July 2019

Minnesota Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

University Park Plaza • 2829 University Ave SE, Suite 530 • Minneapolis, MN 55414-3251
https://mn.gov/boards/pharmacy

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.

2019 Legislative Changes

The Minnesota Legislature passed, and Governor Tim Walz signed, several bills that have provisions that will affect licensees and registrants of the Board. Only some of the provisions will be described in this article. Additional information can be found on the Board's website, including a document that provides comprehensive information on all the changes. Several frequently asked questions documents that focus on specific policy areas are being drafted and will also be posted.

Limits on Opiate Prescriptions

The following provisions took effect on July 1, 2019. This excerpt, from House File (HF) 400 - Opioids, addresses **limits on filling dates.**

> No prescription for an opiate or narcotic pain reliever listed in Schedules II through IV of section 152.02 may be initially dispensed more than 30 days after the date on which the prescription was issued. No subsequent refills indicated on a prescription for a Schedule III or IV opiate or narcotic pain reliever may be dispensed more than 30 days after the previous date on which the prescription was initially filled or refilled. After the authorized refills for Schedule III or IV opiate or narcotic pain relievers have been used up or are expired, no additional authorizations may be accepted for that prescription. If continued therapy is necessary, a new prescription must be issued by the prescriber.

The following excerpt is also from HF 400 - Opioids, and addresses limits on the quantity of opiates prescribed.

Limit on quantity of opiates prescribed.

(a) When used for the treatment of acute pain, prescriptions for opiates or narcotic pain relievers listed in Schedules II through IV in section 152.02 shall not exceed a seven-day supply for an adult and shall not exceed a five-day supply for a minor under 18 years of age.

(b) Notwithstanding paragraph (a), when used for the treatment of acute dental pain, including acute pain associated with wisdom teeth extraction surgery or acute pain associated with refractive surgery, prescriptions for opiate or narcotic pain relievers listed in Schedules II through IV of section 152.02 shall not exceed a four-day supply.

(c) For the purposes of this subdivision, "acute pain" means pain resulting from disease, accidental or intentional trauma, surgery, or another cause, that the practitioner reasonably expects to last only a short period of time. Acute pain does not include chronic pain or pain being treated as part of cancer care, palliative care, or hospice or other end-of-life care.

(d) Notwithstanding paragraph (a) or (b), if, in the professional clinical judgment of a practitioner, more than the limit specified in paragraph (a) or (b) is required to treat a patient's acute pain, the practitioner may issue a prescription for the quantity needed to treat the patient's acute pain.

ID Requirements for CS Prescriptions

The following is an excerpt of a change to HF 400 - Opioids that will require more frequent checks of IDs when controlled substances (CS) are dispensed.

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National Pharmacy Compliance News

July 2019

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.

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.*

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Identification requirement for controlled substance prescriptions. No person may dispense a controlled substance included in Schedules II through V without requiring the person purchasing the controlled substance, who need not be the patient for whom the controlled substance prescription is written, to present valid photographic identification, unless the person purchasing the controlled substance is known to the dispenser. A doctor of veterinary medicine who dispenses a controlled substance must comply with this subdivision.

Pharmacist Administration of Certain Injectable Drugs

HF 400 - Opioids was updated to address pharmacist administration of certain injectable drugs. The definition of "practice of pharmacy" was amended to include the administration of additional types of drugs. Note that the language adopted for administration of mental health drugs mentions protocols or collaborative practice agreements with not only physicians and advanced practice registered nurses (APRNs), but also with dentists, optometrists, podiatrists, and veterinarians. However, it would not be within the scope of practice of those other practitioners to prescribe and administer mental health drugs. That effectively means that collaborative practice agreements and protocols in this area will need to be with physicians or APRNs. The definition of practice of pharmacy now includes the following actions.

> . . . intramuscular and subcutaneous administration used for the treatment of alcohol or opioid dependence [eg, Vivitrol®] . . . drug administration, through intramuscular and subcutaneous administration used to treat mental illnesses as permitted under the following conditions:
>
> (i) upon the order of a prescriber and the prescriber is notified after administration is complete; or
>
> (ii) pursuant to a protocol or collaborative practice agreement as defined by section 151.01, subdivisions 27b and 27c, and participation in the initiation, management, modification, administration, and discontinuation of drug therapy is according to the protocol or collaborative practice agreement between the pharmacist and a dentist, optometrist, physician, podiatrist, or veterinarian, or an advanced practice registered nurse authorized to prescribe, dispense, and administer under section 148.235. Any changes in drug therapy or medication administration made pursuant to a protocol or collaborative practice agreement must be documented by the pharmacist in the patient's medical record or reported by the pharmacist to a practitioner responsible for the patient's care.

Syringe and Needle Access

The law regarding **syringe and needle access,** Minnesota Statute Section 151.40, was amended to clarify that a prescription is not necessary for the purchase of needles and syringes. This has been the Board's long-standing interpretation of this section. However, in finding a defendant not guilty of illegally possessing syringes, a district court judge opined that prescriptions were required unless one of several exceptions applied to the individual. New language was added that states **(emphasis added):** "a person who self-administers drugs pursuant to either the prescription **or the direction** of a practitioner, or a family member, caregiver, or other individual who is designated by such person to assist the person in obtaining and using needles and syringes for the administration of such drugs" may legally possess needles and syringes. This means that a practitioner may simply direct a patient to use needles and syringes to self-administer a drug, rather than having to issue a prescription.

The amended statute also allows pharmacies that choose to sell up to 10 needles and syringes without the prescription or direction of a practitioner, to advertise that fact. Prior to this change, pharmacies that sold up to 10 syringes and needles, "no questions asked," were not allowed to advertise that they sold syringes and needles in that manner.

It also clarifies that individuals who purchase up to 10 needles and syringes from a pharmacy, despite not doing so based on the prescription or direction of a practitioner, can legally possess those needles and syringes.

Emergency Prescription Refills

The Minnesota statute regarding emergency prescription refills has been updated. Pharmacists will be allowed to refill prescriptions, even if no refills remain, provided that:

- the patient has been compliant with taking the medication and has consistently had the drug filled or refilled as demonstrated by records maintained by the pharmacy;
- the pharmacy from which the legend drug is dispensed has record of a prescription drug order for the drug in the name of the patient who is requesting it, but the prescription drug order does not provide for a refill, or the time during which the refills were valid has elapsed;
- the pharmacist has tried but is unable to contact the practitioner who issued the prescription drug order,

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or another practitioner responsible for the patient's care, to obtain authorization to refill the prescription;

- ♦ the drug is essential to sustain the life of the patient or to continue therapy for a chronic condition;
- ♦ failure to dispense the drug to the patient would result in harm to the health of the patient; and
- ♦ the drug is not a CS listed in Minnesota Statute Section 152.02, Subdivisions three to six, except for a CS that has been specifically prescribed to treat a seizure disorder, in which case the pharmacist may dispense up to a 72-hour supply.

If those conditions are met, the amount of the drug dispensed by the pharmacist to the patient must not exceed a 30-day supply, or the quantity originally prescribed, whichever is less, except as provided for CS. If the standard unit of dispensing for the drug exceeds a 30-day supply, the amount of the drug dispensed or sold must not exceed the standard unit of dispensing. A pharmacist cannot dispense or sell the same drug to the same patient, as allowed under this new provision, more than one time in any 12-month period.

The pharmacist must notify the practitioner who issued the prescription drug order no later than 72 hours after the drug is sold or dispensed. The pharmacist must request and receive authorization before any additional refills may be dispensed. If the practitioner declines to provide authorization for additional refills, the pharmacist must inform the patient of that fact.

Insurers and pharmacy benefits managers are required to pay for these emergency refills, even though there were no refills remaining.

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