MINNESOTA BOARD OF PHARMACY

Opiate Antagonist Protocol

Background

This protocol has been prepared as required by Minnesota Session Laws, 2016 Regular Session, Chapter 124. This protocol was developed for the use of the Commissioner of Health to distribute to the medical consultants of community health boards or to be used by Minnesota Department of Health practitioners designated by the Commissioner. Pharmacists may also use this protocol when working in collaboration with other practitioners. Pharmacists are **not** required to use this protocol in order to be involved in the prescribing of opiate antagonists. Instead, they can work with a physician, advanced practice registered nurse (APRN) or physician assistant (PA) to develop a different protocol as allowed by Minn. Stats. §151.01, subd. 27(6).

Protocol

1. General considerations

    a. Pharmacists who enter into this protocol with a physician, APRN nurse, or PA are authorized to issue prescriptions for naloxone, in accordance with the provisions of this protocol. The physician, APRN or PA is considered to be the prescriber of record.

    b. Pharmacists who enter into this protocol must keep a written copy of it at each location from which they issue prescriptions or dispense naloxone. 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 name and contact information for the responsible practitioner and

each pharmacist working under the protocol. To the extent that a practitioner agrees to allow all pharmacists that work for a pharmacy, a chain of pharmacies or a health care system to participate in the protocol, the individual pharmacists do not need to be named.

c. While not required by law, the responsible practitioner and pharmacists should strongly consider completing appropriate training related to opioid overdoses and the use of naloxone, unless they have already done so. Examples of such training are:

i. Pharmacist Letter: **https://pharmacistsletter.therapeuticresearch.com/logon.aspx?bu=/ce/ceCourse.aspx?pc=16-242** (requires account)
ii. Boston College and SAMHSA Program: **http://www.opioidprescribing.com/naloxone_module_1-landing**
iii. College of Psychiatric & Neurologic Pharmacists: **https://cpnp.org/guideline/naloxone** (requires account)
iv. California Society of Addiction Medicine: **http://www.csam-asam.org/naloxone-resources**
v. Prescribe to Prevent Videos for Pharmacists, Prescribers and Patients: **http://prescribetoprevent.org/video/**
vi. Substance Abuse and Mental Health Service Administration SAMSHA: **http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2016/SMA16-4742**
vii. Emergency Medical Service Training **http://steverummlerhopefoundation.org/emergency-medical-service-training/**

2. Procedure

a. When an individual requests naloxone (or other opioid antagonist), or when a pharmacist in his or her professional judgement decides to advise an individual of the availability of naloxone (or other 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 naloxone would be administered have a known hypersensitivity to naloxone (if yes, do not furnish)?

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

c. When naloxone (or other opioid antagonist) is dispensed:

1) The pharmacist shall provide the individual to whom naloxone (or other opioid antagonist) is dispensed ("recipient") with appropriate written information and with counseling on the product dispensed, including information concerning administration, effectiveness, adverse effects, storage conditions, shelf-life, safety, and any other information deemed necessary in the professional judgment of the pharmacist. A pharmacist dispensing naloxone (or other 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.

2) 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.

3) The pharmacist shall provide the recipient with information and appropriate resources concerning proper disposal of medications and needles/syringes.

4) The pharmacist shall answer all questions the recipient may have regarding the naloxone (or other opioid antagonist) that is dispensed.

3. Authorized drugs.

    a. The issuance of prescriptions and the dispensing done pursuant to this protocol is limited to naloxone (or other appropriate opiate antagonist that may be developed). A pharmacist may supply naloxone hydrochloride as an intramuscular injection, intranasal spray, autoinjector or any other FDA- approved product. A pharmacist may not dispense a compounded version of naloxone. A pharmacist may also recommend optional items when appropriate, such as alcohol pads, rescue breathing masks, and protective gloves.

    b. In selecting a product for which a prescription will be generated, the pharmacist shall obtain sufficient information from the recipient to make a decision that is based on: products available; how well the product can be administered by the individuals likely to be involved in administering the product; and any other pertinent factor.

4. Records. The pharmacist must generate a written or electronic prescription for any naloxone dispensed. If a written prescription is prepared, it shall be signed in the following format: *[signature of pharmacist], R.Ph. per naloxone protocol with [name of practitioner], [credential – i.e. MD, DO, APRN, PA]*. 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.

5. Notification. If the recipient is the potential individual to whom the naloxone will be administered, the recipient is considered to be the patient. In that case, with patient consent, the pharmacist shall notify the patient's primary care provider of any drug or device dispensed. If the patient does not have a primary care provider, or does not consent to have the primary care provider notified, then

the pharmacist shall provide the recipient with a written record of the drug or device dispensed and advise the patient to consult an appropriate health care provider of the patient's choice.

Names and Contact Information of Responsible Practitioner and Pharmacists (enter below)

(Note: to the extent that a practitioner agrees to allow all pharmacists that work for a pharmacy, a chain of pharmacies or a health care system to participate in the protocol, the individual pharmacists do not need to be named. However, a statement indicating that all pharmacists may participate should be included).