

State of Utah

SPENCER J. COX Governor

DEIDRE M. HENDERSON Lieutenant Governor

Department of Health & Human Services

TRACY S. GRUBER Executive Director

NATE CHECKETTS Deputy Director

DR. MICHELLE HOFMANN Executive Medical Director

DAVID LITVACK Deputy Director

NATE WINTERS Deputy Director

Utah Statewide Standing Order Dispensing Opioid Antagonists for Opioid Overdose Prevention

Purpose:

Opioid overdose can be reversed and death prevented by timely administration of an opioid antagonist. As authorized by State law, this standing order is intended to increase access to FDA approved opioid antagonists for those who might be at risk of an overdose or who might be in a position to assist someone at risk of an overdose.

Authority:

This standing order shall be considered a prescription for a FDA approved opioid antagonist for an eligible person or entity. This standing order authorizes a pharmacist to dispense a FDA approved opioid antagonist to any eligible person or entity. This standing order authorizes any eligible person or entity in the State of Utah, including but not limited to any wholesaler licensed in the State of Utah, to possess, store, deliver, distribute, or administer FDA approved opioid antagonists.

Pursuant to the authority provided in UCA 26B-4-510(2), this standing order authorizes a pharmacist licensed under UCA 58-17b Pharmacy Practice Act to dispense an opioid antagonist according to the provisions of UCA 26B-4-510 and R156-17b-625 and the requirements of this standing order.

Immunity:

UCA <u>\$26B-4-510</u> provides protection from civil liability for a pharmacist who dispenses an opioid antagonist according to this standing order.

Dispensing Guidelines:

The following individuals may receive a FDA approved opioid antagonist under this standing order:

- an individual who is at increased risk of experiencing an opioid overdose;
- a family member, friend or other person who could assist an individual at increased risk of an opioid overdose, including an individual on behalf of:
 - a law enforcement agency or correctional setting;
 - o the Utah Department of Health and Human Services;
 - a Utah local health department;
 - a community based organization (e.g., 501c3, churches, YMCAs, public libraries);
 - an organization that provides substance abuse or mental health treatment, recovery or support services;
 - o an organization that provides services to the homeless;
 - an organization that provides training in proper administration of an opioid antagonist;
 - an organization that provides harm reduction services;
 - Native American Tribal Communities;
 - o first responders (e.g., fire, emergency medical services);

- educational facilities;
- o schools; or
- an individual on behalf of an overdose outreach provider for use as provided in <u>UCA §26B-4-511</u>.

Authorized Products:

Opioid antagonist formulations may be dispensed under this standing order as long as they have been approved by the FDA. When dispensing a commercially packaged take-home kit, proper care should be given to make sure the recipient is aware of the type of kit they have and where instructions for the take home kit are located. Administration of these kits should be as directed.

Prices vary widely for the different products and reimbursement practices vary by insurer.

- Currently, some insurance plans cover naloxone, but not other forms of opioid antagonists. Check coverage and dispense based on coverage and pharmacy benefit criteria.
- Medicaid patients of record may be covered by their insurance. All forms of an opioid antagonist are covered by Medicaid without prior authorization for their patients.
- For patients without insurance coverage, referral can be made to any other local resource for which the pharmacy is aware. The Utah Department of Health and Human Services Executive Medical Director will not submit prior authorization forms for this standing order. If prior authorization is required for a particular product, another type of product should be provided that does not require prior authorization. The patient may also work with their healthcare provider to submit a prior authorization form on their behalf.

Reporting:

As required in <u>R156-17b-625</u>, the pharmacist-in-charge (or a responsible corporate officer) for each pharmacy licensee that dispenses an opioid antagonist under this standing order shall affirm that the pharmacy licensee has complied with the protocol in <u>UCA 26B-4-510</u> and shall report the following information:

- the total number of single doses dispensed during the reporting period; and
- the name of each product dispensed along with the total number of single doses of that particular product.

The report must be submitted no later than 10 days after December 31 of each calendar year through a link that will be provided to enrolled pharmacies by the Utah Department of Health and Human Services.

Registration:

Pharmacies that plan to dispense an opioid antagonist under this standing order are asked to voluntarily enroll with the Utah Department of Health and Human Services at https://pubredcap.health.utah.gov/surveys/?s=JJ7D8FYDAM.

In addition to any other requirements under Utah or federal law, the pharmacy licensee must keep the data specified in R156-17b-625(5).

Education:

Pharmacists who dispense an opioid antagonist under this order should understand the key warnings established by the FDA's Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee, including:

- risk of recurrent respiratory and CNS depression as the duration of effect of an opioid antagonist may be shorter than the opioids being antagonized. It is recommended that medical care is sought, surveillance maintained, and additional doses administered, if needed;
- risk of limited efficacy with partial agonists or mixed agonists/antagonists;

- abrupt postoperative reversal of opioid depression may result in adverse cardiovascular effects, primarily in patients who had preexisting cardiovascular disorders or received other drugs that may have similar adverse cardiovascular effects; and
- precipitation of severe opioid withdrawal, particularly in opioid dependent patients and neonates. It is recommended these patients be monitored for the development of opioid withdrawal.

Educational materials to provide to an individual when an opioid antagonist is dispensed and educational materials for dispensers can be found at https://opidemic.utah.gov/resources/. Naloxone training can be found at https://opidemic.utah.gov/naloxone/naloxone-training/.

Effective Period for this Order:

The Utah Department of Health and Human Services will review this standing order and request input from the Utah Board of Pharmacy as new information becomes available to provide recommendations and support of revisions prior to a re-issue as needed or at least every 2 years.

Michelle Hofmann (Oct 26, 2023 18:04 MDT)

10/26/2023

Michelle G. Hofmann, MD, MPH, MHCDS, FAAP **Executive Medical Director** Utah Department of Health and Human Services

Date

DEA Number: BH8966321 NPI Number: 1760550628