October 2019

# Minnesota Board of Pharmacy News

*Published to promote compliance of pharmacy and drug law*

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*https://mn.gov/boards/pharmacy*

## Disciplinary Actions

Because of space limitations, information on disciplinary actions is no longer included in the *Minnesota Board of Pharmacy Newsletter.* A document that provides information about recent Board disciplinary actions can be found on the Minnesota Board of Pharmacy's website under the "Resources/FAQs" menu item.

## Board Member Appointments

Effective July 2, 2019, Governor Tim Walz reappointed Samantha Schirmer, MS, and Stuart Williams, JD, as public members of the Board. Governor Walz also appointed Amy Paradis, PharmD, RPh, to the pharmacist member seat that had been occupied by Kurt Henn, PharmD, RPh. The Board and its staff thank Dr Henn for his service to the public and the Board, congratulate Ms Schirmer and Mr Williams on their reappointments, and welcome Dr Paradis to the Board.

Ms Schirmer graduated from the University of Minnesota Duluth (UMD) in May 2009 with two degrees: a bachelor of science in biochemistry and molecular biology and a bachelor of arts with a major in chemistry and a minor in French. She subsequently received a master of science in chemistry from UMD in September 2012. She has worked for LEGEND Technical Services, Inc, in St Paul, MN, since December 2012, where she is the organic department manager. Ms Schirmer is a public member and was first appointed by Governor Mark Dayton in January 2016.

Mr Williams is an attorney with the Minnesota law firm of Henson & Efron, P.A., where his practice includes business litigation and environmental law. He was first appointed to the Board by Governor Dayton in 2011 and was reappointed in 2015. Mr Williams also serves as a public member on the Minnesota Board of Medical Practice, the Minnesota Department of Human Services Drug Formulary Committee, and the Minnesota Supreme Court's Client Security Board. He formerly served on the Minnesota Boards of Nursing and Psychology and the Minnesota Lawyers Professional Responsibility Board. Mr Williams graduated from the University of North Carolina at Chapel Hill with a bachelor of arts degree and a juris doctor degree with honors.

Dr Paradis, of Fairmont, MN, has over 16 years of pharmacy experience, including hospital, retail, and long-term care practice. She spent many years as a hospital pharmacist at Mayo Clinic Health System in Fairmont before making the change to Sterling Pharmacy in 2010. Dr Paradis is currently the pharmacist-in-charge at Sterling Long Term Care Pharmacy in Worthington, MN. During her time there, she has managed numerous special projects, including the development of policy and procedure manuals for the long-term care organization and the nursing homes they service, as well as the licensing and contracting for new pharmacy setups. Dr Paradis received her doctor of pharmacy degree from South Dakota State University.

## 2019 Legislative Changes

Information about some of the many provisions that were enacted by the Minnesota Legislature during its 2019 session was provided in the July 2019 issue of the Board's quarterly newsletter. Additional provisions include the following:

### CBD Sales

First, please note that the following information does not apply to the sale of **food products** that contain cannabidiol (CBD) derived from hemp. The legislation enacted by the Minnesota Legislature during the 2019 session did not address the sale of food products containing CBD derived from hemp. It is the Board's understanding that nothing in the Minnesota statutes allows CBD to be added to food products. In addition, United States Food and Drug Administration (FDA) has stated that CBD cannot be added to foods and cannot be sold as a dietary supplement. The Legislature did address the sale of products other than food that contain CBD: basically, a wide variety of products that

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# National Pharmacy Compliance News

**October 2019**

NABPF
National Association of Boards of Pharmacy Foundation




## 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.

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can be ingested, inhaled, insufflated, applied topically, or otherwise be administered to humans or animals.

Effective January 1, 2020, products containing CBD derived from hemp can be legally sold under Minnesota state law only if all the conditions below are met.

- The product has been tested by an independent, accredited laboratory (using generally accepted standards for herbal and botanical substances) to confirm that the product:
  - contains the amount or percentage of cannabinoids that is stated on the label of the product;
  - does not contain more than trace amounts of any pesticides, fertilizers, or heavy metals; and
  - does not contain a delta-9-tetrahydrocannabinol concentration that exceeds the concentration permitted for industrial hemp as defined in Minnesota Statutes, section 18K.02, subdivision 3.
- The product bears a label that contains, at a minimum:
  - the name, location, contact phone number, and website of the manufacturer of the product;
  - the name and address of the independent, accredited laboratory used by the manufacturer to test the product;
  - an accurate statement of the amount or percentage of cannabinoids found in each unit of the product meant to be consumed; and
  - a statement stating that the product does not claim to diagnose, treat, cure, or prevent any disease and has not been evaluated or approved by FDA, unless the product has been so approved.
- The information required to be on the label must be prominently and conspicuously placed and in terms that can be easily read and understood by the consumer.
- The label must not contain any claim that the product may be used or is effective for the prevention, treatment, or cure of a disease or that it may be used to alter the structure or function of human or animal bodies, unless the claim has been approved by FDA.

Until January 1, 2020, all products containing CBD derived from hemp are illegal to sell under Minnesota state law. (However, prior to that date, the Board does not intend to take enforcement action against sellers of any products that already meet the new requirements listed above). After that date, any CBD-containing product (other than a food product) that does not meet the new requirements will be considered an illegal misbranded and/or adulterated drug. It is a crime (misdemeanor) to sell misbranded or adulterated drugs. County or city prosecutors can bring criminal charges against sellers of misbranded and adulterated products. The Board can take administrative action, including:

- embargo – prohibiting a business or individual from selling a product or removing it from the premises without permission from the Board or a court. A court might subsequently issue an order of condemnation, requiring the seller to destroy the product at its expense; and
- cease and desist order – ordering a business or individual to stop selling such products.

The area within a business that is licensed by the Board as a pharmacy cannot stock or sell a product containing CBD derived from hemp unless the product meets the new requirements previously listed. Prior to January 1, 2020, the Board will exercise enforcement discretion to allow pharmacies to sell compliant products. After that date, pharmacies simply need to follow the new law, like any other business. Pharmacies may wish to check with FDA about federal statutes and rules, with their legal counsels, and with their malpractice insurers. As with all products, the Board expects pharmacists to use sound professional judgment in making recommendations to patients.

## Pharmacy Sale of Minimal Quantities of Drugs for "Office Use"

For many years, the sale by pharmacies of even minimal quantities of drugs to physicians, dentists, and the medical directors of ambulance services was included in the definition of "drug wholesaling." Pharmacies engaged in such sales were therefore required to be licensed by the Board as drug wholesalers. The new law excludes "the distribution of minimal quantities of a drug by a licensed **retail** pharmacy to a licensed **practitioner** for office use" from the definition of wholesale distribution (emphasis added). Consequently, pharmacies do not need a drug wholesaler license to make such sales. The law does not define "minimal quantities" so pharmacists will need to use professional judgment and common sense when making sales to practitioners for office use. In Minnesota, a "retail" pharmacy is one licensed in the outpatient/community pharmacy category.

If a pharmacy sells more than "minimal quantities" of drugs to licensed practitioners for office use, or if it sells drugs to entities or individuals other than licensed practitioners, it will need a separate drug wholesaler license – but there are no longer any provisions in the statutes that allow pharmacies to wholesale drugs differently than any other entity licensed as a wholesaler. So, a pharmacy must pay the full drug wholesaler registration fee ($5,260) and it must

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comply with all the requirements that any wholesaler must comply with, including the requirements that:

- a fingerprint-based criminal background check of a facility manager or designated representative be conducted; and
- a surety bond of either $25,000 or $100,000 be submitted to the Board (the amount depends on gross revenues of the wholesaler).

## *Hospital Discharge Orders for Patients Being Transferred to Skilled Nursing Facilities*

If a patient is discharged from a hospital and transferred to a skilled nursing facility, an interagency transfer form (ITF) may be used as a chart order (as defined in Minnesota Statutes §151.01, subdivision 16b). For a pharmacy to use the ITF for the purpose of filling prescriptions, the following information must be included:

> the name of the patient, another patient identifier such as birth date or medical record number, the drug ordered, and any directions that the practitioner may prescribe concerning strength, dosage, frequency, and route of administration.

A chart order differs from a prescription in that **when an electronically generated prescription is printed out on paper, it must be manually signed by the prescriber.** The statutory definition referenced above states that a chart order must be manually or electronically signed – but it does not state that an electronically generated chart order that is printed out on paper must be manually signed. Consequently, an ITF that is electronically signed can be used by a pharmacy to dispense drugs if it is either manually signed or if a statement such as "electronically signed by prescriber" is printed on the ITF. This does **not** apply to controlled substance (CS) prescriptions. Written orders for Schedule II CS **must** go directly to the pharmacy. Verbal or written orders for Schedule III-V CS must go directly to the pharmacy unless the nurse is an "agent" of the provider as defined by Drug Enforcement Administration. However, an "agent" is not allowed to transmit the order as an electronic prescription. For more information, see Receipt of Prescriptions/Orders from Long-Term Care Facilities on the Board's website.



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