# Opioid Antagonist STATEWIDE PROTOCOL

#### Iowa Board of Pharmacy

#### I. <u>Purpose</u>

For this protocol, "opioid antagonist" means an opioid antagonist approved by the United States Food and Drug Administration (FDA) for reversal of an opioid overdose. This statewide protocol is intended to ensure that an opioid antagonist may be readily obtainable by any person ("eligible recipient") who is:

- An individual at risk of opioid-related overdose.
- A family member, friend, or other person in a position to assist a person at risk of opioid-related overdose.
- A first responder employed by a law enforcement agency, fire department, or emergency service program if allowed by the first responder's scope of practice.
- A school employee.
- A patient who is prescribed an opioid pain reliever.
- A patient who is prescribed medication to treat opioid use disorder.

## II. <u>Authority</u>

Pursuant to <u>Iowa Code section 155A.46</u>, a pharmacist may order and dispense an opioid antagonist pursuant to a protocol developed by the Iowa Board of Pharmacy ("board") in consultation with the Department of Health and Human Services to individuals aged 18 years and older, only in accordance with this protocol. For this protocol, the pharmacist's order shall constitute a prescription. For this protocol, "pharmacist" shall include a licensed pharmacist or registered pharmacist-intern who has completed the training requirements identified in Section III (Qualification).

#### III. Qualification

A pharmacist shall document successful completion of a continuing education program approved by the Accreditation Council for Pharmacy Education (ACPE) of at least onehour duration related to overdose-reversal opioid antagonist utilization prior to dispensing an opioid antagonist pursuant to this protocol.

#### IV. <u>Authorization</u>

This protocol is authorization for a pharmacist to order and dispense an opioid antagonist and devices for its administration.

## V. <u>Order to dispense</u>

Upon satisfactory assessment that the person to receive an opioid antagonist is an eligible recipient pursuant to this statewide protocol, and upon completion of training regarding recognizing and responding to suspected opioid-related overdose, the pharmacist may dispense one or more opioid antagonist that is FDA-approved for the treatment of opioid overdose. The pharmacist shall utilize an assessment form provided by the board. The assessment shall include an attestation that the recipient will make available all received training materials to any individual that may be in a position to administer the opioid antagonist. The pharmacist shall determine the appropriate opioid antagonist to be dispensed. Each opioid antagonist dispensed shall include step-by-step instructions for administration of the opioid antagonist.

#### VI. <u>Patient education required</u>

Upon assessment and determination that the individual is eligible to receive and possess an opioid antagonist pursuant to this protocol, a pharmacist shall, prior to dispensing the opioid antagonist, provide training and education to the recipient including, but not limited to, the information identified herein. A pharmacist may provide to the recipient written materials that include, but may not be limited to, the information identified herein, but the written materials shall not be in lieu of direct pharmacist consultation with the recipient.

Training and education shall include:

- calling 911 and performing basic life support as needed.
- signs and symptoms of overdose.
- all possible adverse reactions, including withdrawal effects.
- appropriate use and directions of opioid antagonists, including readministration, proper storage, and expiration dating.
- If applicable, information about substance abuse or behavioral health treatment programs or use in pregnancy.

## VII. Labeling

A prescription label shall be affixed to the opioid antagonist as required in <u>rule 657</u>—<u>6.10(126,155A)</u>, except that the expiration date of the product shall not be rendered illegible. The prescription shall be dispensed in the name of the eligible recipient.

## VIII. <u>Records and reporting</u>

Each pharmacy shall maintain the original record of each assessment, regardless of the eligibility determination following assessment, and dispensing of an opioid antagonist to each eligible recipient. These records shall be available for inspection or copying by the board or its authorized agent for at least two (2) years from the date of assessment or the

date of dispensing, whichever is later. Opioid antagonist dispensing shall be reported to the Iowa Prescription Monitoring Program pursuant to <u>Iowa Code section 124.551(2)"a"</u>. As soon as reasonably possible, the pharmacist shall notify the recipient's primary health care provider of the opioid antagonist product dispensed to the recipient. If the recipient does not have a primary health care provider, the pharmacist shall provide the recipient with a written record of the opioid antagonist product dispensed and shall advise the recipient to consult a physician.

## IX. Effective date

This protocol is effective July 1, 2023 and shall be in effect unless otherwise amended or terminated by the board.