have minimal impact or may provide the ability for efficiencies in the profession. There are also proposed rule changes that will be more impactful for the profession and will require effort to ensure compliance depending on the practice setting.

Each proposed rule change is posted on the Board's website for review. The Board will make appropriate changes based on the comments received at the hearing as well as those communicated to the Board during the open comment period. The Board encourages you to continue to monitor the rules as they move forward for adoption. During the Board's compliance officer visits, there will be further details provided on the impacts of the rules and on the steps needed to ensure pharmacies will be compliant as the rules are finally implemented. It is likely the rules will not be finalized until the last quarter of 2019.

Collaborative Agreement Law Changes

The North Dakota Legislature approved, and Governor Burgum signed into law, Senate Bill 2231, which further streamlines the ability of a pharmacist to enter into a collaborative agreement with a practitioner for initiation and modification of therapy. This law essentially removes the requirement for a collaborative agreement to be formally approved by each administrative Board that governs the licensees involved. Most of the other tenets of the law remain unchanged. The law will be effective on August 1, 2019.

Collaborative agreements have provided the opportunity for North Dakota health care professionals to work together, collaboratively, for the betterment of therapeutic outcomes and to address the challenges of their patients. When the law was originally passed, this was an innovative model; however, these agreements are very commonly utilized across the nation to positively impact patients.

The Board encourages you to work with your local practitioners to develop models of care through collaborative practice agreements that will allow you to provide a better level of care to your patients while assisting to streamline processes for the practitioner. There are many innovative models that have been developed and implemented across North Dakota and the nation. Collaborative agreements present an opportunity for pharmacists to practice at the

continued on page 4

National Pharmacy Compliance News

June 2019

NABPF
National Association of Boards of Pharmacy Foundation

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.

FDA Launches Pilot Program to Improve Security of Drug Supply Chain With an Innovative Approach

Food and Drug Administration (FDA) has launched a pilot program allowing participants representing the various parts of the drug supply chain to pilot innovative and emerging approaches for enhanced tracing and verification of prescription drugs in the United States' supply chain. The program is in line with FDA's ongoing efforts to prevent suspect and illegitimate products from entering the supply chain, according to an FDA press release. Eligible manufacturers, repackagers, and other stakeholders can apply to participate in the program, which will inform the development of the enhanced electronic, interoperable track-and-trace system for industry set to go into effect in 2023 in accordance with the Drug Supply Chain Security Act (DSCSA), enacted by Congress on November 27, 2013.

The pilot technologies of this program may become part of FDA's enhanced expectations for reliable track-and-trace systems, which will be designed to reduce diversion of drugs distributed domestically and to keep counterfeit drugs from entering the supply chain. The DSCSA pilot project program is intended to help identify and evaluate the most efficient processes to comply with and apply drug supply chain security requirements and will aid in identifying attributes the system will need for enhanced product tracing and verification, as well as electronic means to share the information. FDA recently issued draft guidance on the use of product identifiers with a unique serial number to improve verification down to the package level. FDA has also provided draft guidance for verification systems to quarantine and investigate suspect and illegitimate drugs.

Additional information on the FDA pilot program is available in a February 8, 2019 announcement in the *Federal Register.*

FDA Announces New Efforts to Increase Oversight and Strengthen Regulation of Dietary Supplements

Noting that three in four Americans now take at least one dietary supplement on a regular basis, and that the dietary supplement industry has expanded to include as many as 80,000 different products for consumers, FDA Commissioner Scott Gottlieb, MD, has announced new plans to increase the agency's oversight of dietary supplements. These initiatives include communicating to the public as soon as possible when there is a concern about a dietary supplement on the market, ensuring that the regulatory framework is flexible enough to adequately evaluate product safety, and continuing to work closely with industry partners. FDA is also developing new enforcement strategies to respond to entities that violate standards established under the Dietary Supplement Health and Education Act of 1994.

On February 11, 2019, FDA sent 12 warning letters and five online advisory letters to foreign and domestic companies that are illegally selling more than 58 products. The products are illegally marketed as unapproved new drugs that make unproven claims about preventing, treating, or curing Alzheimer's disease, as well as a number of other serious diseases and health conditions, such as diabetes and cancer. In his statement, Gottlieb noted that most stakeholders in the industry act responsibly, but he expressed concern over the ability of bad actors to exploit the system by providing potentially dangerous products and making unproven or misleading claims about the health benefits supplements may offer.

FDA is planning a public meeting on this topic during the second quarter of 2019. For more information, view the FDA statement at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm631065.htm.*

Trump Administration Releases National Drug Control Strategy to Reduce Drug Trafficking and Abuse

As the opioid crisis continues to claim the lives of tens of thousands of Americans each year, the Office of National Drug Control Policy has released its *National Drug Control Strategy.* The *Strategy* breaks down the administration's priorities in addressing the crisis, with an emphasis on three areas: prevention, treatment and recovery, and reducing availability.

- **Prevention** efforts are focused on educating both consumers and caregivers about the dangers of opioid misuse and include a new national media campaign, continued efforts to expand prescription monitoring programs (PMPs), and improving the ability of state, local, and tribal communities to identify and prevent substance abuse.
- **Treatment and recovery recommendations** in the *Strategy* include improving access to naloxone, improving evidence-based addiction treatment, and eliminating barriers for accessing treatment.

- **Reducing availability** strategies are focused on disrupting illegal supply chains, defeating drug traffickers, increased cooperation with international partners, and combating illegal internet drug sales.

The document notes that the "most important criterion of success" is saving lives and calls for the federal government to work closely with state and local governments, as well as other stakeholders. Additional information, including the full strategy document, is available on the White House website at *https://www.whitehouse.gov/opioids.*

National Association of Boards of Pharmacy® (NABP®) and its member boards of pharmacy remain committed to advancing best practices for PMPs in the interest of public health. NABP's PMP data sharing system, NABP PMP InterConnect®, facilitates the secure transfer of PMP data across state lines and provides an effective means of combating drug diversion and drug abuse nationwide. In addition, NABP and its member boards continue efforts to educate consumers about prescription drug safety. The NABP $AWAR_XE$® Prescription Drug Safety Program's Drug Disposal Locator Tool has more than 6,000 disposal locations and continues to add new locations to provide consumers with a safe way to dispose of medication and help prevent misuse and abuse of prescription medications. For more information about PMP InterConnect and the $AWAR_XE$ program, visit the Initiatives section of the NABP website at *www.nabp.pharmacy.*

New Study Predicts Opioid Epidemic Will Worsen Over the Next Decade

More than 700,000 people will die from opioid overdoses between 2016 and 2025, and annual overdose deaths will reach nearly 82,000 by 2025, estimates a new study published to *JAMA Network Open.* The estimate is based on an analysis of data from the National Survey on Drug Use and Health and the Centers for Disease Control and Prevention from 2002 to 2015.

Researchers also projected that intervention efforts focused on lowering the incidence of prescription opioid misuse would help to reduce the number of deaths 3.8% to 5.3%, a figure the researchers described as "modest," due to the changing nature of the opioid crisis. The study notes that more people are directly initiating opioid use with illicit opioids rather than prescription drugs, and illicit opioids have become more lethal with the availability of illegally manufactured fentanyl.

The researchers encourage policymakers to take "a stronger and multipronged approach" to reduce the impact of the ongoing opioid overdose epidemic. The full article is available at *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723405.*

FDA Warns of Potential Blood Pressure Medication Shortages Due to Recalls

FDA is warning health care providers and consumers of a shortage of angiotensin II receptor blockers, commonly used to treat high blood pressure. A growing list of medications containing valsartan, losartan, and irbesartan have been recalled from the market for containing an impurity that may present a cancer risk to patients. The issue was first detected in the summer of 2018, according to a statement posted to the FDA website. Since then, FDA has placed a Chinese manufacturer of the active ingredient on import alert to stop their imports, and FDA is working with other manufacturers to recall affected medications.

In the statement, FDA notes that the risk to individual patients remains very small, but that there is still reason to be concerned about the potential health risks. Medications with these impurities are believed to have been in the market for about four years.

"Now that these risks are identified, we're applying what we've learned to the evaluation of similar manufacturing processes where we now know these risks could arise," the statement notes. The FDA press release is available at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm629796.htm.*

FDA Releases Two Draft Guidances Related to REMS Programs

FDA has released two new draft guidances to ensure risk mitigation programs put in place for certain drugs and biologics, as required for approval, are working. The agency's primary risk management tool is FDA-approved product labeling. However, in limited cases, FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to help ensure a drug's benefits outweigh its risks.

The following guidances relate to the assessment of REMS programs:

- **REMS Assessment: Planning and Reporting Guidance for Industry** describes how to develop a REMS Assessment Plan.
- **Survey Methodologies to Assess REMS Goals That Relate to Knowledge Guidance for Industry** provides recommendations on conducting REMS assessment surveys to evaluate patient or health care provider knowledge of REMS-related information.

FDA states that the goal in providing this guidance for REMS is to ensure constant improvement of their safety programs and establish the most efficient and effective programs moving forward, to optimize patient care and keep consumers safe and healthy. More information on REMS is available on the FDA website at *https://www.fda.gov/drugs/drugsafety/rems.*

continued from page 1

top of their scope of practice and be reimbursed for their services and knowledge.

Legislation Modifies and Expands the Ability of Pharmacists to Provide Administrations

The legislature overwhelmingly approved HB 1498, and it was signed into law by Governor Burgum. This legislation broadens the ability of a pharmacist to administer medications to patients receiving emergency services including, but not limited to, emergency room or code situations in health facilities.

The legislation also removed the need for a pharmacist to receive a biannual certification issued by the Board to provide injections. It did, however, maintain the need for the Board to modify and expand on rules to govern the authority of a pharmacist to obtain and maintain an ability to administer drugs.

The Board will need to adjust the administrative rules set forward in NDAC 61-04-11 to address this legislation to further outline the changes in the law. It is likely that the Board will be discussing this at its next few meetings and will be drafting the necessary changes in the administrative rule for considerations by interested parties. Please watch for a future administrative rule to provide comments on any changes.

Legislation to Require Consent or Notice Prior to Shipping Prescriptions

HB 1382 was enacted by the legislature and signed into law by Governor Burgum. The language of the bill is provided below and will go into effect on January 1, 2020.

SECTION 1. Section 19-02.1-16.3 of the North Dakota Century Code is created and enacted as follows:

Mail order and home delivery - Prior consent - Refund.

1. If a pharmacy offers a prescription through home delivery or mail order delivery services, the pharmacy may not initiate delivery of a refill unless:
   a. The pharmacy obtains prior consent from the patient or the patient's authorized representative; or
   b. The pharmacy provides the patient with notice of the upcoming delivery through more than one communication attempt, by different means, and the patient or the patient's authorized representative does not respond indicating the patient does not want the refill.
2. If a pharmacy delivers a refill in violation of subsection 1:
   a. Within thirty days of the patient's or the patient's authorized representative's notification of the pharmacy of the unwanted refill, the pharmacy shall refund all payments received by the pharmacy relating to the unwanted refill.
   b. Within thirty days of the pharmacy's, patient's, or patient's authorized representative's notification of the health plan or the pharmacy benefits manager of the unwanted refill, the health plan and pharmacy benefits manager shall refund all payments received relating to the unwanted refill.

SECTION 2. EFFECTIVE DATE. This Act becomes effective January 1, 2020.

Pharmacists Are Encouraged to Sign Up for an NDHIN 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 on the number of users that can be enrolled for an NDHIN Direct email account. NDHIN Direct is offered free of charge to all who participate in 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 at *www.ndhin.org/providers/participating-providers.*

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

You can sign up today at *www.ndhin.org/services/ndhin-enrollment.* For more information on NDHIN Direct, visit *www.ndhin.org/services/ndhin-direct* or email ndhin@nd.gov.

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