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North Dakota State Board of Pharmacy News

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Passage of Senate Bill 2221 – Practice Changes

The North Dakota Legislature recently passed, and Governor Doug Burgum has signed into law, Senate Bill (SB) 2221. This legislation carried an emergency clause, which makes it effective immediately upon signature of the governor.

Included in the bill are three distinct provisions that expand pharmacists' authority to further impact patients.

1. This legislation authorizes pharmacists to provide immunizations, injections, and other administrations to patients as young as three years of age or older.
2. This legislation expands the pharmacist's ability to provide "emergency pharmacy practice" dispensing. This extends the one-time emergency fill from 72 hours to a 30-day supply and allows the pharmacy to bill using the pharmacist's National Provider Identifier number. This is a similar authorization to an executive order from Governor Burgum, which has been in place since April. Please note that any decision to dispense via emergency pharmacy practice must be based on provisions a-e, which are listed in the law.
3. This legislation gives the North Dakota State Board of Pharmacy the authority to establish statewide protocols for public health issues. The Board intends to establish statewide protocols for pharmacists' ability to provide immunizations and tobacco cessation products by drafting and implementing rules. At this point, there is no actionable authorization that you can establish within your practice. However, please be aware that this will be forthcoming and prepare. Please stay in touch while the Board navigates the rulemaking process, and submit your input to ensure that the Board is establishing the right framework for you to best impact your patients' health.

As always, if you have any questions, please feel free to contact the Board office.

Adjustment in Sales Limit on Products Containing Ephedrine and Pseudoephedrine

Through the passage of SB 2294, the legislature expanded the limit of the package size of scheduled listed products (ephedrine and pseudoephedrine) from the existing 2 g of product base to 2.4 g of product base. Practically, this means that sales of the commercially available 24-hour pseudoephedrine products in the 10-count containers will be able to be sold to patients over the counter. Notably, this law change (North Dakota Century Code 19-03.4-08) is set to go into effect on August 1, 2021.

The adjustment will be made in the National Precursor Log Exchange system to update the existing process of scanning in patient identification as well as the product to validate that a sale is able to be made at the retailer. The 30-day sales limit, currently set at 9 g, remains unchanged.

Legislation for Pharmacy Technicians Enacted by Legislature

SB 2279 was enacted by the legislature this session, which allows the Board to develop rules regulating registered pharmacy technicians' ability to provide administrations of medications as delegated under an authorized licensed pharmacist. Across the nation, there has been an increased trend of competently educated pharmacy technicians given the authority to aid in providing immunizations as a technical practice of pharmaceutical services.

The coronavirus disease 2019 (COVID-19) pandemic brought about the United States Department of Health and Human Services Public Readiness and Emergency Preparedness Act Declaration, which allows pharmacy technicians to provide COVID-19 immunizations. Part of that declaration requires the pharmacy technician to

continued on page 4

National Pharmacy Compliance News

June 2021

NABPF
National Association of Boards of Pharmacy Foundation

Guidelines, Materials Available to Health Care Providers for Safely Administering COVID-19 Vaccines

Guidelines and materials are available to support health care providers with safely administering the coronavirus disease 2019 (COVID-19) vaccine, including safe practice recommendations from the Institute for Safe Medication Practices (ISMP) and a United States Pharmacopeia (USP) toolkit.

After numerous reports of errors or hazards associated with the administration of COVID-19 vaccines, ISMP is sharing safe practice recommendations.

A new USP toolkit is also available to facilitate operational efficiencies that can help accelerate delivery and support safe handling of COVID-19 vaccines while maintaining quality and ultimately the public's trust. Download the USP toolkit.

FDA Issues Guidance to Protect Consumers From Methanol Poisoning

Food and Drug Administration (FDA) has issued guidance for industry, *Policy for Testing of Alcohol (Ethanol) and Isopropyl Alcohol for Methanol, Including During the Public Health Emergency (COVID-19).* The guidance is intended to help pharmaceutical manufacturers and pharmacists who engage in drug compounding to avoid using pharmaceutical alcohol contaminated with or substituted with methanol in drug products. FDA noted that methanol is not an acceptable ingredient for any drug product and should not be used. The guidance is available on the FDA website.

Standardize Concentrations for Oral Liquid Preparations

ISMP Institute for Safe Medication Practices An ECRI Affiliate

This column was prepared by ISMP, an ECRI affiliate. Have you experienced a medication error or close call? Report such incidents in confidence to ISMP's National Medication Errors Reporting Program online at www.ismp.org *or by email to ismpinfo@ismp.org to activate an alert system that reaches manufacturers, the medical community, and FDA. To read more about the risk reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert! newsletters at* www.ismp.org.

Few would disagree that standardizing the concentrations of drugs has enormous potential for increasing safety, especially in pediatric care. Standardization limits the risk of variation, especially when patients are transitioned from hospital to home or have prescriptions filled at different pharmacies. However, ISMP has learned of multiple instances in which unrecognized differences or changes in drug concentrations led to confusion and dosing errors.

In one example, a patient was prescribed hydroxyurea, an antineoplastic agent. The community pharmacy compounded a 50 mg/mL suspension for the patient with instructions to take 13 mL (650 mg) for each dose. When the patient was later admitted to the hospital, the inpatient pharmacy prepared their standard concentration of 100 mg/mL, but the same dose volume of 13 mL was ordered. As a result, the patient received doses of 1,300 mg for several days before the error was recognized. It is unclear why the community pharmacy prepared a 50 mg/mL concentration. Perhaps the prescriber ordered that concentration or that was the concentration with which the pharmacist was most familiar.

Similar concentration mix-ups have been reported in literature. In one case, the oral class 1c antiarrhythmic medication flecainide was involved. The parents of a nine-month-old infant were told to increase the child's dose volume of flecainide to 4 mL, assuming the concentration was 5 mg/mL as in the original prescription.[1] However, the parents refilled the prescription at a different pharmacy and received the drug in a 20 mg/mL concentration. The patient received 80 mg/4 mL, a fourfold overdose, resulting in wide complex tachycardia and QRS prolongation.

There have been efforts, including those by a collaborative led by the University of Michigan[2]and the American Society of Health-System Pharmacists (ASHP)[3], to publish lists of consensuses and literature-based standard concentrations. In fact, for the medications involved in the cases above, both the University of Michigan and ASHP standard recommendations are in alignment – hydroxyurea 100 mg/mL and flecainide 20 mg/mL. However, the outreach and communication of these standardization efforts do not appear to be reaching prescribers and pharmacists. Both inpatient and outpatient practitioners need to get on the same set of standard concentrations for compounded oral liquids. It is imperative that both medical and pharmacy professional organizations develop and implement effective strategies to reach and influence practitioners to use the published standard concentrations. ISMP urges prescribers and pharmacists to review the University of Michigan and

ASHP lists and consider adopting the proposed standard concentrations. Your efforts can help reduce the risk of medication errors.

It is also important for pharmacists to provide patients or caregivers with appropriately sized metric-only dosing devices (eg, oral syringes) to measure and administer doses. Label directions for patients and caregivers should include the dose in terms of mL (not teaspoonfuls), matching the dosing device. The community pharmacy label should also include the concentration next to the drug name. To be sure patients or caregivers are able to use the dosing device and measure the proper dose, use the teach-back method to demonstrate how to measure and administer prescribed amounts. This also gives pharmacists, patients, and caregivers an opportunity to catch an error.

References

1. Wang GS, Tham E, Maes J, et al. Flecainide toxicity in a pediatric patient due to differences in pharmacy compounding. Int J Cardiol. 2012;161(3):178-9.
2. *www.mipedscompounds.org/*
3. *www.ashp.org/-/media/assets/pharmacy-practice/s4s/docs/Compound-Oral-Liquid.ashx*

Opioid Use Disorder Educational Programs, Resources Available for Pharmacists

Through its Opioid Use Disorder (OUD) Education Program, the College of Psychiatric and Neurologic Pharmacists (CPNP) provides educational programs and resources that can help pharmacists during the ongoing opioid epidemic. These educational opportunities include Accreditation Council for Pharmacy Education-approved, on-demand programs covering subjects such as pharmacotherapy for OUD, comorbid disorders, and chronic pain and OUD. Toolkits and guides are available to assist pharmacists in the areas of intervention, medication management, and naloxone access.

These educational materials and resources can be accessed through the CPNP website.

National Diabetes Prevention Program – How Pharmacists Can Get Involved

Pharmacists can play a key role in preventing type 2 diabetes by helping to expand the reach of the National Diabetes Prevention Program (National DPP) – a program led by the Centers for Disease Control and Prevention (CDC) that makes it easier for patients with prediabetes or who are at risk for type 2 diabetes to participate in evidence-based lifestyle changing programs to reduce their risk and improve overall health. CDC offers an action guide for community pharmacists that outlines ways pharmacies can raise awareness of prediabetes. The National DPP is a partnership among private and public organizations to screen and test for prediabetes and refer people with prediabetes to a CDC-recognized lifestyle change program participating in the National DPP, and deliver the National DPP lifestyle change program. More information about how pharmacists can participate is available on the CDC website.

Surgery Patients Receive More Opioids in the US Than in Other Countries

Patients in the US are prescribed a disproportionally higher number of opioids after surgeries compared to surgery patients in other countries, according to a new study. The study, published in the *Journal of the American College of Surgeons,* reviewed data from 2,024 surgery patients and found that 83% of US patients without pain were prescribed opioids, compared with 8.7% of non-US patients without pain. The authors concluded that US patients are prescribed more amounts of opioids at higher rates regardless of the severeness of their post-surgical pain. The authors recommend that more efforts are made toward ensuring that opioid prescriptions are tailored to patients' needs.

The full text of the study can be accessed by visting *www.journalacs.org/article/S1072-7515(20)32336-X/fulltext.*

Study Finds 94% Drop in Symptomatic COVID-19 Cases With Pfizer's Vaccine

A study by Israel's largest health care provider, health maintenance organization Clalit, reported that there is a 94% drop in symptomatic COVID-19 cases with the Pfizer vaccine. The study represents 600,000 people who received two doses of the Pfizer COVID-19 vaccine in Israel. Clalit, which covers more than half of all Israelis, noted the same group who received the COVID-19 vaccine doses was also 92% less likely to develop serious illness from the virus. The study compared the vaccine recipient group to another group of the same size and medical history who had not received the vaccines. Read the full study here.

NABP Executive Director/Secretary Addresses Pharmacists' Involvement in COVID-19 Vaccination During FIP Webinar

NABP Executive Director/Secretary Lemrey "Al" Carter, PharmD, MS, RPh, presented during the International Pharmaceutical Federation's (FIP's) Regulators' Forum on pharmacists' involvement with COVID-19 vaccination on February 4, 2021. The webinar addressed a new regulatory vaccination preparedness self-assessment tool and risk assessment, the expanded roles for pharmacists, and data FIP has collected on vaccinations by pharmacists. View the webinar here.

continued from page 1

be competently educated, CPR trained, and appropriately registered in the state of their practice. They must also complete a formal course to ensure competencies in providing administrations. It is important to note that these actions are taken only under the supervision and control of an authorized licensed pharmacist.

The Board is preparing to establish administrative rules to operationalize this for current registered pharmacy technicians who have completed the educational and training program to meet the standards the Board would outline. Currently, the Board sees many technicians getting trained and administering COVID-19 vaccines. This would continue that progress beyond the pandemic, and hopefully serve to provide greater access for patients who desire or need vaccinations in the future.

Drug Disposal Program

The Board has operated a drug disposal program for pharmacies to offer patients and citizens a safe location to dispose of unused controlled substance (CS) medications. Thanks to the outstanding participation by over 130 pharmacies in the state, over 13 tons of medications from patients have safely been destroyed. This continues to have a huge impact on reducing the medications that patients may have in their homes, which could have potentially ended up being diverted or misused. The Board thanks you for all your efforts in offering this service and educating patients about it!

This program, offered through the Sharps MedSafe system, continues to be provided by the Board free of charge to qualifying, eligible, participating pharmacies committed to providing this service to their patients. The Board is dedicated to funding a disposal program long-term to ensure the maximum opportunity for patients to properly destroy CS, preventing diversion or abuse. With the escalation in opioid overdose becoming more prevalent during the pandemic, it is important that the pharmacy profession is committed to providing an avenue for patients to safely dispose of their medications.

If your pharmacy wants to begin offering this service to the public, the Board welcomes your participation. Please reach out to the Board office at any time for further information, and the Board will be happy to connect you to a representative from Sharps to address any questions or concerns.

Immunization and Medication Administration Guidance

As a result of House Bill 1498 from the 2019 legislative session and the Board's subsequent rule changes, the scope for a pharmacist or intern to administer medications, including immunizations, has been expanded. These changes removed the need for the Board to issue the two-year injection certificate based on an individual providing proof of the various requirements.

The new standards still maintain the need for individuals to stay up to date with CPR or basic cardiac life-support certification and obtain/maintain the continuing professional competencies necessary, according to the standard of care, for the administrations they intend to provide.

The Board has transitioned to a streamlined process for a pharmacist/intern to add the "administration authority" to their license issued by the Board. Once attestations are made and approved, this "administration authority" will be designated on the pharmacist's or intern's license, which will constitute legal authority for providing administrations according to their practice.

There are two ways to update and maintain your "administration authority" on your license:

1. During your next license renewal, check the three statements (shown below) affirming each standard. There is no need to submit certificates unless specifically requested by the Board.
2. Outside of license renewal, you may add the "administration authority" by using the "Change Address/Data/Administration Authority" function on the Board website and attest to the standards below. Each tenet must be affirmed that you meet and will continue to meet for any administrations you intend to perform.

- ♦ I affirm that I have and will maintain a current certification in cardiopulmonary resuscitation or basic life support.
- ♦ I affirm that I have successfully completed educational requirements set forward in section 43-15.31.5 according to the administrations that I intend to perform. (Requirement can be completed through formal doctor of pharmacy program or through external educational training.)
- ♦ I affirm that I have and will continue to maintain the appropriate continuing competency training on administrations in which I intend to perform.

If you have any questions, please feel free to contact the Board office directly.

Attention Pharmacists: Do You Have an NDHIN Communicate Account?

North Dakota Health Information Network (NDHIN) Communicate direct secure message provides a secure, encrypted method of exchanging protected health information such as prescriptions, lab reports, consults, and other clinical information between providers, payers, the health department, etc.

NDHIN Communicate 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 that can be enrolled for an NDHIN Communicate account. NDHIN Communicate is offered free of charge to all who participate in the NDHIN. There are over 877 authorized users from 122 different facilities currently using NDHIN Communicate, and the numbers continue to grow. You can view a list of current NDHIN participants by going to *https://www.ndhin.nd.gov/providers/providers-map.*

NDHIN Communicate 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 it faster, less expensive, and more secure.

You can sign up today by visiting *https://www.ndhin.nd.gov/services/enrollment* or for more information on NDHIN Communicate, visit *https://www.ndhin.nd.gov/services/communicate-direct-secure-messaging* or send an email to ndhin@nd.gov.

North Dakota State Board of Pharmacy Licensure Statistics (as of April 14, 2021)

Pharmacists	2020	2021
Active Status Pharmacists	1,215	1,266
Inactive Status Pharmacists	74	67
Out-of-State Status Pharmacists	887	834
Lifetime – 50-Year Pharmacists	156	166
Pharmacy Technicians		
Active Pharmacy Technicians	844	858
Inactive Pharmacy Technicians	53	55
Technicians-in-Training	211	199
Interns		
NDSU PharmD Student Interns	329	305
Pre-Pharmacy or Other PharmD Students	92	76
Pharmacies		
North Dakota Pharmacies	270	272
Out-of-State	706	758
Wholesale Licenses Issued	1,366	1,465
Third-Party Logistics	130	147
Veterinary Retail Facilities	16	17
Veterinary Dispensing Technicians	45	38

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