



Pharmacist Prescribing Protocol Opioid Antagonists

Background

Minn. Stats. §151.37, subd. 16, states the following:

“A pharmacist is authorized to prescribe opiate antagonists for the treatment of an acute opiate overdose . . . the board shall develop a standardized protocol for the pharmacist to follow in prescribing an opiate antagonist. In developing the protocol, the board shall consult with the Minnesota Board of Medical Practice; the Minnesota Board of Nursing; the commissioner of health; professional pharmacy associations; and professional associations of physicians, physician assistants, and advanced practice registered nurses.”

This protocol was developed by Board staff after consulting with the above-mentioned agencies and professional associations. It was approved at the Board’s December 30, 2020 meeting. Although the statutes use the phrase “opiate” antagonist, the more appropriate word to use is “opioid” – which includes both naturally occurring forms of opioids as well as synthetic forms such as fentanyl and methadone. Consequently, opioid will be used for this document. Pharmacists who independently prescribe opioid antagonists must follow *this* protocol. When prescribing per this protocol, the pharmacist is the prescriber-of-record.

Pharmacists can continue to issue legally valid opioid antagonist prescriptions through the use of other protocols that they enter into with a physician, advanced practice registered nurse (APRN), or physician assistant (PA) as allowed by [Minn. Stats. §151.01, subd. 27\(6\)](#) and [Minn. Stats. §151.37, subd. 2](#). They can also issue legally valid opioid antagonist prescriptions using the protocol that the Board developed for use by the Minnesota Department of Health, pursuant to [Minn. Stats. §151.37, subd. 13](#). When doing so, they would enter into the protocol with a local community health board medical consultant or the MDH Medical Director. (Information is available at: <https://www.health.state.mn.us/naloxone>). When working under these other protocols, the practitioner, not the pharmacist, is the prescriber-of-record.

Definitions

1. “Opioid antagonist” means naloxone or other product approved by the U.S. Food and Drug Administration for emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.
2. “Recipient” means the person to whom an opioid antagonist is being supplied. The recipient might be someone other than the person for whom the use of the opioid antagonist is intended.

General considerations

1. Pharmacists who use this protocol must keep a written copy of it at each location at which they issue prescriptions for or dispense an opioid antagonist. They must make a copy of the protocol available upon the request of a representative of the Board of Pharmacy. This protocol must list the names of each pharmacist who is issuing prescriptions for opioid antagonists at the location.
2. Before pharmacists can prescribe an opioid antagonist under this protocol, they must successfully complete a training program *specifically developed for prescribing* opioid antagonists for the treatment of an acute opioid overdose. The program must be offered by a college of pharmacy, by a continuing education provider that is accredited by the Accreditation Council for Pharmacy Education (ACPE), or a program approved by the Board. Any training program approved by the Board must be based upon the most recent recommendations for management of opioid overdoses issued by the Centers for Disease Control and Prevention (CDC), Minnesota Department of Health (MDH), Minnesota Department of Human Services (DHS), or the Institute for Clinical Systems Improvement (ICSI).
 - a. Upon the request of a representative of the Board, pharmacists must provide proof that they have completed the training.
 - b. Pharmacists may request Board approval of a continuing education program by downloading the [Continuing Education Program Approval Form for Non-ACPE Program Attendees](#), filling it out, and submitting it to the Board, along with information about the program. This form does *not* need to be submitted for a program offered by a college of pharmacy or by a continuing education provider that is accredited by ACPE.
 - c. Note that the program must be developed for the *prescribing* of opioid antagonists. For example, a continuing education program that deals only with the pharmacology of an opioid antagonist would not be sufficient.
3. Pharmacists and pharmacies are encouraged to post a notice or to otherwise alert customers that pharmacists may prescribe and dispense opioid antagonists.

Procedures

When an individual requests an opioid antagonist, or when a pharmacist in his or her professional judgement decides to advise an individual of the availability of opioid antagonist, the pharmacist shall complete the following steps:

1. Screen for the following (in the primary spoken language of the recipient, upon request and when possible):
 - a. Does the recipient understand that opioid antagonists can only be used for opioid overdoses and cannot be used for other drug overdoses?
 - b. Does the person to whom the opioid antagonist would be administered have a known hypersensitivity to the drug? (If yes, do not furnish).

- c. Provide training in opioid overdose prevention and recognition, the administration of the opioid antagonist, and in the appropriate response to an opioid overdose, including the need to pursue immediate, follow-up treatment (e.g., calling 911).

2. When an opioid antagonist is dispensed:

- a. The pharmacist shall provide the recipient with appropriate written information and with counseling on the product dispensed:
 - i. administration, including
 - a) an opioid antagonist may be administered in cases of unknown or mixed substance overdoses
 - b) an opioid antagonist should be administered if the patient's sensitivity to the drug is unknown
 - ii. effectiveness
 - iii. adverse effects
 - iv. storage conditions and shelf-life
 - v. information concerning "Steve's Law" which provides immunity from prosecution when an individual calls emergency services for an overdose
 - vi. a recommendation that 911 be called if the opioid antagonist is administered
 - vii. and any other information deemed necessary in the professional judgment of the pharmacist.

A pharmacist dispensing an opioid antagonist pursuant to this protocol shall not permit the recipient to waive the provision of the written information or the counseling required by this protocol. Whenever possible, the pharmacist should provide information, whether written or oral, to the recipient in the primary language of the recipient.

- b. The pharmacist shall provide the recipient with information about, and/or referrals to, substance abuse treatment resources if the recipient indicates interest in substance abuse treatment or recovery services.
- c. The pharmacist shall provide the recipient with information and appropriate resources concerning proper disposal of medications and needles/syringes. The pharmacist may also inform the recipient that the pharmacy is allowed to sell up to ten clean needles/syringes without a prescription.
- d. When applicable, the pharmacist should encourage the patient to discuss the risks of opioid overdose with prescribers who have issued opioid prescriptions.

Authorized drugs

1. Prescribing and dispensing done pursuant to this protocol is limited to FDA-approved opioid antagonist products. A pharmacist may not prescribe or dispense a compounded version of an opioid antagonist. A pharmacist may also recommend optional items when appropriate, such as alcohol pads, rescue breathing masks, and protective gloves.
2. In selecting a product for which a prescription will be issued, the pharmacist shall obtain sufficient information from the recipient to make a decision that is based on: products available; recipient or patient preference; how well the product can be administered by the individuals likely to be involved in administering the product; insurance coverage and other cost factors; and any other pertinent factor.

Records

The pharmacist must generate a written or electronic prescription for any opioid antagonist dispensed. The prescription must include all of the information required by [Minn. Stats. §151.01, subd. 16a](#). The prescription must be processed in the same manner that any other prescription is processed, pursuant to the applicable statutes and rules for the dispensing of prescription drugs. The prescription shall be kept on file and maintained for a minimum of two years, as required by the rules of the Minnesota Board of Pharmacy. Pharmacists are reminded that prescriptions paid for by Medicare and Medicaid must be kept on file for even longer periods of time.

Names of Pharmacists Who Will Be Prescribing Pursuant to this Protocol

Location at which prescribing will occur

Pharmacy or facility name: _____

Pharmacy of facility address: _____

Names of Prescribing pharmacists:

1) _____

2) _____

3) _____

4) _____

5) _____

6) _____

7) _____

8) _____

9) _____

10) _____