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North Dakota State Board of Pharmacy News

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Board Moves for Final Adoption of Compounding Standards

The North Dakota State Board of Pharmacy has approved the final version of rules related to the changing of the compounding standards to require compliance with the current United States Pharmacopeia (USP) Chapters <795> and <797> standards. Previously, the compounding standards had specific language that was similar to the USP versions. This revision will reference the <795> and <797> standards in the administrative code.

The Board's pharmacy inspectors continue to monitor compliance with the compounding standards currently in place and have seen great improvements in compliance with the current compounding standards. Also included in the revision is a modification to office use compounding. The Board encourages you to review this to ensure that you are in compliance with the standards. Specific to sterile compounding, Dennis DelaBarre, RPh, the Board's sterile compounding compliance officer, has received the Certification in Sterile Compounding for Inspectors. This certification is the standard across the nation to ensure inspectors are up to date and continually educated about sterile compounding procedures and best practices.

Partial Fill of Schedule II Medications

In September 2016 the Board sent out a memo to all the pharmacies across the state informing them of a recent **federal** law change relative to partial filling of Schedule II medications. Below is the context of the memo:

> In July 2016, in an effort to address the prescription opioid abuse crisis the Comprehensive Addiction and Recovery Act of 2016 was signed into Law.
>
> One of the provisions of this act provides for partial filling of Schedule II prescriptions. Previously, the partial filling of a Schedule II prescription was only permissible if the pharmacist was not able to provide the full quantity prescribed at the time of the filling, with the remainder filled within 72 hours. Partial filling had been allowed for nursing home patients in a nursing home setting or under hospice care.
>
> The Act specifically amends 21 United States Code §829 by adding subsection (f), which allows for the partial filling of a Schedule II prescriptions if the following conditions are met:
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> - It is not prohibited by state law;
> - The prescription is written and filled in accordance with federal and state law;
> - The partial fill is requested by the patient or the practitioner who wrote the prescription and;
> - The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.
>
> The Act also provides that the remaining portion of a partially filled Schedule II prescription may be filled not later than 30 days after the date on which the prescription was written. However, if the partial filling of a Schedule II is the result of an emergency situation oral prescription, the pre-existing partial fill time frame of 72 hours after the prescription was issued remains. There is no prohibition on partial fill of Schedule II prescriptions in North Dakota Laws and Rules.

The change made allowing partial fill of Schedule II prescriptions was meant to create opportunities to decrease the amount of unnecessary, unwanted, and unused prescription opioid medications. However, this law change is applicable for **all** Schedule II prescriptions. The Board feels that this new provision allows the profession an opportunity to work with practitioners and patients to limit the amount of Schedule II medications that are dispensed in certain circumstances. An example being: **a patient with a tooth extraction obtaining a partial fill to limit the amount of opioids initially dispensed, with the remaining amount available to have filled should it become necessary.** This also has opportunities as third parties like North Dakota Medicaid look to design strategies to limit the amount of medication that may be received on the first partial fill while, if appropriate, having the remaining quantity dispensed within 30 days.

As always, it is important to discuss opportunities to utilize this expanded authority with your practitioners and how this may be useful in the care of your patients, with the goal of limiting the amount of unwanted, unused, unnecessary opioids and other Schedule II medications in North Dakota households.

Leftover prescription medications being diverted continues to be a major issue with drug overdoses and abuse. Limiting the amount of unused controlled substances in household medicine cabinets will also limit the exposure that our citizens, youth or otherwise, have to divert them.

FOUNDATION

National Pharmacy

The applicability of articles in the *National Pharmacy Compliance*
by examining the law of

National Vaccine Safety Surveillance Program Available for Reporting Adverse Events

The Vaccine Adverse Event Reporting System (VAERS) eSubmitter program, a national vaccine safety surveillance program cosponsored by the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA), is available for the reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States. VAERS information is analyzed by CDC and FDA to identify new safety concerns. VAERS reports can be filed by anyone, including health care providers, manufacturers, state immunization programs, and vaccine recipients. Vaccine recipients are encouraged to seek help from their health care provider when filling out the VAERS form. Health care providers can find information about submitting a report on the VAERS website at *https://vaers.hhs.gov/professionals/index*.

Improper and Unsafe Vaccine Storage

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition *by visiting* www.ismp.org. *ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

Few issues are more important than proper storage and handling of vaccines, because their ability to prevent disease is dependent on these factors. To maintain stability, most vaccines must be stored in a refrigerator or freezer, and many also require protection from light. Excessive heat or cold – even a single exposure in some instances – can reduce vaccine potency. These temperature excursions are often due to improper refrigeration or freezer units, inadequate thermostat controls, and refrigeration/freezer units with inadequate space to allow good air circulation and even temperatures.

Improper and unsafe storage can also result in serious errors caused by selecting the wrong vaccines, diluents, and other medications with look-alike names and/or labeling and packaging. Storing vaccines close to each other has led to dispensing and administering the wrong vaccine or wrong form of vaccine (eg, adult versus pediatric). Storing vaccines too close to non-biologic medications in a refrigerator or freezer has also led to serious adverse outcomes, particularly when the mix-up involved a vaccine and a high-alert medication. For example, vials of insulin have frequently been mistaken as influenza vaccine, and various neuromuscular blocking agents have been used to reconstitute vaccines or were mistaken as influenza or hepatitis B vaccines.

Store vaccines in their own dedicated refrigeration and freezer units. Regular temperature monitoring is necessary, and technology is available to assist with alarmed, continuous monitoring devices that can alert staff via email and pager if a unit is out of specified range. Separate vaccine vials and syringes into bins or other containers according to vaccine type and formulation, keeping diluents with the appropriate vaccines. Never store different vaccines in the same containers. Do not store vaccines with similar labels, names, abbreviations, or overlapping components immediately next to each other or on the same shelf. Separate the storage areas of pediatric and adult formulations of vaccines. Label the specific locations where vaccines are stored to facilitate correct age-specific selection and to remind staff to combine the contents of vials. ISMP's March 26, 2015 newsletter[1] contains additional strategies, as does a Vaccine Storage & Handling Toolkit available from CDC.[2]

References

1. ISMP. Recommendations for practitioners to prevent vaccine errors. Part 2: analysis of ISMP vaccine errors reporting program (VERP). *ISMP Medication Safety Alert!* 2015;20(6):1-6.
2. CDC. Vaccine storage & handling toolkit. www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf. June 2016.

Coalition Reports Impact of Educational Efforts on Safe Acetaminophen Use

The Acetaminophen Awareness Coalition reports that progress has been made to increase consumer awareness about the safe use of acetaminophen. The coalition also notes a decline in unintentional overdoses. The National Poison Data System's 2015 report indicates unintentional acetaminophen exposures, including dosing errors and accidental misuse, have decreased through 2013 after a peak in 2009. In addition, a nationwide survey indicates the number of consumers who understand that exceeding the recommended daily dose of acetaminophen may lead to liver damage has increased to 87% in 2013 from 78% in 2010. The survey also reports the number of consumers who think it is important to check the medicine label for the maximum daily dose increased to 98% in 2013 from 93% in 2010.

Developed in 2011, the Know Your Dose campaign encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use. The Know Your Dose campaign offers a list of helpful health tips to share with patients, including the following:

(1) Read and follow the label.
(2) Know which medicines contain acetaminophen.
(3) Take only one medicine at a time that contains acetaminophen.

(4) Ask a health care provider or pharmacist about dosing instructions or medicines that contain acetaminophen.

Pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website, *www.knowyourdose.org*.

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information in the Center for Drug Evaluation and Research presents a series of CE webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of FDA's expanded access program and the pregnancy and lactation labeling rule. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm*.

Fresenius Kabi Recalls Sensorcaine-MPF (Bupivacaine HCl) Injection, USP

In April 2016, Fresenius Kabi USA recalled a single lot of Sensorcaine®-MPF (bupivacaine HCl) injection, USP, 0.75%, 7.5 mg/mL, 30 mL fill in a 30 mL vial, because of visible particulate matter characterized as glass observed by the company during inspection of reserve samples. The recalled product was shipped in the US to wholesaler and distributor outlets between March 4, 2016, and March 21, 2016, and has an expiration date of September 2019. The recall affects lot number 6111504, product code 470237, and National Drug Code number 63323-472-37. The product is supplied as 0.75% strength in a 30 mL single-dose flint molded vial and is packaged in units of 25. To date, Fresenius Kabi has not received any reports of adverse events regarding this recall, indicates the press release posted to the FDA website.

Health care facilities that have the affected lot are instructed to immediately discontinue distributing, dispensing, or using the lot and return all units to Fresenius Kabi. Distributors are instructed to immediately notify their customers who have been shipped or may have been shipped the recalled product. Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program at *www.fda.gov/MedWatch*. Additional details are available on FDA's website at *www.fda.gov/Safety/Recalls/ucm497812.htm*.

Oral Liquid Docusate Sodium by PharmaTech Recalled Due to Contamination

In July 2016, FDA alerted health care providers that PharmaTech, LLC, of Davie, FL, voluntarily recalled all non-expired lots of Diocto Liquid, a docusate sodium solution distributed by Rugby Laboratories of Livonia, MI. The affected product was distributed nationwide in one-pint (473 mL) bottles with a Rugby label. FDA confirmed the product has been contaminated with *Burkholderia cepacia,* a bacteria linked to an outbreak in five states. The safety alert indicates FDA has received several adverse event reports of *B. cepacia* infections in patients, and some of these reports identify liquid docusate sodium products manufactured by companies other than PharmaTech. FDA and CDC continue to investigate the extent of this issue in order to identify other potentially contaminated liquid docusate sodium products. FDA joins CDC in recommending that clinicians not use any liquid docusate sodium product as a stool softener or for any other medical purpose. Adverse events or side effects may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch*. More information may be found in the safety alert on FDA's website at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm511528.htm*.

NABP Seeks Pharmacists From Districts 1, 5, and 7 to Serve as Volunteer Item Writers

The National Association of Boards of Pharmacy® (NABP®) is seeking pharmacists who reside in states in the following districts to serve as volunteer item writers:

- **District 1:** Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.
- **District 5:** Iowa, Minnesota, Nebraska, North Dakota, and South Dakota.
- **District 7:** Alaska, Idaho, Montana, Oregon, Washington, and Wyoming.

In an effort to secure more individuals representative of these areas of the country, NABP encourages pharmacists in all areas of practice as well as school and college of pharmacy faculty who reside in these states to apply.

NABP uses volunteer item writers to develop questions for the following examination programs: North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), Pharmacy Curriculum Outcomes Assessment® (PCOA®), and Pharmacist Assessment for Remediation Evaluation® (PARE®).

Interested individuals should complete the online Item Writer Volunteer Interest Form available at in the Meetings section of the NABP website. Individuals who are selected will receive further information on opportunities to attend and participate in NABP-hosted workshops.

For more information about NABP item writing, visit the Meetings section of the NABP website at www.nabp.pharmacy, or contact CompAssess@nabp.pharmacy.

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Counseling on New and Refilled Prescriptions

As a reminder, North Dakota law requires that a pharmacist counsel on **all prescriptions.** Violations of this were noted by compliance officers during inspections and in some recent complaints. The law reads as follows:

> **43-15-31.2. Prescription drug information required.**
>
> With each prescription dispensed, the licensed pharmacist or the licensed intern pharmacist, in addition to labeling the prescription in accordance with law, must explain to the patient or the patient's agent the directions for use and a warning of the potential harmful effect of combining any form of alcoholic beverage with the medication and any additional information, in writing if necessary, to assure the proper utilization of the medication or device prescribed. For those prescriptions delivered outside the confines of the pharmacy, the explanation must be by telephone or in writing, provided that this does not apply to those prescriptions for patients in hospitals or institutions where the medication is to be administered by a nurse or other individual licensed to administer medications, or to those prescriptions for patients who are to be discharged from a hospital or institution.

There are many reasons why a pharmacist is required to counsel patients. Counseling is a safeguard that gives a pharmacist the opportunity to make a visual verification that everything is correct before delivery to the patient. It allows the pharmacist to check one last time for any discrepancies between the actual prescription and the prescription product dispensed before it goes to the patient for ingestion. It ensures that the patient understands how to take the medication properly.

It not only allows a safety check, but it also educates the patient and opens the lines of communication to address any concerns the patient may have. Patients usually have a basic understanding of their drug therapy and can alert you to changes in their health. Gathering this information leads to better patient care, improved outcomes, a reduction in dispensing errors, and ensuring the general well-being of the patient. The lack of counseling or failure to properly counsel leads to unnecessary errors and possibly limits therapy outcomes.

Prescriptive Authority for Naloxone

The Board finalized rules (North Dakota Administrative Code 61-04-12) implementing the authority given by Senate Bill 2104, which granted prescriptive privileges for naloxone to pharmacists in North Dakota. This important measure will be one of the tools the profession of pharmacy can utilize to help save lives from the illicit and prescription drug abuse issues currently affecting so many.

The process for a pharmacist to prescribe naloxone is available on the Board's website along with information that can be provided to patients and patients' loved ones. The process is very straightforward and involves reviewing the context of the rule, completing one of the educational programs, and informing the Board of your intentions to prescribe this lifesaving drug. The Board will make the locations where pharmacists are prescribing naloxone available to the public for their information.

Please strongly consider providing this service in your pharmacy location.

2017 Legislative Session

The 2017 North Dakota Legislative Session is right around the corner. It certainly will be a challenging session on a budgetary basis for the state, and many tough decisions will need to be made. As always, there most likely will be multiple pieces of legislation 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 pharmacists may be dealing with. However, it is important that the legislature be made aware of not only the challenges that pharmacy is facing but also the successes that the profession has created. The profession continues to be looked at for solutions to issues in the delivery of health care across the state. It is important that you, their 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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