



# Minnesota Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## **Disciplinary Actions**

Because of space limitations, information on disciplinary actions is no longer being 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 website](#) under the “Resources/FAQs” menu item.

## **United States Pharmacopeia Standards**

In May 2007, the Board promulgated rules that adopted United States Pharmacopeia (USP) Chapter <795> Pharmaceutical Compounding—Nonsterile Preparations and Chapter <797> Pharmaceutical Compounding—Sterile Preparations as the standards for compounding in this state. Medications are routinely and regularly compounded in Minnesota each year to meet the unique needs of patients. However, without adequate and enforced standards, compounding can sometimes lead to disasters like the fungal meningitis outbreak of 2012 that was caused by the improper compounding of sterile, injectable products. USP Chapters <795> and <797> provide these standards, helping to minimize risk to Minnesota patients.

USP Chapters <795> and <797> are undergoing revision. The Chapter <795> public comment period closed on July 31, 2018. USP's intent is to publish the revised Chapter <795> by June 1, 2019. The Chapter <797> public comment period opened on July 27, 2018, and closes on November 30, 2018. The intent is to have the new version published by June 1, 2019. The new versions are scheduled to become enforceable on December 1, 2019.

In February 2016, the new USP Chapter <800> became available. It will become official and enforceable in December 2019, along with the revisions to Chapters <795> and <797>. It sets updated standards for the safe handling of hazardous drugs that not only apply to compounding pharmacies, but also to community pharmacies.

Its goal is to provide protection to employees, patients, and the general public.

In January 2018, Food and Drug Administration (FDA) published a final guidance on Section 503A Pharmacy Compounding. The 503A designation refers to traditional compounding pharmacies filling patient-specific compounded prescriptions. The final guidance restricts the compounding of drug products that are essentially copies of commercially available drugs and sets the conditions under which drug products may be compounded.

The following are recommendations for keeping up to date with the changes. First, USP itself provides good resources about each chapter, the revisions, and the publication dates. And, in response to questions regarding Chapters <795> and <797>, USP developed a frequently asked questions page on its website. Second, USP Chapters <795>, <797>, and <800> each have a gap analysis, which provides a self-assessment tool that can help determine a pharmacy's compliance with each of the chapters. It is important to note that the new USP Chapter <800> may require adjustments to a facility or its floor plan to be compliant. The gap analysis helps identify the issues a pharmacy will need to address prior to December 2019. The FDA website also has many good guidance documents regarding compounding.

The Board expects pharmacies to be in compliance with the revised standards by December 1, 2019.

## **Expedited Partner Treatment Is Legal in Minnesota**

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The Board was recently contacted by the Minnesota Department of Health (MDH) regarding complaints from

*continued on page 4*

# National Pharmacy Compliance News

October 2018



**NABPF**

National Association of Boards  
of Pharmacy Foundation

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.

## **SAMHSA Publishes Guidance for Treating OUD**

To help broaden health care professionals' understanding of medications that can be used to treat Americans with opioid use disorder (OUD), the Substance Abuse and Mental Health Services Administration (SAMHSA) offers guidance on clinical best practices in the February 2018 publication titled *Treatment Improvement Protocol 63, Medications for Opioid Use Disorder*. The publication reviews the use of the three Food and Drug Administration (FDA)-approved medications used to treat OUD – methadone, naltrexone, and buprenorphine – and other strategies and services needed to support recovery for people with OUD.

Additionally, in February 2018, SAMHSA released the publication *Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants*, which offers standard approaches for health care professionals. This publication provides evidence-based treatment options, including pharmacotherapy with methadone, buprenorphine, and buprenorphine/naloxone, for pregnant women with OUD. The clinical guidance also helps health care professionals and patients determine the most clinically appropriate action for a particular situation and informs individualized treatment decisions. Both publications can be found in the Publications section of SAMHSA's website at [www.samhsa.gov](http://www.samhsa.gov).

## **FDA Issues Final Guidance Policy on Outsourcing Facilities**

In May 2018, FDA issued a new policy designed to address any ambiguity around how to define the physical features and operations of outsourcing facilities. According to FDA Commissioner Scott Gottlieb, MD, the policy in the final guidance, *Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act*, will help to:

- ◆ ensure that compounded drugs are made under appropriate quality standards;
- ◆ provide transparency to patients and health care providers about the standards under which the compounded drugs that they purchase are made; and

- ◆ respond to stakeholder feedback requesting guidance on the meaning of “facility” under section 503B.

In the guidance, FDA explains that a section 503A establishment compounding drugs pursuant to patient-specific prescriptions may be located near or in the same building as the outsourcing facility provided that they are completely separate. As explained in the guidance, the boundaries between the section 503A establishment and outsourcing facility should be clear and may include permanent physical barriers, such as walls or locked doors, and the two operations should not share rooms, equipment, supplies, or pass-through openings (eg, they may not subdivide a room with temporary barriers such as curtains). The guidance further explains that the labeling should clearly identify the compounder who produced the drug. Lastly, the guidance reminds industry and stakeholders that all drug products compounded in an outsourcing facility are regulated under section 503B and are subject to current good manufacturing practice requirements, even if those drug products are compounded pursuant to patient-specific prescriptions. Additional information can be located at [www.fda.gov/newsevents/newsroom/fdainbrief/ucm607339.htm](http://www.fda.gov/newsevents/newsroom/fdainbrief/ucm607339.htm).

## **EU-US Mutual Recognition Agreement Now Operational Between FDA and 12 Member States**

In January 2018, FDA confirmed the capability of four more European Union (EU) member states – Czech Republic, Greece, Hungary, and Romania – to carry out good manufacturing practice inspections at a level equivalent to the United States. With the addition of the four EU member states, FDA can now rely on inspection results from 12 EU member states. The mutual recognition agreement between the EU and US to recognize inspections of manufacturing sites for human medicines conducted in their respective territories is progressing as planned, with plans for the agreement to be operational in all EU member states by July 15, 2019, indicates a European Medicines Agency (EMA) press release. In 2017, FDA determined the agency will recognize eight European drug regulatory authorities in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom as capable of conducting

inspections of manufacturing facilities that meet FDA requirements. The EMA news release, “Four more EU Member States benefit from EU-US mutual recognition agreement for inspections,” can be found in the News and Events section at [www.ema.europa.eu](http://www.ema.europa.eu).

### **US Surgeon General Advisory Urges More Individuals to Carry Naloxone**

In an April 2018 advisory, US Surgeon General Jerome M. Adams, MD, MPH, emphasizes the importance of more individuals knowing how to use naloxone and keeping it within reach. Surgeon General Adams recommends that family, friends, and those who are personally at risk for an opioid overdose keep the drug on hand. As stated in the advisory, expanding the awareness and availability of naloxone is a key part of the public health response to the opioid epidemic. The Surgeon General advisory on naloxone is part of the Trump Administration’s ongoing effort to respond to the sharp increase among drug overdose deaths, notes a US Department of Health and Human Services (HHS) news release. HHS also has a website, [www.hhs.gov/opioids](http://www.hhs.gov/opioids), with resources and information for individuals who want to fight the opioid crisis in their communities or find help for someone in need. The advisory and news release can be found at [www.surgeongeneral.gov](http://www.surgeongeneral.gov).

### **Expanding Pharmacists’ Scope of Practice Linked to Improved Cardiovascular Outcomes**

Elevating pharmacy involvement in patient care and using a team-based care model are among the effective strategies for preventing cardiovascular disease that were identified in a new guide developed by the Centers for Disease Control and Prevention’s (CDC’s) Division for Heart Disease and Stroke Prevention (DHDSP). The guide, *Best Practices for Cardiovascular Disease Prevention Programs: A Guide to Effective Health Care System Interventions and Community Programs Linked to Clinical Services*, describes the scientific evidence behind each strategy, including collaborative drug therapy management, enabled by a collaborative practice agreement, and medication therapy management. To be included in the guide, strategies had to be supported by multiple high-quality research studies that demonstrated evidence of effectiveness in controlling blood pressure or cholesterol levels. More details about the best practice strategies along with resources and tools for implementing the strategies identified by CDC’s DHDSP can be found at [www.cdc.gov/dhdsp/pubs/guides/best-practices/index.htm](http://www.cdc.gov/dhdsp/pubs/guides/best-practices/index.htm).

### **Pharmacists Are Critical to Drug Supply Chain Integrity, States FIP**

Medicines are specialized commodities and, if they are not managed rationally or appropriately, they are equivalent to a dangerous substance, indicates the International Pharmaceutical Federation (FIP). In a May 2018 report, *Pharmacists in the supply chain: The role of the medicines expert in ensuring quality and availability*, FIP provides a global picture of the role of pharmacists in supply chains, the tasks currently undertaken by pharmacists in different countries, and pharmacists’ unique competencies. Based on reviews of literature, survey data, and case studies from nine countries, pharmacists were identified as having expertise that is critical to supply chain integrity. According to FIP, pharmacists and those who are involved in the planning, procurement, manufacture, storage, and distribution of medicines must:

- ♦ consider how to most effectively use the skills of the staff and personnel available;
- ♦ provide and seek training where needed; and
- ♦ keep their systems and role descriptions under review in order to adapt to changing circumstances.

FIP’s report and news release can be located at [www.fip.org/news\\_publications](http://www.fip.org/news_publications).

### **Emergency Department Visits for Opioid Overdoses Rose 30%**

From July 2016 through September 2017, reports of emergency department (ED) visits for opioid overdoses – including prescription pain medications, heroin, and illicitly manufactured fentanyl – rose 30% in all parts of the US, according to a CDC report. The Midwest saw opioid overdoses increase 70% during this time period. According to the March 9, 2018 *Morbidity and Mortality Weekly Report*, coordinated action between EDs, health departments, mental health and treatment providers, community-based organizations, and law enforcement can prevent opioid overdose and death. People who have had an overdose are more likely to have another; thus, being seen in the ED is an opportunity for action. EDs can provide naloxone, link patients to treatment and referral services, and provide health departments with critical data on overdoses. The CDC report, “Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses — United States, July 2016–September 2017,” can be accessed at <http://dx.doi.org/10.15585/mmwr.mm6709e1>.

continued from page 1

medical providers about pharmacists refusing to fill prescriptions for expedited partner therapy (EPT) for chlamydia or gonorrhea. This is happening in pharmacies and pharmacy systems located in urban areas, as well as in rural areas and small towns, across Minnesota. Pharmacists play an important role in ensuring treatment for chlamydia and gonorrhea through the EPT program, and this alert is to provide information on the EPT statute, so pharmacists can fulfill this role.

EPT has been legal in Minnesota since May 2008. The Minnesota statute allows health care providers to prescribe treatment for chlamydia and/or gonorrhea to a patient in a quantity sufficient to treat the patient and his or her sex partner(s) – when the patient believes one or more partner will not go to a clinic for evaluation. The process, while legal, does present several challenges:

- ◆ The health care provider does not see the sexual partner in person, something that, while previously considered poor medical practice, has become standard practice around the country for treating sexual partners since the benefit outweighs the risk for EPT.
- ◆ Prescriptions may be written without the name of the person to be treated, which is the requirement for normal prescriptions, but it is legal for pharmacists to fill these prescriptions.
- ◆ With electronic prescribing becoming more prevalent, written prescriptions are not being issued as often as they used to be, but EPT may require e-prescribing systems to create paper versions that can be given to patients when possible.
- ◆ Without a name provided for the person being treated, the pharmacist may be unable to check for cross-reactions and allergies at the time of dispensing through the pharmacy system and may need to do so in conjunction with the partner who is presenting the EPT prescription.
- ◆ The partner being treated may not have insurance and will need to pay for the medication out of pocket.

Even with these challenges, EPT is an important part of the tool kit that needs to be utilized to reduce the high rates of chlamydia and gonorrhea currently seen in the US and many other developed countries. Without EPT, many individuals would not receive treatment for highly infectious, easily curable sexually transmitted diseases (STDs), which could lead to further transmission. Studies have shown that when partners receive treatment through EPT (when other options are not available), the rates of STDs are reduced. A simple pilot study of EPT conducted by MDH shortly after EPT became legal in

Minnesota revealed that a high percentage of patients were confident that their partners had taken the medications they were prescribed or given.

The Board was instrumental in developing the EPT legislative language. The legislation was written to remove barriers preventing infected people from receiving treatment. It is common for patients diagnosed with and treated for chlamydia and/or gonorrhea to become reinfected after resuming sexual contact with their previous partner because that partner has not been treated. This increases the likelihood that some patients will experience serious complications, as well as one or both people continuing to pass the infections on to others.

In many instances, partners who know about their exposure to an STD will go into a clinic to be tested and treated. While this is the preferred method of clinical intervention, sometimes partners refuse to be seen in a clinic. In these cases, EPT can ensure the partner does receive treatment. In some situations, patients do not know the names of their partners or are unwilling to provide the names. Some partners may also prefer to remain anonymous and not give their names to other health care providers, including the pharmacist.

When individuals come to a pharmacy to get their prescriptions filled, the pharmacist can encourage partners to provide their names. When individuals understand the reason why their names are needed, some people will be willing to provide them. If they choose not to, the prescription may still be filled within the legal limits of the statute. Having a process in place for handling these situations can help prevent confusion and potential misunderstandings. Pharmacies are encouraged to work with their computer system vendors/information technology departments to determine how to process EPT prescriptions without a patient name. Pharmacies may need to create a fake name that can be utilized for EPT unnamed prescriptions. For example, John Doe #1, John Doe #2, etc.

At this point in time, insurers and health plans do not cover the cost of medications to treat partners of their members, resulting in the need for partners to pay for their medications out of pocket.

Pharmacies are strongly encouraged to process, dispense, and educate patients on EPT medications as outlined in “Expedited Partner Therapy (EPT) for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*: Guidance for Medical Providers in Minnesota,” provided by MDH, [available here](#). Additional information was recently published in the summer issue of *Minnesota Pharmacist*, and the topic will be covered at upcoming educational

continued on page 5

*continued from page 4*

events hosted by the Minnesota Pharmacists Association. Please contact the Board with questions/concerns.

### **Pharmacist Continuing Education**

Minnesota-licensed pharmacists are reminded that they should have certified completion of their continuing education (CE) by October 1 for the two-year CE cycle that ended on September 30, 2018. During every CE cycle, many pharmacists fail to certify completion of their CE and they are automatically included in the Board's CE audit. Those pharmacists, and other pharmacists selected at random, will be required to submit proof of having completed the required number of CE hours. Those pharmacists selected for the audit who do not supply proof of having completed the CE requirement will not be allowed to renew their license (and will therefore not be able to practice) until the matter is resolved. If you have not yet certified completion of your CE for the cycle that ended on September 30, 2018, please call the Board's office for assistance at 651/201-2825.

### **Return of Drugs From Long-Term Care Facilities**

During inspections, Board surveyors continue to discover pharmacies that take returns of unused drugs from long-term care (LTC) facilities for the purpose of having those drugs disposed of as pharmaceutical waste. (That is, the pharmacy allows drugs to be sent by the LTC facility back to the pharmacy.) The surveyors are often told that this is a "service" that the facilities expect. Regardless of what the expectations of the facilities might be, **this "service" is illegal**. Pharmacies are not allowed to routinely take back drugs from LTC facilities for the purpose of disposing of them as pharmaceutical waste.

Pharmacies are allowed to take back medications that are dispensed in error. In addition, pharmacies are allowed to

place Drug Enforcement Administration-compliant waste collection receptacles in LTC facilities into which staff at the facility can place expired or discontinued drugs for disposal. Pharmacies can find additional information about the proper manner in which to assist such facilities with drug disposal at <https://www.pca.state.mn.us/sites/default/files/w-hhw2-07.pdf>. Pharmacies cannot provide even the permitted service free of charge – that would most likely be a violation of federal Medicare and Medicaid anti-kickback and fraud regulations.

Pharmacies are allowed to accept returns **for redispensing**, as long as they follow the provisions of [Minnesota Rules 6800.2700](#). Please note that drugs that are properly returned in unit-dose packaging **cannot** be removed from that packaging and placed back into stock bottles. If that occurs, the drugs in those stock bottles become misbranded and adulterated, and therefore subject to detention or embargo (which prohibits them from being dispensed). When accepting the return of drugs for redispensing, the original payer must be credited for the amount of the drug returned. If that credit is not given, the pharmacy is engaging in insurance or Medicare/Medicaid fraud. The Board's executive director is obligated by statute to report such fraud to the appropriate state agency for action.

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Page 5 – October 2018

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