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North Dakota State Board of Pharmacy News

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Board Moves Rule Package Toward Final Adoption

At the North Dakota State Board of Pharmacy's May 2019 meeting, Board members reviewed comments received by the regulatory community regarding the package of rules that was discussed at the public hearing held at the North Dakota Pharmacists Association convention. After modifications, the Board moved all the rules forward with the exception of the rule regarding the handling of hazardous drugs (see article below). The rules will be reviewed by legislators at the Administrative Rules Committee meeting in September 2019. The rules are expected to be effective October 1, 2019, except for the changes to the compounding standards, which would be effective December 1, 2019, to align with the effective dates of the revised and new United States Pharmacopeia (USP) Chapters <795>, <797>, and <800>.

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 will be discussing these with you during their visits. Please visit the Board's website and review the changes to ensure that you are compliant. The changes are currently listed under the Proposed Laws and Rules section.

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

The Board discussed the proposed rule changes requiring compliance with 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 forward the changes 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 of 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, please ensure that you are working toward compliance with the chapter. It is expected that the rule will be finalized in September 2019, with it being effective December 1, 2019. A USP Chapter <800> toolkit is provided on the Board website and 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.

Rule Hearing Scheduled for September 19

The Board is proposing to make administrative rule changes to account for three pieces of legislation that were passed by the North Dakota Legislature and signed by Governor Doug Burgum during the last legislative session. This legislation includes Senate Bill (SB) 2306, which describes provisional licensure for members of the military or military spouses; SB 2231, which pertains to limited prescriptive practices for pharmacists (collaborative agreements); and House Bill 1498, which includes pharmacists' administration of medications.

continued on page 4

National Pharmacy Compliance News

September 2019

NABPF
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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.

FDA Changes Opioid Labeling to Give Providers Better Information on Tapering

Noting that the agency remains focused on striking the right balance between policies that reduce the rates of opioid addiction while still allowing patients and health care providers access to appropriate pain treatments, Food and Drug Administration (FDA) has announced required changes to the prescribing information for all opioid analgesic medications used in the outpatient setting. The changes, announced in a Drug Safety Communication, provide expanded information to health care providers on how to safely decrease the dose in patients who are physically dependent on opioids. FDA intends for this information to be used when health care providers and patients have decided together that a decrease in dose or discontinuation of opioids is appropriate.

"Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms. In turn, these symptoms can lead patients to seek other sources of opioid pain medicines, which may be confused with drug-seeking for abuse," the agency said in the communication. "Patients may attempt to treat their pain or withdrawal symptoms with illicit opioids, such as heroin, and other substances."

In addition to these changes, an FDA press release also announced that additional policies related to the opioid crisis are forthcoming. These include a requirement for immediate-release formulations of opioids to be made available in fixed-quantity packaging that contain doses more typical of what patients may need for common acute pain conditions and procedures. The full press release is available in the News and Events section of the FDA website.

DEA Warns of Scam Calls Targeting Pharmacists and Other DEA-Registered Providers

Health care providers and other members of the public have reported receiving phone calls from people claiming to represent Drug Enforcement Administration (DEA), and threatening legal action against them if a large fine is not paid immediately over the phone. According to a DEA press release, this scam used fake names and badge numbers, or the names of well-known senior officials with DEA, and threatened victims with arrest, prosecution, imprisonment, and revocation of their DEA numbers. The agency emphasizes that DEA will never contact practitioners by phone to demand money or any form of payment. DEA will not request any personal or sensitive information by phone, and notification of legitimate investigation or legal action is made via official letter or in person.

DEA asks anyone who receives a call from a person purporting to be a DEA special agent or other law enforcement official asking for money to refuse the demand and report the threat using the online form or by calling 877/792-2873. Reporting these calls will assist DEA in investigating and stopping this activity.

FDA Officials Outline 2019 Efforts to Improve Quality of Compounded Drugs

Recognizing the important roles compounded drugs can play in patient care, FDA plans to continue its efforts to improve the quality of compounded drugs. According to a statement posted to the FDA website, these priorities include:

- maintaining quality manufacturing compliance,
- strengthening and refining regulations on compounding from bulk drug substances,
- finalizing the agency's memorandum of understanding with the states, and
- issuing revised draft guidance for compounding by hospital and health systems.

"We've worked to refine our existing practices, shape new policies and increase the frequency of our communications with industry, Congress, states and patients concerning our programs," then-Commissioner Scott Gottlieb, MD, and Deputy Commissioner Anna Abram said in a statement published on the FDA website. "We anticipate that 2019 will be an equally productive year for the FDA's compounding program, with better quality continuing to be our top priority as part of our ongoing effort . . . to improve the quality of compounded products for consumers . . ."

In addition, Gottlieb and Abram's statement notes that the agency will continue to work closely with stakeholders on these steps and any other compounding-related measures not outlined in the statement.

China Agrees to Stricter Fentanyl Production Laws Following Pressure From US Lawmakers

China has announced that all variations of the powerful opioid product, fentanyl, will be treated as controlled substances (CS). According to a press release from Senator Tom Cotton, the announcement came after a bipartisan group of United States lawmakers, including Cotton, introduced Senate Bill 1044, a bill designed to apply pressure to the Chinese government to make all forms of synthetic opioids illegal and to provide US law enforcement with more tools and resources to go after illicit traffickers in China, Mexico, and other countries.

"Combating the flow of illicit fentanyl into our country is imperative in the fight to save American lives from the opioid crisis," Senate Minority Leader Chuck Schumer said in the press release. "We must hold China accountable for their role in the fentanyl trade. China's new regulation to make all fentanyl categories illegal is an important step and the administration deserves praise for their efforts to secure this change. However, we have to demonstrate that we will demand China enforce these laws and take strong action against opioid traffickers."

In a December meeting with President Donald Trump, China's President Xi Jinping promised to classify fentanyl as a CS following a 2018 report by the US-China Economic and Security Review Commission that found China to be "the largest source of illicit fentanyl and fentanyl-like substances" in the US, according to a report from NPR. The latest increase in opioid-related overdose deaths has been largely attributed to the availability of illegally manufactured fentanyl.

Two Lots of Transdermal Fentanyl Patches Recalled Due to Product Mislabeling

Alvogen, Inc, of Pine Brook, NJ, is recalling two lots of Fentanyl Transdermal System 12 mcg/h transdermal patches to the consumer level after a small number of cartons were found to contain 50 mcg/h patches. Though the 50 mcg/h patches are individually labeled correctly, accidental application of the higher dosage patch instead of the prescribed 12 mcg/h patch could result in serious, life-threatening, or fatal respiratory depression. The company has not received any reports of adverse events related to this issue.

The company is notifying its distributors and direct customers by certified letter and is arranging for the return and replacement of all recalled products. Pharmacies are asked to stop dispensing any product subject to the recall. Consumers that have affected products should immediately remove any patch currently in use and contact their health care provider. Patients with unused product should return it to the point of purchase for replacement.

Additional information on the recall, including the affected lot numbers and customer service contact information, is available in a press release posted to the FDA website. Adverse reactions and quality problems can be reported to the FDA MedWatch Safety Information and Adverse Event Reporting Program.

FDA Releases Toolkit to Help Promote Safe Opioid Disposal

FDA has made a new resource available for consumers and health care providers to help promote and educate individuals about how to safely dispose of unused opioids. The free Safe Opioid Disposal – Remove the Risk Outreach Toolkit includes video, radio, and print public service announcements, social media graphics and posts, fact sheets, drop-in content, and website badges that health care providers and other interested individuals and organizations can use to promote the message of opioid safety. The toolkit and its resources can be accessed on the Ensuring Safe Use of Medicine section of the FDA website.

An additional resource available to help consumers find disposal kiosks available year round is the National Association of Boards of Pharmacy® (NABP®) Drug Disposal Locator Tool, available in the AWAR$_X$E® Prescription Drug Safety section of the NABP website, *www.nabp.pharmacy/initiatives/AWARxE.* With more than 6,500 disposal sites in the continually updated database, consumers can enter location information to find the nearest disposal sites to them using a map.

Additional information about the FDA campaign can be found at *https://www.fda.gov/drugs/buying-using-medicine-safely/ensuring-safe-use-medicine.*

continued from page 1

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 the 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.

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 change was intended 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 based on 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.

The hearing for the proposed administrative rule changes will occur on September 19, 2019. Each rule draft is available on the Board's website for review. If you have comments or suggestions, please reach out to the Board so your comments can be considered by the Board in its deliberations.

Pharmacy Inspections Moving to an Online Form

Board staff and compliance officers are putting the finishing touches on a streamlined inspection process. Communications will be sent out to pharmacies introducing them to the new process, which will still involve a self-inspection and the compliance officer coming on site to ensure compliance and finalize the inspection. The Board is hopeful that this makes the process more streamlined while allowing for a more purposeful inspection each year. If you have any questions, feel free to contact the Board at any time.

Findings of 2019 CE Audit of Registered Pharmacy Technicians

- 86 pharmacy technicians were randomly audited
- 60 pharmacy technicians were found compliant, per CPE Monitor®
- 20 pharmacy technicians were compliant with additional documentation
- 6 pharmacy technicians did not have adequate continuing education (CE) hours

Those not in compliance received administrative fines and/or suspensions according to the North Dakota Administrative Code.

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