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MN HOUSE RESEARCH

Opioid Regulation in Minnesota

December 2018

Executive Summary

This publication provides an overview of the state laws governing the prescribing, dispensing, and disposal of opioids and opioid antagonists.

Opioids generally. Opioids are drugs that are most commonly used to alleviate moderate to severe pain. Opioids "work" by attaching themselves to proteins called opioid receptors in nerve cells in the brain, spinal cord, or gastrointestinal track. When attached to these receptors, opioids can reduce the perception of pain and produce a sense of well-being and pleasure. Opioids are regulated by the federal government and the states as controlled substances. State laws relating to opioids and other controlled substances comply with federal law, and often refer to federal requirements or incorporate the language of federal law.

Prescribing opioids. Health care providers authorized to prescribe prescription drugs generally can prescribe opioids, but must register with the federal Drug Enforcement Administration. The state regulates various aspects of opioid and controlled substance prescribing, such as methods of prescribing and quantity limits. Pharmacists and other health care professionals may dispense an opioid or other prescription drug under a protocol entered into with a physician or other prescriber. Prescribers serving Medical Assistance and MinnesotaCare enrollees must participate in the opioid prescribing improvement program administered by the Department of Human Services.

Dispensing opioids. The state regulates the dispensing of opioids, by requiring some individuals to present valid identification when purchasing controlled substances, requiring certain warning labels, and placing limits on refills and partial refills of controlled substances. The state places requirements on pharmacies related to the retention of controlled substance prescriptions and labeling controlled substance containers. There are also requirements related to the dispensing of methadone by treatment programs.

The Prescription Monitoring Program. The Minnesota Board of Pharmacy administers the Prescription Monitoring Program, which collects data on controlled substance prescriptions in order to prevent abuse. Physicians and other prescribers must maintain a user account with the program but are not required to consult the program's database before prescribing opioids or other controlled substances to a patient.

Opioid antagonists – general provisions. Opioid antagonists are opioids that can be administered to prevent or stop an opioid overdose. State law allows law enforcement officers, EMS personnel, and others to administer opiate antagonists if authorized by a prescriber through a protocol or standing order. In addition, pharmacists may issue prescriptions for opioid antagonists under the terms of a protocol. The Board of Pharmacy has developed an opiate antagonist protocol that may be voluntarily used by prescribers and pharmacists, and which is used in protocols entered

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into by a prescriber authorized by the Minnesota Department of Health and local pharmacists. State law contains various training and education requirements related to opioid antagonists.

Opioid antagonists – Good Samaritan provisions. State law provides immunity to health care professionals who prescribe, dispense, distribute, or administer an opioid antagonist directly or by standing order, and to non-health care professionals (e.g. friends and family) who administer opioid antagonists to persons thought to be suffering from a drug overdose. Persons who seek medical attention for another person experiencing a drug overdose are also immune from prosecution if certain criteria are met.

Disposal of opioids and other controlled substances. Opioids and other controlled substances must be collected and disposed of according to federal regulations and state law and related rules. Law enforcement agencies and pharmacies are two types of sites that may accept discarded opioids and prescription drugs from households, long-term care facilities, and schools. Each county sheriff is required to maintain a collection receptacle for the disposal of controlled substances and other prescription drugs.

Contents

Opioids Generally

Definition

Opioids are drugs that are most commonly used to alleviate moderate to severe pain. They are also sometimes used to treat coughs and diarrhea. Two opioids—methadone and buprenorphine—are used in medication assisted treatment for opioid addiction. This publication follows current practice by using the term "opioid" to refer to both drugs derived from the opium poppy ("opiates") and drugs that contain synthetic compounds that have effects similar to opiates ("opioids."). Opioids include both prescription pain medications such as oxycodone and fentanyl, and illegal opioids such as heroin and nonpharmaceutical fentanyl.

Pharmacology[1]

Opioids "work" by attaching themselves to proteins called opioid receptors in nerve cells in the brain, spinal cord, or gastrointestinal tract. When attached to these receptors, opioids can reduce the perception of pain and produce a sense of well-being and pleasure.

Persons who use opioids for nonmedical purposes may take the drug in a form that provides for more rapid delivery to the brain to increase the euphoric effect (e.g., smoking or inhaling the drug, or injecting the drug into the bloodstream). This can increase the risk of medical complications and opioid overdoses. The repeated use of opioids over time, whether for medical or nonmedical purposes, can lead to increased tolerance, whereby a person requires a higher dose of the drug to obtain the same effect.

Each specific opioid can have a different pharmacological effect, depending on the type of opioid receptor to which it attaches, and whether the opioid fully activates the receptor ("full agonist"), partially activates the receptor ("partial agonist"), or prevents or reverses activation of the receptor ("antagonist").

Opioids that function as antagonists (such as naloxone—commonly known by the brand name Narcan) can block opioid receptors and prevent opioids that are agonists from attaching to the receptor; this can prevent or reverse the effect of an opioid overdose. Some opioids, such as buprenorphine, both activate and block opioid receptors, and are therefore used in medication-assisted treatment (MAT) for opioid addiction.[2]

Regulation

Opioids are regulated by the federal government and the states as controlled substances.[3] The federal Controlled Substances Act (CSA) governs the manufacture, distribution, and use of prescription opioids, illegal opioids, and other controlled substances.[4] Among other things, the CSA:

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[1] This section summarizes more detailed information provided in Nora D. Volkow, "America's Addition to Opioids: Heroin and Prescription Drug Abuse," National Institute on Drug Abuse, May 14, 2014, presentation to the Senate Caucus on International Narcotics Control, and Nora D. Volkow, "What Science Tells Us About Opioid Abuse and Addiction," National Institute on Drug Abuse, Jan. 27, 2016, presentation to the Senate Judiciary Committee.

[2] Medication-assisted treatment (MAT) is described by the federal Substance Abuse and Mental Health Services Administration (SAMHSA) as the use of FDA-approved medications, in combination with counseling and behavioral therapies, to treat substance use disorders using a "whole-patient" approach. Drugs commonly used in MAT include: methadone (an opioid agonist that may be dispensed daily in liquid form in special clinics), naltrexone (an opioid antagonist that may be dispensed as a daily pill or monthly injection), and buprenorphine (an opioid agonist/antagonist that may be dispensed as tablets, cheek film, or an implant). "Medication-Assisted Treatment (MAT)," Substance Abuse and Mental Health Services Administration, Feb. 7, 2018, https://www.samhsa.gov/medication-assisted-treatment.

[3] This publication does not address any criminal penalties related to opioids and other drug-related crimes. Since opioids are regulated as controlled substances, many of the provisions described apply to controlled substances generally.

[4] 21 U.S. Code, chapter 13, sections 801 et seq. and 21 C.F.R. part 1300, et seq., and Brian T. Yeh, "The Controlled Substances Act: Regulatory Requirements," Congressional Research Service, Dec. 13, 2012, 7-5700. Many nonopioid drugs are also regulated as controlled substances (e.g., LSD, cannabis, methamphetamine, anabolic steroids, certain antidiarrheal, and cough medications).

- establishes schedules of controlled substances;
- requires entities and persons that handle controlled substances (e.g., manufacturers, distributors, physicians, hospitals, and pharmacies) to register with the Drug Enforcement Administration (DEA);
- regulates the dispensing and distribution of controlled substances;
- establishes recordkeeping requirements and security controls; and
- includes criminal provisions related to the illegal manufacture, possession, and distribution of controlled substances.

One of goals of the DEA registration requirement and related recordkeeping and security measures is to create a "closed system" for opioid distribution and prevent the diversion of opioids to persons other than those for whom opioids have been legally prescribed.

States may regulate the distribution and use of controlled substances through their own controlled substance acts. If a state law conflicts with the CSA, the CSA overrides state law, except that a state may regulate controlled substances more strictly than required under the CSA.[5] For example, certain cough syrups containing codeine are Schedule V controlled substances under federal law, but are Schedule III controlled substances under Minnesota law. However, Minnesota laws regulating controlled substances are primarily based on federal law, and in many instances, incorporate language from the CSA.

Controlled Substance Schedules

Controlled substances are classified into Schedules I to V, depending upon the medical use of the drug and the drug's abuse or dependency potential.[6] Schedule I drugs are those that have a high potential for abuse and for which there is no accepted medical use. Schedule II drugs have an accepted medical use, but also a high potential for abuse and creating severe psychological and/or physical dependence. Drugs in schedules III to V have progressively lower potential for abuse and physical and psychological dependence. Most opioids are listed in Schedules I (heroin), II (methadone, hydrocodone, oxycodone, fentanyl, morphine, codeine), and III (buprenorphine).

Minnesota law places more stringent regulations on drugs that are controlled substances than on drugs that are not controlled substances. While some Minnesota laws apply specifically and only to opioids, other laws apply to all controlled substances (including opioids).

[5] See CRS, Brian T. Yeh, "Legal Authorities Under the Controlled Substances Act to Combat the Opioid Crisis," Congressional Research Services, April 16, 2018, 7-5700, pp. 17-18.

[6] The Minnesota controlled substances schedules are found in Minnesota Statutes, section 152.02, subdivisions 2 to 6.

Prescribing Opioids

Prescribing by Health Care Providers

Physicians, dentists, podiatrists, and advanced practice registered nurses may prescribe, administer, and dispense a controlled substance in Schedules II through V. Optometrists may prescribe, administer, and dispense controlled substances in schedules IV and V, provided the drug is used to treat an eye condition.[7] (Minn. Stat. § 152.12, subd. 1). A physician assistant, as delegated by the supervising physician, may also prescribe, administer, and dispense controlled substances in Schedules II through V.

These individuals must have a current federal DEA registration number in order to prescribe a controlled substance; this number must be included in any prescription. (Minn. Stat. §§ 147A.18; 152.11, subd. 1). Physicians, dentists, podiatrists, advanced practice registered nurses, and optometrists may also delegate prescribing and/or administering to certain other health professionals. (Minn. Stat. § 152.12, subd. 1).

Under the CSA, physicians and other practitioners who prescribe or dispense opioids to individuals for medication maintenance treatment or detoxification treatment must annually obtain from the DEA a separate federal registration for that purpose, in addition to the regular required DEA registration.[8]

A physician or other practitioner may apply for a waiver from this separate registration requirement in order to prescribe buprenorphine (a drug used for opioid dependence treatment) in settings other than opioid treatment program facilities (e.g., an office, community hospital, health department, or correctional facility).[9]

Patient Evaluation

A prescription for controlled substances in schedules II to IV is not valid unless it is based on a documented patient evaluation that includes a patient examination, and is "adequate to establish a diagnosis and identify underlying conditions and contraindications to treatment." The requirement also applies to other specified drug classes. (Minn. Stat. § 151.37, subd. 2, para. (d))

Electronic Prescribing

Prescribers, dispensers, providers, and group purchasers are required to use electronic prescribing ("e-prescribing"), and to establish, maintain, and use an electronic prescription program that complies with

[7] A veterinarian may prescribe, administer, and dispense controlled substances in schedules II to V, but only for animals. (Minn. Stat., § 152.12, subd. 2)

[8] 21 U.S.C. § 823 (g) (1).

[9] In order to qualify for a waiver, the practitioner must meet certain training and certification criteria and treat no more than a specified number of patients. See "Medication Assisted Treatment – Qualify for a Physician Waiver," Substance Abuse and Mental Health Services Administration, Nov. 21, 2016, https://www.samhsa.gov/medication-assisted-treatment/buprenorphine-waiver-management/qualify-for-physician-waiver; 21 U.S.C. 823(g)(2)(B)(iii) as amended by the Support for Patients and Communities Act: Pub.L. No. 115-271, signed into law Oct. 24, 2018.

the standards specified in Minnesota Statutes, section 62J.497, and federal regulations.[10] The Minnesota Department of Health has issued a fact sheet on the electronic prescribing requirement; this fact sheet recognizes that additional resources are needed to fully implement electronic prescribing and directs prescribers, dispensers, providers, and group purchasers to implement the mandate as soon as possible.[11]

Transmission by Facsimile

Prescriptions for controlled substances in schedules II to V that are transmitted by facsimile are void unless they comply with applicable federal requirements.[12] (Minn. Stat. § 152.11, subd. 1, (c)).

Oral Prescriptions

In an emergency situation, an oral prescription for a schedule II controlled substance may be filled, as authorized by federal law, if it is then promptly put in writing and filed by the pharmacist. (Minn. Stat. § 152.11, subd. 1a) An oral prescription for a schedule III, IV, or V controlled substance may be filled if it is promptly put in writing by the pharmacist and other requirements are met. (21 C.F.R. 1306.21)

Quantity Limit

The 2017 Legislature limited opioid prescriptions for dental pain and pain from refractive eye surgery to a four-day supply. A practitioner using his or her professional judgment can override this limit. Opioid prescriptions for other medical purposes are not subject to the limit. (Minn. Stat. § 152.11, subd. 4)

Prescribing under a Protocol

Pharmacists (and other specified health professionals) may dispense an opioid or other prescription drug under the terms of a protocol entered into with a physician or other licensed practitioner with prescribing authority. This means that a licensed practitioner may prescribe a prescription drug without reference to a specific patient, by directing a pharmacist, nurse, physician assistant, medical student or resident, licensed dietician, or licensed nutritionist to follow a protocol that specifies the patient conditions to which the protocol applies and the circumstances under which the drug may be prescribed or administered. (Minn. Stat. § 151.37, subd. 2, para. (a)).

Opioid Prescribing Improvement Program

The opioid prescribing improvement program, administered by the Department of Human Services (DHS), was established by the 2015 Legislature to reduce opioid dependency and substance use that

[10] See 21 C.F.R., parts 1300, 1304, 1306, and 1311. Federal regulations allow, but do not require, the use of electronic prescriptions for controlled substances. Part 1311 establishes detailed requirements for electronic prescriptions for controlled substances.

[11] Minnesota Department of Health, Minnesota Electronic Prescribing Mandate – Guidance and Compliance, Nov. 21, 2017, http://www.health.state.mn.us/e-health/eprescribing/docs/erxmandatefactsheet.pdf.

[12] See 21 C.F.R., part 1306. This regulation in part allows prescriptions for schedule II controlled substances to be transmitted by facsimile, if the original written prescription is presented to the pharmacist for review prior to actual dispensing and the original prescription is maintained in accordance with specified regulations. There are exceptions to the requirement that the original prescription be presented, for controlled substances that are directly administered to the patient or prescribed for patients in long-term care or hospice facilities.

results, in part, from the prescribing practices of health care providers. Under the program, DHS provides opioid prescribing data to prescribers and may require provider improvement plans and take action against providers (including monitoring prescribing practices more frequently, mandating use of the prescription monitoring program, and terminating providers from Medical Assistance (MA) and MinnesotaCare). Providers who prescribe to MA and MinnesotaCare enrollees must participate; other providers may voluntarily participate.

The Minnesota Opioid Prescribing Work Group was established by the 2015 Legislature to provide recommendations to the commissioners of human services and health on the opioid prescribing improvement program. The work group issued prescribing guidelines for opioids in 2018, for intended use by physicians in primary care and specialty outpatient settings who manage pain.[13] (Minn. Stat. § 256B.0638).

Dispensing Opioids

Requiring Identification

Pharmacies and other dispensers[14] must require purchasers of Schedule II or III controlled substances to present valid photographic identification, unless the person purchasing the controlled substance, or the patient for whom the prescription is written, is known by the dispenser. This requirement for identification applies only to controlled substances that are not covered, in whole or in part, by a health insurer or other third-party payor. (Minn. Stat. § 152.11, subd. 2d).

Warning Label

The 2017 Legislature required pharmacies and dispensers to include the following warning label, when dispensing drugs containing opioids:

> "Caution: Opioid. Risk of overdose and addiction." (Minn. Stat. § 151.212, subd. 2)

In addition, pharmacies and dispensers must include the following warning labels when dispensing controlled substances:

> "Caution: Taking this drug alone or with alcohol may impair your ability to drive."[15] (Minn. Stat. § 151.212, subd. 2; Minn. Rules, part 6800.4150)

> "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed" (Minn. Rules, part 6800.4150)

[13] Minnesota Department of Human Services and Minnesota Department of Health, Minnesota Opioid Prescribing Guidelines, First edition, 2018. March 2018, https://mn.gov/dhs/assets/mn-opioid-prescribing-guidelines_tcm1053-337012.pdf.

[14] Minnesota law allows licensed practitioners to prescribe, administer, and dispense prescription drugs. A "licensed practitioner" includes physicians, dentists, optometrists, podiatrists, veterinarians, APRNs, and other specified health care professionals (Minn. Stat. §§ 151.01, subd. 23 and 151.37, subd. 2).

[15] This label must also be included with "other drugs deemed appropriate in the professional judgment of the pharmacist, and dispensed to or for an adult patient, other than an inpatient of a hospital or nursing home..."

Refills

Prescriptions for schedule II controlled substances cannot be refilled. (Minn. Stat. § 152.11, subd. 1a). Prescriptions for schedule III and IV controlled substances cannot be filled or refilled more than six months following the date the prescription was issued, and cannot be refilled more than five times. (Minn. Stat. § 152.11, subd. 2). Prescriptions for schedule II and V controlled substances cannot be filled or refilled more than 12 months following the date the prescription was issued. (Minn. Rules, part 6800.3510)

Partial Refills

Prescriptions for Schedule II controlled substances can be partially filled under federal law if the partial fill is requested by the patient or prescriber, the total quantity dispensed in partial fillings does not exceed the total quantity prescribed, and other requirements are met. The remaining portion of the prescription may not be filled after 30 days from when the prescription was written. (21 U.S.C. 829 (f)).

Prescriptions for controlled substances in schedules III to V may be partially filled, provided that each partial filling is recorded in the same manner as a refilling, the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and no dispensing occurs beyond six months from the date the prescription was issued. (21 C.F.R. 1306.23).

Additional Pharmacy Duties

Pharmacies that dispense controlled substances must keep the original prescription (or an original electronic or facsimile prescription) on file for at least two years and must allow inspection by government entities. Pharmacies must also label the container in which a controlled substance is dispensed with instructions for use. (Minn. Stat. § 152.11, subd. 1, paras. (d) and (e)).

Dispensing of Methadone

Patients receiving methadone as part of medication-assisted treatment for opioid addiction must receive the medication under the supervision of a physician. Methadone may be dispensed only through an opioid treatment program certified by the federal Substance Abuse and Mental Health Services Administration (SAMHSA).[16]

[16] See Substance Abuse and Mental Health Services Administration, "Methadone," https://www.samhsa.gov/medication-assisted-treatment/treatment/methadone; 42 Code of Federal Regulations, Part 8.

The Prescription Monitoring Program

Establishment

The 2007 Legislature directed the Minnesota Board of Pharmacy to establish and administer the Prescription Monitoring Program (PMP). The PMP collects data on controlled substance prescriptions and makes that data available to authorized users, in order to prevent the abuse of controlled substances. (Minn. Stat. § 152.126). Collection of controlled substance prescription data began on January 4, 2010, and information in the program database has been available since April 15, 2010.

Reporting of Prescription Information

Pharmacies and other dispensers are required to report to the program, on a daily basis, information on controlled substance prescriptions that they dispense. The information that must be reported includes, but is not limited to, the name or the recipient, name of the prescription medication, the date the prescription was written, quantity dispensed and date of dispensing, name of the prescriber, and if the prescription is new or a refill. Reporting is not required for: (1) prescriptions dispensed for individuals residing in certain long-term care facilities or a Minnesota sex offender program facility, when the drug is distributed through an automatic drug distribution system; or (2) controlled substances dispensed as drug samples. (Minn. Stat. § 152.126, subd. 4).

Use of the Database

Physicians, pharmacists, and other specified individuals may access the program's database to:

1) identify individuals who obtain controlled substances from dispensers in quantities or with a frequency inconsistent with generally recognized standards
2) identify individuals who present forged or otherwise false or altered prescriptions
3) accomplish other purposes specified in state law

(Minn. Stat. § 152.126, subds. 5 and 6).

Required Registration and Maintenance of a User Account

Since July 1, 2017, every prescriber practicing within the state and authorized to prescribe controlled substances, and every pharmacist practicing within the state, is required to register and maintain a user account with the PMP. (Minn. Stat. § 152.126, subd. 6). However, prescribers are not required to consult the PMP database before prescribing opioids or other controlled substances to a patient.[17]

[17] Beginning October 1, 2021, federal law will require providers to consult the PMP database before prescribing a schedule II controlled substance to most MA enrollees (Support for Patients and Communities Act, Pub.L. No. 115-271, § 5042).

Opioid Antagonists – General Provisions

Administration of Opioid Antagonists by Police and Others

Law enforcement officers, emergency medical service (EMS) personnel, and the staff of community-based disease prevention or social service programs may administer opiate antagonists (naloxone)[18] if authorized through a standing order or protocol by a physician, APRN, or physician assistant authorized to prescribe drugs. The peace officer, emergency medical responder, or program staff must have had training in recognizing the signs of opioid overdose and using opioid antagonists. (Minn. Stat. § 151.37, subd. 12).

Board of Pharmacy Opiate Antagonist Protocol

Pharmacists may issue legally valid prescriptions for naloxone (and other prescription drugs) under the terms of a protocol established with a physician or other prescriber. (Minn. Stat. § 151.37, subd. 2). Technically, the pharmacist is not prescribing; the physician or other prescriber is considered to be the prescriber of record.

The Board of Pharmacy, at the direction of the 2016 Legislature, developed an opioid antagonist protocol.[19] This protocol is not mandatory--prescribers and pharmacists may develop and use another protocol, or choose not to participate in any protocol. The commissioner of health may designate a practitioner authorized to prescribe opioid antagonists to enter into this protocol with local pharmacists, upon the request of the applicable community health board. The commissioner and the practitioner are immune from civil liability or criminal penalty for prescribing, dispensing, distributing, or administering an opioid antagonist in good faith, under Minnesota Statutes, section 604A.04, subdivision 3. The intent of this provision is to expand the availability of naloxone through pharmacies, by allowing pharmacists who have not already entered into a guideline or protocol with a prescriber to enter into a protocol with the practitioner designated by the commissioner of health. (Minn. Stat. § 151.37, subd. 13).

Naloxone Training and Education

Minnesota law specifies training and education requirements for EMS and other personnel receiving opioid antagonists, persons undergoing comprehensive assessments, and the staff of certain treatment programs. The Opiate Antagonist Protocol developed by the Board of Pharmacy includes training requirements for individuals who request naloxone.

For an EMS responder, peace officer, or community health or social services staff member to receive an opioid antagonist, the individual must have training in the recognition of signs of opioid overdose and the use of opioid antagonists as part of the emergency response. (Minn. Stat. § 151.37, subd. 12; initially passed by the 2014 Legislature, Laws 2014, ch. 232, § 2).

[18] Minnesota Statutes, section 151.37, subdivision 12 uses the term "opiate antagonist," defined as "naloxone hydrochloride or any similarly acting drug approved by the federal Food and Drug Administration for the treatment of a drug overdose."

[19] Minnesota Board of Pharmacy, Opiate Antagonist Protocol, last revised Sept. 30, 2016. http://www.health.state.mn.us/divs/healthimprovement/content/documents/OpiateAntagonistProtocolRevision09302016.pdf

A person undergoing a comprehensive assessment for opioid use disorder must receive education on the use, availability, and administration of naloxone. (Minn. Stat. § 245G.05, subd. 1). In addition, a substance use disorder treatment license holder must require staff to undergo training on naloxone if the provider maintains a supply for emergency treatment. (Minn. Stat. § 245G.08, subd. 3).

Also, under the Board of Pharmacy's opiate antagonist protocol, a pharmacist dispensing naloxone must provide training, written information, and counseling to any individual who requests naloxone.

Treatment Facilities and Naloxone

Licensed substance use disorder treatment providers may maintain a supply of naloxone on site if they enter into a written standing order protocol with a physician and staff are trained to administer naloxone. (Minn. Stat. § 245G.08, subd. 3).

Opioid Antagonists – Good Samaritan Provisions[20]

Expanded Access to Opioid Antagonists: Standing Orders and Immunity

A licensed health care professional who is authorized to prescribe drugs may prescribe, dispense, distribute, or administer an opioid antagonist directly or by standing order, and has immunity from civil liability or criminal penalty for doing so in good faith. This immunity applies even if the opiate antagonist is administered by someone other than the person to whom it is prescribed, or administered to someone other than the person to whom it is prescribed. The effect of this provision is to expand access to opioid antagonists, by allowing prescribers to establish standing orders that allow a wide range of individuals and entities to be involved in the prescribing, distribution, dispensing, and administering of opioid antagonists to persons at risk for an opioid overdose, and to persons (e.g., friends and family members) who know of someone at risk for an opioid overdose. (Minn. Stat. § 604A.04, subd. 3). Related provisions of state law provide immunity to friends, family members, and others when they administer an opioid antagonist to a person suffering from an opioid overdose.

Immunity for Administration of Opioid Antagonists by Nonhealth Care Professionals

A person who is not a health care professional and who acts in good faith to administer an opioid antagonist to someone he or she believes is suffering a drug overdose is immune from criminal prosecution and civil liability resulting from that act. (Minn. Stat. § 604A.04, subd. 2).

Immunity for Seeking Medical Attention for Overdose

A person who in good faith seeks medical attention for another person who is experiencing a drug-related overdose is immune from criminal prosecution for specified crimes if:

[20] The provisions described in this section were initially passed by the 2014 Legislature (Laws of Minn. 2014, ch. 232, §§ 3 and 4).

1) the evidence used for the prosecution was obtained because of the person's seeking medical assistance; and
2) the person seeks medical attention for an immediate health or safety concern, and is the first person to do so. The person seeking medical attention must also provide a name and contact information, remain on the scene until medical assistance arrives, and cooperate with authorities.

(Minn. Stat. § 604A.05)

Disposal of Opioids and Other Controlled Substances

Disposal Generally

Controlled substances must be collected and disposed of according to federal regulations.[21] Disposal must also comply with the requirements of Minnesota Statues, section 116.07,[22] and related rules that apply to the disposal of hazardous waste. (Minn. Stat. § 152.105).

Disposal by Entities that Are Not Pharmacies

Minnesota law allows the following entities to dispose of prescription drugs:

- law enforcement agencies
- hazardous waste transporters that have notified the Pollution Control Agency (PCA)
- facilities permitted by the PCA to treat, store, or dispose of hazardous waste
- facilities licensed by the PCA or a metropolitan county as a very small quantity generator collection program or household hazardous waste collection program
- sanitary districts

When disposing of legend drugs that are controlled substances, these entities must follow the requirements of Minnesota Statutes, section 152.105, meaning they must comply with federal regulations and state laws and related rules that apply to the disposal of hazardous waste. (Minn. Stat. § 151.37, subd. 6).

Collection from Households and Long-term Care Facilities

Law enforcement agencies and pharmacies are the two types of sites in Minnesota that can accept discarded prescription drugs (including opioids) from households, long-term care facilities, and

[21] 21 C.F.R. parts 1300, 1301, 1304, 1305, 1307, and 1317. These are regulations issued by the DEA. Part 1317 specifies controlled substance disposal requirements for DEA registrants, methods of collecting controlled substances from ultimate users (normally the patients for whom the drug is prescribed) and nonregistrants, and methods and procedures for destroying controlled substances.

[22] Subdivision 2(d) of this section specifies the general duties of the Pollution Control Agency (PCA), which include adopting standards for the "management, identification, labeling, classification, storage, collection, transportation, processing, and disposal of hazardous waste." The PCA rules on hazardous waste disposal can be found in Minnesota Rules, chapter 7045. These rules, in part, classify types of hazardous waste, set standards for generators and transporters of hazardous waste, and set standards for facilities that treat, store, and dispose of hazardous waste.

schools.[23] Law enforcement agencies and pharmacies are not required to serve as collection sites for these prescription drugs.

Collection and Disposal by Pharmacies

The 2016 Legislature authorized pharmacies to collect and dispose of controlled substances in schedules II through V in compliance with the requirements of Minnesota Statutes, section 152.105, meaning they must comply with federal regulations on the collection and disposal of controlled substances, and state laws and related rules that apply to the disposal of hazardous waste.[24] (Minn. Stat. § 151.37, subd. 6a)

County Collection Receptacles

Each county sheriff is required to maintain, or contract for the maintenance of, a collection receptacle for the disposal of controlled substances and other legend drugs. The receptacles must comply with federal law.[25] The sheriff must maintain and operate the collection receptacles in compliance with federal regulations.[26] (Minn. Stat. § 152.105, subd. 2).

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[23] Minnesota Pollution Control Agency, Collecting Pharmaceuticals from Households and Long Term Care Facilities, February 2018.

[24] Minnesota Pollution Control Agency, Collecting Pharmaceuticals from Households and Long Term Care Facilities, https://www.pca.state.mn.us/sites/default/files/w-hhw2-07.pdf, February 2018; and Minnesota Pollution Control Agency, Collecting Pharmaceuticals from Households and Schools: Requirements for Law Enforcement Agencies, https://www.pca.state.mn.us/sites/default/files/w-hhw2-06.pdf, November 2016.

[25] Federal requirements for receptacles are specified in 21 Code of Federal Regulations, part 1317.75.

[26] 21 C.F.R. parts 1300, 1301, 1304, 1305, 1307, and 1317.