(08_25) MED-NMF-US-00020 OPVEE P&T-DUR Written Res

Uploaded by: Alonzo Whyte
Position: FAV

OPVEE® (nalmefene) nasal spray

To Whom it May Concern:

Thank you for your interest in OPVEE® (nalmefene) nasal spray. As requested, an overview of OPVEE®, including the clinical development program and safety, is provided below. Please see the full Prescribing Information for complete efficacy and safety data. Should you wish to discuss further, please contact your Indivior Medical Outcomes and Value Liaison (MOVL).

OPVEE® is for emergency treatment of known or suspected overdose induced by natural or synthetic opioids in patients 12 years and older, as manifested by respiratory and/or central nervous system depression. OPVEE® is for immediate administration as emergency therapy in settings where opioids may be present and is not a substitute for emergency medical care.

OPVEE® is contraindicated in patients who are allergic to nalmefene or any of the other ingredients. Additional Important Safety Information is provided later in the document.

OPVEE® is for intranasal use only, in a ready to use device with no assembly required. OPVEE® does not need to be primed prior to administration. OPVEE® delivers its entire contents automatically, upon activation. OPVEE® should not be reused as each unit-dose device contains a single dose of nalmefene.

OPVEE® should be administered as quickly as possible because prolonged respiratory depression may result in damage to the central nervous system or death and emergency medical assistance should be sought after administration of the first dose of OPVEE® in the event of a suspected, potentially life-threatening opioid emergency. Patients should remain under continued surveillance until emergency personnel arrive. Additional doses of OPVEE® may be required until emergency medical assistance becomes available. OPVEE® may be re-administered using a new nasal spray, in the nose, every 2 to 5 minutes if the patient does not respond or responds and then relapses into respiratory depression. OPVEE® should be administered according to the printed instructions on the Quick Start Guide and the Instructions for Use.

OPVEE® is available as a unit-dose nasal spray that delivers available as 2.7 mg nalmefene (equivalent to 3 mg of nalmefene hydrochloride) in 0.1 mL. Each carton contains two unit-dose nasal spray devices.

Please continue to next page for more information on the clinical development program and safety.

PHARMACOKINETIC (PK) STUDIES (OPNT003-PK-001 and OPNT003-PK-002)

PHARMACOKINETIC EVALUATION OF INTRANASAL NALMEFENE (OPNT003-PK-001)

Study Overview

- In a cross-over pharmacokinetic study of 68 healthy adult volunteers, the relative bioavailability of one 2.7 mg OPVEE® nasal spray in one nostril was compared to a single dose of nalmefene 1.0 mg administered as an intramuscular injection. The pharmacokinetic parameters obtained in this study are shown in Table 1 and the plasma concentration time profiles are presented in Figure 1. The safety and tolerability of OPVEE® was also evaluated.

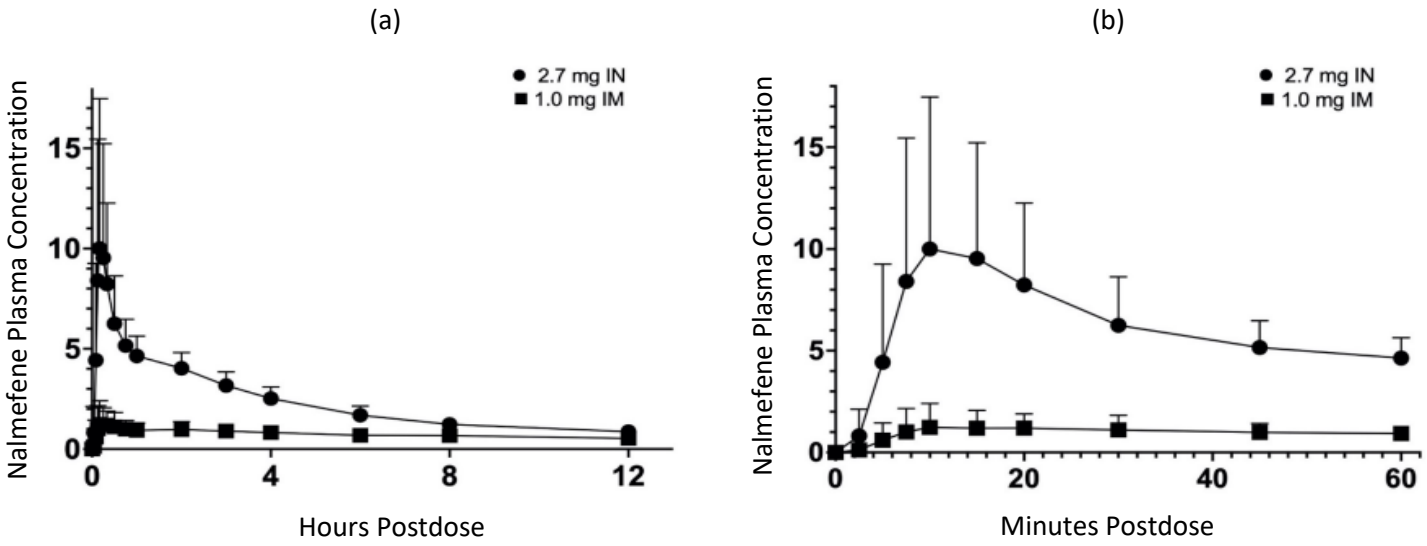
Study Results

Table 1: PK Parameters of Nalmefene after IN Administration of 2.7 mg OPVEE® and IM Administration of 1.0 mg of Nalmefene

PK parameters	OPVEE® 2.7 mg	Nalmefene IM 1.0 mg
T_{max} (h)[a]	0.250 (0.0833-2.00)	0.33 (0.117-18.0)
C_{max} (ng/mL)[b]	10.4 (62.6)	1.50 (59.4)
$T_{1/2}$ (h)[b]	11.4 (20.8)	10.6 (18.5)
F_{rel}[b]	0.806 (10.9)	NA

[a]: T_{max} (h): Time to reach max concentration in hours—presented as median (range); [b]: Arithmetic mean (Coefficient of variation percentage); C_{max}(ng/mL): Max concentration; F_{rel} : Mean bioavailability; IM: Intramuscular; IN: Intranasal; NA: Not applicable; $T_{1/2}$ (h): Half-life in hours.

Figure 1: Mean Plasma Concentration-Time Profiles of Nalmefene (a) 0-12 hours and (b) 0-60 minutes Following IN Administration of OPVEE® (2.7 mg) and IM Injection of Nalmefene (1.0 mg)



Values represent the mean and standard deviation (n=68)

- Most common adverse reactions were nasal discomfort and dizziness.
- The relative frequencies of treatment-related common adverse events that occurred in greater than 5% of healthy adult volunteers in OPNT003-PK-001 are presented in Table 3 on page 5.

PHARMACOKINETIC EVALUATION OF INTRANASAL NALMEFENE USING THREE DOSING REGIMENS (OPNT003-PK-002)

Study Overview

- In a second cross-over pharmacokinetic study of 24 healthy adult volunteers, the pharmacokinetics of OPVEE® were evaluated when given as three different dosing regimens. The safety and tolerability of OPVEE® was also evaluated.
- Volunteers were exposed to one spray of OPVEE® in one nostril, one spray of OPVEE® in each nostril, and two sprays of OPVEE® in one nostril.

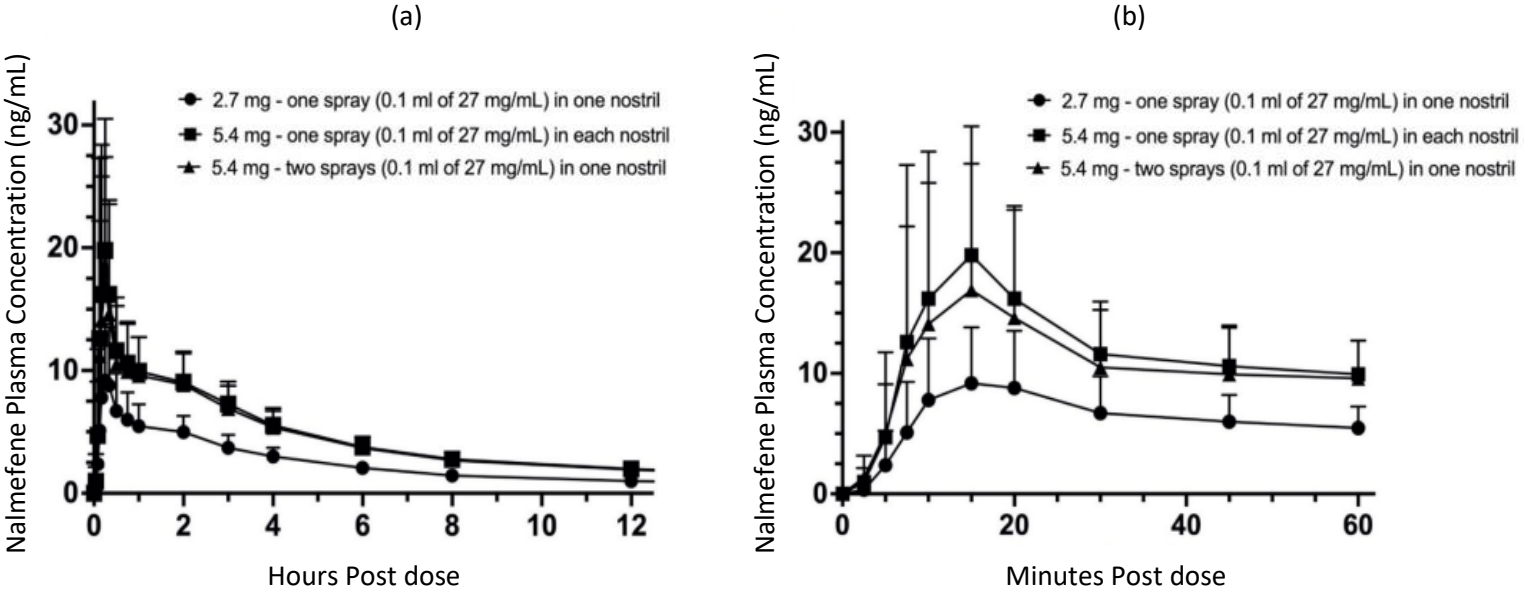
Study Results

Table 2: PK Parameters of Nalmefene After IN Dose of 2.7 mg Nalmefene (One OPVEE® nasal spray in One Nostril), IN Dose of 5.4 mg Nalmefene (One OPVEE® nasal spray in Each Nostril) and IN Dose of 5.4 mg Nalmefene (Two OPVEE® nasal sprays in One Nostril)

PK parameters	OPVEE® 2.7 mg (one spray)	IN Nalmefene 5.4 mg (one OPVEE® spray in each nostril)	IN Nalmefene 5.4 mg (two OPVEE® sprays in one nostril)
T_{max} (h)[a]	0.267 (0.167-2.03)	0.250 (0.117-3.00)	0.250 (0.117-2.03)
C_{max} (ng/mL)[b]	9.75 (49.4)	18.9 (88.0)	16.1 (62.9)
$T_{1/2}$ (h)[c]	11.4 (22.0)	11.3 (16.6)	11.3 (16.5)

[a]: T_{max} (h): Time to reach max concentration in hours—presented as median (range); [b]: C_{max}(ng/mL): Max concentration—presented as geometric mean (coefficient of variation percentage); [c]: $T_{1/2}$ (h): Half-life in hours—presented as arithmetic mean (coefficient of variation percentage); IN: Intranasal.

Figure 2: Mean Plasma Concentration of Nalmefene, (a) 0-12 hours and (b) 0-60 minutes Following IN Administration of 2.7 mg Nalmefene (One OPVEE® nasal spray in One Nostril), IN Dose of 5.4 mg Nalmefene (One OPVEE® nasal spray in Each Nostril) and IN Dose of 5.4 mg Nalmefene (Two OPVEE® nasal sprays in One Nostril)



Values represent the mean and standard deviation (n=24)

- Most common adverse reactions were pain in the nose, nasal congestion, nasal discomfort and nausea.
- The relative frequencies of treatment-related common adverse events that occurred in greater than 5% of healthy adult volunteers in OPNT003-PK-002 are presented in Table 3 on page 5.

PHARMACODYNAMIC (PD) STUDY (OPNT003-OOD-001)

PHARMACODYNAMIC EVALUATION OF INTRANASAL NALMEFENE (OPNT003-OOD-001)

Study Overview

- The effect of 2.7 mg OPVEE® on remifentanil-induced respiratory depression in an experimental ventilatory-response to hypercapnia model, assessed by changes in minute ventilation (MV), was evaluated in 61 opioid-experienced, non-dependent volunteers.
- Volunteers received a hypercapnic gas mixture (50% O2, 43% N2, 7% CO2) at -25 minutes. Just prior to initiation of remifentanil infusion at -15 minutes is the baseline MV (marked as 100% in Figure 3 and marked as observed data as liters/minute in Figure 4).
- Fifteen minutes after initiating remifentanil infusion, nadir in MV is observed at time zero, at which point OPVEE® was administered. The subjects were then monitored for changes in MV over 120 minutes.

Study Results

- Following OPVEE® administration the time to onset of effect, that is onset of reversal of respiratory depression, was observed between 2.5 to 5 minutes (Figure 3 and Figure 4).
- At 5 minutes the estimated mean increase in MV was 5.745 L/min (Figure 3).
- Full recovery of respiratory drive was noted between 5 and 15 minutes after OPVEE® administration (Figure 3 and Figure 4).

Figure 3: Percentage recovery of respiratory drive after infusion of remifentanil in CO2 stimulated MV (mean +/- SD) in adult healthy volunteers treated with OPVEE®

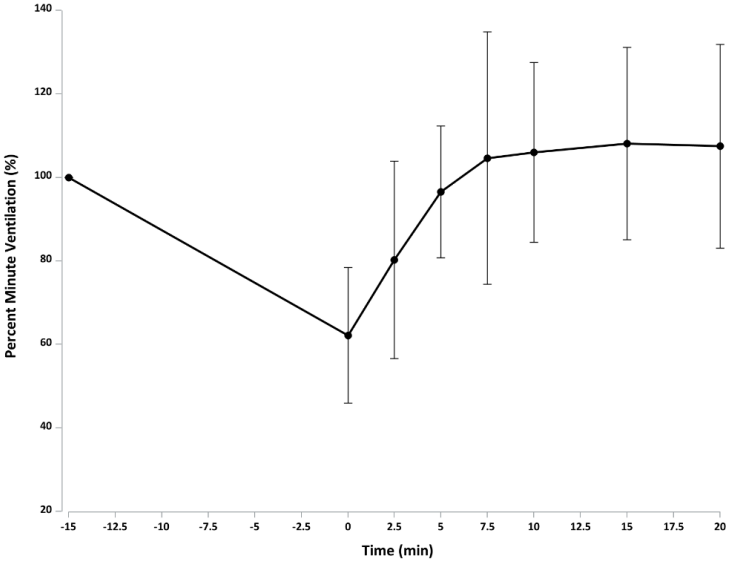
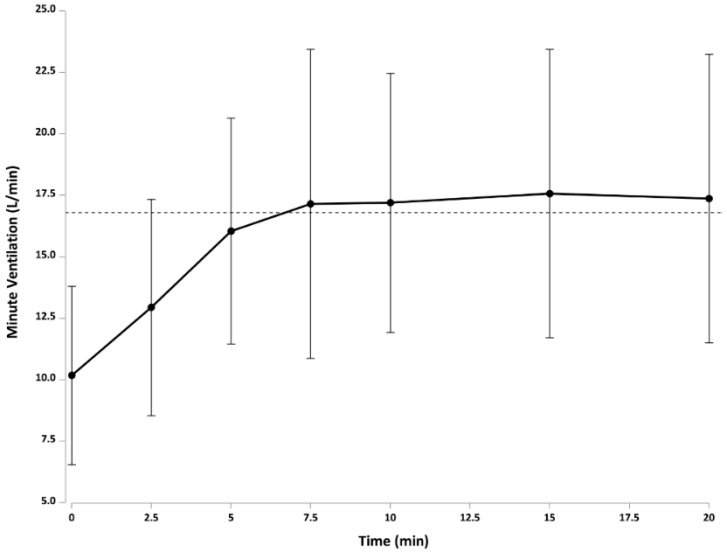


Figure 4: Reversal of Remifentanil-Induced Respiratory Depression (Mean MV +/- SD) by OPVEE®



Remifentanil (an initial bolus of 0.5 µg/kg dose followed by an infusion rate of 0.175 µg/kg/min) was administered for 15 min prior to test agents and continued for the duration of the study. In Figure 4, the dashed line represents the mean minute ventilation (MV) prior to remifentanil administration.

CO2: carbon dioxide; Min: minute; MV: minute ventilation; SD: standard deviation

- Most common adverse reactions were headache, nausea, hot flush and dizziness.
- The relative frequencies of treatment-related common adverse events that occurred in greater than 5% of healthy adult volunteers in OPNT003-OOD-001 are presented in Table 3 on page 5.

SAFETY OUTCOMES FOR PK AND PD STUDIES (OPNT003-PK-001, OPNT003-PK-002, AND OPNT003-OOD-001)

Table 3: Relative Frequencies of Treatment-Related Common Adverse Events That Occurred in Greater Than 5% of Healthy Adult Volunteers

System Organ Class Preferred Term	OPVEE® 2.7 mg			IN Nalmefene 5.4 mg	
	Total 2.7 mg n (%)	PD Study n (%)	PK Studies n (%)	PK Study (One OPVEE® spray in each nostril) n (%)	PK Study (Two OPVEE® sprays in one nostril) n (%)
Total	**N=150**	**N=61**	**N=89**	**N=23**	**N=24**
Respiratory, thoracic and mediastinal disorders					
Nasal discomfort	43 (28.7%)	5 (8.2%)	38 (42.7%)	3 (13.0%)	3 (12.5%)
Nasal congestion	6 (4.0%)	2 (3.3%)	4 (4.5%)	1 (4.3%)	4 (16.7%)
Rhinalgia (pain in the nose)	4 (2.7%)	1 (1.6%)	3 (3.4%)	2 (8.7%)	6 (25.0%)
Nervous system disorders					
Headache	40 (26.7%)	34 (55.7%)	6 (6.7%)	1 (4.3%)	0
Dizziness	14 (9.3%)	9 (14.8%)	5 (5.6%)	0	1 (4.2%)
Gastrointestinal disorders					
Nausea	25 (16.7%)	22 (36.1%)	3 (3.4%)	5 (21.7%)	1 (4.2%)
Vomiting	9 (6.0%)	7 (11.5%)	2 (2.2%)	1 (4.3%)	0
Vascular disorders					
Hot flush	12 (8.0%)	12 (19.7%)	0	0	0
Psychiatric disorder					
Anxiety	7 (4.7%)	7 (11.5%)	0	0	0
Skin and subcutaneous tissue disorders					
Hyperhidrosis (increased sweating)	3 (2.0%)	3 (6.6%)	0	0	1 (4.2%)

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS

Risk of Recurrent Respiratory and Central Nervous System Depression: While the duration of action of nalmefene is as long as most opioids, a recurrence of slowed breathing (respiratory depression) is possible after treatment with OPVEE®. Watch patients and give repeat doses of OPVEE® using a new device, as necessary, while awaiting emergency medical assistance.

Risk of Limited Efficacy with Partial Agonists or Mixed Agonists/Antagonists: Improvement in respiratory depression caused by medicines such as buprenorphine and pentazocine may not be complete. Repeat doses of OPVEE® may be required.

Precipitation of Severe Opioid Withdrawal: Use in patients who are opioid dependent may cause symptoms of opioid withdrawal like body aches, fever, sweating, runny nose, sneezing, goose bumps, yawning, weakness, shivering or trembling, nervousness, restlessness or irritability, diarrhea, nausea or vomiting, abdominal cramps, increased blood pressure, and rapid heart rate. Some patients may become aggressive when an opioid overdose is treated.

Abrupt postoperative reversal of opioid depression may result in adverse cardiovascular (CV) effects. These events have primarily occurred in patients with preexisting CV disorders or who received other drugs with similar adverse CV effects. Monitor these patients closely in an appropriate healthcare setting.

In newborns, opioid withdrawal may be life-threatening if not recognized and properly treated and may also include convulsions, excessive crying, and hyperactive reflexes.

Risk of Opioid Overdose from Attempts to Overcome the Blockade: Taking large or repeated doses of opioids, such as heroin or prescription pain pills to overcome blockade, may lead to opioid intoxication and death.

ADVERSE REACTIONS

Most common adverse reactions (incidence at least 2%) are nasal discomfort, headache, nausea, dizziness, hot flush, vomiting, anxiety, fatigue, nasal congestion, throat irritation, pain in the nose, decreased appetite, changes in sense of taste, skin redness, and increased sweating.

To report a pregnancy or side effects associated with taking OPVEE® or any safety related information, product complaint, request for medical information, or product query, please contact PatientSafetyNA@indivior.com or 1-877-782-6966.

See accompanying full Prescribing Information, or for more information about OPVEE®, visit www.OPVEE.com.

References:

1. Prescribing Information for OPVEE®.

SB 408 - Public Health - Opioid Overdose Reversal

Uploaded by: Andrea Mansfield

Position: FAV

Maryland Chiefs of Police Association
Maryland Sheriffs' Association

MEMORANDUM

TO: The Honorable Pamela Beidle, Chair and
Members of the Senate Finance Committee

FROM: Darren Popkin, Executive Director, MCPA-MSA Joint Legislative Committee
Andrea Mansfield, Representative, MCPA-MSA Joint Legislative Committee
Natasha Mehu, Representative, MCPA-MSA Joint Legislative Committee

DATE: February 20, 2024

RE: **SB 408 - Public Health – Opioid Overdose Reversal Drugs – Standing Orders**

POSITION: SUPPORT

The Maryland Chiefs of Police Association (MCPA) and the Maryland Sheriffs' Association (MSA) SUPPORT SB 408. This bill requires standing orders issued by a licensed health care provider to allow individuals to choose any formulation of opioid reversal drug approved by the Federal Food and Drug Administration (FDA).

MCPA and MSA are composed of leadership from local law enforcement agencies who protect the safety and well-being of more than 16,000 officers across the state. Our officers are often the first to respond to overdose situations. Officers need the tools to save the lives of those who may be overdosing, but also need to protect themselves from substances that may be laced with fentanyl. In 2022, a deputy sheriff in Indiana collapsed after coming into contact with fentanyl while patting down a suspect. This could easily occur right here in Maryland.

MCPA and MSA are aware of several forms of opioid overdose reversal medications approved by the FDA and believe access to all options could benefit individuals experiencing overdoses and officers in the field. As we work together as a State to address the opioid epidemic, MCPA and MSA believe access should be provided to ALL tools to keep Marylanders and officers alive.

For these reasons, MCPA and MSA strongly SUPPORT SB 408 and urge a favorable committee report.

532 Baltimore Boulevard, Suite 308
Westminster, Maryland 21157
667-314-3216 / 667-314-3236

SB408_ERC_FAV.pdf
Uploaded by: Corrie Simkin-Brocato
Position: FAV

February 20, 2024

Senate Finance Committee

Senate Bill 408- Public Health - Opioid Overdose Reversal Drugs - Standing Orders

POSITION: FAVORABLE

We are writing to support Senate Bill 408 - Public Health - Opioid Overdose Reversal Drugs - Standing Orders. As Managing Partners of Elevate Recovery Centers, an outpatient substance use treatment provider located in Maryland, we see firsthand the impact of opioid use-related overdoses on our community. Increasing access to opioid overdose reversal drugs will save lives and give more individuals an opportunity for recovery.

SB408 is designed to enhance the accessibility and autonomy in the use of opioid overdose reversal drugs. The bill mandates that licensed health care providers with prescribing authority must allow individuals the choice of any FDA-approved opioid reversal drug formulation when issuing a standing order. Key points of the bill include:

A standing order, as defined by the bill, is a written instruction for prescribing and dispensing an opioid overdose reversal drug approved by the FDA. This standing order can be issued by licensed health care providers who either work for the Department of Health or a local health department, or who have a written agreement with an authorized entity.

When issuing a standing order for an opioid reversal drug, the prescribing health care provider must allow individuals to choose any formulation of any opioid reversal drug that has been approved by the FDA. This provision aims to provide patients with greater control over their treatment options and ensure they have access to the most suitable medication for their needs.

Licensed health care providers who issue a standing order can delegate the dispensing of FDA-approved opioid overdose reversal drugs to employees or volunteers of authorized entities, ensuring broader access to these life-saving medications.

Pharmacists are permitted to dispense FDA-approved opioid overdose reversal drugs in accordance with a therapy management contract, further expanding access to these crucial treatments.

The bill is set to take effect on October 1, 2024, and represents a significant step towards improving public health responses to the opioid crisis by ensuring that individuals at risk of opioid overdose, or those in a position to assist someone at risk, have timely and unrestricted access to opioid overdose reversal drugs.

It is for these reasons that we politely ask for a favorable report on Senate Bill 408. Thank you.

Nicholas Acosta
Managing Partner
Elevate Recovery Centers

Basile Ferro
Managing Partner
Elevate Recovery Centers

Standing Order -- Kentucky.pdf
Uploaded by: Eric Gally
Position: FAV

** Pharmacy Provider Notice #310- Opioid Antagonist Provider Protocol & OTC Naloxone Coverage **

September 5th, 2023

The Department for Medicaid Services (DMS) remains committed to ensuring Kentucky Medicaid members have access to life saving medications used for preventing and responding to opioid overdose.

Attached to this notice you will find an updated statewide Opioid Antagonist Dispensing Protocol issued by DMS Medical Director, Judith Theriot. Opvee nasal spray (Nalmefene 2.7 mg / 0.1 ml) has been added to the medication list. This will allow enrolled pharmacies in Kentucky to receive reimbursement for dispensing naloxone and nalmefene to members who do not have a prescription.

Effective October 5th, DMS will cover Over-the-Counter (OTC) naloxone 4 mg nasal spray on the Fee-For-Service and Managed Care Organizations (MCOs) Over-the-Counter Covered Drug List. The Opioid Antagonist Dispensing Protocol may be used to dispense this product.

Pharmacies should input Dr. Theriot's National Provider ID (NPI) in the Prescriber ID field. DMS does not currently enroll pharmacists as providers. Therefore, the Pharmacist/Pharmacy NPI should not be used in the Prescriber ID field.

****All noted procedures must be followed to receive reimbursement****.

Thank you for helping Kentucky Medicaid members maintain access to cost-effective medications by selecting drugs on the preferred drug list whenever possible. For any additional information or questions that you may have, please contact Magellan Medicaid Administration at kyproviders@magellanhealth.com for Fee-for-Service members or the Kentucky MedImpact team at KYMCOPBM@medimpact.com for Managed Care Organization (MCO) members.

Sincerely,

ShaLeigh Hammons, CPhT

ShaLeigh Hammons, CPhT
Account Manager I
kyproviders@magellanhealth.com

Kentucky Medicaid Fee-for-Service Pharmacy Program's Contact Information		
Clinical Support Center	1-800-477-3071 Sunday – Saturday 24 hours a day	Please contact the Clinical Support Center to request a prior authorization (PA) or to check the status of a request. **NOTE: The only drugs that are now required to be submitted via fax are Brand Medically Necessary.**

Kentucky Medicaid Fee-for-Service Pharmacy Program's Contact Information		
Pharmacy Support Center	1-800-432-7005 Sunday – Saturday 24 hours a day	Please contact the Pharmacy Support Center when claims assistance is required. Timely filing, lock-in, and early refill (ER) overrides can be obtained through this Call Center.
Provider Services	1-877-838-5085 Monday – Friday 8:00 a.m. – 4:30 p.m.	Please contact Provider Services if you have questions about enrollment or when updating your license or bank information.
Member Services	1-800-635-2570 Monday – Friday 8:00 a.m. – 5:00 p.m.	Please contact Member Services if you are a member or if you as the provider have questions regarding the member's benefits or eligibility coverage dates.

Kentucky Statewide Physician Protocol to Initiate Dispensing of Opioid Antagonists for Opioid Overdose Prevention and Response

Purpose

This statewide physician protocol signed by a physician with the Kentucky Department for Public Health specifies the criteria and procedures for eligible pharmacists who have met the requirements and received certification from the Kentucky Board of Pharmacy, according to and in accordance with the Kentucky Board of Pharmacy administrative regulations 201 KAR 2:360 to initiate the dispensing of opioid antagonists. *This signed protocol is intended for pharmacists that **do not** have a medical provider to issue a protocol.*

<table>
<tr><th colspan="3">Opioid Antagonist Dispensing Protocol</th></tr>
<tr><td>Eligible Candidates</td><td colspan="2">▪ Persons with a history of receiving medical care for acute opioid poisoning or overdose
▪ Persons with a suspected history of substance abuse or nonmedical opioid use
▪ Persons receiving high-dose opioid prescriptions (e.g., >50mg morphine equivalent)
▪ Persons who are opioid naïve and receiving a first prescription for methadone for pain
▪ Persons starting buprenorphine or methadone for addiction treatment
▪ Persons on opioid prescriptions for pain in combination with:
◦ Smoking, chronic obstructive pulmonary disease (COPD), emphysema, sleep apnea, or other respiratory illness
◦ Renal dysfunction, hepatic disease, or cardiac disease
◦ Known or suspected alcohol use
◦ Concurrent benzodiazepine or other sedative prescriptions
◦ Concurrent antidepressant prescription
▪ Persons who may have difficulty accessing emergency medical services
▪ Voluntary request by a person or agency</td></tr>
<tr><td>Medication</td><td>Nasal Spray

Naloxone HCl 4 mg / 0.1 ml (Narcan)
or
Naloxone HCl 8 mg / 0.1 ml (Kloxxado)
or
Nalmefene 2.7 mg / 0.1 ml (Opvee) (for patients 12 and older)

Dispense #1 carton</td><td>Pre-filled Syringe

Naloxone 5 mg/0.5ml injection (Zimhi) (for patients 12 and older)

Dispense #1 carton</td></tr>
<tr><td>Directions for Use</td><td>◦ Call 911.
◦ Do not prime.
◦ Spray in nostril upon signs of opioid overdose.
◦ May repeat in 2–5 minutes in opposite nostril if no or minimal breathing, then as needed (if doses are available), every 2 – 5 minutes.</td><td>◦ Call 911.
◦ Administer into the anterolateral aspect of the thigh, through clothing if necessary upon signs of opioid overdose.
◦ May repeat in 2-3 minutes if no or minimal breathing and responsiveness, then as needed (if doses are available), every 2-3 minutes.</td></tr>
</table>

Education	▪ Pharmacist dispensing an opioid antagonist to a person or agency not operating a harm reduction program shall provide verbal counseling and written educational materials, appropriate to the product and dosage form of dispensed.
Documentation	▪ Provide education both verbally and in written form for take-home use. ▪ Include name and title of person providing education to recipient of the opioid antagonist prescription. ▪ Document via prescription record each person who receives an opioid antagonist prescription under this protocol.
Contraindications	▪ Patients with known hypersensitivity or allergy to naloxone hydrochloride or nalmefene. ▪ Naloxone crosses the placenta and may precipitate withdrawal in the fetus. The fetus should be evaluated for signs of distress after naloxone is used. Naloxone should only be used in pregnant women with opioid dependence in situations of life-threatening overdose. (Pregnancy Category C)
Notification of Participation	Pharmacists choosing to participate in opioid antagonist distribution under the authority of this Statewide Protocol shall notify the Department for Public Health when initiating their participation. A facsimile of this signed form shall be emailed to Naloxoneprotocol@ky.gov or faxed to 502-564-9377 within seven (7) days of dispensing naloxone.

Opioid Antagonist Statewide Physician Protocol Signatures:

Judy Ann Theriot, MD, CPE

Judith Ann Theriot, MD, CPE
Medical Director
Kentucky Department for Medicaid Services

National Provider ID: 1811990476

July 12, 2023 Date Signed

This order is effective immediately upon signing and may be revised or revoked by the Kentucky Department for Public Health according to their direction.

By signing this Statewide Physician Protocol, the pharmacist attests that he/she is naloxone-certified by the Kentucky Board of Pharmacy, and has read and understands this Protocol.

Pharmacist _____ **Date Signed** _____

Printed Name _____

Pharmacy Name	**Store number(s)**
Pharmacy Address and email, if available	

- A copy of this Signed Protocol must be maintained on file and be readily retrievable at each participating pharmacy site.
- This Signed Protocol must be renewed **annually**.

Kentucky Public Health
Prevent. Promote. Protect.

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Uploaded by: Eric Gally
Position: FAV

STATE OF NEW HAMPSHIRE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

129 PLEASANT STREET, CONCORD, NH 03301
603-271-9544 1-800-852-3345 Ext. 9544
Fax: 603-271-4912 TDD Access: 1-800-735-2964
www.dhhs.nh.gov

Jonathan R. Ballard
Chief Medical Officer

Standing Order for Community Organizations Dispensing of Opioid Antagonists

Naloxone and nalmefene are indicated for the reversal of opioid overdose induced by natural or synthetic opioids in the setting of respiratory depression or unresponsiveness. It should not be given to anyone known to be hypersensitive to the agent. This standing order authorizes community organizations in New Hampshire to dispense opioid antagonists to any person who is:

- Either a person at risk of experiencing an opiate-related overdose; OR a family member, friend, or other person in a position to assist a person at risk of experiencing such an overdose; AND who has been provided opioid overdose response training.

1. **Intranasal Naloxone**:

- Naloxone HCl Nasal Spray 4mg (**Narcan** – brand name)

  Dispense up to four two-pack boxes of single-step Naloxone HCl Nasal Spray 4mg (Narcan – brand name) which contains two (2) 4mg doses of naloxone HCl in 0.1 ml of nasal spray. Dispensing instructions: Call 911. Spray the contents of one sprayer (0.1ml) into one nostril. May repeat every 2-3 minutes if symptoms of an opioid emergency persist, alternating nostrils.

- Naloxone HCl 1mg/ml delivered with mucosal atomizer

  Dispense two 2ml Luer-lock needleless syringes prefilled with Naloxone HCl 1mg/mL and equivalent quantity mucosal atomizing devices. Dispensing instructions: Call 911. Administer naloxone in accordance with written step-by-step instructions for administration of intranasal naloxone provided by organization personnel.

- Naloxone HCl Nasal Spray 8mg (**Kloxxado** – brand name)
  - Dispense one package of Naloxone HCl Nasal Spray 8mg (Kloxxado – brand name). Dispensing instructions: Call 911. Spray the contents of a new sprayer into one nostril. May repeat every 2-3 minutes with a new sprayer if symptoms of an opioid emergency persist, alternating nostrils. Written step-by-step instructions for administration of intranasal naloxone must be given to patient and reviewed with patient by organization personnel.

2. **Intranasal Nalmefene**

- Nalmefene Nasal Spray 2.7mg (**OPVEE** – brand name)
  a. Dispense one package of Nalmefene nasal spray only for use on persons age 12 and older. Dispensing instructions: Call 911. Spray the contents into one nostril. May repeat every 2-5 minutes with a new sprayer if symptoms of an opioid emergency persist. Written step-by-step instructions for use of nalmefene must be given to patient and reviewed with patient by organization personnel.

3. **Intramuscular Naloxone**:

- Naloxone HCl 0.4mg/ml delivered intramuscularly

  Dispense 1x 10ml vial or 2 x 1ml single dose vials; and 1 intramuscular (IM) single packaged syringe and 1-1 ½ inch size needle.

  Dispensing instructions: Call 911. Draw up and administer 1ml naloxone in accordance with written step-by-step instructions for administration of intramuscular naloxone as reviewed by agency personnel. May repeat in 2-3 minutes if symptoms of an opioid emergency persist.

4. **Agency Instructions:** Written step-by-step instructions for administration of opioid antagonists must be given to persons and reviewed with persons by agency personnel. Instructions must provide opioid overdose response counseling covering, at a minimum: 1.) Recognition of an opioid overdose; 2.) Calling 911; 3.) Administration of opioid antagonists; and 4.) Orientation to and explanation of the contents of the opioid antagonist package. In accordance with NH RSA 318-B:15, IV, New Hampshire law allows an organization to dispense or distribute opioid antagonists pursuant to a prescription or standing order, when acting in good faith and with reasonable care, and in accordance with specific procedures, training and safeguards, as outlined in this Standing Order.

Jonathan Ballard MD

Jonathan Ballard, MD, MPH, MPhil
Chief Medical Officer

Expiration Date: 12/31/2025
Unlimited refills authorized
NH Med License: 15614

Standing Order -- New Jersey.pdf
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PHILIP D. MURPHY
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Lt. Governor

JUDITH M. PERSICHILLI, RN, BSN, MA
Commissioner

2nd REVISED STANDING ORDER FOR PHARMACISTS TO DISPENSE OPIOID ANTIDOTE FOR OVERDOSE PREVENTION

CONTROL NUMBER: 2021-01 (2nd Revised)

This revised standing order is issued pursuant to P.L.2021, c.152 ("Act"), which provides that the Commissioner of Health, or, if the commissioner is not a duly licensed physician, the Deputy Commissioner for Public Health Services, "shall issue a standing order authorizing all licensed pharmacists in the State to dispense an opioid antidote to any individual or entity, regardless of whether the individual or entity holds an individual prescription for the opioid antidote."

The purpose of this standing order is to make opioid antidotes as easily accessible and as widely available as possible in order to provide treatment to people experiencing a suspected overdose. Nothing in this standing order shall be construed to restrict in any way the ability of any individual or entity to be dispensed an opioid antidote.

The Act defines the following terms:

- "Opioid antidote" as "any drug, regardless of dosage amount or method of administration which has been approved by the United States Food and Drug Administration (FDA) for the treatment of an opioid overdose. 'Opioid antidote' includes, but is not limited to naloxone hydrochloride, in any dosage amount, which is administered through nasal spray or any other FDA-approved means or methods. "

- "Drug overdose" means "an acute condition including, but not limited to, physical illness, coma, mania, hysteria, diminished consciousness, respiratory depression, or death resulting from the consumption or use of a controlled dangerous substance or another substance with which a controlled dangerous substance was combined and that a layperson would reasonably believe to require medical assistance."

- "Recipient" means "any individual who or entity that is prescribed or dispensed an opioid antidote" in accordance with N.J.S.A. 24:6J-4 or N.J.S.A. 45:14-67.2

including, but not be limited to, "private citizens, emergency medical responders, emergency medical response entities, law enforcement officers, law enforcement agencies, recognized places of public access, employees and volunteers providing services at, through, or on behalf of a recognized place of public access, public and nonpublic schools, school nurses and other staff at a public or nonpublic school, sterile syringe access programs, and staff and employees of a sterile syringe access program. The term 'recipient' shall not include a prescriber or a licensed pharmacist acting within a professional capacity."

I. AUTHORIZATION

A. This standing order may be used by any recipient as a prescription or third-party prescription to obtain an opioid antidote from a pharmacy. This standing order authorizes pharmacists who maintain active licenses to practice pharmacy in the State of New Jersey and who are in good standing with the New Jersey Board of Pharmacy to dispense an opioid antidote, as defined herein, to any recipient regardless if the recipient has an individual prescription for an opioid antidote. A pharmacist dispensing an opioid antidote shall furnish the recipient with the overdose prevention information set forth in Section III below.

II. ORDER TO DISPENSE FOR PHARMACISTS

A. Unlimited refills are authorized with opioid antidotes.
B. A pharmacist may dispense any other items necessary for the administration of opioid antagonists as determined by the pharmacist's professional judgment (including but not limited to, syringes and mucosal atomization devices), consistent with State and federal law.
C. The dissemination of overdose prevention information, as required by Section III below, shall be documented by the dispensing pharmacist in the recipient's medical record or another appropriate record, log or other similar recordkeeping location.

III. INFORMATION

Upon dispensing an opioid antidote, a pharmacist shall provide the following overdose prevention information to the person receiving the opioid antidote, which information shall include, but is not limited to, the following:

A. Information on opioid overdose prevention and recognition;
B. Instructions on how to perform rescue breathing and resuscitation;
C. Information on dosage and instructions regarding administration in conjunction with the packaging insert included with the opioid antidote;
D. Information describing the importance of calling 911 for assistance with an

opioid overdose;

E. Instructions regarding appropriate care of an overdose victim after administration of an opioid antidote; and

F. Information on contraindications and precautions.

IV. ADDITIONAL INFORMATION

In addition to the required information provided by a pharmacist to a recipient pursuant to Section III above, a pharmacist may also direct the recipient to the following website for additional information regarding opioid overdose prevention and opioid antidotes: https://nj.gov/humanservices/dmhas/initiatives/naloxone.html.

V. EXPIRATION AND REVIEW

This revised standing order supersedes the standing orders issued on August 31, 2021 and August 24, 2022.

This revised standing order shall not expire unless and until all forms of opioid antidotes have been approved as over-the-counter medications or until otherwise withdrawn in writing by the Department of Health. This revised standing order will be reviewed periodically and updated as relevant developments in the law or science about opioid antidote administration occur.

A pharmacist dispensing an opioid antidote shall maintain records as required by the Board of Pharmacy.

New Jersey Department of Health
Issuing Official

Margaret C Fisher

Margaret Fisher, MD
Acting Deputy Commissioner
Public Health Services
New Jersey Department of Health
NPI Number: 1932165701
NJ License Number: 25MA07136300

9/7/22
Date

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NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

Pursuant to North Carolina State Health Director's Opioid Antagonist Standing Order for Pharmacists
List of Approved Opioid Antagonists for Pharmacist Dispensing

Table 1: Naloxone Products

Product	Route of Administration	Directions for Use in Event of Suspected Opioid Overdose	Ancillary Products Required
Naloxone 4 mg/0.1 mL Nasal Spray *Dispense one carton containing two doses*	Intranasal	Call 911. Administer a single spray in one nostril. If no to minimal response after 2-3 minutes, an additional dose may be given in the alternate nostril.	N/A
Naloxone 8 mg/0.1 mL Nasal Spray *Dispense one carton containing two doses*	Intranasal	Call 911. Administer a single spray in one nostril. If no to minimal response after 2-3 minutes, an additional dose may be given in the alternate nostril.	N/A
Naloxone 1 mg/1 mL *Dispense two 2 mL Luer-Jet™ Luer-Lock prefilled syringes (for use with mucosal atomization device)*	Intranasal	Call 911. Spray 1 mL (½ of prefilled syringe contents) into each nostril via intranasal mucosal atomization device. If no to minimal response after 2-3 minutes, may repeat dose.	Two intranasal mucosal atomization devices (MAD 300)
Naloxone 3 mg/0.1mL	Intranasal	Call 911. Administer a single spray in one nostril. If no to minimal response after 2-3 minutes, an additional dose may be given.	N/A
Naloxone 0.4 mg/1 mL *Dispense two 1 mL single dose vials*	Injection	Call 911. Inject 1 mL into the muscle of the outer thigh or upper arm. If no to minimal response after 2-3 minutes, may repeat dose.	Two 3 mL syringes Two 23-25 gauge, 1-1.5 inch needles
Naloxone 5 mg/0.5 mL[1] *Dispense one carton containing two doses*	Injection	Call 911. Inject contents of one prefilled syringe intramuscularly or subcutaneously into the anterolateral aspect of the thigh. If no to minimal response after 2-3 minutes, may repeat dose.	N/A

[1] Naloxone 5 mg/0.5 mL (ZIMHI™) is intended to be administered by individuals 12 years of age or older.

Table 2: Non-Naloxone Products

Nalmefene 2.7 mg/0.1mL[2]	Intranasal	Call 911. Administer a single spray into nostril. Additional doses, using a new nasal spray with each dose, may be given every 2-5 minutes if the person does not respond.	N/A

[2] Nalmefene 2.7 mg/0.1mL (OPVEE®) is indicated for use in adults and pediatric patients aged 12 years and older.

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Board of Pharmacy Adds Nalmefene as an Overdose Reversal Drug - Effective 10/31/23

On October 31, 2023, nalmefene (OPVEE®) will be added as an overdose reversal drug (ORD) per OAC 4729-8-01. By classifying nalmefene as an ORD, it can be distributed in the same manner as naloxone.

To assist Ohioans in understanding laws governing the distribution of overdose reversal drugs, the State of Ohio Board of Pharmacy developed a comprehensive guide, which can be accessed here: www.pharmacy.ohio.gov/ORD.

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Enrolled
House Bill 2395

Sponsored by Representatives DEXTER, BYNUM, GRAYBER, HIEB, REYNOLDS, Senators HAYDEN, JAMA, PATTERSON, STEINER; Representatives ANDERSEN, BOWMAN, CHAICHI, EVANS, FAHEY, GAMBA, HARTMAN, HOLVEY, HUDSON, JAVADI, KROPF, MARSH, NELSON, NERON, NOSSE, PHAM H, PHAM K, RUIZ, TRAN, WALTERS, Senators FREDERICK, GELSER BLOUIN, KNOPP, LIEBER, SOLLMAN, TAYLOR (Presession filed.)

CHAPTER .....

AN ACT

Relating to substance use; creating new provisions; amending ORS 146.100, 339.867, 339.869, 339.870, 339.871, 430.389, 431A.855, 431A.865, 475.525, 475.744, 689.681, 689.682, 689.684 and 689.686; repealing section 7a, chapter ___, Oregon Laws 2023 (Enrolled House Bill 2421); and declaring an emergency.

Whereas the residents of the State of Oregon acknowledge that the opioid crisis in which we see ourselves is the result of a complex set of political, economic and societal factors emanating from policy and systemic decisions going back decades; and

Whereas the residents of this state acknowledge the need to act quickly to prevent more unnecessary loss of life; and

Whereas the residents of this state acknowledge that a multipronged approach focused on substance use prevention, harm reduction and treatment must be adopted; and

Whereas the residents of this state acknowledge the need to make data-driven and scientifically based decisions when possible; and

Whereas the residents of this state acknowledge that drug use does not define a person and we must remember to act courageously and compassionately; and

Whereas the residents of this state acknowledge that we must make conscious efforts to minimize and remove stigma around substance use treatment; and

Whereas the Legislative Assembly created the Opioid Settlement Prevention, Treatment and Recovery Board and tasked the board with allocating funds from the Opioid Settlement Prevention, Treatment and Recovery Fund to support access to harm reduction, drug treatment and opioid data; now, therefore,

Be It Enacted by the People of the State of Oregon:

SHORT-ACTING OPIOID ANTAGONISTS

SECTION 1. ORS 689.681 is amended to read:

689.681. (1) As used in this section:

(a) "Kit" means a [*dose of naloxone*] **package of one or more doses of a short-acting opioid antagonist** and the necessary medical supplies to administer the [*naloxone*] **short-acting opioid antagonist**.

[*(b) "Opiate" means a narcotic drug that contains:*]

[*(A) Opium;*]

[*(B) Any chemical derivative of opium; or*]

[*(C) Any synthetic or semisynthetic drug with opium-like effects.*]

[*(c) "Opiate overdose" means a medical condition that causes depressed consciousness and mental functioning, decreased movement, depressed respiratory function and the impairment of the vital functions as a result of ingesting opiates in an amount larger than can be physically tolerated.*]

(b) "Opioid" means a natural, synthetic or semisynthetic chemical that interacts with opioid receptors on nerve cells in the body and brain to reduce the intensity of pain signals and feelings of pain.

(c) "Opioid overdose" means a medical condition that causes depressed consciousness, depressed respiratory function or the impairment of vital bodily functions as a result of ingesting opioids.

(d) "Short-acting opioid antagonist" means any short-acting drug approved by the United States Food and Drug Administration for the complete or partial reversal of an opioid overdose.

(2) Notwithstanding any other provision of law, a pharmacy, a health care professional [*or*]**,** a pharmacist with prescription and dispensing privileges**, a law enforcement officer, a firefighter, an emergency medical services provider** or any other person designated by the State Board of Pharmacy by rule may**:**

(a) Distribute and administer [*naloxone*] **a short-acting opioid antagonist** and distribute the necessary medical supplies to administer the [*naloxone*] **short-acting opioid antagonist**[*.*]**;**

(b) Distribute multiple kits to:

(A) An individual who has experienced an opioid overdose or is likely to experience an opioid overdose;

(B) Family members of an individual described in subparagraph (A) of this paragraph; and

(C) Any other individual who requests one or more kits; and

(c) [*The pharmacy, health care professional or pharmacist may also*] Distribute multiple kits to social service agencies under ORS 689.684 or to other persons who work with individuals who have experienced an [*opiate overdose*] **opioid overdose**. The social services agencies or other persons may redistribute the kits to individuals likely to experience an [*opiate overdose*] **opioid overdose** or to family members of the individuals.

(3)**(a)** A person acting in good faith, if the act does not constitute wanton misconduct, is immune from **criminal and** civil liability for any act or omission of an act committed during the course of distributing and administering [*naloxone*] **a short-acting opioid antagonist** and distributing the necessary medical supplies to administer the [*naloxone*] **short-acting opioid antagonist** under this section.

(b) A person acting in good faith is immune from criminal and civil liability for the person's failure or refusal to distribute or administer a short-acting opioid antagonist or distribute the necessary medical supplies to administer a short-acting opioid antagonist under this section, if the person's failure or refusal does not constitute wanton misconduct.

SECTION 2. ORS 689.682 is amended to read:

689.682. **(1) As used in this section:**

(a) "Opioid" means a natural, synthetic or semisynthetic chemical that interacts with opioid receptors on nerve cells in the body and brain to reduce the intensity of pain signals and feelings of pain.

(b) "Opioid overdose" means a medical condition that causes depressed consciousness, depressed respiratory function or the impairment of vital bodily functions as a result of ingesting opioids.

(c) "Short-acting opioid antagonist" means any short-acting drug approved by the United States Food and Drug Administration for the complete or partial reversal of an opioid overdose.

[*(1)*] **(2)** In accordance with rules adopted by the State Board of Pharmacy under ORS 689.205, a pharmacist may prescribe [*naloxone*] **a short-acting opioid antagonist** and the necessary medical supplies to administer the [*naloxone*] **short-acting opioid antagonist**.

[*(2)*] **(3)** If a prescription is presented to a pharmacist for dispensing an opiate or opioid in excess of a morphine equivalent dose established by rule by the board, the pharmacist may offer to prescribe and provide, in addition to the prescribed opiate or opioid, a [*naloxone kit consisting of a dose of naloxone*] **short-acting opioid antagonist** and the necessary medical supplies to administer the [*naloxone*] **short-acting opioid antagonist**.

SECTION 3. ORS 689.684 is amended to read:

689.684. (1) For purposes of this section, "social services agency" includes, but is not limited to, homeless shelters and crisis centers.

(2) A person may administer to an individual [*naloxone*] **a short-acting opioid antagonist, as defined in ORS 689.681,** that was not distributed to the person if:

(a) The individual to whom the [*naloxone*] **short-acting opioid antagonist** is being administered appears to be experiencing an [*opiate overdose*] **opioid overdose** as defined in ORS 689.681; and

(b) The person who administers the [*naloxone*] **short-acting opioid antagonist** is an employee of a social services agency or is trained under rules adopted by the State Board of Education pursuant to ORS 339.869.

(3) For the purposes of protecting public health and safety, the Oregon Health Authority may adopt rules for the administration of [*naloxone*] **short-acting opioid antagonists** by employees of a social services agency under this section.

SECTION 4. ORS 689.686 is amended to read:

689.686. (1) A retail or hospital outpatient pharmacy shall provide written notice in a conspicuous manner that [*naloxone*] **a short-acting opioid antagonist, as defined in ORS 689.681,** and the necessary medical supplies to administer [*naloxone*] **the short-acting opioid antagonist** are available at the pharmacy.

(2) The State Board of Pharmacy may adopt rules to carry out this section.

SECTION 5. (1) The amendments to ORS 689.681, 689.682, 689.684 and 689.686 by sections 1 to 4 of this 2023 Act become operative on January 1, 2024.

(2) The State Board of Pharmacy may take any action before the operative date specified in subsection (1) of this section that is necessary to enable the board to exercise, on and after the operative date specified in subsection (1) of this section, all of the duties, functions and powers conferred on the board by the amendments to ORS 689.681, 689.682, 689.684 and 689.686 by sections 1 to 4 of this 2023 Act.

STANDING ORDERS

SECTION 6. Sections 7 and 8 of this 2023 Act are added to and made a part of ORS chapter 689.

SECTION 7. (1) As used in this section, "opioid," "opioid overdose" and "short-acting opioid antagonist" have the meanings given those terms in ORS 689.681.

(2)(a) The Public Health Officer appointed under ORS 431.045, or a physician licensed under ORS chapter 677 who is employed by the Oregon Health Authority, may issue a standing order to prescribe a short-acting opioid antagonist, and the necessary medical supplies to administer the short-acting opioid antagonist, to:

(A) An individual who is at risk of experiencing an opioid overdose;

(B) An individual who or entity that may encounter an individual who is likely to experience an opioid overdose; and

(C) The owner of a building or facility described in section 8 of this 2023 Act.

(b) The Public Health Officer or physician may issue a standing order within certain geographic areas of the state or statewide, and may withdraw a standing order at any time.

(3) Upon the request of an individual or entity, a pharmacist shall dispense a short-acting opioid antagonist and the necessary medical supplies to administer the short-acting opioid antagonist pursuant to a standing order issued under subsection (2) of this section.

(4) An individual or an entity may possess, store, deliver or distribute a short-acting opioid antagonist and the necessary medical supplies to administer the short-acting opioid antagonist, and may administer a short-acting opioid antagonist, pursuant to a standing order issued under subsection (2) of this section.

(5)(a) An individual acting in good faith, if the act does not constitute wanton misconduct, is immune from criminal and civil liability for any act or omission of an act committed during the course of possessing, storing, delivering or distributing a short-acting opioid antagonist and the necessary medical supplies to administer the short-acting opioid antagonist and during the course of administering a short-acting opioid antagonist.

(b) An individual is immune from criminal and civil liability for the individual's failure or refusal to possess, store, deliver or distribute a short-acting opioid antagonist and the necessary medical supplies to administer the short-acting opioid antagonist, or failure or refusal to administer a short-acting opioid antagonist.

(6) The State Board of Pharmacy and the authority, in consultation with one another, may adopt rules to carry out this section.

SECTION 8. (1) As used in this section, "kit," "opioid," "opioid overdose" and "short-acting opioid antagonist" have the meanings given those terms in ORS 689.681.

(2) The owner of any building or facility to which the public has legal access may have in the building or facility one or more kits stored in a location in the building or facility easily accessible by members of the public if the kit or kits are obtained pursuant to a standing order issued under section 7 of this 2023 Act.

(3)(a) A member of the public may administer the short-acting opioid antagonist contained in a kit described in subsection (2) of this section to an individual experiencing, or who appears to be experiencing, an opioid overdose. The member of the public acting in good faith, if the act does not constitute wanton misconduct, is immune from criminal and civil liability for:

(A) Any act or omission of an act committed during the course of administering the short-acting opioid antagonist under this section; and

(B) Not administering the short-acting opioid antagonist.

(b) The owner and any staff members of a building or facility described in subsection (2) of this section in which a kit, obtained pursuant to a standing order issued under section 7 of this 2023 Act, is located, are immune from criminal and civil liability for any act or omission of an act committed during the course of the administration of, or for the failure or refusal to administer, the short-acting opioid antagonist contained in the kit located in the building or facility.

(4) The Oregon Health Authority shall publish, on a website operated by or on behalf of the authority, a list of the types of buildings and facilities, and the locations of buildings and facilities, described in subsection (2) of this section, for which the authority prioritizes the provision of kits.

(5) The authority may adopt rules to carry out this section. In adopting rules under this subsection, the authority shall consult with the State Board of Pharmacy.

SECTION 9. (1) Sections 7 and 8 of this 2023 Act become operative on January 1, 2024.

(2) The Oregon Health Authority and State Board of Pharmacy may take any action before the operative date specified in subsection (1) of this section that is necessary to enable the authority and the board to exercise, on and after the operative date specified in subsection (1) of this section, all of the duties, functions and powers conferred on the authority and the board by sections 7 and 8 of this 2023 Act.

SCHOOLS

SECTION 10. ORS 339.867 is amended to read:

339.867. As used in ORS 339.869 and 339.870:

(1)**(a)** "Medication" means:

[*(a)*] **(A)** Medication that is not injected;

[*(b)*] **(B)** Premeasured doses of epinephrine that are injected;

[*(c)*] **(C)** Medication that is available for treating adrenal insufficiency; and

[*(d)*] **(D)** Naloxone or any similar medication that is in any form available for safe administration and that is designed to rapidly reverse an overdose of an opioid drug.

[*(2)*] **(b)** "Medication" does not include nonprescription sunscreen.

(2) "Opioid overdose" has the meaning given that term in ORS 689.681.

(3) "Short-acting opioid antagonist" has the meaning given that term in ORS 689.681.

SECTION 11. ORS 339.869 is amended to read:

339.869. (1) The State Board of Education, in consultation with the Oregon Health Authority, the Oregon State Board of Nursing and the State Board of Pharmacy, shall adopt:

(a) Rules for the administration of prescription and nonprescription medication to students by trained school personnel and for student self-medication. The rules shall include age appropriate guidelines and training requirements for school personnel.

(b) Rules for the administration of premeasured doses of epinephrine by school personnel trained as provided by ORS 433.815 to any student or other individual on school premises who the personnel believe in good faith is experiencing a severe allergic reaction, regardless of whether the student or individual has a prescription for epinephrine.

(c)(A) Rules for the administration of medication that treats adrenal insufficiency by school personnel trained as provided by ORS 433.815 to any student on school premises whose parent or guardian has provided for the personnel the medication as described in ORS 433.825 (3) and who the personnel believe in good faith is experiencing an adrenal crisis, as defined in ORS 433.800.

(B) Rules adopted under this paragraph must:

(i) Include guidelines on the designation and training of school personnel who will be responsible for administering medication; and

(ii) Specify that a school district is only required to train school personnel when the school district has been notified by a parent or guardian that a student enrolled in a school of the school district has been diagnosed with adrenal insufficiency.

(d) Guidelines for the management of students with life-threatening food allergies and adrenal insufficiency, which must include:

(A) Standards for the education and training of school personnel to manage students with life-threatening allergies or adrenal insufficiency.

(B) Procedures for responding to life-threatening allergic reactions or an adrenal crisis, as defined in ORS 433.800.

(C) A process for the development of individualized health care and allergy or adrenal insufficiency plans for every student with a known life-threatening allergy or adrenal insufficiency.

(D) Protocols for preventing exposures to allergens.

(e) Rules for the administration of [*naloxone or any similar medication that is in any form available for safe administration and that is designed to rapidly reverse an overdose of an opioid drug by trained school personnel*] **a short-acting opioid antagonist** to any student or other individual on school premises who the [*personnel believe*] **individual administering the short-acting opioid antagonist believes** in good faith is experiencing an **opioid** overdose [*of an opioid drug*].

(2)(a) School district boards shall adopt policies and procedures that provide for:

(A) The administration of prescription and nonprescription medication to students by trained school personnel, including the administration of medications that treat adrenal insufficiency;

(B) Student self-medication; and

(C) The administration of premeasured doses of epinephrine to students and other individuals.

(b) Policies and procedures adopted under paragraph (a) of this subsection shall be consistent with the rules adopted by the State Board of Education under subsection (1) of this section. A school

district board shall not require school personnel who have not received appropriate training to administer medication.

(3)(a) School district boards may adopt policies and procedures that provide for the administration of [*naloxone or any similar medication that is in any form available for safe administration and that is designed to rapidly reverse an overdose of an opioid drug*] **a short-acting opioid antagonist**.

(b) Policies and procedures adopted under paragraph (a) of this subsection shall be consistent with the rules adopted by the State Board of Education under subsection (1) of this section.

(4)(a) A school district board shall provide to the parent or legal guardian of each minor student enrolled in a school in the school district information regarding short-acting opioid antagonists. The information described in this subsection must include at least:

(A) A description of short-acting opioid antagonists and their purpose;

(B) A statement regarding, in an emergency situation, the risks of administering to an individual a short-acting opioid antagonist and the risks of not administering to an individual a short-acting opioid antagonist;

(C) A statement that all schools within the school district have access to short-acting opioid antagonists and the necessary medical supplies to administer the short-acting opioid antagonist on site; and

(D) A statement that a representative of a school may administer to a student a short-acting opioid antagonist in an emergency if the student appears to be unconscious and experiencing an opioid overdose.

(b) A school district board shall ensure that the parent or legal guardian of a minor student enrolled in a school within the school district is immediately notified when a short-acting opioid antagonist is administered to the student if the short-acting opioid antagonist is administered while the student is at school, on school property under the jurisdiction of the school district or at any activity under the jurisdiction of the school district.

SECTION 12. ORS 339.870 is amended to read:

339.870. [*(1)*] **(1)(a)** A school administrator, teacher or other school employee designated by the school administrator is not liable in a criminal action or for civil damages as a result of the administration of nonprescription medication, if the school administrator, teacher or other school employee in good faith administers nonprescription medication to a [*pupil*] **student** pursuant to written permission and instructions of the [*pupil's*] **student's** parents or guardian.

(b) A school administrator, teacher or other school employee may administer a short-acting opioid antagonist to a student who experienced or is experiencing an opioid overdose without written permission and instructions of the student's parents or guardian.

[*(2)*] **(2)(a)** A school administrator, teacher or other school employee designated by the school administrator is not liable in a criminal action or for civil damages as a result of the administration of prescription medication, if the school administrator, teacher or other school employee in compliance with the instructions of a physician, physician assistant, nurse practitioner, naturopathic physician or clinical nurse specialist, in good faith administers prescription medication to a [*pupil*] **student** pursuant to written permission and instructions of the [*pupil's*] **student's** parents or guardian.

(b) A person may not maintain an action for injury, death or loss that results from acts or omissions of a school administrator, teacher or other school employee during the administration of a short-acting opioid antagonist as described in subsection (1)(b) of this section unless it is alleged and proved by the complaining party that the school administrator, teacher or other school employee was grossly negligent in administering the short-acting opioid antagonist.

(c) Unless it is alleged and proved by the complaining party that the school district or member of the school district board was grossly negligent in administering the short-acting opioid antagonist, a person may not maintain an action for damages for injury, death or loss

that results from acts or omissions of a school district or members of the school district board during the administration of a short-acting opioid antagonist:

(A) As described in subsection (1)(b) of this section; or

(B) By any person who administers the short-acting opioid antagonist to a student or other individual who the person believes is experiencing an opioid overdose and the administration occurs on school premises, including at a school, on school property under the jurisdiction of the school district or at any activity under the jurisdiction of the school district.

(3) The civil and criminal immunities imposed by subsections (1) and [*(2)*] **(2)(a)** of this section do not apply to an act or omission amounting to gross negligence or willful and wanton misconduct.

SECTION 13. ORS 339.871 is amended to read:

339.871. (1) A school administrator, school nurse, teacher or other school employee designated by the school administrator is not liable in a criminal action or for civil damages as a result of a student's self-administration of medication, as described in ORS 339.866, if the school administrator, school nurse, teacher or other school employee, in compliance with the instructions of the student's Oregon licensed health care professional, in good faith assists the student's self-administration of the medication, if the medication is available to the student pursuant to written permission and instructions of the student's parent, guardian or Oregon licensed health care professional.

(2) A school administrator, school nurse, teacher or other school employee designated by the school administrator is not liable in a criminal action or for civil damages as a result of the use of medication if the school administrator, school nurse, teacher or other school employee in good faith administers[*:*]

[*(a)*] autoinjectable epinephrine to a student or other individual with a severe allergy who is unable to self-administer the medication, regardless of whether the student or individual has a prescription for epinephrine[*; or*]

[*(b) Naloxone or any similar medication that is in any form available for safe administration and that is designed to rapidly reverse an overdose of an opioid drug to a student or other individual who the school administrator, school nurse, teacher or other school employee believes in good faith is experiencing an overdose of an opioid drug*].

(3) A school district and the members of a school district board are not liable in a criminal action or for civil damages as a result of the use of medication if:

(a) Any person in good faith administers autoinjectable epinephrine to a student or other individual with a severe allergy who is unable to self-administer the medication, regardless of whether the student or individual has a prescription for epinephrine; and

(b) The person administered the autoinjectable epinephrine on school premises, including at a school, on school property under the jurisdiction of the district or at an activity under the jurisdiction of the school district.

[*(4) A school district and the members of a school district board are not liable in a criminal action or for civil damages as a result of the use of medication if:*]

[*(a) Any person in good faith administers naloxone or any similar medication that is in any form available for safe administration and that is designed to rapidly reverse an overdose of an opioid drug to a student or other individual who the person believes in good faith is experiencing an overdose of an opioid drug; and*]

[*(b) The person administered the naloxone or similar medication on school premises, including at a school, on school property under the jurisdiction of the district or at an activity under the jurisdiction of the school district.*]

[*(5)*] **(4)** The civil and criminal immunities imposed by this section do not apply to an act or omission amounting to gross negligence or willful and wanton misconduct.

SECTION 14. (1) The amendments to ORS 339.867, 339.869, 339.870 and 339.871 by sections 10 to 13 of this 2023 Act become operative on January 1, 2024.

(2) The State Board of Education may take any action before the operative date specified in subsection (1) of this section that is necessary to enable the board to exercise, on and after the operative date specified in subsection (1) of this section, all of the duties, functions

and powers conferred on the board by the amendments to ORS 339.867, 339.869, 339.870 and 339.871 by sections 10 to 13 of this 2023 Act.

DRUG PARAPHERNALIA

SECTION 15. Section 16 of this 2023 Act is added to and made a part of ORS 475.525 to 475.565.

SECTION 16. (1) Notwithstanding ORS 475.525 (3), it is unlawful to provide single-use drug test strips or drug testing tools to a minor who is under 15 years of age unless the strips or tools are provided to the minor as part of the minor's substance use disorder treatment provided by a mental health care provider and the strips or tools are provided by the mental health care provider.

(2) As used in this section, "mental health care provider" means a:

(a) Physician licensed under ORS chapter 677;

(b) Physician assistant licensed under ORS 677.505 to 677.525;

(c) Psychologist licensed under ORS 675.010 to 675.150;

(d) Nurse practitioner licensed under ORS 678.375 to 678.390;

(e) Clinical social worker licensed under ORS 675.530;

(f) Licensed professional counselor licensed under ORS 675.715;

(g) Licensed marriage and family therapist licensed under ORS 675.715;

(h) Naturopathic physician licensed under ORS chapter 685;

(i) Chiropractic physician licensed under ORS chapter 684;

(j) Community mental health program established and operated pursuant to ORS 430.620 when approved to do so by the Oregon Health Authority pursuant to rule; or

(k) Organizational provider, as defined in ORS 430.637, that holds a certificate of approval.

SECTION 17. ORS 475.525 is amended to read:

475.525. (1) It is unlawful for any person to sell or deliver, possess with intent to sell or deliver or manufacture with intent to sell or deliver drug paraphernalia, knowing that it will be used to unlawfully plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, conceal, inject, ingest, inhale or otherwise introduce into the human body a controlled substance as defined by ORS 475.005.

(2) For the purposes of this section, "drug paraphernalia" means all equipment, products and materials of any kind that are marketed for use or designed for use in planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing, concealing, injecting, ingesting, inhaling or otherwise introducing into the human body a controlled substance in violation of ORS 475.752 to 475.980. Drug paraphernalia includes, but is not limited to:

(a) Kits marketed for use or designed for use in unlawfully planting, propagating, cultivating, growing or harvesting of any species of plant that is a controlled substance or from which a controlled substance can be derived;

(b) Kits marketed for use or designed for use in manufacturing, compounding, converting, producing, processing or preparing controlled substances;

(c) Isomerization devices marketed for use or designed for use in increasing the potency of any species of plant that is a controlled substance;

[*(d) Testing equipment marketed for use or designed for use in identifying or in analyzing the strength, effectiveness or purity of controlled substances;*]

[*(e)*] **(d)** Scales and balances marketed for use or designed for use in weighing or measuring controlled substances;

[*(f)*] **(e)** Diluents and adulterants, such as quinine hydrochloride, mannitol, mannite, dextrose and lactose, marketed for use or designed for use in cutting controlled substances;

[*(g)*] **(f)** Lighting equipment specifically designed for growing controlled substances;

[*(h)*] **(g)** Containers and other objects marketed for use or designed for use in storing or concealing controlled substances; and

[*(i)*] **(h)** Objects marketed for use or designed specifically for use in ingesting, inhaling or otherwise introducing a controlled substance into the human body, such as:

[*(A) Metal, wooden, acrylic, glass, stone, plastic or ceramic pipes with or without screens;*]

[*(B) Water pipes;*]

[*(C) Carburetion tubes and devices;*]

[*(D)*] **(A)** Smoking and carburetion masks;

[*(E)*] **(B)** Roach clips, meaning objects used to hold burning material that has become too small or too short to be held in the hand; **or**

[*(F)*] **(C)** Miniature cocaine spoons and cocaine vials[*;*]**.**

[*(G) Chamber pipes;*]

[*(H) Carburetor pipes;*]

[*(I) Electric pipes;*]

[*(J) Air-driven pipes;*]

[*(K) Chillums;*]

[*(L) Bongs; and*]

[*(M) Ice pipes or chillers.*]

(3) For purposes of this section, "drug paraphernalia" does not include hypodermic syringes or needles**, single-use drug test strips, drug testing tools or any other item designed to prevent or reduce the potential harm associated with the use of controlled substances, including but not limited to items that reduce the transmission of infectious disease or prevent injury, infection or overdose**.

(4) The provisions of ORS 475.525 to 475.565 do not apply to persons registered under the provisions of ORS 475.125 or to persons specified as exempt from registration under the provisions of that statute.

(5)(a) The provisions of ORS 475.525 to 475.565 do not apply to a person who sells or delivers marijuana paraphernalia as defined in ORS 475C.373 to a person 21 years of age or older.

(b) In determining whether an object is drug paraphernalia under this section or marijuana paraphernalia under ORS 475C.373, a trier of fact shall consider, in addition to any other relevant factor, the following:

(A) Any oral or written instruction provided with the object related to the object's use;

(B) Any descriptive material packaged with the object that explains or depicts the object's use;

(C) Any national or local advertising related to the object's use;

(D) Any proffered expert testimony related to the object's use;

(E) The manner in which the object is displayed for sale, if applicable; and

(F) Any other proffered evidence substantiating the object's intended use.

(6) A person acting in good faith is immune from civil liability for any act or omission of an acting committed during the course of distributing an item described in subsection (3) of this section.

SECTION 18. ORS 475.744 is amended to read:

475.744. (1) A person may not sell or give a**:**

(a) Hypodermic device to a minor unless the minor demonstrates a lawful need for the hypodermic device by authorization of a physician, naturopathic physician licensed under ORS chapter 685, physician assistant licensed under ORS 677.505 to 677.525, nurse practitioner licensed under ORS 678.375 to 678.390, parent or legal guardian or by other means acceptable to the seller or donor.

(b)(A) Pipe to a minor unless the minor demonstrates a lawful need for the pipe by authorization of a physician, naturopathic physician licensed under ORS chapter 685, physician assistant licensed under ORS 677.505 to 677.525 or nurse practitioner licensed under ORS 678.375 to 678.390, or the minor's parent or legal guardian; and

(B) The minor obtains the consent of the minor's parent or legal guardian to possess the pipe.

(2) As used in this section[,]**:**

(a) "Hypodermic device" means a hypodermic needle or syringe or medication packaged in a hypodermic syringe or any instrument adapted for the subcutaneous injection of a controlled substance as defined in ORS 475.005.

(b) "Pipe" means:

(A) Metal, wooden, acrylic, glass, stone, plastic or ceramic pipes with or without screens;

(B) Water pipes;

(C) Carburetion tubes and devices;

(D) Chamber pipes;

(E) Carburetor pipes;

(F) Electric pipes;

(G) Air-driven pipes; and

(H) Ice pipes or chillers.

SECTION 19. Section 16 of this 2023 Act and the amendments to ORS 475.525 and 475.744 by sections 17 and 18 of this 2023 Act apply to conduct occurring on or after the effective date of this 2023 Act.

OVERDOSE REPORTING

SECTION 20. (1) As used in this section:

(a) "Cause of death" has the meaning given that term in ORS 146.003.

(b) "Local mental health authority" has the meaning given that term in ORS 430.630.

(c) "Manner of death" has the meaning given that term in ORS 146.003.

(d) "Opioid" means a natural, synthetic or semisynthetic chemical that interacts with opioid receptors on nerve cells in the body and brain to reduce the intensity of pain signals and feelings of pain.

(e) "Opioid overdose" means a medical condition that causes depressed consciousness, depressed respiratory function or the impairment of vital bodily functions as a result of ingesting opioids.

(f) "Third-party notification" means notification from a source other than a patient in a program administered by a local mental health authority during the patient's treatment.

(g) "Urban Indian health program" means an urban Indian health program in this state that is operated by an urban Indian organization pursuant to 25 U.S.C. 1651 et seq.

(2)(a) The Oregon Health Authority shall provide guidance for communication among local mental health authorities to improve notifications and information sharing when an individual who is 24 years of age or younger dies and the presumed cause of death is suspected to be the result of an opioid overdose or other overdose. The guidance may address community opioid overdose and other overdose response and efforts to address the potential of future related deaths. The Oregon Health Authority may collaborate with the following entities in providing the guidance described in this subsection:

(A) Local mental health authorities;

(B) The nine federally recognized Indian tribes in this state;

(C) County juvenile departments;

(D) Community-based substance use disorder treatment programs;

(E) Urban Indian health programs;

(F) The Oregon Youth Authority;

(G) The Department of Human Services;

(H) Community developmental disabilities programs; and

(I) Any other organization identified by the Oregon Health Authority or a local mental health authority as necessary to preserve the public health.

(b) The Oregon Health Authority may develop post-intervention guidance to enable local mental health authorities to deploy uniform and effective post-intervention efforts. In developing the guidance, the authority may consult with the entities described in paragraph (a) of this subsection.

(3) No later than 72 hours after receiving a third-party notification, including notice under ORS 146.100, of the death of an individual described in subsection (2)(a) of this section, if the decedent was not domiciled in the county where the death occurred, the local mental health authority shall provide notice of the death to the local mental health authority in the county where the decedent was domiciled.

(4) The local mental health authority in the county where an individual described in subsection (2)(a) of this section was domiciled may notify the local mental health authority in any other county in which the decedent had significant contacts, as described by the Oregon Health Authority by rule.

(5) After receiving notice of the death of an individual described in subsection (2)(a) of this section, each local mental health authority in a county in which the decedent had significant contacts may inform the Oregon Health Authority, in a manner and format determined by the authority, of activities implemented to support individuals and any local entities affected by the death and to prevent the risk of future related deaths. The Oregon Health Authority may serve as a resource to the local mental health authorities as needed by the community.

(6) In compliance with any state or federal laws regulating public disclosure of such information, the notification described in subsections (3) and (4) of this section must contain the following information regarding the decedent to enable the local mental health authorities described in subsections (3) and (4) of this section to deploy effective post-intervention efforts:

(a) The name of the decedent;

(b) The dates of birth and death of the decedent;

(c) The suspected manner of death;

(d) The suspected cause of death; and

(e) Any other information that the local mental health authority determines necessary to preserve the public health.

SECTION 21. ORS 146.100 is amended to read:

146.100. (1) Death investigations shall be under the direction of the district medical examiner and the district attorney for the county where the death occurs.

(2) For purposes of ORS 146.003 to 146.189, if the county where death occurs is unknown, the death shall be deemed to have occurred in the county where the body is found, except that if in an emergency the body is moved by conveyance to another county and is dead on arrival, the death shall be deemed to have occurred in the county from which the body was originally removed.

(3) The district medical examiner or an assistant district medical examiner for the county where death occurs shall be immediately notified of:

(a) All deaths requiring investigation; and

(b) All deaths of persons admitted to a hospital or institution for less than 24 hours, although the medical examiner need not investigate nor certify such deaths.

(4) No person having knowledge of a death requiring investigation shall intentionally or knowingly fail to make notification thereof as required by subsection (3) of this section.

(5) The district medical examiner or medical-legal death investigator shall immediately notify the district attorney for the county where death occurs of all deaths requiring investigation except for those specified by ORS 146.090 (1)(d) to (g).

(6) All peace officers, health care providers as defined in ORS 192.556, supervisors of penal institutions, supervisors of youth correction facilities, juvenile community supervision officers as defined in ORS 420.905, and supervisors of hospitals or institutions caring for the ill or helpless shall cooperate with the medical examiner or medical-legal death investigator by providing a decedent's

medical records and tissue samples and any other material necessary to conduct the death investigation of the decedent and shall make notification of deaths as required by subsection (3) of this section. A person who cooperates with the medical examiner or medical-legal death investigator in accordance with this subsection does not:

(a) Waive any claim of privilege applicable to, or the confidentiality of, the materials and records provided.

(b) Waive any claim that the materials and records are subject to an exemption from disclosure under ORS 192.311 to 192.478.

(c) Violate the restrictions on disclosing or providing copies of reports and other materials in ORS 419A.257.

(7) Records or materials described in subsection (6) of this section may be released by the medical examiner or medical-legal death investigator only pursuant to a valid court order.

(8)(a) If a death is suspected to be suicide and the decedent was 24 years of age or younger, the district medical examiner or medical-legal death investigator shall notify the local mental health authority in the county where the death occurred and, if the decedent was a member of a federally recognized [*Oregon tribe*] **Indian tribe in Oregon**, shall also notify the tribe's mental health authority.

(b) For the purposes of this subsection, the manner of death is suspected to be suicide if the district medical examiner, the assistant district medical examiner, a pathologist authorized under ORS 146.045 (2)(b) or a designee of the district medical examiner, including a medical-legal death investigator, confirms orally or in writing that the district medical examiner, assistant district medical examiner, pathologist or designee of the district medical examiner reasonably believes that the manner of death was suicide.

(c) The notification under this subsection must include the decedent's name, date of birth, date of death, suspected manner of death and cause of death.

(d) The notification under this subsection may include any other information that the district medical examiner or medical-legal death investigator determines is necessary to preserve the public health and that is not otherwise protected from public disclosure by state or federal law, including information regarding the decedent's school attended and extracurricular activities.

(e) The district medical examiner or medical-legal death investigator must provide the notification under this subsection no later than:

(A) 48 hours after receiving notification of the death if the county where the death occurred has a population of 400,000 or more; or

(B) 72 hours after receiving notification of the death if the county where the death occurred has a population of fewer than 400,000.

(9)(a) If a death is suspected to be the result of an opioid overdose or other overdose and the decedent was 24 years of age or younger, the district medical examiner or medical-legal death investigator shall notify the local mental health authority in the county where the death occurred and, if the decedent was a member of a federally recognized Indian tribe in Oregon, shall also notify the tribe's mental health authority.

(b) For purposes of this subsection, the cause of death is suspected to be the result of an opioid overdose or other overdose if the district medical examiner, the assistant district medical examiner, a pathologist authorized under ORS 146.045 (2)(b) or a designee of the district medical examiner, including a medical-legal death investigator, confirms orally or in writing that the district medical examiner, assistant district medical examiner, pathologist or designee of the district medical examiner reasonably believes that the cause of death was the result of an opioid overdose or other overdose.

(c) The notification under this subsection must include the decedent's name, date of birth, date of death, suspected manner of death and cause of death. The notification may include the information described in subsection (8)(d) of this section and be provided as required under subsection (8)(e) of this section.

[*(f)*] **(10)** As used in this [*subsection,*] **section:**

(a) "Local mental health authority" has the meaning given that term in ORS 430.630.

(b) "Opioid" means a natural, synthetic or semisynthetic chemical that interacts with opioid receptors on nerve cells in the body and brain to reduce the intensity of pain signals and feelings of pain.

(c) "Opioid overdose" means a medical condition that causes depressed consciousness, depressed respiratory function or the impairment of vital bodily functions as a result of ingesting opioids.

SECTION 22. Section 20 of this 2023 Act and the amendments to ORS 146.100 by section 21 of this 2023 Act apply to deaths occurring on and after the operative date specified in section 23 of this 2023 Act.

SECTION 23. (1) Section 20 of this 2023 Act and the amendments to ORS 146.100 by section 21 of this 2023 Act become operative on January 1, 2024.

(2) The Oregon Health Authority may take any action before the operative date specified in subsection (1) of this section that is necessary to enable the authority to exercise, on and after the operative date specified in subsection (1) of this section, all of the duties, functions and powers conferred on the authority by section 20 of this 2023 Act and the amendments to ORS 146.100 by section 21 of this 2023 Act.

CONFORMING AMENDMENTS

SECTION 24. ORS 430.389 is amended to read:

430.389. (1) The Oversight and Accountability Council shall oversee and approve grants and funding to implement Behavioral Health Resource Networks and increase access to community care, as set forth below. A Behavioral Health Resource Network is an entity or collection of entities that individually or jointly provide some or all of the services described in subsection (2)(d) of this section.

(2)(a) The Oversight and Accountability Council, in consultation with the Oregon Health Authority, shall provide grants and funding to agencies or organizations, whether government or community based, to establish Behavioral Health Resource Networks for the purposes of immediately screening the acute needs of people who use drugs and assessing and addressing any ongoing needs through ongoing case management, harm reduction, treatment, housing and linkage to other care and services. Recipients of grants or funding to provide substance use disorder treatment or services must be licensed, certified or credentialed by the state, including certification under ORS 743A.168 (8), or meet criteria prescribed by rule by the Oversight and Accountability Council under ORS 430.390. A recipient of a grant or funding under this subsection may not use the grant or funding to supplant the recipient's existing funding.

(b) The council and the authority shall ensure that residents of each county have access to all of the services described in paragraph (d) of this subsection.

(c) Applicants for grants and funding may apply individually or jointly with other network participants to provide services in one or more counties.

(d) A network must have the capacity to provide the following services and any other services specified by the council by rule:

(A) Screening by certified addiction peer support or wellness specialists or other qualified persons designated by the council to determine a client's need for immediate medical or other treatment to determine what acute care is needed and where it can be best provided, identify other needs and link the client to other appropriate local or statewide services, including treatment for substance [*abuse*] **use** and coexisting health problems, housing, employment, training and child care. Networks shall provide this service 24 hours a day, seven days a week, every calendar day of the year. Notwithstanding paragraph (b) of this subsection, only one grantee in each network within each county is required to provide the screenings described in this subparagraph.

(B) Comprehensive behavioral health needs assessment, including a substance use disorder screening by a certified alcohol and drug counselor or other credentialed addiction treatment professional. The assessment shall prioritize the self-identified needs of a client.

(C) Individual intervention planning, case management and connection to services. If, after the completion of a screening, a client indicates a desire to address some or all of the identified needs, a case manager shall work with the client to design an individual intervention plan. The plan must address the client's need for substance use disorder treatment, coexisting health problems, housing, employment and training, child care and other services.

(D) Ongoing peer counseling and support from screening and assessment through implementation of individual intervention plans as well as peer outreach workers to engage directly with marginalized community members who could potentially benefit from the network's services.

(E) Assessment of the need for, and provision of, mobile or virtual outreach services to:

(i) Reach clients who are unable to access the network; and

(ii) Increase public awareness of network services.

(F) Harm reduction services and information and education about harm reduction services.

(G) Low-barrier substance use disorder treatment.

(H) Transitional and supportive housing for individuals with substance use disorders.

(e) If an applicant for a grant or funding under this subsection is unable to provide all of the services described in paragraph (d) of this subsection, the applicant may identify how the applicant intends to partner with other entities to provide the services, and the Oregon Health Authority and the council may facilitate collaboration among applicants.

(f) All services provided through the networks must be evidence-informed, trauma-informed, culturally specific, linguistically responsive, person-centered and nonjudgmental. The goal shall be to address effectively the client's substance use and any other social determinants of health.

(g) The networks must be adequately staffed to address the needs of people with substance use disorders within their regions as prescribed by the council by rule, including, at a minimum, at least one person qualified by the Oregon Health Authority in each of the following categories:

(A) Certified alcohol and drug counselor or other credentialed addiction treatment professional;

(B) Case manager; and

(C) Certified addiction peer support or wellness specialist.

(h) Verification of a screening by a certified addiction peer support specialist, wellness specialist or other person in accordance with subsection (2)(d)(A) of this section shall promptly be provided to the client by the entity conducting the screening. If the client executes a valid release of information, the entity shall provide verification of the screening to the Oregon Health Authority or a contractor of the authority and the authority or the authority's contractor shall forward the verification to the court, in the manner prescribed by the Chief Justice of the Supreme Court, to satisfy the conditions for dismissal under ORS 153.062 or 475.237.

(3)(a) If moneys remain in the Drug Treatment and Recovery Services Fund after the council has committed grants and funding to establish behavioral health resource networks serving every county in this state, the council shall provide grants and funding to other agencies or organizations, whether government or community based, and to the nine federally recognized tribes in this state and service providers that are affiliated with the nine federally recognized tribes in this state to increase access to one or more of the following:

(A) Low-barrier substance use disorder treatment that is evidence-informed, trauma-informed, culturally specific, linguistically responsive, person-centered and nonjudgmental;

(B) Peer support and recovery services;

(C) Transitional, supportive and permanent housing for persons with substance use disorder;

(D) Harm reduction interventions including, but not limited to, overdose prevention education, access to [*naloxone hydrochloride*] **short-acting opioid antagonists, as defined in ORS 689.681,** and sterile syringes and stimulant-specific drug education and outreach; or

(E) Incentives and supports to expand the behavioral health workforce to support the services delivered by behavioral health resource networks and entities receiving grants or funding under this subsection.

(b) A recipient of a grant or funding under this subsection may not use the grant or funding to supplant the recipient's existing funding.

(4) In awarding grants and funding under subsections (2) and (3) of this section, the council shall:

(a) Distribute grants and funding to ensure access to:

(A) Historically underserved populations; and

(B) Culturally specific and linguistically responsive services.

(b) Consider any inventories or surveys of currently available behavioral health services.

(c) Consider available regional data related to the substance use disorder treatment needs and the access to culturally specific and linguistically responsive services in communities in this state.

(d) Consider the needs of residents of this state for services, supports and treatment at all ages.

(5) The council shall require any government entity that applies for a grant to specify in the application details regarding subgrantees and how the government entity will fund culturally specific organizations and culturally specific services. A government entity receiving a grant must make an explicit commitment not to supplant or decrease any existing funding used to provide services funded by the grant.

(6) In determining grants and funding to be awarded, the council may consult the comprehensive addiction, prevention, treatment and recovery plan established by the Alcohol and Drug Policy Commission under ORS 430.223 and the advice of any other group, agency, organization or individual that desires to provide advice to the council that is consistent with the terms of this section.

(7) Services provided by grantees, including services provided by a Behavioral Health Resource Network, shall be free of charge to the clients receiving the services. Grantees in each network shall seek reimbursement from insurance issuers, the medical assistance program or any other third party responsible for the cost of services provided to a client and grants and funding provided by the council or the authority under subsection (2) of this section may be used for copayments, deductibles or other out-of-pocket costs incurred by the client for the services.

(8) Subsection (7) of this section does not require the medical assistance program to reimburse the cost of services for which another third party is responsible in violation of 42 U.S.C. 1396a(25).

SECTION 25. ORS 431A.855 is amended to read:

431A.855. (1)(a) The Oregon Health Authority, in consultation with the Prescription Monitoring Program Advisory Commission, shall establish and maintain a prescription monitoring program for monitoring and reporting:

(A) Prescription drugs dispensed by pharmacies licensed by the State Board of Pharmacy that are classified in schedules II through IV under the federal Controlled Substances Act, 21 U.S.C. 811 and 812, as modified by the board by rule under ORS 475.035;

(B) Prescribed gabapentin and [*naloxone*] **short-acting opioid antagonists, as defined in ORS 689.681,** dispensed by pharmacies; and

(C) Other drugs identified by rules adopted by the authority.

(b)(A) To fulfill the requirements of this subsection, the authority shall establish, maintain and operate an electronic system to monitor and report drugs described in paragraph (a) of this subsection that are dispensed by prescription.

(B) The electronic system must:

(i) Operate and be accessible by practitioners and pharmacies 24 hours a day, seven days a week; and

(ii) Allow practitioners to register as required under ORS 431A.877 and to apply for access to the electronic system in accordance with rules adopted by the authority under subsection (2) of this section.

(C) The authority may contract with a state agency or private entity to ensure the effective operation of the electronic system.

(2) In consultation with the commission, the authority shall adopt rules for the operation of the electronic prescription monitoring program established under subsection (1) of this section, including standards for:

(a) Reporting data;

(b) Providing maintenance, security and disclosure of data;

(c) Ensuring accuracy and completeness of data;

(d) Complying with the federal Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191) and regulations adopted under that law, including 45 C.F.R. parts 160 and 164, federal alcohol and drug treatment confidentiality laws and regulations adopted under those laws, including 42 C.F.R. part 2, and state health and mental health confidentiality laws, including ORS 179.505, 192.517 and 192.553 to 192.581;

(e) Ensuring accurate identification of persons or entities requesting information from the database;

(f) Accepting printed or nonelectronic reports from pharmacies that do not have the capability to provide electronic reports;

(g) Notifying a patient, before or when a drug classified in schedules II through IV is dispensed to the patient, about the prescription monitoring program and the entry of the prescription in the electronic system; and

(h) Registering practitioners with the electronic system.

(3) The authority shall submit an annual report to the commission regarding the prescription monitoring program established under this section.

SECTION 26. ORS 431A.865 is amended to read:

431A.865. (1)(a) Except as provided under subsections (2) and (3) of this section, prescription monitoring information submitted under ORS 431A.860 to the prescription monitoring program established in ORS 431A.855:

(A) Is protected health information under ORS 192.553 to 192.581.

(B) Is confidential and not subject to disclosure under ORS 192.311 to 192.478.

(b) Except as provided under subsection (3)(a)(H) of this section, prescription monitoring information submitted under ORS 431A.860 to the prescription monitoring program may not be used to evaluate a practitioner's professional practice.

(2) The Oregon Health Authority may review the prescription monitoring information of an individual who dies from a drug overdose.

(3)(a) Except as provided in paragraph (c) of this subsection, the Oregon Health Authority shall disclose prescription monitoring information reported to the authority under ORS 431A.860:

(A) To a practitioner or pharmacist, or, if a practitioner or pharmacist authorizes the authority to disclose the information to a member of the practitioner's or pharmacist's staff, to a member of the practitioner's or pharmacist's staff. If a practitioner or pharmacist authorizes disclosing the information to a member of the practitioner's or pharmacist's staff under this subparagraph, the practitioner or pharmacist remains responsible for the use or misuse of the information by the staff member. To receive information under this subparagraph, or to authorize the receipt of information by a staff member under this subparagraph, a practitioner or pharmacist must certify that the requested information is for the purpose of evaluating the need for or providing medical or pharmaceutical treatment for a patient to whom the practitioner or pharmacist anticipates providing, is providing or has provided care.

(B) To a dental director, medical director or pharmacy director, or, if a dental director, medical director or pharmacy director authorizes the authority to disclose the information to a member of the dental director's, medical director's or pharmacy director's staff, to a member of the dental director's, medical director's or pharmacy director's staff. If a dental director, medical director or pharmacy director authorizes disclosing the information to a member of the dental director's, medical director's or pharmacy director's staff under this subparagraph, the dental director, medical director or pharmacy director remains responsible for the use or misuse of the information by the

staff member. To receive information under this subparagraph, or to authorize the receipt of information by a staff member under this subparagraph:

(i) A dental director must certify that the requested information is for the purposes of overseeing the operations of a coordinated care organization, dental clinic or office, or a system of dental clinics or offices, and ensuring the delivery of quality dental care within the coordinated care organization, clinic, office or system.

(ii) A medical director must certify that the requested information is for the purposes of overseeing the operations of a coordinated care organization, hospital, health care clinic or system of hospitals or health care clinics and ensuring the delivery of quality health care within the coordinated care organization, hospital, clinic or system.

(iii) A pharmacy director must certify that the requested information is for the purposes of overseeing the operations of a coordinated care organization, pharmacy or system of pharmacies and ensuring the delivery of quality pharmaceutical care within the coordinated care organization, pharmacy or system.

(C) In accordance with subparagraphs (A) and (B) of this paragraph, to an individual described in subparagraphs (A) and (B) of this paragraph through a health information technology system that is used by the individual to access information about patients if:

(i) The individual is authorized to access the information in the health information technology system;

(ii) The information is not permanently retained in the health information technology system, except for purposes of conducting audits and maintaining patient records; and

(iii) The health information technology system meets any privacy and security requirements and other criteria, including criteria required by the federal Health Insurance Portability and Accountability Act, established by the authority by rule.

(D) To a practitioner in a form that catalogs all prescription drugs prescribed by the practitioner according to the number assigned to the practitioner by the Drug Enforcement Administration of the United States Department of Justice.

(E) To the Chief Medical Examiner or designee of the Chief Medical Examiner, for the purpose of conducting a medicolegal investigation or autopsy.

(F) To designated representatives of the authority or any vendor or contractor with whom the authority has contracted to establish or maintain the electronic system established under ORS 431A.855.

(G) Pursuant to a valid court order based on probable cause and issued at the request of a federal, state or local law enforcement agency engaged in an authorized drug-related investigation involving a person to whom the requested information pertains.

(H) To a health professional regulatory board that certifies in writing that the requested information is necessary for an investigation related to licensure, license renewal or disciplinary action involving the applicant, licensee or registrant to whom the requested information pertains.

(I) Pursuant to an agreement entered into under ORS 431A.869.

(b) The authority may disclose information from the prescription monitoring program that does not identify a patient, practitioner or drug outlet:

(A) For educational, research or public health purposes;

(B) For the purpose of educating practitioners about the prescribing of opioids and other controlled substances;

(C) To a health professional regulatory board;

(D) To a local public health authority, as defined in ORS 431.003; or

(E) To officials of the authority who are conducting special epidemiologic morbidity and mortality studies in accordance with ORS 413.196 and rules adopted under ORS 431.001 to 431.550 and 431.990.

(c) The authority may not disclose, except as provided in paragraph (b) of this subsection:

(A) Prescription drug monitoring information to the extent that the disclosure fails to comply with applicable provisions of the federal Health Insurance Portability and Accountability Act of

1996 (P.L. 104-191) and regulations adopted under that law, including 45 C.F.R. parts 160 and 164, federal alcohol and drug treatment confidentiality laws and regulations, including 42 C.F.R. part 2, and state health and mental health confidentiality laws, including ORS 179.505, 192.517 and 192.553 to 192.581.

(B) The sex of a patient for whom a drug was prescribed.

(C) The identity of a patient for whom [*naloxone*] **a short-acting opioid antagonist, as defined in ORS 689.681,** was prescribed.

(d) The authority shall disclose information relating to a patient maintained in the electronic system established under ORS 431A.855 to that patient at no cost to the patient within 10 business days after the authority receives a request from the patient for the information.

(e)(A) A patient may request the authority to correct any information related to the patient that is maintained in the electronic system established under ORS 431A.855 that is erroneous. The authority shall grant or deny a request to correct information within 10 business days after the authority receives the request. If a request to correct information cannot be granted because the error occurred at the pharmacy where the information was inputted, the authority shall inform the patient that the information cannot be corrected because the error occurred at the pharmacy.

(B) If the authority denies a patient's request to correct information under this paragraph, or fails to grant a patient's request to correct information under this paragraph within 10 business days after the authority receives the request, the patient may appeal the denial or failure to grant the request. Upon receiving notice of an appeal under this subparagraph, the authority shall conduct a contested case hearing as provided in ORS chapter 183. Notwithstanding ORS 183.450, the authority has the burden in the contested case hearing of establishing that the information is correct.

(f) The information in the prescription monitoring program may not be used for any commercial purpose.

(g) In accordance with ORS 192.553 to 192.581 and federal laws and regulations related to privacy, any person authorized to prescribe or dispense a prescription drug who is entitled to access a patient's prescription monitoring information may discuss the information with or release the information to other health care providers involved with the patient's care for the purpose of providing safe and appropriate care coordination.

(4)(a) The authority shall maintain records of the information disclosed through the prescription monitoring program including:

(A) The identity of each person who requests or receives information from the program and any organization the person represents;

(B) The information released to each person or organization; and

(C) The date and time the information was requested and the date and time the information was provided.

(b) Records maintained as required by this subsection may be reviewed by the Prescription Monitoring Program Advisory Commission.

(5) Information in the prescription monitoring program that identifies an individual patient must be removed no later than three years from the date the information is entered into the program.

(6) The authority shall notify the Attorney General and each individual affected by an improper disclosure of information from the prescription monitoring program of the disclosure.

(7)(a) If the authority or a person or entity required to report or authorized to receive or release prescription information under this section violates this section or ORS 431A.860 or 431A.870, a person injured by the violation may bring a civil action against the authority, person or entity and may recover damages in the amount of $1,000 or actual damages, whichever is greater.

(b) Notwithstanding paragraph (a) of this subsection, the authority and a person or entity required to report or authorized to receive or release prescription information under this section are immune from civil liability for violations of this section or ORS 431A.860 or 431A.870 unless the authority, person or entity acts with malice, criminal intent, gross negligence, recklessness or willful intent.

(8) Nothing in ORS 431A.855 to 431A.900 requires a practitioner or pharmacist who prescribes or dispenses a prescription drug to obtain information about a patient from the prescription monitoring program. A practitioner or pharmacist who prescribes or dispenses a prescription drug may not be held liable for damages in any civil action on the basis that the practitioner or pharmacist did or did not request or obtain information from the prescription monitoring program.

(9) The authority shall, at regular intervals, ensure compliance of a health information technology system described in subsection (3) of this section with the privacy and security requirements and other criteria established by the authority under subsection (3) of this section.

SECTION 27. If House Bill 2421 becomes law, section 7a, chapter ___, Oregon Laws 2023 (Enrolled House Bill 2421) (amending ORS 109.675), is repealed.

CAPTIONS

SECTION 28. The unit captions used in this 2023 Act are provided only for the convenience of the reader and do not become part of the statutory law of this state or express any legislative intent in the enactment of this 2023 Act.

EFFECTIVE DATE

SECTION 29. This 2023 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2023 Act takes effect on its passage.

Passed by House March 6, 2023

Repassed by House June 24, 2023

.....
Timothy G. Sekerak, Chief Clerk of House

.....
Dan Rayfield, Speaker of House

Passed by Senate June 24, 2023

.....
Rob Wagner, President of Senate

Received by Governor:

.....M.,....., 2023

Approved:

.....M.,....., 2023

.....
Tina Kotek, Governor

Filed in Office of Secretary of State:

.....M.,....., 2023

.....
Secretary of State

HB411_REC180_FAV.pdf
Uploaded by: John Kotz
Position: FAV

February 21, 2024

House Health & Government Operations Committee

House Bill 411- Public Health - Opioid Overdose Reversal Drugs - Standing Orders

POSITION: FAVORABLE

We are writing to support House Bill 411- Public Health - Opioid Overdose Reversal Drugs - Standing Orders. As Director of Operations of Recovery180, a 3.1 substance use treatment provider located in multiple sites in Maryland, we see firsthand the impact opioid use-related overdoses have on our community. Increasing access to opioid overdose reversal drugs will save lives and give more individuals an opportunity for recovery.

HB411 is designed to enhance the accessibility and autonomy in the use of opioid overdose reversal drugs. The bill mandates that licensed health care providers with prescribing authority must allow individuals the choice of any FDA-approved opioid reversal drug formulation when issuing a standing order. Key points of the bill include:

A standing order, as defined by the bill, is a written instruction for prescribing and dispensing an opioid overdose reversal drug approved by the FDA. This standing order can be issued by licensed health care providers who either work for the Department of Health or a local health department, or who have a written agreement with an authorized entity.

When issuing a standing order for an opioid reversal drug, the prescribing health care provider must allow individuals to choose any formulation of any opioid reversal drug that has been approved by the FDA. This provision aims to provide patients with greater control over their treatment options and ensure they have access to the most suitable medication for their needs.

Licensed health care providers who issue a standing order can delegate the dispensing of FDA-approved opioid overdose reversal drugs to employees or volunteers of authorized entities, ensuring broader access to these life-saving medications.

Pharmacists are permitted to dispense FDA-approved opioid overdose reversal drugs in accordance with a therapy management contract, further expanding access to these crucial treatments.

The bill is set to take effect on October 1, 2024, and represents a significant step towards improving public health responses to the opioid crisis by ensuring that individuals at risk of opioid overdose, or those in a position to assist someone at risk, have timely and unrestricted access to opioid overdose reversal drugs.

It is for these reasons that we politely ask for a favorable report on House Bill 411. Thank you.

Kind Regards,

Dr. John Kotz
Director of Operations, Recovery180

Kathleen O'Brien Testimony SB408.pdf
Uploaded by: Kathleen O'Brien
Position: FAV

February 20, 2024

Chair Senator Pamela Beidle, Chair
Vice Chair Senator Katherine Klausmeier
Senate Finance Committee
3 East, Miller Senate Office Building
Annapolis, Maryland 21401

RE: SB408 – Public Health - Opioid Overdose Reversal Drugs - Standing Orders

Chair Beidle, Vice Chair Klausmeier and members of the Senate Finance Committee,

I am Kathleen O'Brien, Ph.D and I have spent my whole career dedicated to quality Behavioral Healthcare, including addiction treatment. **I urge a favorable report on Senate Bill 408.**

Previously, I was the CEO of Walden Sierra Behavioral Health, a nationally-recognized behavioral health organization that served counties across Southern Maryland until 2018 with a comprehensive integrated continuum of care for individuals suffering from the effects of substance use, trauma, and other brain-based conditions. I am now the CEO of Walden Wise, a non-profit which focuses on the emotional health of children. I am submitting this testimony personally and not representing my organization.

I support this legislation because Maryland must ensure our first responders and health professionals have access to all the opioid reversal drug approved by the federal Food and Drug Administration. This legislation will require updates to the state's so-called "Standing Order" to include all FDA-approved opioid reversal drugs. This will ensure we are ready for the introduction of new, more effective, or less expensive medicines that may be approved in the future. With this change, Maryland would join several other states who have already made this change to their standing orders.

The opioid and overdose crisis continues, and it has evolved as Fentanyl has taken hold as the cause of 81 percent of overdose deaths in Maryland. Despite all the amazing work by first responders, health care professionals, and many others across the state, there does not seem to be an end in sight. Governor Moore has shown tremendous leadership in his first year in office, broadening the state's response to opioids and overdoses by enhancing coordination between and across all levels of government. But just as the opioid epidemic is evolving and ever changing, so too must Maryland's response. Now is the time to take steps to prepare for the future of this crisis, like updating the standing order.

We must take meaningful steps to treat the long-term and underlying cause of this crisis: the disease of addiction itself. But for addiction treatment to be an option for those who suffer an overdose, they must be able to be revived from an overdose and survive to get into treatment. Ensuring our first responders and health professionals have access to all FDA-approved the opioid reversal drugs will help.

To effectively treat addiction, we need to invest in the state's behavioral health system and to foster collaboration, innovation, and improvement in the delivery of behavioral health services across

Maryland. The limited access to behavioral health services and fragmented integration of mental health and substance use care within the broader healthcare system too often leads to delayed treatment, worsening of conditions, and adverse health outcomes. A shortage of behavioral health professionals also poses a significant challenge. Variations in the quality of behavioral health services which impact the overall effectiveness of the behavioral health system.

Disparities in behavioral health outcomes among underserved populations, including racial and ethnic minorities, low-income individuals, and rural communities, perpetuate inequalities in access, treatment, and outcomes. Culturally competent care is essential to address these disparities and ensure equitable access to high-quality behavioral health services for all individuals.

With Gov. Moore providing excellent leadership on the continuing and evolving crisis of opioids and overdoses, we must harness the collective expertise, resources, and collaborative power needed to address the complex challenges faced by Marylanders. Changing our thinking from a crisis mindset to planning and preparing long term will allow us to address the underlying disease of addiction more comprehensively and ensure we are prepared to address the next opioid or other drug like xylazine that could emerge.

Ensuring access to all FDA-approved opioid reversal drug approved is an important step forward so that together, we can create a future where every individual has equitable access to comprehensive behavioral health services, where disparities are diminished, and where innovative approaches lead to better health outcomes and improved well-being for all. Instead of being gripped by the crisis of opioids and overdoses, Maryland can be a beacon of hope, driving real and meaningful change in the lives of our communities.

Thank you for your consideration of this important legislation. **I strongly urge you to issue a favorable report on Senate Bill 408.**

Sincerely,

Kathleen O’Brien, Ph.D

240215 Dr Thomas Maryland Center for Health Equity

Uploaded by: Stephen Thomas

Position: FAV

Maryland Center for Health Equity
2242 SPH Building (# 255)
College Park, Maryland 20742-2611

February 20, 2024

Senator Pamela Beidle, Chair
Senator Katherine Klausmeier, Vice Chair

Senate Finance Committee
3 East, Miller Senate Office Building
Annapolis, Maryland 21401

SUBJECT: SB408 – Public Health - Opioid Overdose Reversal Drugs - Standing Orders

Chair Beidle,

I am Dr. Stephen B. Thomas, Professor of Health Policy and Management and Director, the University of Maryland Center for Health Equity. I speak in my personal capacity today. I appreciate the opportunity to my support for House Bill 411 – Public Health - Opioid Overdose Reversal Drugs - Standing Orders. I urge a favorable report on Senate Bill 408.

As you are aware, in recent years the opioid epidemic has impacted too many people and families across Maryland and the United States. It is vital that our first responders, health care providers, and average citizens have the education and tools to help their fellow citizens in life threatening overdose situations. Fentanyl has emerged as the leading cause of overdose deaths in in Maryland – according to December 15th Maryland Matters article, "Deputy Secretary Lord said that between July 2022 and July 2023, there were 2,583 fatal overdoses in Maryland, and fentanyl was involved in about 81% of deaths."

Scientists and health professionals are constantly looking to improve the responses to these overdoses, and it is important that Maryland include any formulation of any opioid reversal drug approved by the federal Food and Drug Administration in the standing order. It is my understanding that several other states have already taken the same step.

By updating the standing order to include all FDA approved opioid reversal drugs, we will be ready for the introduction of new, more effective, or less expensive medicines that may be approved in the future. As the state's standing order is only updated annually, we do not want to be left in a situation where there is a new, more effective, or less costly reversal drug that is not available to Maryland's first responders, health professionals and citizens.

In addition, just as fentanyl has emerged as the preeminent killer in the state's overdoses, one day another drug will take its place, such as xylazine. By updating the standing order, Maryland will be ready to ensure that reversal drugs better suited to reversing this next drug, or the one after that, can be quickly made available.

Opioids and overdoes are a public health crisis without question. It is critical that we mobilize our communities and trusted voices within them to help spread the awareness messages to help prevent overdose deaths. That also means equipping them with the education and tools to respond to overdoses as they happen so they can help save lives.

I have spent the last two decades working to spread awareness for colorectal cancer screenings and COVID vaccinations through trusted community leaders in Black and Brown communities. I helped built the HAIR program — Health Advocates In-Reach and Research — while working with barber shops in Pittsburgh around 2005 to spread awareness for colorectal cancer screenings to a population of mostly Brown and Black people, who have a history of mistrust with the health care system. I then brought the program to the University of Maryland in 2010 and expanded it to COVID vaccinations when the pandemic hit.

My current research at University of Maryland focuses on the translation of evidence-based science on chronic disease into community-based interventions designed to eliminate racial and ethnic disparities in health and health care. I have also focused on understanding how social context shapes attitudes and behaviors of underserved, poorly served, and never-served segments of our society toward participation in health promotion and disease prevention activities. Much of my research has been centered on how the legacy of the Syphilis Study at Tuskegee (1932–72) has impacted trust and influenced the willingness of African Americans to participate in medical and public health research.

Previously I was a member of the Maryland Health Quality and Cost Council's Health Disparity Work Group. The final report of our work was translated into legislation and passed into law as the Maryland Health Improvement and Disparities Reduction Act of 2012. In 2014, Democratic Gov. O'Malley appointed me to serve on the Maryland Health Care Commission and I was reappointed in 2019 by Gov. Larry Hogan.

I am deeply committed to helping to address the public health challenges of underserved communities across Maryland and the country, and ensuring these communities have trust in the health care system and public health systems. I believe that updating the standing order to include all FDA approved opioid reversal drugs is a smart move for Maryland and it will show our citizens that nothing is being held back from our first responders and health providers that could save lives because of where someone lives or the color of their skin.

Thank you for your consideration. Again, I urge a favorable report on Senate Bill 408.

Sincerely,

Stephen B. Thomas
Professor, Department of Health Services Administration
Director, Maryland Center for Health Equity
University of Maryland, School of Public Health
Office Number: 301 405-8859
Email: sbt@umd.edu

SB408_RHTC_FAV.pdf
Uploaded by: Therese Hessler
Position: FAV

February 20, 2024

Senate Finance Committee

Senate Bill 408- Public Health - Opioid Overdose Reversal Drugs - Standing Orders

POSITION: FAVORABLE

The Recovery Housing and Treatment Centers Coalition of Maryland (RHTC) writes to support Senate Bill 408- Public Health - Opioid Overdose Reversal Drugs - Standing Orders. We are a coalition of recovery residences, group homes, and treatment centers throughout Maryland, which work to educate the importance of maintaining and expanding recovery facilities and services in Maryland and the benefits that such facilities have on persons in recovery, the community, and the State.

Senate Bill 408 is designed to enhance the accessibility and autonomy in the use of opioid overdose reversal drugs. The bill mandates that licensed health care providers with prescribing authority must allow individuals the choice of any FDA-approved opioid reversal drug formulation when issuing a standing order. Key points of the bill include:

A standing order, as defined by the bill, is a written instruction for prescribing and dispensing an opioid overdose reversal drug approved by the FDA. This standing order can be issued by licensed health care providers who either work for the Department of Health or a local health department, or who have a written agreement with an authorized entity.

When issuing a standing order for an opioid reversal drug, the prescribing health care provider must allow individuals to choose any formulation of any opioid reversal drug that has been approved by the FDA. This provision aims to provide patients with greater control over their treatment options and ensure they have access to the most suitable medication for their needs.

Licensed health care providers who issue a standing order can delegate the dispensing of FDA-approved opioid overdose reversal drugs to employees or volunteers of authorized entities, ensuring broader access to these life-saving medications.

Pharmacists are permitted to dispense FDA-approved opioid overdose reversal drugs in accordance with a therapy management contract, further expanding access to these crucial treatments.

The bill is set to take effect on October 1, 2024, and represents a significant step towards improving public health responses to the opioid crisis by ensuring that individuals at risk of opioid overdose, or those in a position to assist someone at risk, have timely and unrestricted access to opioid overdose reversal drugs.

It is for these reasons that we politely ask for a favorable report on Senate Bill 408. Thank you.

For more information call or email:
Therese M. Hessler, Ashlar Government Relations | 301-503-2576 | therese@ashlargr.com

SB 408 - Support - MPS WPS.pdf
Uploaded by: Thomas Tompsett
Position: FAV

February 14, 2024

The Honorable Pamela Beidle
Senate Finance Committee
Miller Senate Office Building – 3 East
Annapolis, MD 21401

RE: Support – Senate Bill 408: Public Health - Opioid Overdose Reversal Drugs - Standing Orders

Dear Chairman Beidle and Honorable Members of the Committee:

The Maryland Psychiatric Society (MPS) and the Washington Psychiatric Society (WPS) are state medical organizations whose physician members specialize in diagnosing, treating, and preventing mental illnesses, including substance use disorders. Formed more than sixty-five years ago to support the needs of psychiatrists and their patients, both organizations work to ensure available, accessible, and comprehensive quality mental health resources for all Maryland citizens; and strive through public education to dispel the stigma and discrimination of those suffering from a mental illness. As the district branches of the American Psychiatric Association covering the state of Maryland, MPS/WPS represent over 1000 psychiatrists and physicians currently in psychiatric training.

MPS/WPS support Senate Bill 408: Public Health - Opioid Overdose Reversal Drugs - Standing Orders (SB 408). Opioid overdose reversal drugs (OORDs) are life-saving medications that counteract the effects of opioids like heroin and fentanyl. OORDs restore normal breathing to an individual who has overdosed and thus prevent death. An individual can administer an OORD through three formulations: intramuscularly, intravenously, and intranasally.

§13–3106 of the Maryland Health General Article allows for a standing order for OORDs. SB 408 wisely takes the next step and allows individuals who will benefit from or administer an OORD approved by the federal Food and Drug Administration to choose which formulation works best for them.

Therefore, for all the reasons above, MPS/WPS ask the committee for a favorable report on SB 408. If you have any questions regarding this testimony, please feel free to contact Thomas Tompsett Jr. at tommy.tompsett@mdlobbyist.com.

Respectfully submitted,
The Maryland Psychiatric Society and the Washington Psychiatric Society
Legislative Action Committee

SB 408 - FIN - LOO.pdf
Uploaded by: Jason Caplan
Position: UNF

Maryland
DEPARTMENT OF HEALTH
Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

February 21, 2023

The Honorable Pamela Beidle
Chair, Senate Finance Committee
3 East Miller Senate Office Building
Annapolis, Maryland 21401

RE: Senate Bill 408 – Public Health - Opioid Overdose Reversal Drugs - Standing Orders – Letter of Opposition

Dear Chair Beidle and Committee Members:

The Maryland Department of Health (MDH) respectfully submits this letter of opposition for Senate Bill (SB) 408 – Public Health - Opioid Overdose Reversal Drugs - Standing Orders.

SB 408 would require health care providers, when writing standing orders for an opioid reversal drug, to allow an individual to choose *any formulation* of *any opioid overdose reversal drug* (OORDs) approved by the Food and Drug Administration (FDA). MDH is dedicated to addressing the overdose crisis in Maryland and is actively providing overdose reversal medications via a statewide standing order, which includes all formulations of naloxone and technical support for pharmacists on how to educate individuals who access naloxone via the standing order on how best to utilize the medication. Additionally, through the Overdose Response Program (ORP) housed within the Center for Harm Reduction Services, MDH provides overdose reversal education technical assistance and distributes naloxone to community-based organizations at no cost to those organizations. Naloxone is a well-known opioid overdose reversal medication with a long-standing history of safe use in community-based settings. MDH has provided years of public health education to the community around the appropriate administration of this formulation in conjunction with the activation of the emergency medical system. The effectiveness of MDH's overdose education and naloxone distribution strategies (OEND), as described above, reflect best practice standards based on a large body of evidence within the scientific literature.[1]

SB 408, if passed as written, would require MDH to include novel formulations of overdose reversal medications approved by the FDA, which lack evidence of efficacy in community-based settings. New OORDs, namely nalmefene hydrochloride, have recently become available - however, in the case of nalmefene hydrochloride, clinicians have expressed concern about the use of the formulation in the community setting due to the increased likelihood of inducing opioid withdrawal and have urged further study of the formulation.. .This view has also been expressed by the American College

[1] Razaghizad, A., Windle, S. B., Filion, K. B., Gore, G., Kudrina, I., Paraskevopoulos, E., ... & Eisenberg, M. J. (2021). The effect of overdose education and naloxone distribution: an umbrella review of systematic reviews. American journal of public health, 111(8), e1-e12.

of Medical Toxicology and the American Academy of Clinical Toxicology, which released a joint statement expressing concern about the utilization of nalmefene as an overdose reversal agent in community-based settings until additional studies supporting its utility can be conducted.[2]

The current formulations of overdose reversal medications MDH provides via standing order and through the ORP have decades of scientific evidence supporting their utilization and are more competitively priced than new formulations on the market. Given these dynamics, MDH believes SB408 will not be helpful to the state's efforts to reduce overdose mortality and may create additional harm. The newer formulations of overdose reversal agents should undergo additional study in community-based settings prior to being incorporated into public health strategy.

If you have any further questions, please contact Sarah Case-Herron, Director, Office of Governmental Affairs at sarah.case-herron@maryland.gov.

Sincerely,

Laura Herrera Scott, M.D., M.P.H.
Secretary

[2] Stolbach, A. I., Mazer-Amirshahi, M. E., Nelson, L. S., & Cole, J. B. (2023). American College of Medical Toxicology and the American Academy of Clinical Toxicology position statement: nalmefene should not replace naloxone as the primary opioid antidote at this time. Clinical Toxicology, 61(11), 952-955.

SB408_MACDS_UNF.pdf
Uploaded by: Sarah Price
Position: UNF

MARYLAND ASSOCIATION
OF CHAIN DRUG STORES

SB408 Public Health - Opioid Overdose Reversal Drugs - Standing Orders
Finance Committee
February 20th, 2024

Position: Unfavorable

Background: SB408 would require that an individual be allowed to choose their preferred formulation for an opioid reversal drug under a standing order.

Comments: The Maryland Association of Chain Drug Stores (MACDS) does not oppose choice for patients, but the need for and ultimate intent of this legislation is unclear. The existing statewide standing order already allows individuals to choose their preference of opioid reversal medications. We are not opposed to ensuring that choice remains in place outside of the current or future statewide standing orders. Our concern is specific to whether this legislation would, as a result, require that all pharmacies carry all formulations of opioid reversal drugs, which is unclear. MACDS would oppose a mandate requiring that every pharmacy carry every formulation at all times. If that would be the result of this legislation, we would respectfully request an amendment removing that mandate, or clarifying that that is not the case if that is not the intent of this bill.

We hope that the Committee will consider this concern when deliberating on the bill, and we will seek conversation with the sponsors to clarify the intent and can follow up with the Committee should our position change. Thank you for your consideration.

NCADD-MD - 2024 SB 408 LOI - Standing Order - Sena
Uploaded by: Nancy Rosen-Cohen
Position: INFO

Senate Finance Committee
February 20, 2024

Senate Bill 408
Public Health - Opioid Overdose Reversal Drugs - Standing Orders

Letter of Information

NCADD-Maryland wishes to express its concerns about the unintended consequences of Senate Bill 408.

This Committee has been a strong proponent of open access to opioid overdose reversal medications over the years. We are grateful for that support. While we favor consumer choice, we believe this bill will require the Maryland Department of Health to purchase all formulations and brands of overdose reversal products. MDH supplies hundreds of Overdose Response Programs (ORPs) with naloxone products for free. These products are then distributed as widely as possible to people in the community who live with, work with, and love people who are at risk of overdosing.

We are concerned that this bill will put MDH in the position of having to spend already stretched dollars for an ever-increasing array of overdose reversal medications. We are also concerned that this would create a logistical burden for ORPs if they would need to either have on hand or know where to refer someone to a formulation or brand requested.

If the Committee decides to move forward with this bill, we would hope that its reach would be limited to pharmacies and not apply to MDH and the ORPs who work to save people's lives every day.

National Council on Alcoholism & Drug Dependence – Maryland Chapter
28 E. Ostend Street, Suite 303, Baltimore, MD 21230 · 410-625-6482 · fax 410-625-6484
www.ncaddmaryland.org