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North Dakota State Board of Pharmacy News

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Board Finalizes Administrative Rule Changes

The North Dakota State Board of Pharmacy has finalized a package of rules that were discussed at a public hearing held at the North Dakota Pharmacist Association convention in April 2019. After modifications, the Board moved all the rules forward with the exception of the handling of hazardous drugs (see article below). The rules were reviewed by legislators at the administrative rules committee meeting in September. These changes became effective October 1, except for the changes to the compounding standards, which became effective on December 1, 2019.

Many of the rules would be considered modernization adjustments; however, there are a few substantive changes that will require your attention to ensure compliance. Compliance officers have been and will continue discussing these with you during their visits. Please visit the Laws/Rules section of the Board's website to review the changes and ensure you are compliant.

Board's Decision on Enforceability of USP Chapter <800>

The Board discussed the proposed rule changes requiring compliance with United States Pharmacopeia (USP) Chapter <800> Hazardous Drugs—Handling in Healthcare Settings at the July 18, 2019 Board meeting. The Board determined that compliance with USP Chapter <800> will only be required for pharmacies engaged in compounding of hazardous drugs. The Board accomplished this by moving the changes forward to the compounding standards (61-02-01-03) requiring compliance with USP Chapter <800>. However, the Board did not move forward the rule requiring compliance with USP Chapter <800> for pharmacies not engaged in compounding of hazardous drugs.

This approach is consistent with USP's interpretation on Chapter <800> with regard to the chapter's compendial applicability. Again, at this time, USP Chapter <800> will not be required for pharmacies that are not engaging in compounding (eg, tablet splitting is not considered compounding). For pharmacies that are engaged in compounding of hazardous drugs, at any level, ensure that you are working toward compliance with the chapter. The rule was finalized in September and became effective December 1. A USP Chapter <800> Toolkit is provided on the Board's website that will assist pharmacies in North Dakota with compliance. The toolkit was developed by Jesse Rue, PharmD, RPh, of Challenger Healthcare Consulting LLC, and provides a straightforward road map with template documents that can be modified to comply with USP Chapter <800>.

Even if your pharmacy is not required to comply with USP Chapter <800>, the Board still recommends that every pharmacy look at the processes built in USP Chapter <800> for ways to properly educate staff and take steps to minimize the exposure to hazardous drugs in your location.

USP <795> and <797> Appeal Causes Delay to Recently Published Versions

On September 23, 2019, USP announced a postponement to the revisions of USP Chapters <795> and <797>. USP's decision was based on an active pending appeal that was made to certain content areas of the revised chapters. Of note, USP Chapter <800> is not pending appeal and became effective December 1, 2019.

Since North Dakota's rules reference USP Chapters <795> and <797>, the enforceable chapter will continue to be the existing chapter revisions currently in place, which were published in 2014 and 2008, respectively. As the previous article states, USP Chapter <800> will need to be complied with when engaged in compounding of hazardous drugs. If any licensees have questions

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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.

USP Postpones Official Dates of USP General Chapters Revisions and Additions

United States Pharmacopeial Convention (USP) has announced that the effective date of the following changes to USP general chapters will be postponed:

- General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations
- General Chapter <797> Pharmaceutical Compounding – Sterile Preparations
- General Chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging

The delay is in accordance with USP's Bylaws, which require the official date of the standard to be postponed while an appeal is pending. In the meantime, conformance with the official versions of Chapters <795> and <797>, including the section "Radiopharmaceuticals as CSPs," will remain official, according to a notice posted to the USP website.

Revisions to USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings are not subject to pending appeals, and will become official on December 1, 2019. During this interim period, Chapter <800> is "informational and not compendially applicable," according to the USP notice. However, the organization encourages utilization of the chapter in the interest of advancing public health. USP also notes that it plays no role in enforcement and that regulators continue to have the authority to make their own determinations regarding enforceability of Chapter <800>.

FDA Issues Statement on Compounded Bulk Drug Substances Ruling

A US district court judge in Washington, DC, recently upheld Food and Drug Administration's (FDA's) interpretation of clinical need regarding bulk substances that may be used by outsourcing facilities in drug compounding. In response to the ruling, FDA has released a statement commending the decision as a "victory for public health in the first such case since the Drug Quality and Security Act (DQSA) was enacted."

In March 2019, FDA announced that vasopressin would not be included as an approved bulk drug substance because there is already an approved product on the market to meet the same medical needs. The ruling was in response to a challenge of that interpretation. In their statement, the agency states that they will continue to evaluate bulk drug substances nominated for use in compounding by outsourcing facilities using the same interpretation of clinical need.

"Our compounding work remains a top priority at the agency. We've long recognized that compounded drugs can serve an important role for patients whose medical needs cannot be met by an FDA-approved drug product," the agency states. "But compounded drugs are not approved by the FDA and, therefore, have not been evaluated for safety, efficacy or quality. We've seen first-hand the harm they can cause patients when they're not appropriately compounded."

HHS, FDA Publish New Action Plan for Importation of Certain Prescription Drugs

The US Department of Health and Human Services (HHS) and FDA have published a Safe Importation Action Plan to allow for the safe importation of certain drugs originally intended for foreign markets. The action plan outlines two possible pathways:

- **Pathway 1** would rely on the authority in the Federal Food, Drug, and Cosmetic Act Section 804 to authorize demonstration projects to allow importation of drugs from Canada. The proposed rules would include conditions to ensure the importation poses no additional risk to consumers and must result in a significant cost reduction.
- **Pathway 2** would allow manufacturers to import versions of FDA-approved drug products that they sell in foreign countries that are the same as the US versions. Manufacturers would use a new National Drug Code for those products, potentially allowing them to offer a lower price than what their current distribution contracts require.

The action plan states that the final proposal for these rules may differ from the descriptions "to reflect further consideration of the relevant issues."

"Today's proposal is the result of the hard work by the dedicated staff of the FDA, in close collaboration with HHS and the White House, to identify potential pathways we can pursue to support the safe importation of certain prescription drugs," said Acting FDA Commissioner Ned Sharpless, MD in a press release. "We've been keenly focused on ensuring the importation approaches we've outlined pose no additional risk to the public's health and safety. We know there are many operational challenges to address through each of these pathways, and are actively working through them as we look to formally announce these policies, with opportunity for public comment, in the coming months."

The full action plan can be accessed via the HHS website at *https://www.hhs.gov/sites/default/files/safe-importation-action-plan.pdf.*

Pain Reliever Misuse Decreased by 11% in 2018, NSDUH Survey Indicates

Prescription drug misuse, including abuse of stimulants and pain relievers, decreased in 2018, according to the recently released 2018 National Survey on Drug Use and

Health (NSDUH). The annual survey, conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA), a division of HHS, is a primary resource for data on mental health and substance use, including abuse of prescription drugs, among Americans.

Key findings of the 2018 NSDUH include:

- Past-year abuse of psycotherapeutics decreased from 6.6 from 6.2%.
- Past-year abuse of pain relievers decreased from 4.1% to 3.6%.
- Past-year abuse of stimulants decreased from 2.1% to 1.9%.
- Past-year abuse of opioids decreased from 4.2% to 3.7%.

"This year's National Survey on Drug Use and Health contains very encouraging news: The number of Americans misusing pain relievers dropped substantially, and fewer young adults are abusing heroin and other substances," said HHS Secretary Alex Azar. "At the same time, many challenges remain, with millions of Americans not receiving treatment they need for substance abuse and mental illness. Connecting Americans to evidence-based treatment, grounded in the best science we have, is and will remain a priority for President Donald Trump, for HHS, and for SAMHSA under Assistant Secretary Elinore McCance-Katz."

A recorded presentation of the data, along with a written summary and the full report are available on the SAMHSA website at *https://www.samhsa.gov/data/nsduh/reports-detailed-tables-2018-NSDUH.*

Additional Efforts Needed to Improve Naloxone Access, CDC Says

A new Vital Signs report published by the Centers for Disease Control and Prevention (CDC) states that naloxone dispensing has grown dramatically since 2012, with rates of naloxone prescriptions dispensed more than doubling from 2017 to 2018 alone. However, the rate of naloxone dispensed per high-dose opioid dispensed remains low, with just one naloxone prescription dispensed for every 69 high-dose opioid prescriptions.

The researchers for the report examined dispensing data from IQVIA, a health care, data science, and technology company that maintains information on prescriptions from 50,400 retail pharmacies, representing 92% of all prescriptions in the US. According to their analysis, dispensing rates were higher for female recipients than for male recipients, and higher for persons aged 60-64 years than for any other age group. The researchers also found that the rate of naloxone prescriptions dispensed varied substantially across US counties, with rural and micropolitan counties more likely to have a low-dispensing rate.

"Comprehensively addressing the opioid overdose epidemic will require efforts to improve naloxone access and distribution in tandem with efforts to prevent initiation of opioid misuse, improve opioid prescribing, implement harm reduction strategies, promote linkage to medications for opioid use disorder treatment, and enhance public health and public safety partnerships," the report states in its conclusion. "Distribution of naloxone is a critical component of the public health response to the opioid overdose epidemic."

The Vital Signs report can be accessed at *www.cdc.gov/mmwr/volumes/68/wr/mm6831e1.htm.*

Altaire Pharmaceuticals Recalls Multiple OTC Ophthalmic Products

Due to a lack of sterility assurance, Altaire Pharmaceuticals, Inc, is voluntarily recalling over-the-counter (OTC) drug products and lots sold as generic ophthalmic medications at Walgreens, Walmart, CVS, and other retail pharmacies. To date, there have been no reports of adverse events related to the recalled products.

A full list of the affected products and lot numbers, as well as instructions on how to return the product, are available through the following press releases:

- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall Of Multiple Ophthalmic Products Sold At CVS
- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products Sold at Wal Mart
- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products Sold at Walgreens
- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products

Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program.

Pharmacists Invited to Participate in NAPLEX Pharmacy Practice Survey

The National Association of Boards of Pharmacy® (NABP®) sent email invitations to randomly-selected pharmacists in all areas of practice encouraging them to participate in the NAPLEX Pharmacy Practice Analysis Survey. Analysis of the survey results is used to evaluate the North American Pharmacist Licensure Examination® (NAPLEX®) competency statements.

The analysis of practice supports the relevance of the NAPLEX competency statements, which define the content for the examination. This analysis helps ensure that competency statements, otherwise known as the examination "blueprint," are in line with pharmacy practice standards and measure the knowledge, skills, and abilities of entry-level pharmacists. In addition, the review supports the NABP mission to protect the public health by providing the state boards of pharmacy with a reliable means of assessing competency that assists them with licensure decisions to support safe and effective practice.

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about these chapters and compliance issues, please do not hesitate to reach out to the Board office at any time.

Rule Hearing Held on September 19

The Board is proposing to make administrative rule changes to account for three pieces of legislation that were passed by the legislature and signed by Governor Doug Burgum during the last legislative session. This legislation includes Senate Bill (SB) 2306 – Provisional Licensure for Members of the Military or Military Spouses, SB 2231 – Limited Prescriptive Practices for Pharmacists (Collaborative Agreements), and House Bill 1498 – Pharmacist Administration of Medications.

Military and Spouses Provisional Licensure

Legislation was enacted to allow members of the military and their spouses to be eligible for provisional occupational licenses to assist in the movement of these families to North Dakota. The legislation allows an individual licensed in another state and working under that license for at least two of the last four years to apply for provisional licensure for that occupation in North Dakota.

The Board's proposed rules will contain changes to outline a process for provisional licensure for a pharmacist and a separate proposal to allow for provisional registration for a pharmacy technician. Fees for this license apply one year after the first renewal period (ie, upon second renewal). Additionally, it is proposed for a pharmacist applicant to have three months to pass the Multistate Pharmacy Jurisprudence Examination® upon obtaining a provisional license. Each applicant would still need to be working toward meeting the qualifications for licensure during the two-year provisional license period and go through the National Association of Boards of Pharmacy® Electronic Licensure Transfer Program® to ensure any disciplinary action is screened.

Collaborative Practice Agreements

Revisions have been made by the legislature to remove the boards of pharmacy, nursing, and medicine from approving collaborative practice agreements. This was meant to help streamline the process for professionals to work together to advance patient care. In response to this, the Board is proposing to repeal Administrative Code Chapter 61-04-08, Limited Prescriptive Practices, which allows the law to be the sole standard to follow. As always, the Board encourages its pharmacists to look at the opportunities to advance models of care utilizing collaborative practice agreements in your pharmacy, especially now without the administrative process.

Administration of Medications

The sections of the law pertaining to the pharmacist's ability to provide medication administration were modified by the legislature to remove the requirement for a separate injection/immunization certification and broaden the authority for a pharmacist to administer medications to the patient. The Board will still grant authority to a pharmacist who has completed the appropriate training and/or education to administer medications to a patient. This approach will likely require a pharmacist to attest to meeting the standards to provide medication administration to their level of knowledge and expertise. This is a move toward the standard of care in the profession of pharmacy and removing the need for a separate certification to be carried for these duties. Each rule draft is available on the Board's website for review.

Dispensing Prescriptions for a Practitioner or Their Family

In the past, the North Dakota State Board of Medicine has requested that the Board of Pharmacy audit pharmacies in one of our cities to determine if prescriptions that were dispensed by pharmacists had been written by a provider for themselves or a member of their family. This is meant for guidance on the issues surrounding prescribing by practitioners for themselves or family members.

Controlled substances: Providers may not legally prescribe controlled substances for themselves or their immediate family members. The Medical Practice Act – North Dakota Century Code (NDCC) 43-17-31 (w.) includes the following clause as "Grounds for Disciplinary Action":

> The prescribing, selling, administering, distributing, or giving to oneself or to one's spouse or child any drug legally classified as a controlled substance or recognized as an addictive or dangerous drug.

Non-controlled substances: Filling non-controlled substances for a provider or their family member is your professional decision. If a provider requests a pharmaceutical for an acute medical condition for themselves or an immediate family member – such as an antibiotic – it is likely appropriate to dispense the medication. However, if the medication is for a chronic medical diagnosis or a medication that has potential for abuse, then the situation is questionable at best or – in the worst case scenario – is a possible violation of NDCC Chapter 61-04-04 "Unprofessional Conduct." It may also be appropriate to review the situation with other

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pharmacists in your community and contact the Board of Pharmacy if polypharmacy is discovered.

These situations are opportunities for pharmacists to assist providers with appropriate pharmaceutical care. Prescriptions written outside of the scope of practice for a prescriber may not technically be illegal, but may invite discipline by their peers on the medical board if patient care is compromised. Alternatively, the provider may be acting appropriately by basing their care on the results of a referral to a specialist or other provider. Use your best judgment, and do not be afraid to ask questions if you are uncomfortable with a situation.

Address Changes

Please ensure that your address, email, and work information are promptly updated with the Board upon any change, as required by law. The Board has an easy process available on its website to make any changes necessary to your records. It will be important to maintain a current email address as this is increasingly becoming the way to communicate important changes and updates from the Board.

Reprinting and Verifying Licenses

Take note that you have the capability to verify any Board license or registration on the Board website. License verification printouts to provide for various entities can be obtained in this way.

The Board's website also allows you to reprint your license or registration at any time. This technology is useful in ensuring all licenses are properly posted at your facility.

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