Free NARCAN® Nasal Spray High School Program Order and Terms and Conditions

The High School and/or State School District identified below (herein, the "School") hereby acknowledges and agrees the NARCAN® (naloxone hydrochloride) Nasal Spray 4mg ("NARCAN®", NDC # 69547-353-02) will be made available and distributed by Emergent Devices Inc. (formerly known as Adapt Pharma Inc.) ("Emergent") to the School free of charge under the *Free NARCAN®* (naloxone hydrochloride) Nasal Spray High School Program. This program is conditioned upon the undersigned completing the following certification and the School represents and warrants to Emergent the following:

- 1. The undersigned is a school or school district whose primary purpose is education for students in grades 9 through 12 and is licensed as an educational facility.
- 2. The School will only receive and use NARCAN® Nasal Spray in accordance with all applicable laws, rules and regulations. In addition, the School will provide to Emergent the appropriate medical license of the registered medical advisor representing the School.
- 3. The School is solely responsible for the proper and safe usage of the product, and training of any school personnel who administer NARCAN® Nasal Spray. Narcan® Nasal Spray is to be used strictly in accordance with its Full Prescribing Information and Instructions for Use, available below. By signing below you certify that you have read and understood the Full Prescribing Information and Instructions for Use, including but not limited to the product indications and safety information, and that your institution will indemnify Emergent against any and all claims regarding the administration of the NARCAN® Nasal Spray product.
- 4. NARCAN® Nasal Spray received by the School will be for the School's own use and the School shall not sell or transfer NARCAN® Nasal Spray received pursuant to the Free NARCAN® Nasal Spray High School Program to any non-school third party.
- 5. NARCAN® (naloxone hydrochloride) 4mg Nasal Spray received under this program is not returnable or refundable.
- 6. The order quantity pursuant to the Free NARCAN® Nasal Spray High Schools Program is limited to **two units per School**.
- 7. Emergent will fulfill or refuse orders, or amend the Terms and Conditions, or discontinue the Free NARCAN® Nasal Spray Program, at its sole discretion. The individual signing the Order and Terms and Conditions has all requisite authority to do so on behalf of the School. All of the information provided by the School is true, complete and accurate.
- 8. Except for the foregoing, it is understood that NARCAN® Nasal Spray is being provided to your school without any quid pro quo or other expectation of benefit by Emergent of any kind.

I have read and certify to the foregoing terms and conditions:

Licensed Prescriber (MD, DO, PA, NP) Mark A. Levine, MD Print Name Name of School *Please see page 2 if requesting for multiple schools* See Attached Signature Address (Please provide physical address - PO Boxes not accepted) 8/31/21 Date NPI: 1790793214 Vermont License: 042.0008661 Prescriber License # / State of Licensure Telephone Number Contact Person Email

Please scan/email the signed & completed Certification Form to Emergent Devices Inc. For program questions, please call Customer Operations @ 844-232-7811.

Scan/Email: schoolsprogram@ebsi.com

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If the requesting organization is a School District representing multiple/individual schools, a listing of all schools (including addresses) that will receive the free NARCAN® " $\check{s}^-\check{s}^{"}$ ¬ $\mathfrak{B}\mu$ product must be provided. Please list them below:

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NARCAN® NASAL SPRAY INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATIONS

NARCAN® (naloxone hydrochloride) Nasal Spray is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. NARCAN® Nasal Spray is intended for immediate administration as emergency therapy in settings where opioids may be present. NARCAN® Nasal Spray is not a substitute for emergency medical care.

IMPORTANT SAFETY INFORMATION

NARCAN® Nasal Spray is contraindicated in patients known to be hypersensitive to naloxone hydrochloride.

Seek emergency medical assistance immediately after initial use, keeping the patient under continued surveillance.

<u>Risk of Recurrent Respiratory and CNS Depression</u>: Due to the duration of action of naloxone relative to the opioid, keep the patient under continued surveillance and administer repeat doses of naloxone using a new nasal spray with each dose, as necessary, while awaiting emergency medical assistance.

<u>Risk of Limited Efficacy with Partial Agonists or Mixed Agonists/Antagonists</u>: Reversal of respiratory depression caused by partial agonists or mixed agonists/antagonists, such as buprenorphine and pentazocine, may be incomplete. Larger or repeat doses may be required.

<u>Precipitation of Severe Opioid Withdrawal</u>: Use in patients who are opioid dependent may precipitate opioid withdrawal characterized by body aches, diarrhea, increased heart rate (tachycardia), fever, runny nose, sneezing, goose bumps (piloerection), sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated and may be characterized by convulsions, excessive crying, and hyperactive reflexes. Monitor for the development of opioid withdrawal.

Risk of Cardiovascular (CV) Effects: Abrupt postoperative reversal of opioid depression may result in adverse CV effects. These events have primarily occurred in patients who had pre-existing CV disorders or received other drugs that may have similar adverse CV effects. Monitor these patients closely in an appropriate healthcare setting after use of naloxone hydrochloride.

The following adverse reactions were observed in a NARCAN® Nasal Spray clinical study: increased blood pressure, musculoskeletal pain, headache, nasal dryness, nasal edema, nasal congestion, and nasal inflammation.

See Instructions for Use and full prescribing information in the use of this product. Click here

To report SUSPECTED ADVERSE REACTIONS, contact Emergent Devices Inc. (formerly known as Adapt Pharma Inc.) at 1-844-4NARCAN (1-844-462-7226) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.



Standing Order for Distribution of Naloxone Prescription for Overdose Prevention.

Medication Covered by this order: Naloxone Hydrochloride (including Narcan® and Evzio) is a medication indicated for reversal of opioid overdose in the event of a drug overdose that is the result of consumption or use of one or more opioid related drugs causing a drug overdose event. It is contraindicated in patients known to be hypersensitive to naloxone hydrochloride.

I. Purpose

This Standing Order is intended to ensure that residents of the State of Vermont who are at risk of experiencing an opioid-related overdose, or who are family members, friends or other persons who are in a position to assist a person at risk of experiencing an opioid-related overdose (Eligible Persons), are able to obtain naloxone. This Order is not intended to be used by organizations who employ or contract with medical staff who are authorized to write prescriptions. Such organizations should utilize the medical professionals with whom they have a relationship to write prescriptions specific to personnel who would be expected to train in the administration of naloxone.

II. Authority

This Standing Order is issued pursuant to 18 V.S.A. § 4240 (c)(1) which permits health care professionals otherwise authorized to prescribe naloxone to prescribe it via standing order to Eligible Persons.

III. Authorization

This standing order may be used by Eligible Persons as a prescription or third-party prescription to obtain naloxone. This order is authorization for pharmacists to dispense naloxone and devices for its administration in the forms prescribed herein.

Eligible Persons should be provided with the following:

- 1. Naloxone/ Narcan Nasal Spray
- 2. Patient information pamphlet with overdose prevention information and step-by-step instructions for overdose response and naloxone administration, and information regarding accessing services including <u>VT Helplink.org</u>

IV. Training, Instructional Materials, and Liability

Prior to obtaining naloxone under this standing order, Eligible Persons shall review instructional materials or complete a training program approved by the Vermont Department of Health such as the one found online at:

https://www.healthvermont.gov/naloxone

Persons who administer naloxone to a person shall be immune from civil or criminal liability so long as he or she believes, in good faith, that the victim is experiencing an opioid-related overdose, and he or she immediately calls for emergency medical services if medical assistance has not yet been sought or is not yet present. A healthcare professional who dispenses or distributes naloxone to persons at risk of experiencing an opioid-related overdose; or a family member, friend, or other person in a position to assist a person at risk shall be immune from civil or criminal liability with regard to the subsequent use of the naloxone¹.

V. Signs and Symptoms of Opioid Overdose

- 1. Unresponsive or unconscious individuals
- 2. Not breathing or slow/shallow respirations
- 3. Snoring or gurgling sounds (due to inadequate breathing)
- 4. Blue lips and/or nail bed
- 5. Pinpoint pupils

Note that individuals in cardiac arrest from all causes share many symptoms with someone with an opioid overdose (unresponsiveness, not breathing, snoring/gurgling sounds and blue skin/nail beds). If there is no pulse, these individuals are in cardiac arrest and require CPR.

VI. Appropriate Use and Directions

Eligible Persons should be aware of the following information when responding to a person who is having a suspected opioid overdose event:

- 1. Call 911 for EMS to be dispatched.
- 2. Naloxone should only be given to someone suspected of opioid overdose as noted in the signs and symptoms listed in Section V above.
- 3. In respiratory arrest or a non-breathing patient: If able to do rescue breathing, rescue breathing takes priority over naloxone administration. If possible also administer naloxone.
- 4. The naloxone should be administered in accordance with the medication's instructions.

For Intra-nasal Narcan Nasal Spray Instructions:

- A. Insert the end of the device into the nostril of the victim. Push the middle portion of the nasal device to spray 4 mg of naloxone into one nostril.
- B. Continue to monitor breathing and pulse. If not breathing, give rescue breathing and chest compressions (2 rescue breaths for every 30 chest compressions) until they are breathing on their own.

¹ See http://legislature.vermont.gov/statutes/section/18/084/04240.

- C. If the person is breathing on their own, place them in the recovery position on to their left side.
- 5. Remain with the person, monitoring their breathing and pulse until they are awake or under care of a medical professional, such as a physician, nurse, or EMS.

Note: In cardiac arrest or pulseless patients: Call 911 for EMS and start CPR if able and trained to do so. In cardiac arrest, CPR is the most important treatment and any attempt to administer naloxone should not interrupt chest compressions and rescue breathing.

VII. Key Information for Persons Carrying naloxone

- 1. If you believe someone is experiencing an opioid overdose, call 911 immediately.
- Remain with the person until first responders arrive. State Law provides that if you seek
 medical assistance for someone who is experiencing a drug overdose, you shall not be
 cited, arrested, or prosecuted for the possession of regulated drugs at the scene of the
 overdose if you call 911, provide all necessary information and remain with the person
 in distress.
- 3. Become familiar with how to use naloxone before someone needs it, by receiving training from your pharmacist, your medical provider, or go to the VDH website at https://www.healthvermont.gov/naloxone
- 4. Be aware that persons who have been administered naloxone are often confused momentarily after regaining consciousness.

VIII. Review

This standing order shall remain in effect until August 31, 2023, unless earlier revoked. This standing order will be reviewed and updated if there is relevant new science about naloxone administration, or if the current Commissioner of Health ceases being Commissioner.

Mark A. Levine, MD, Commissioner

<u>8/31/21</u>

Effective Date

Information for Pharmacists:

Mark A. Levine, MD NPI: 1790793214

Vermont License: 042.0008661

Vermont Department of Health, 108 Cherry Street, Burlington, VT 05401 802-863-7280