LEGISLATIVE ANALYSIS AND PUBLIC POLICY ASSOCIATION

MODEL OVERDOSE REVERSAL AGENTS ACT

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MODEL OVERDOSE REVERSAL AGENTS ACT

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MODEL OVERDOSE REVERSAL AGENTS ACT

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SECTION I. TITLE.

This Act may be cited as the "Model Overdose Reversal Agents Act," "Model Act," or "the Act."

SECTION II. LEGISLATIVE FINDINGS AND PURPOSE.

(a) Legislative findings.—The [legislature][1] finds that:

(1) In the United States, an estimated 1.25 million individuals died from a drug overdose between 1999 and 2023;[2]

(2) In 2023, approximately 75 percent of U.S. drug overdose deaths involved an opioid, with over 90 percent of those involving the "synthetic opioids other than methadone" category that includes illicitly manufactured fentanyl and fentanyl analogs;[3]

(3) Overdose reversal agents available on the market, such as naloxone and nalmefene, can reverse overdoses involving opioids and help prevent fatal overdoses;

(4) The Centers for Disease Control and Prevention reported that, despite an increase in prescriptions for overdose reversal agents, not enough of the medication is getting into the hands of those who need it most;[4]

(5) Expanding access to overdose reversal agents and encouraging citizens of [state] to obtain overdose reversal agents are in [state's] best interests.

[1] This Act contains certain bracketed words and phrases (*e.g.*, "[legislature]"). Brackets indicate instances where state lawmakers may wish to insert state-specific terminology, facts, or provisions.

[2] The drafters calculated this number by combining the 1.147 million overdose deaths reported by the CDC Wonder database between 1999 and 2022 and the provisional reported overdose deaths for the 12-month period ending December 2023 (approximately 104,000). *Drug Overdose Death Rates*, NAT'L INST. ON DRUG ABUSE (May 14, 2024), https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates; *Provisional Drug Overdose Death Counts*, CENTERS FOR DISEASE CONTROL & PREVENTION (May 5, 2024), https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.

[3] *Provisional Drug Overdose Death Counts, supra* note 2.

[4] *Still Not Enough Naloxone Where It's Most Needed*: *Despite Huge Overall Increase in Prescribing, More Needed in Rural Areas*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Aug. 6, 2019), https://www.cdc.gov/media/releases/2019/p0806-naloxone.html. See also *New study shows major shortage of naloxone in nearly every U.S. state*, THE HELLER SCHOOL FOR SOCIAL POLICY AND MANAGEMENT, BRANDEIS U. (Feb. 11, 2022), https://heller.brandeis.edu/news/items/releases/2022/traci-green-lancet-naloxone.html.

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(b) Purpose.—It is the intent of the [legislature] through this Act to, among other things:

(1) Allow authorized healthcare providers to prescribe or dispense an overdose reversal agent to any person or entity in [this state], thereby eliminating any existing [state] restrictions in this regard;

(2) Allow any person or entity in [this state] to receive, possess, store, transfer without cost, or administer an overdose reversal agent, thereby eliminating any existing [state] restrictions in this regard;

(3) Require specified people and entities to offer overdose reversal agents to individuals at increased risk of overdose, including, but not limited to, those released from correctional settings and those treated for an overdose at a hospital or emergency department;

(4) Require an overdose reversal agent to be stored on site at specified locations in [this state] for use by any individual at no cost;

(5) Grant immunity from civil, criminal, or administrative penalty to any person or entity prescribing, dispensing, selling, receiving, possessing, storing, transferring without charge, or administering overdose reversal agents, in the absence of gross negligence, malice, or criminal intent;

(6) Require health insurance coverage of all types of overdose reversal agents and prohibit discriminatory life and health insurance practices; and

(7) Create, and appropriate money to, a bulk overdose reversal agent purchasing fund to assist people or entities in [this state] to fulfill their requirements under this Act.

Commentary

Individuals are dying from drug overdose at a record rate in the United States. In each of the past three years (2021-2023), over 100,000 individuals fatally overdosed.[5] Opioids—primarily synthetic opioids other than methadone—caused the majority of these deaths.[6] However, if naloxone, nalmefene, or any other overdose reversal medication approved by the U.S. Food and Drug Administration (FDA) in the future is quickly and properly administered, an overdose caused by opioids can be reversed.[7] Such medications (hereafter called "overdose

[5] *Provisional Drug Overdose Death Counts*, *supra* note 2.
[6] *Id.*
[7] As of June 2024, available overdose reversal agents work only to reverse overdoses caused by opioids. The drafters do not limit this Act's language to opioids or opioid overdoses, however, in the hopes that one or more ORAs applying to non-opioid-caused overdoses may be developed in the future.

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reversal agents" or "ORAs") are safe, non-addictive drugs that work to interrupt an overdose and save an individual's life. Studies show that overdose deaths decrease when ORAs and overdose education are available to community members.[8] The use of ORAs to stop or prevent an overdose is a crucial tool in controlling the overdose epidemic within the United States.

In April 2018, then U.S. Surgeon General Jerome Adams called for heightened awareness and availability of ORAs to reverse the effects of overdose.[9] Specifically, General Adams called for increasing the availability and distribution of ORAs as a critical component in reducing opioid-related overdose deaths.[10] Likewise, recent National Drug Control Strategies issued by the Office of National Drug Control Policy highlight the need to expand access to naloxone and other overdose reversal agents.[11]

Over the past decade, legislators in various states and in the District of Columbia have made great strides in expanding access to ORAs by enacting countless pieces of legislation.[12] By 2017, every state had an ORA access law in effect in some form and, to varying degrees, states regularly amended those laws to expand ORA access.[13] Indeed, the sheer size of the Legislative Analysis and Public Policy Association's (LAPPA's) most recent state-by-state summary of ORA access laws (250 pages) provides evidence of the robustness of many state laws.[14]

Moreover, in November 2021, LAPPA published its Model Expanded Access to Emergency Opioid Antagonists Act (2021 Model Act).[15] Although the 2021 Model Act contains a host of laudable provisions and commentary, many state laws now meet or exceed some elements of that Act. Additionally, given both the general progression of ORA laws across the country and the emergence of non-prescription, sometimes called "over-the-counter" (OTC), options that are not yet addressed adequately in many state laws, in 2024, LAPPA set out to

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[8] Alexander Y. Walley, et al., *Opioid Overdose Rates and Implementation of Overdose Education and Nasal Naloxone Distribution in Massachusetts: Interrupted Time Series Analysis*, BMJ (Jan. 31, 2013), https://www.bmj.com/content/346/bmj.f174).

[9] *U.S. Surgeon General's Advisory on Naloxone and Opioid Overdose*, U.S. DEP'T OF HEALTH & HUM. SERVS. (last reviewed Apr. 8, 2022), https://www.hhs.gov/surgeongeneral/priorities/opioids-and-addiction/naloxone-advisory/index.html.

[10] *Id.*

[11] *National Drug Control Strategy*, EXEC. OFF. OF THE PRESIDENT, OFF. OF NAT'L DRUG CONTROL POL'Y 4 (May 2024), https://www.whitehouse.gov/wp-content/uploads/2024/05/2024-National-Drug-Control-Strategy.pdf ("Bringing awareness to and widely distributing OORM [opioid overdose reversal medications] is an important step toward slowing the rise in overdose deaths."); *National Drug Control Strategy*, EXEC. OFF. OF THE PRESIDENT, OFF. OF NAT'L DRUG CONTROL POL'Y 10 (Apr. 2022), https://www.whitehouse.gov/wp-content/uploads/2022/04/National-Drug-Control-2022Strategy.pdf ("Expanding access to naloxone, an opioid overdose reversal medication, which could save tens of thousands of lives in a short period of time.").

[12] This Act's drafters are aware that the District of Columbia (D.C.) is not a state. However, from this point forward in the commentary, and for the sole purpose of simplifying sentences, the word "state" includes D.C. unless otherwise indicated.

[13] *See Opioid Antagonist Access: Summary of State Laws,* LEGIS. ANALYSIS & PUB. POL'Y ASS'N, (Oct. 2023), https://legislativeanalysis.org/opioid-antagonist-access-summary-of-state-laws/ (the state-by-state descriptions of laws contain original effective date information).

[14] *Id.*

[15] *Model Expanded Access to Emergency Opioid Antagonists Act*, LEGIS. ANALYSIS & PUB. POL'Y ASS'N (Sept. 2021), https://legislativeanalysis.org/model-expanded-access-to-emergency-opioid-antagonists-act/.

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update the 2021 Model Act. The provisions of this updated Act intentionally push ORA access forward beyond where most, if not all, states are now.

The goal of a model act is to provide a template of suggested legislative provisions that can be followed efficiently to achieve the Act's stated purposes. To that end, this Act gives legislators and policymakers the means to expand access to ORAs in the state and, thus, save more lives. This Act is comprehensive and enables legislators to completely replace any existing ORA laws with this Act or use individual provisions that best address the needs of the state. Much of the 2021 Model Act's commentary remains applicable in 2024. Therefore, the commentary in this Act contains a mix of portions of the 2021 Model Act's commentary and description of how and why this Act differs from the 2021 Model Act.

SECTION III. DEFINITIONS.

[*States may already have definitions in place for some or all of the following listed terms. In such case, states are free to use the existing definitions in place of those listed below.*]

For purposes of this Act, unless the context clearly indicates otherwise, the words and phrases listed below have the meanings given to them in this section:

(a) Administer.—"Administer" means to directly apply, whether by injection, inhalation, ingestion, or other means, an overdose reversal agent to the body of an individual suffering, or believed to be suffering, an overdose;[16]

(b) Correctional setting.—"Correctional setting" means a jail, prison, adult or juvenile detention center, correctional or carceral facility, or other environment in which a state or local entity, public or private, confines a person;[17]

(c) Dosage form.—"Dosage form" means the physical form in which a drug is produced and dispensed, such as a tablet, a capsule, intranasal spray, or an injectable;[18]

(d) First responder.—"First responder" means a state or local law enforcement officer, firefighter, emergency medical services provider, or other individual who, in an official or volunteer capacity, responds to an emergency or critical incident;[19]

[16] *See* KY. REV. STAT. ANN. § 218A.010(1) (West 2024).
[17] *See Model Expanded Access to Emergency Opioid Antagonists Act*, supra note 15, at 6; *Model Withdrawal Management Protocol in Correctional Settings Act*, LEGIS. ANALYSIS & PUB. POL'Y ASS'N 7 (June 2021), https://legislativeanalysis.org/model-withdrawal-management-protocol-in-correctional-settings-act/; *Model Access to Medication for Addiction Treatment in Correctional Settings Act*, LEGIS. ANALYSIS & PUB. POL'Y ASS'N 7 (Oct. 2020), https://legislativeanalysis.org/model-access-to-medication-for-addiction-treatment-in-correctional-settings-act/.
[18] *See Drugs@FDA Glossary of Terms*, U.S. FOOD & DRUG ADMIN. (last reviewed Nov. 11, 2017), https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms.
[19] *See Model Expanded Access to Emergency Opioid Antagonists Act*, *supra* note 15, at 6.

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(e) Harm reduction.—"Harm reduction" means a program, service, support, or resource that attempts to reduce the adverse consequences of substance use among people who use substances and addresses conditions that give rise to substance use, as well as the substance use itself. Harm reduction includes, but is not limited to, drug checking, syringe services programs, overdose reversal agent distribution, and education about Good Samaritan fatal overdose prevention laws;[20]

(f) Healthcare provider.—"Healthcare provider" means a licensed physician, osteopath, dentist, advanced practice registered nurse, physician assistant, registered nurse, pharmacist, or [other individuals authorized by the state or federal government to provide health care that the state wishes to add] operating within the scope of the healthcare provider's authority;[21]

(g) Intensive outpatient program.—"Intensive outpatient program" means a treatment program that addresses substance use disorders or other disorders that do not require detoxification or inpatient supervision and are designated by the American Society of Addiction Medicine as a level 2.1 setting;[22]

(h) Life insurance.—"Life insurance" means insurance upon the lives of human beings and includes policies that also provide endowment benefits, additional benefits incidental to a loss in the event of death, dismemberment, or loss by accident or accidental means, additional benefits to safeguard the contract from lapse or to provide a special surrender value, a special benefit or an annuity, in the event of total and permanent disability of the insured, optional modes of settlement of proceeds, additional benefits to provide for educational loans, and additional benefits providing specified disease coverage, limited benefit health coverage, or accident and sickness coverage;[23]

(i) Non-prescription overdose reversal agent.—"Non-prescription overdose reversal agent" means an overdose reversal agent available to U.S. consumers in a dosage form, route of administration, and strength approved by the U.S. Food and Drug Administration for

[20] *See Model Opioid Litigation Proceeds Act*, LEGIS. ANALYSIS & PUB. POL'Y ASS'N 10 (Sept. 2021), https://legislativeanalysis.org/model-opioid-litigation-proceeds-act/.
[21] *See* ALASKA STAT. ANN. § 17.20.085(a), (e) (West 2024).
[22] MD. CODE ANN., HEALTH – GEN § 8-408(a)(4) (West 2024).
[23] *See* VA. CODE ANN. § 38.2-102 (West 2024).

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purchase without a prescription.

(j) Opioid.—"Opioid" means a natural, synthetic, or semi-synthetic chemical that interacts with opioid receptors on nerve cells in the body and brain and reduces the intensity of pain signals and feelings of pain and includes, but is not limited to heroin, synthetic opioids such as fentanyl, nitazene class drugs, and analgesics such as tramadol, oxycodone, hydrocodone, codeine, and morphine;[24]

(k) Opioid treatment program.—"Opioid treatment program" means a program approved by [the state department of health, state opioid treatment authority, and/or other appropriate department or agency] to provide opioid maintenance therapy under 42 C.F.R. Part 8 and regulations adopted by [the state department of health, state opioid treatment authority, and/or other appropriate department or agency] and registered with the federal Drug Enforcement Administration as a narcotic treatment program;[25]

(l) Overdose.—"Overdose" means a condition, including, but not limited to, extreme physical illness, decreased level of consciousness, respiratory depression, coma, or death resulting from the consumption or use of a substance that requires medical attention, assistance, or treatment, and clinical suspicion for drug overdose, such as respiratory depression, unconsciousness, or altered mental status, without other conditions to explain the clinical condition;[26]

(m) Overdose reversal agent.—"Overdose reversal agent" means a drug or combination of drugs including, but not limited to, naloxone and nalmefene, approved by the U.S. Food and Drug Administration for the complete or partial reversal of an overdose. An overdose reversal agent is either a non-prescription overdose reversal agent or a prescription overdose reversal agent;[27]

(n) Person or entity.—"Person or entity" means any individual, business, corporation, partnership, association, cooperative, company, trust, joint venture, government, political

[24] *See Opioid Basics*, CTRS. FOR DISEASE CONTROL & PREVENTION (last reviewed Jan. 26, 2021), https://www.cdc.gov/opioids/basics/terms.html.
[25] *See* MD. CODE ANN., HEALTH – GEN § 8-408(a)(5) (West 2024).
[26] FLA. STAT. ANN. § 401.253(1)(c) (West 2024).
[27] This definition stems from language used in naloxone/opioid antagonist/ORA access laws across many U.S. jurisdictions, albeit with the modifications described in the Section III commentary below.

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subdivision, school district, educational institution, correctional setting, law enforcement, other first responder, or other legal, commercial, formal, or informal entity or group;[28]

(o) Prescription overdose reversal agent.—"Prescription overdose reversal agent" means an overdose reversal agent available to U.S. consumers in a dosage form, route of administration, and strength that is not approved by the U.S. Food and Drug Administration for purchase without a prescription;

(p) Route of administration.—"Route of administration" means the way in which a drug or agent enters the body, such as by mouth or by injection;[29]

(q) Secure box.—"Secure box" means a container that:

(1) Is securely affixed in a public location;

(2) Can be accessed by individuals for public use;

(3) Is temperature-controlled or stored in an environment with temperature controls;

(4) Is tamper-resistant;

(5) Is equipped with an alarm capable of detecting and transmitting a signal when accessed by individuals; and

(6) Is equipped with an alarm capable of alerting first responders when accessed by individuals, unless equipping the container with such an alarm is commercially impracticable.[30]

(r) Secured machine.—"Secured machine" means a machine that only individuals receiving services from an entity providing harm reduction can access, via a designated access number, personalized magnetic strip card, or any other technology. A secured machine is not a vending machine;[31]

(s) Single state authority.—"Single state authority" means entity designated by the [governor or chief executive officer of this state] as the single state administrative authority responsible for the planning, development, implementation, monitoring, regulation, and evaluation of substance use disorder services, including administering the federal

[28] *See* VA. CODE. ANN. § 1-230 (West 2024).
[29] *See Route of administration*, COLLINS DICTIONARY, https://www.collinsdictionary.com/us/dictionary/english/route-of-administration (last accessed June 27, 2024).
[30] *See* CONN. GEN. STAT. ANN. § 21a-286(a)(7) (West 2023).
[31] *See* CONN. GEN. STAT. ANN. § 21a-286(a)(8) (West 2023).

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Substance Abuse Prevention and Treatment Block Grant;[32]

(t) Strength.—"Strength" means how much of the active ingredient is present in each dosage;[33] and

(u) Vending machine.—"Vending machine" means any self-service device offered for public use upon public or private property which, upon insertion of a coin, coins, or token, or by other means, dispenses items, either in bulk or in package, without the necessity of replenishing the device between each vending operation.[34]

Commentary

This Act uses the defined phrase "overdose reversal agent" (subsection (m)) in place of the phrase used in the 2021 Model Act, "emergency opioid antagonist." Although the two FDA-approved ORAs available in 2024, naloxone and nalmefene, are both opioid antagonists, it is possible that a future FDA-approved ORA will not be. Changing opioid antagonist to ORA eliminates the need to revise this Act later if such event occurs. The ORA definition itself resembles that used in access laws in virtually all U.S. states, except for: (1) the express reference to nalmefene, first approved by the FDA as a nasal spray in May 2023;[35] and (2) subdividing ORAs into the two categories described below.

This Act divides ORAs into two mutually exclusive categories, "non-prescription overdose reversal agents" (subsection (i)) and "prescription overdose reversal agents" (subsection (o)). As with any other drug, the FDA separately approves individual ORA products for consumer use that are a unique combination of active ingredient, proprietary (or generic) name, dosage form/route of administration, and strength.[36] Certain naloxone-based ORA products (nasal sprays with a strength of 3mg/spray or 4mg/spray) are FDA-approved for non-prescription sale. However, the remainder of ORA products, such as injectables, higher strength nasal sprays, or nalmefene-based products, are not. In many instances, the Act treats both ORA categories the same, in which case statutory language uses the overarching term, "overdose reversal agent." Where treatment of the two types of ORAs differs, the drafters use the narrower term applicable to the appropriate category. The drafters created the definitions for both non-prescription overdose reversal agents and prescription overdose reversal agents for this Act, as such definitions do not exist currently in any state laws.

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[32] *See* 34 U.S.C. § 60521(e) (2024).
[33] *Drug@FDA Glossary of Terms*, supra note 18.
[34] *See* CONN. GEN. STAT. ANN. § 21a-34(2) (West 2023).
[35] *FDA Approves Prescription Nasal Spray to Reverse Opioid Overdose*, U.S. FOOD & DRUG ADMIN. (May 22, 2023), https://www.fda.gov/news-events/press-announcements/fda-approves-prescription-nasal-spray-reverse-opioid-overdose.
[36] In the case of Narcan®, the active drug is "naloxone hydrochloride," the dosage form/route of administration is "SPRAY, METERED; NASAL" and the strength is "4MG/SPRAY." *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations: Product Details for NDA 208411,* U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=208411#44682 (data as of May 2024).

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Another important new definition in this Act is the phrase "person or entity" (subsection (n)). As defined, the phrase covers *all* individuals *and* anything organized by, operated by, or made up of individuals regardless of the formality of the organization or operation. Some state laws use the simple term "person" to cover both individuals and entities (see footnote 23, for example). Here, however, the drafters want to make clear that the definition includes both humans and inanimate entities created/operated by humans (*e.g.*, a corporation, limited liability company, or school district) and, thus, "and entity" joins the word "person." The purpose behind using the new phrase is to provide *universal access* to ORAs within a jurisdiction while eliminating the need for either an exhaustive list of approved individuals and organizations or inserting multiple statutory provisions scattered about the Act to cover different groups. The net result of this choice is that the definition will encompass all subsets of individuals or groups in a state, whether it be a police department, a school district, a correctional facility, a church, an organization providing harm reduction, or anything else, without the need for express mention. This defined phrase is used throughout the commentary as well.

Finally, despite somewhat resembling each other, the terms "secure box" (subsection (q)), "secured machine" (subsection (r)), and "vending machine" (subsection (u)), refer to separate things. In the context of ORAs, a secure box is a small storage cabinet, something akin to an automated external defibrillator (AED) or fire extinguisher cabinet, that is installed on the wall of a premises open to the public and allows for public access to an ORA if there is an immediate need. The box has an audible alarm when opened and can, if commercially practicable, alert local first responders upon opening. A secured machine is a machine operated and/or stocked by an organization providing harm reduction services. The contents of a secured machine are only accessible to individuals receiving services from that organization, who must use some form of identifying information or swipe card provided by that organization, to obtain supplies. Unlike a secured machine, a vending machine is accessible by the general public without identification, although the items in a vending machine likely require payment while the items in a secured machine likely do not.

SECTION IV. GENERAL ACCESS PROVISIONS.

(a) Prescribing.—Notwithstanding any law or regulation to the contrary, a healthcare provider allowed by [this state] or federal law to prescribe drugs is authorized to prescribe an overdose reversal agent to any person or entity.

(b) Dispensing.—Notwithstanding any law or regulation to the contrary, a healthcare provider allowed by [this state] or federal law to dispense drugs is authorized to dispense an overdose reversal agent to any person or entity.

(c) Other authorized actions.—Notwithstanding any law or regulation to the contrary, any person or entity is authorized to:

(1) Purchase one or more overdose reversal agents;

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(2) Receive one or more overdose reversal agents from any person or entity without charge;

(3) Possess or store one or more overdose reversal agents; or

(4) Give, donate, or transfer without charge one or more overdose reversal agents to any person or entity.

(d) Administration.—Notwithstanding any law or regulation to the contrary, any individual may administer an overdose reversal agent to another individual if the administering individual believes, in good faith, that the receiving individual is experiencing an overdose.

(e) Standing order or protocol.—The [chief medical officer of this state, state department of health director, state board of pharmacy director, and/or other individual as appropriate] shall:

(1) Establish a statewide [standing order or other type of protocol] allowing any person or entity access to all overdose reversal agents, including non-prescription overdose reversal agents, without an individual prescription; and

(2) Keep such [standing order or other type of protocol] in force until the [legislature] repeals this provision.

(f) Purchase agreement.—Any person or entity may enter into a purchase agreement with any other person or entity in this or any other state to purchase one or more overdose reversal agents.

(g) Possession on school grounds.—Notwithstanding any law or regulation to the contrary, every student at a public or private middle school, high school, trade school, or institution of higher education in [this state] is authorized to possess non-prescription overdose reversal agents while on school grounds or at any school sponsored activity.

(h) Vending machines.—Any person or entity may operate, or enter into an agreement with another person or entity in this or any other state to operate, a vending machine in [this state] for the purpose of distributing an overdose reversal agent, so long as the operating person or entity:

(1) Addresses the environmental controls necessary to keep the overdose reversal agent within the manufacturer's required storage temperature range at all times except

during a power outage;

(2) Establishes procedures for the regular replenishment of such overdose reversal agent; and

(3) Requires that the educational information developed by the [state department of health and/or other appropriate departments] pursuant to Section IX(a) is posted on or near the vending machine in the language or languages spoken in the community in which such vending machine is installed.

(i) Secured machines.—Any person or entity providing harm reduction interventions may include an overdose reversal agent in such person or entity's secured machine in [this state], so long as the person or entity:

(1) Addresses the environmental controls necessary to keep the overdose reversal agent within the manufacturer's required storage temperature range at all times except during a power outage;

(2) Establishes procedures for the regular replenishment of such overdose reversal agent; and

(3) Requires that the educational information developed by the [state department of health and/or other appropriate departments] pursuant to Section IX(a) is posted on or near the secured machine in the language or languages spoken in the community in which such secured machine is installed.

(j) No identification required.—

(1) No individual shall be required to provide identifying information, including any state-issued identification, as a condition for purchasing, receiving, possessing, storing, transferring, or administering an overdose reversal agent.

(2) Subsection (j)(1) does not prohibit a person or entity providing harm reduction interventions from asking an individual to voluntarily provide demographic information for research purposes.

(k) Elimination of certain training requirements.—Notwithstanding any law or regulation to the contrary, no person or entity in [this state] shall require an individual in this or any other state to obtain training prior to gaining access to, possession of, or the ability to administer a non-prescription overdose reversal agent.

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The following subsection is optional

(l) [Violations.—A willful violation of subsections (j)(1) or (k) is a [civil infraction] punishable by a penalty of not more than [$50] for the first occurrence and [$100] for each subsequent occurrence.]

Commentary

Every provision included in this Act aims to expand access to, and education about, ORAs beyond the laws and policies already in place across the U.S.[37] Here, in Section IV, the focus is on general access provisions applicable to all individuals and entities (as defined in Section III).

The subsections covering prescribing (subsection (a)), dispensing (subsection (b)), other authorized activities (subsection (c)), and administering (subsection (d) resemble provisions in Section V of the 2021 Model Act and many state laws. The primary difference between this Act and most already existing versions is the use of the defined term "any person or entity" in some provisions, which expands these activities universally, as opposed to limiting the authorization to a subset of individuals and groups listed separately. As a result, this Act does not contain separate provisions pertaining to first responders or schools/school districts that are commonly found in state laws. Everyone and everything in a state is encompassed under Section IV with respect to general access provisions. Note that, per Section III, the definition of healthcare provider used in subsections (a) and (b) (as well as later provisions within this Act) does not include veterinarians, meaning that these authorizations do not directly allow veterinarians to prescribe or dispense ORAs to humans. There is some merit in allowing veterinarians to do this, however, particularly if one or more veterinarians in an office handle high potency synthetic opioids. If state policymakers wish to expand the authorization, they can expand the definition of healthcare provider.

Subsection (e) is a condensed and revised version of the standing order provision in the 2021 Model Act (Section IV of that Act). All states and some U.S. territories have a means by which an individual can obtain a prescription status ORA without an individual prescription for such product. In many cases, but not all, this is through a statewide standing order. Therefore, spending time on the mechanics of the process in a model law does not seem necessary. The point of the new subsection is two-fold. First, by whatever means the state chooses, the state must provide access to all ORAs including those with prescription status, without an individual prescription. Second, the standing order (or whatever other means) cannot expire until the legislature repeals the provision. The 2021 Model Act provided that the standing order would expire upon the availability of a non-prescription ORA. In retrospect, this was premature, as consumers who cannot afford the cash price for non-prescription ORAs need to use prescription drug coverage to pay for them. The easiest (or perhaps only) way for this to work is for the consumer to have a prescription for the non-prescription ORA which a pharmacist can then bill

[37] For a detailed description of such laws, *see Opioid Antagonist Access: Summary of State Laws*, *supra* note 13.

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to the individual's insurance. (The requirement for insurers to cover non-prescription ORAs is found in Section X.) Having the standing order (or other means chosen by the state) apply to non-prescription ORAs eliminates the need for the consumer to secure an individual prescription for this purpose. Thus, the standing order (or other means) needs to apply to all ORAs, not just prescription ORAs, and should not condition the order's (or other means') expiration on non-prescription availability. This is accomplished in subsection (e).

Although it is covered by the breadth of subsection (c), subsection (f) makes it expressly clear that any person or entity can enter into an agreement with another person or entity (in any state, not just the enacting state) to purchase ORAs. The 2021 Model Act contained two similar provisions, each applying to a particular set of entities (public educational institutions and correctional settings). With the use of "person or entity" in this Act, there only needs to be one purchase agreement provision that applies to everyone and every entity.

In 2024, California and Colorado introduced bills expressly allowing some students to physically carry certain forms of ORAs on school grounds.[38] Although a student's possession of an ORA on school grounds is covered by subsection (c)(3), new subsection (g), inspired by those two bills, makes it expressly clear that middle school, high school, trade school, and college students may physically carry non-prescription ORAs on school grounds. The drafters chose to limit the authorization to non-prescription ORAs, as opposed to all ORAs, so as to not conflict with many schools' requirements that a school nurse control access to prescription medications. The suggested amount of two doses corresponds with the number of doses that come in one package of the non-prescription ORAs available as of June 2024 (Narcan®, RiVive™, Amneal, Teva, Walgreens, and Padagis generics).

The provisions covering vending machines (subsection (h)) and secured machines operated by organizations providing harm reduction (subsection (i)) are based on Connecticut law.[39] (A description of the difference between these two machines can be found at the end of the commentary to Section III.) Again, as with subsections (f) and (g), such machines are covered under this Act by earlier provisions in Section IV. However, these two subsections represent express authorizations for supplying ORAs in this manner.

Requiring individuals, particularly people who use drugs, to provide identification as a condition to receiving harm reduction services creates a barrier to those services. Accordingly, subsection (j) expressly disallows any such formal or informal requirement for identification for any activity related to purchasing, possessing, storing, transferring or administering an ORA. As a practical matter, however, if an individual wants to use health insurance benefits to pay for an ORA, the person or entity submitting the insurance claim (a pharmacy, most likely) will need health insurance policy information from the purchaser, which contains identifying information. However, this is not a condition to purchasing an ORA outright, but rather a voluntary choice by

[38] S.B. 997, 2023-2024 Reg. Sess. (Cal. 2024); H.B. 1003, 74th Gen. Assemb., 2nd Reg. Sess. (Colo. 2024). Colorado's bill is now law, with the student possession provision to be placed at COLO. REV. STAT. ANN. § 22-1-119.7 (West 2024) ("Student possession and administration of opiate antagonists and possession of non-laboratory detection tests").

[39] *See* CONN. GEN. STAT. ANN. § 21a-286 (West 2024).

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the purchaser to provide health insurance policy information in order to obtain insurance benefits. The drafters created this statutory language for this Act, which is not based on any existing state law.

Many state laws expressly require all individuals, or at least certain groups of individuals (such as law enforcement officers or school employees) to obtain training on administering an ORA as a prerequisite for access to it. For example, under California law, "[a] person who is prescribed or possesses an opioid antagonist pursuant to a standing order shall receive the training provided by an opioid overdose prevention and treatment training program."[40] If the same individual purchases a non-prescription ORA from a generally accessible shelf at a retailer, however, the only instruction the individual receives about use comes from the packaging, if the individual chooses to read it. Indeed, a primary part of the FDA's non-prescription approval process is for the manufacturer to develop packaging that provides sufficient instructions for use and then prove that purchasers understand those instructions.[41] To eliminate this inconsistency, the drafters created subsection (k), which is not based on any state law or bill. The drafters want to make clear that they do not oppose training and education related to identifying overdoses, ORAs, or harm reduction. However, training should never become a barrier to an individual's access to ORAs, particularly non-prescription ORAs. Accordingly, subsection (k) provides that no person or entity can condition an individual's access to a non-prescription ORA on receiving training. Required training can still occur but not as a prerequisite to access. The drafters did not extend this prohibition to prescription ORAs, many of which require the use of injection devices. Subsection (k) is in Section IV, rather than Section IX (covering education and training), because the subsection is a universal prohibition applicable to all people and entities.

Optional subsection (l) is a compliance mechanism designed to discourage individuals or entities from willfully refusing to follow the requirements contained in subsections (j)(1) or (k). Ideally, the monetary penalty should be large enough that a person or entity will choose compliance, but not so large as to become overly harsh. Pursuant to Section XII, money collected from violators will be placed in the bulk overdose reversal agent purchasing fund.

Finally, in developing this Act, the drafters considered expressly confronting an issue overlooked in almost all current state ORA laws—unused ORAs that are past their printed expiration date. There is scientific research showing that naloxone retains its effectiveness and

[40] CAL. CIV. CODE § 1714.22(d)(1) (West 2024).

[41] "An application or efficacy supplement to an application for an Rx-to-OTC switch should contain both efficacy and safety data demonstrating that the drug product is safe to use in the nonprescription setting. . . . Additionally, the applicant must provide data that demonstrate consumers can understand how to use the drug safely and effectively without the supervision of a healthcare professional. . . . FDA will approve an Rx-to-OTC switch application when FDA determines that the previous prescription status is 'not necessary for the protection of the public health by reason of the drug's toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, and . . . the drug is safe and effective for use in self-medication as directed in proposed labeling.'" *Prescription-to-Nonprescription (Rx-to-OTC) Switches*, U.S. FOOD & DRUG ADMIN. (contents current as of June 28, 2022), https://www.fda.gov/drugs/drug-application-process-nonprescription-drugs/prescription-nonprescription-rx-otc-switches (quoting 21 C.F.R. § 310.200(b)).

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ability to reverse an opioid overdose well past the expiration date printed on the package.[42] (The only other ORA currently available, nalmefene, is too new for there to be much (or any) scientific research on its effectiveness post-expiration.) On the one hand, it is not permissible under federal or state law for pharmacies or governmental entities to dispense or distribute expired medications. On the other hand, individuals or small entities providing ORAs to community members may not have the financial resources to replace stockpiles of unused ORAs every few years. Moreover, even if an individual purchases or otherwise receives an unexpired ORA dose, the dose may be past its printed expiration date by the time the individual needs to use it. Given the arguments both ways, the drafters debated about including express provisions addressing the donation of or the administration of expired ORAs. Ultimately, the drafters decided against adding these provisions, so as to not expressly encourage the distribution or use of expired ORAs. Each jurisdiction should determine whether to include express reference to expired ORAs in legislation or health department policy, which some states already do. [43]

SECTION V. PERSONS OR ENTITIES REQUIRED TO OFFER OVERDOSE REVERSAL AGENTS.

(a) In general.—The following persons or entities shall offer [two doses] of an overdose reversal agent in the situations identified:

(1) A healthcare provider issuing an initial or renewal prescription for an opioid;

(2) A healthcare provider dispensing an opioid in an outpatient setting;

(3) An opioid treatment program or intensive outpatient program, whenever an individual receives services from such program;

(4) A hospital, hospital emergency department, or freestanding emergency department, upon discharge of an individual treated for an overdose, or upon discharge of an

[42] *See* Schuyler Pruyn, et al., *Quality Assessment of Expired Naloxone Products from First-Responders' Supplies*, PREHOSPITAL EMERGENCY CARE (Feb. 4, 2019), https://www.tandfonline.com/doi/full/10.1080/10903127.2018.1563257; Mohammad F Hossain, et al., *Chemical Stability of Naloxone Products Beyond Their Labeled Expiration Dates*, J. OPIOID MGMT. (Jan. 2022), https://wmpllc.org/ojs/index.php/jom/article/view/3155.

[43] *See, e.g.*, COLO. REV. STAT. ANN. § 13-21-108.7(3)(a) (West 2024) (granting immunity to "a person, other than a health-care provider or a health-care facility, who acts in good faith to furnish or administer an opiate antagonist, including an expired opiate antagonist . . ."); *Illinois Department of Human Services Division of Substance Use Prevention & Recovery Expired Naloxone Guidance*, ILLINOIS DEPT. OF HUMAN SERV. (Mar. 26, 2021), https://www.dhs.state.il.us/OneNetLibrary/27896/documents/SUPR/Guidelines/IDHSSUPRExpiredNaloxoneGuidance.pdf ("Naloxone presents no potential for misuse, a common motivating factor for medicine disposal programs, and expired naloxone may still be able to effectively reverse an opioid overdose. Furthermore, Illinois law does not explicitly prohibit the distribution of expired naloxone . . . . If the individual encounters someone experiencing a suspected opioid overdose prior to replacing their expired naloxone kit, they can use it. . . . Consider donating naloxone supplies that are expired or nearing expiration, as disposing of expired naloxone is neither required nor encouraged."); *Stop Opioid Overdose with Naloxone*, CALIFORNIA DEPT. OF PUBLIC HEALTH (last updated May 20, 2024), https://www.cdph.ca.gov/Programs/CCDPHP/sapb/pages/naloxone.aspx ("Expired naloxone is better than no naloxone: If you have expired or soon-to-expire intranasal Narcan® or injectable (intramuscular) naloxone that has been properly stored, contact a local syringe services program about donating the naloxone.").

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individual with a medical record indicating the existence or likely existence of a substance use disorder;

(5) A long-term care facility, upon discharge of an individual who was opioid dependent prior to admission to the facility; and

(6) A correctional setting, upon release of an individual from that correctional setting.

(b) Accompanying information.—Any person or entity required by this section to offer an overdose reversal agent to an individual must contemporaneously provide that individual with the educational information developed by the [state department of health and/or other appropriate departments] pursuant to Section IX(a) in writing, as a posted display, orally, or in another accessible form for an individual with a disability.

(c) Payment and insurance coverage.—

(1) Nothing in this section prohibits the person or entity offering the overdose reversal agent doses pursuant to subsection (a) from seeking insurance reimbursement under the individual's public or private health insurance coverage, if any, for the doses accepted by the individual.

(2) An individual who accepts overdose reversal agent doses offered pursuant to subsection (a) who has no health insurance coverage or who is insured under [state Medicaid program] shall not be charged an out-of-pocket cost for the doses.

(3) Other than the individuals identified in subsection (c)(2), an individual who accepts overdose reversal agent doses offered pursuant to subsection (a) shall not be charged an out-of-pocket cost that exceeds the copayment for the overdose reversal agent doses under the individual's applicable insurance coverage or federal healthcare benefit.

(d) Bulk purchasing fund.—To the extent that funding and supplies allow, a person or entity required by this section to offer doses of an overdose reversal agent may obtain doses that are not covered by public or private health insurance from the bulk overdose reversal agent purchasing fund established pursuant to Section XII.

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Commentary

While Section IV pertains to things that all people or entities are *allowed* to do, this section, and the next two sections after it, address the individuals or entities that *must* provide, or provide access to, ORAs.

Across the U.S., there are many examples of laws requiring certain individuals or business entities to offer ORAs (or prescriptions for ORAs) to individuals with an elevated risk of suffering an overdose. As of October 2023, 23 states (and the 2021 Model Act, in Section VII) have a provision related to co-prescribing an ORA in conjunction with an opioid prescription.[44] Several states (and the 2021 Model Act, in Section X) require correctional settings to offer ORAs to individuals upon release.[45] Additionally, some states require hospitals to offer ORAs to individuals treated for overdoses,[46] while a few require certain substance use disorder treatment facilities to do the same.[47] There are also examples of state laws (or state standing orders) requiring, or at least encouraging, pharmacists to offer ORAs when dispensing an opioid prescription.[48] This section takes all these various provisions and collects them into one place. The combined effect is a model provision that exceeds the existing provisions in any one state.

Subsection (a) covers situations where the listed people or entities must offer individuals with an elevated risk of overdose two doses of an ORA. The drafters placed brackets around the dosage amount to note that state policymakers may wish to increase or decrease this default amount. As between offering individuals a prescription for an ORA or the ORA doses themselves, the clear preference is to offer the actual doses. Both the 2021 Act and an earlier draft of this Act contained an exception for some healthcare providers identified in subsection (a) to offer an ORA prescription in lieu of the doses themselves. Research, however, suggests that individuals given ORA prescriptions do not tend to get those prescriptions filled.[49] Accordingly, and at the request of a workgroup member, the drafters removed this provision, thus requiring all people and entities listed in subsection (a) to offer ORA doses.

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[44] *Opioid Antagonist Access: Summary of State Laws*, *supra* note 13, at 9.
[45] *See, e.g.,* COLO. REV. STAT. ANN. § 17-1-113.4(2)(b) (West 2024); MD. CODE ANN., HEALTH – GEN. § 8-408(d) (West 2024); MINN. STAT. ANN. § 241.415 (West 2024); N.M. STAT. ANN. § 33-2-51(A) (West 2024); OKLA. STAT. ANN. tit. 57, § 4.1(B) (West 2024).
[46] *See, e.g.,* MD. CODE ANN., HEALTH – GEN. § 19-310.3(2) (West 2024); N.J. STAT. ANN. § 24:6J-5.1 (West 2023); OKLA. STAT. ANN. tit. 63, § 1-706.21(B) (West 2024); VA. CODE ANN. § 32.1-127(B)(27) (WEST 2024).
[47] *See, e.g.,* MD. CODE ANN., HEALTH – GEN. § 8-408(c) (West 2024) (covering "each opioid treatment program and each intensive outpatient treatment program"); N.M. STAT. ANN. § 24-23-3 (West 2024) (covering "an opioid treatment center agency operating a federally certified program to dispense methadone or other narcotic replacement").
[48] *See, e.g.,* COLO. REV. STAT. ANN. § 12-280-123(c) (West 2024); 225 ILL. COMP. STAT. ANN. 85/19.1(c) (West 2024), KY. REV. STAT. ANN. § 217.177(2)(c) (West 2024); UTAH CODE ANN. § 58-37-7(4)(b) (West 2024); *Delaware Division of Public Health Community Based Naloxone Program Standing Orders*, DEL. HEALTH & SOCIAL SERV. (June 27, 2018), https://www.dhss.delaware.gov/dhss/dph/files/naloxonestandingorders.pdf.
[49] Megan McElhinny, et al., *Adult Emergency Department Naloxone Education and Prescription Program: Video and Pamphlet Education Comparison*, J. SUBST ABUSE TREAT. (Mar. 2, 2021), https://www.jsatjournal.com/article/S0740-5472(21)00072-6/fulltext.

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There is some question about whether Veterans Administration (VA) medical facilities and healthcare providers would fall under the provisions of subsection (a). The general rule, as stated by the U.S. Department of Veterans Affairs, is that "[u]nder well-established interpretations of the Supremacy Clause, Federal laws and policies authorizing VA health care professionals to practice according to VA standards preempt conflicting State law: that is, a State law that prevents or unreasonably interferes with the performance of VA duties."[50] However, "[w]hen a State law does not conflict with the performance of Federal duties in these ways, VA health care professionals are required to abide by the State law."[51] Ultimately, the answer boils down to how state policymakers define "healthcare provider" and whether the VA concludes that provisions such as subsection (a) unreasonably interfere with performance of VA providers' duties. Of course, the VA could establish similar requirements through federal regulation or guidance.

The time at which a person at an elevated risk of overdose is offered an ORA is also a suitable time to provide that individual with education about ORAs. Subsection (b) requires a person or entity offering doses of ORAs to provide the information developed by the state department of health pursuant to Section IX. This includes information about recognizing and seeking medical attention for an overdose, administering an ORA, and state laws providing immunity for administering an ORA and seeking medical attention for the overdose. The idea to provide this information when providing ORA doses, as well as the contents of the educational information, is consistent with the 2021 Model Act. As written, subsection (b) requires the specified persons or entities to provide this information to all individuals who are offered the ORA doses, not just the individuals who accept them. To lessen the burden somewhat, the people or entities offering the doses can provide this information via a posted display. As part of Section IX, the state department of health (or other state agency creating the information) must develop a downloadable version of its education information in a form and length suitable for physically giving to an individual or posting publicly.

There remains a question about who is responsible for paying for the ORA doses given out under this section. In an ideal world, there would be an unlimited supply of no-cost ORAs made available by states to the individuals or entities that must offer ORAs pursuant to subsection (a). However, states do not have unlimited funds to do this. Moreover, at their core, many of the circumstances listed in subsection (a) are a healthcare provider providing medical care to a patient. Typically, Medicaid or other public or private health insurance pays for medical care provided by a healthcare provider to a patient, including drugs prescribed or dispensed by those providers.[52] Therefore, it is not a logical stretch to conclude that public or private health insurance should pay for the ORA doses given out in these situations. Indeed, allowing healthcare providers to bill various types of health insurance for ORAs given to discharged

[50] *Authority of VA Professionals to Practice Health Care*, 85 Fed. Reg. 71,838, 71,842 (Nov. 12, 2020), https://www.federalregister.gov/documents/2020/11/12/2020-24817/authority-of-va-professionals-to-practice-health-care.
[51] *Id.*
[52] For now, ignore the added complexity due to some ORAs being non-prescription, rather than prescription drugs.

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patients is the crux of two different Colorado statutory provisions[53] and a pending Congressional bill perhaps influenced by those laws.[54] At the same time, requiring an individual to pay out-of-pocket for an ORA offered in a situation where the individual did not expect to purchase one, or has no means or way to pay, is unwise.

Subsections (c) and (d) aim to provide the following options for people or entities required to offer an ORA. Under subsection (c)(1), the person or entity offering the ORA doses can seek Medicaid/other insurance reimbursement for doses accepted, assuming that: (1) the person or entity is an authorized healthcare provider under the applicable insurance; and (2) the applicable insurance covers the ORA. Under subsection (c)(2), the individual accepting the ORA cannot be charged an out-of-pocket cost if the individual has no health insurance or is covered by the state Medicaid program. Individuals who have other health insurance can be charged no more than the ORA copayment under the applicable insurance or federal benefit (*e.g.*, VA health care is not considered a health insurance plan).[55] Section X of this Act requires Medicaid and all other non-federally administered health insurance providers in a state to provide insurance coverage for all ORAs, both prescription and non-prescription. If state policymakers do not enact a provision like Section X, however, then the form of ORA given out may affect its eligibility for insurance reimbursement. In cases where the there is no insurance reimbursement available, either because the individual is uninsured or the insurance does not cover an ORA, subsection (d) allows the person or entity required to offer the doses to obtain the ORA from the bulk purchasing fund established under Section XII as funding and supplies allow. As insurance coverage is a very nuanced area of state (and federal) law, legislators may need to adjust the language of subsections (c) and (d) to implement these provisions.

SECTION VI. EMERGENCY ACCESS TO OVERDOSE REVERSAL AGENTS.

(a) First responders.—Each entity employing first responders within [state] shall:

(1) Provide overdose reversal agents to their first responders;

(2) Develop procedures for carrying an overdose reversal agent that optimize first responders' capacity to timely assist in response to an overdose; and

(3) Require the first responders to carry the overdose reversal agents in accordance with the procedures developed pursuant to subsection (a)(2).

(b) Access at certain locations.—The following entities shall store, in a visible and accessible location known to at least [two] employees, [two doses] of an overdose reversal agent for

[53] COLO. REV. STAT. ANN. § 10-16-153(2) (West 2024); COLO. REV. STAT. ANN. § 25.5-5-509(2)(b) (West 2024).
[54] Hospitals As Naloxone Distribution Sites Act, H.R. 5506, 118th Cong. (2023).
[55] In some cases, this may be $0. For example, under VA regulations, "opioid antagonists furnished to a veteran who is at high risk for overdose of a specific medication or substance" are exempt from copayment requirements. 38 C.F.R. § 17.110(c)(12) (2024).

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use by any individual without charge at:

(1) All public and private middle schools;

(2) All public and private high schools;

(3) All law enforcement and other first responder [precincts/stations];

(4) All dormitories at institutions of higher education;

(5) Each building at an institution of higher education capable of holding at least [*n*] individuals;

(6) [All or a subset of] emergency phones at an institution of higher education;

(7) All public libraries;

(8) All state and local public or private correctional settings;

(9) All hospital-based and freestanding emergency departments;

(10) Each public or governmental building or public transportation [stations/hubs] capable of holding at least [*n*] individuals;

(11) All hotels and motels;

(12) All indoor or outdoor entertainment venues or amusement parks capable of holding at least [*n*] individuals;

(13) All restaurants, nightclubs, and bars;

(14) All recovery residences; and

(15) Any other location not covered by paragraphs (1)-(14) above that is required by [state] or federal law to possess a defibrillator or epinephrine injector.

(c) Secure box.—Owners and operators of the entities and locations identified in subsection (b) are encouraged, but not required, to place publicly available overdose reversal agents in a secure box.

(d) Accompanying information.—Each location identified in subsection (b) shall post the educational information developed by the [state department of health and/or other appropriate departments] pursuant to Section IX(a) on or near the location of the overdose reversal agent in the language or languages spoken in the community in which such secured machine is installed.

(e) Inspection and compliance.—

(1) The [state department of health, state department of corrections, state department of

education, and/or other appropriate department] is authorized to inspect any location subject to subsection (b) for adherence to this Act at any time such location is open.

(2) Failure to comply with subsection (b) shall be:

(A) A [civil infraction] punishable by a penalty of not more than [$50] for the first occurrence and [$100] for each subsequent occurrence]; and

(B) Corrected within [five (5)] days or less, unless an extension is granted by the [state department of health, state department of corrections, state department of education, and/or other appropriate department].

(f) Bulk purchase fund.—To the extent that funding and supplies allow, a person or entity required by this section to provide access to an overdose reversal agent may obtain the overdose reversal agent from the bulk overdose reversal agent purchasing fund established pursuant to Section XII.

(g) Education and training.—Subject to the limitation set forth by Section IV(k) regarding training related to non-prescription overdose reversal agents, any person or entity required by this section to provide access to an overdose reversal agent is encouraged to provide the person or entity's employees and volunteers with training covering the subject matter identified in Section IX(b).

Commentary

Two ways to increase access to ORAs when needed (*i.e.*, when an overdose occurs) are to: (1) require first responders to carry them; and (2) require locations where individuals live or gather to keep them on hand. The 2021 Model Act contains separate sections requiring correctional settings (Section X) and public educational institutions and universities (Section XI) to keep one or more ORAs on hand for timely use in the case of an overdose. Moreover, the 2021 Model Act (in Section XIII) proposed a "pilot program establishing bystander access" with the goal of establishing one or more publicly accessible locations storing ORA for emergency use within a state.

Within state laws, there are examples of each kind of requirement as well, although not to a widespread extent. A handful of states require law enforcement officers or other first responders to carry ORAs to the extent that funding and supplies allow.[56,57] A few other states require certain middle schools, high schools, or institutions of higher education to keep ORAs on

[56] *See, e.g.,* Me. Rev, Stat, Ann. tit. 22, § 2353(3) and (3A) (West 2024); MINN. STAT. ANN. § 144E.103 (West 2023); N.M. STAT. ANN. § 29-7-7.6(A) (West 2024); W. VA. CODE ANN. § 16-46-4(a) (West 2024).

[57] In addition to statewide requirements found in statute, numerous individual state and local first responder agencies encourage, or even require, first responders to carry ORAs pursuant to agency policy.

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hand.[58] A few states also require specified public places to stock ORAs[59] with Maryland recently enacting a law requiring ORAs to be "co-located" in AED boxes by a specified future date.[60]

Section VI of this Act takes elements of the 2021 Model Act and state ORA laws and condenses them into one location. Subsection (a) requires an entity employing first responders to provide them with ORAs and develop procedures for how and when they must carry them to best respond to overdose emergencies. There is some nuance to determining which first responders need to carry ORAs (*e.g.*, do first responders working inside a station/precinct need to?) and whether the ORA must be physically on the individual or only in place which provides "ready access." Accordingly, the drafters chose statutory language modeled upon a New Mexico provision, which leaves it to the individual entities to develop procedures.[61]

The list of locations in subsection (b) where ORAs must be kept is intended to be incredibly broad and more extensive than any state law currently in force. This subsection contains the requirement for schools and correctional settings to stock ORAs, eliminating the need for a separate section for those locations. The drafters realize that state legislators may choose to narrow subsection (b)'s list prior to enacting a law based on this provision. Legislators also have the option to set occupancy levels under which the requirement does not apply. The Act notes several instances where an occupancy floor may make sense. One workgroup member commented that ORAs inside of buildings at institutions of higher education may not be accessible if the building closes at night or on weekends. In response, the drafters added the provision about placing ORA near emergency telephones, which may be outside. Because of the sheer volume of emergency telephones on a campus and the fact that outdoor temperatures create challenges for storage conditions, the drafters note, in the bracketed text, that state policymakers may only wish to require ORAs at "some" emergency phone locations and not all of them.[62]

Ideally, ORAs for public use in emergencies will be kept in secured boxes, defined in Section III and described in the commentary thereto. This costs money, however, so, at this time, the drafters only encourage the use of secure boxes in subsection (c), rather than requiring it. Moreover, similar to the accompanying information section in Section V(c), subsection (d) in this section requires the locations specified in subsection (b) to post the educational information developed pursuant to Section IX near the location of the ORA.

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[58] *See Opioid Antagonist Access: Summary of State Laws*, *supra* note 13, at 11-12.

[59] Cal Health & Safety Code § 11870 to 11872 (West 2024) (stadiums, concert venues, and amusement parks); N.J. STAT. ANN. § 24:6J-7 (West 2023) (recognized places of public access); N.Y. PUB. HEALTH LAW § 3309 (8) (West 2024) (nightlife establishments).

[60] 2024 Maryland Laws Ch. 764 (S.B. 1099).

[61] N.M. STAT. ANN. § 29-7-7.6(A) (West 2024).

[62] As an example of the many locations on a college campus where laws could require ORAs be kept, the Louisiana Board of Regents requires all public institutions of higher education to keep ORAs at: (1) all institution-owned student residential facilities; (2) law enforcement and safety departments; (3) health, wellness, and counseling centers; (4) student unions and centers; (5) recreation centers; (6) pharmacies; (7) athletic training facilities; (8) law centers; (9) health sciences centers; and (10) collegiate recovery program facilities. *Board of Regents (BOR) Opioid Education, Training, and Reporting Policy*, LA. BD. OF REGENTS (last accessed July 2, 2024), https://www.laregents.edu/wp-content/uploads/2022/10/BOR-Opioid-Education-Training-and-Reporting-Final-Policy.pdf.

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Subsection (e) allows the appropriate state department or agency to inspect the locations listed in subsection (b) for adherence to this section. As between a monetary penalty (*i.e.*, subsection (e)(2)(A)) and correcting the deficiency (*i.e.*, subsection (e)(2)(B)), fixing the issue is the more important outcome. However, the drafters recognize that some financial incentive may be necessary. As noted in the Section IV commentary, the monetary penalty should be large enough that a person or entity will choose compliance (as opposed to just paying for violations as a "cost of doing business") but not so large as to become overly harsh or deter investment in a program.

Subsection (f) expressly allows both entities employing first responders and entities responsible for the locations listed in subsection (b) to seek to obtain the required ORAs from the bulk overdose reversal agent purchasing fund established in Section XII.

SECTION VII. SALE OF OVERDOSE REVERSAL AGENTS.

(a) Stock of prescription agents.—The following entities shall make a good faith effort to maintain a continuous supply of prescription overdose reversal agents in stock and available for purchase at all times:
  (1) Retail pharmacies licensed under [state code provision]; and
  (2) Mail order pharmacies licensed under [state code provision].

(b) Stock of non-prescription agents.—The following entities shall make a good faith effort to keep a continuous supply of non-prescription overdose reversal agents in stock and available for purchase at all times:
  (1) Retail pharmacies licensed under [state code provision]; and
  (2) Retailers licensed under [state code provision] that sell at least one non-prescription drug in addition to an overdose reversal agent and have total annual sales exceeding [$ X].

(c) Non-prescription product location.—Any person or entity selling a non-prescription overdose reversal agent in [state] may not place such overdose reversal agent:
  (1) Behind a pharmacy counter;
  (2) In a locked cabinet; or
  (3) In any location that requires a purchaser to ask an employee to access it or go to a pharmacy counter to purchase it.

(d) No identification.—No individual shall be required to provide identifying information,

including any [state]-issued identification, as a condition for purchasing a non-prescription overdose reversal agent.

(e) Signage.—Every entity subject to subsection (b) shall, in each physical location in [state], display in a prominent position near the location of the non-prescription overdose reversal agent product on the retail shelf that it may be possible to use health insurance to purchase the non-prescription overdose reversal agent.

(f) Inspection and compliance.—

(1) The [state department of health, state board of pharmacy, and/or other appropriate department] is authorized to inspect any location described in subsections (a) or (b) at any time such location is open for adherence to this section.

(2) Failure to comply with this section shall be:

(A) A [civil infraction] punishable by a penalty of not more than [$200] for the first occurrence and [$500] for each subsequent occurrence]; and

(B) Corrected within [five (5)] days or less, unless all non-prescription overdose reversal agents are in shortage according to the U.S. Food and Drug Administration, or an extension is granted by the [state department of health, state board of pharmacy, and/or other appropriate department].

Commentary

Although non-prescription ORAs are available generally, there are concerns, backed by multiple press reports, that consumers face difficulty purchasing them.[63] This is because retailers do not stock them or because retail pharmacies continue to treat all ORAs as prescription-only products requiring interaction with a pharmacist or pharmacy staff for various reasons, including concerns about theft. The primary purpose of this section is to combat these concerns. The section is not based on an existing statute, although portions of it are based on Massachusetts statute and state department of health guidance, as described below.

Subsection (b) directs all retail pharmacies, and certain retail stores, to make a good faith effort to always keep non-prescription ORAs in stock. An earlier draft of this Act required

[63] *See, e.g.,* Jackie Fortiér & Nicole Leonard, *Narcan, Now Available Without a Prescription, Can Still be Hard to Get*, KFF HEALTH NEWS (Oct. 11, 2023), https://kffhealthnews.org/news/article/narcan-naloxone-otc-opioids-cost/; Chris Serres, *Narcan Saves Lives—But Finding It Can Be Onerous in Massachusetts*, BOSTON GLOBE (Jan. 18, 2024), https://www.bostonglobe.com/2024/01/18/metro/narcan-over-the-counter-overdoses-mass/; Sara G. Miller & Berkeley Lovelace, Jr., *Where's the Narcan? At Pharmacies Across the U.S., the OTC Antidote Can Be Hard to Find*, NBC NEWS (Mar. 11, 2024), https://www.nbcnews.com/health/health-news/Narcan-opioid-overdose-drug-otc-access-varies-us-stores-rcna135324.

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retailers to keep a certain specified number of non-prescription ORAs in stock. This elicited a concern from a working group member about what would happen if a consumer purchased a retailer's entire stock at once. In response, the drafters lessened the requirement somewhat. (Policymakers, of course, could revise the provision to specify an amount kept in stock.) Although most retail stores in a state should fall under the requirements of subsection (b), the drafters left room for retail stores who do little in terms of gross sales, or who do not sell non-prescription drugs at all, to avoid the requirement. As shown by the bracketed language, the drafters leave it to state legislators to identify the appropriate sales volume warranting the exception.

In an earlier draft of this Act, Section VII only pertained to the retail sale of non-prescription ORAs. However, a workgroup member suggested that the Act require pharmacies to keep prescription ORAs in stock as well. Thus, the drafters expanded the section's title and added in subsection (a). The language of both subsections (a) and (b) is based on a Massachusetts law that requires "pharmacies located in areas with high incidents of opiate overdose . . . to maintain a continuous supply of naloxone rescue kits or opioid antagonist medications."[64]

Subsection (c) prohibits sellers of non-prescription ORAs from placing the product in locations that require a consumer to ask for employee help to purchase it as that prevents anonymous purchases. These directions are based on a December 2023 memo from the Massachusetts Department of Health to retailers about sales of non-prescription ORAs.[65] Should a consumer wish to use health insurance coverage to pay for the non-prescription ORA, the consumer will need to visit the pharmacy counter (or submit a claim to their insurer directly). However, retailers should not require consumers who wish to pay for non-prescription products "out of pocket" to visit the pharmacy counter.

Under Section IV(j), this Act provides that no individual shall be required to provide identifying information as a condition for purchasing an ORA. Subsection (d) restates this requirement, as it applies to purchasing non-prescription ORAs, more directly. Again, as a practical matter, if the purchaser wants to use health insurance coverage to pay for the non-prescription ORA, the purchaser will need to provide identifying information to the pharmacy or other healthcare provider submitting the claim. That is a voluntary choice by the purchaser, however, rather than an outright condition to purchasing the ORA.

Subsection (f) allows the appropriate state department(s) to inspect retailers for adherence to this section. As between a monetary penalty (*i.e.*, subsection (f)(2)(A)) and correcting the deficiency (*i.e.*, subsection (f)(2)(B)), fixing the issue is the more important outcome. However, the drafters recognize that some financial incentive may be necessary. As noted in Section IV commentary, the monetary penalty should be large enough that a person or

[64] MASS. GEN. LAWS ANN. ch. 94C, § 19C (West 2024).
[65] Memorandum to Massachusetts Retailers, MA. DEPT. OF PUBLIC HEALTH (Dec. 20, 2023), https://www.mass.gov/memorandum/over-the-counter-otc-naloxone.

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entity will choose compliance (as opposed to merely paying for violations as a "cost of doing business") but not so large as to become overly harsh.

SECTION VIII. IMMUNITY AND GOOD SAMARITAN PROTECTIONS.

(a) Prescribing.—Any healthcare provider who, in good faith and in the absence of gross negligence, malice, or criminal intent, prescribes an overdose reversal agent to a person or entity is immune from civil or criminal liability and shall not be subject to administrative action for the issuance of such prescription or the ultimate outcome of such prescribing.

(b) Dispensing.—Any healthcare provider or entity who, in good faith and in the absence of gross negligence, malice, or criminal intent, dispenses an overdose reversal agent to a person or entity is immune from civil or criminal liability and shall not be subject to administrative action for the dispensing of an overdose reversal agent or the ultimate outcome of such dispensing.

(c) Giving, donating, transferring without charge, or selling.—Any person or entity who, in good faith and in the absence of gross negligence, malice, or criminal intent, gives, donates, transfers without charge, or sells an overdose reversal agent to another person or entity is immune from civil or criminal liability and shall not be subject to administrative action for giving, donating, transferring without charge, or selling an overdose reversal agent or the ultimate outcome of such action.

(d) Administering.—Any individual who, in good faith and in the absence of gross negligence, malice, or criminal intent, administers an overdose reversal agent to an individual suffering, or believed to be suffering, from an overdose is immune from civil or criminal liability and shall not be subject to administrative action for administering an overdose reversal agent or the ultimate outcome of such administration.

(e) Good Samaritan protections.—Notwithstanding any law or regulation to the contrary, any individual who summons emergency medical assistance contemporaneously with administering an overdose reversal agent shall, in addition to the protections afforded under this Act, receive the protections afforded by [state Good Samaritan provisions pertaining to overdoses].

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Commentary

This section aims to build on existing laws and provide uniform civil and criminal immunity to all individuals involved in prescribing, dispensing, distributing, or administering ORAs, thus, helping to encourage individuals to obtain and use them. Virtually all states have some form of the provisions contained in subsections (a)-(d). State laws, however, vary regarding the level of immunity provided. As of October 2023, every state but three (New Mexico, New York, and Oregon) expressly provides some level of immunity to healthcare providers who prescribe an ORA.[66] Likewise, all but three states (New York, Oklahoma, and Wyoming) expressly provide some level of immunity to healthcare providers who dispense an ORA.[67] Only one state (South Dakota) does not expressly provide a level of immunity to laypeople who administer an ORA.[68]

As compared to the immunity provisions in the 2021 Model Act and in force today in most states, subsection (c) expands the immunity to cover any "person or entity." This matches the expanded authorizations for these actions granted in Section IV. Subsection (d) uses "individual" rather than "person or entity" because a non-human entity cannot perform the act of administering an ORA to an individual.

Subsection (e) addresses a related, but different, immunity. As of April 2024, only two states (Kansas and Wyoming) do not have a Good Samaritan fatal overdose prevention ("GSFOP") law, which offers some form of immunity from liability for individuals who act in good faith to seek medical help for someone experiencing an overdose.[69] This subsection expressly provides that any person who administers an ORA will receive the protections under this section and the state's GSFOP law. Unfortunately, GSFOP laws vary widely among the states, both in terms of what protections apply (protection from arrest, charge, prosecution, or the like) and what violations those protections shield (simple drug possession only, drug paraphernalia, parole violations, or the like) Although it is outside the scope of this Act, legislators and policymakers should consider strengthening or revising existing GSFOP laws to better encourage bystanders to administer an ORA and contact emergency services or law enforcement for additional help.

[66] *Opioid Antagonist Access: Summary of Laws*, *supra* note 13, at 5.
[67] *Id.*, at 6.
[68] *Id.,* at 7.
[69] *Good Samaritan Fatal Overdose Prevention and Drug-induced Homicide: Summary of Laws*, LEGIS. ANALYSIS & PUB. POL'Y ASS'N 4-5 (April 2024), https://legislativeanalysis.org/good-samaritan-fatal-overdose-prevention-and-drug-induced-homicide-summary-of-state-laws/.

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SECTION IX. EDUCATIONAL INFORMATION AND TRAINING PROGRAMS.

(a) Educational information.—

(1) Within six (6) months of the effective date of this Act, the [state department of health and/or other appropriate state agencies or departments] shall publish, both on its website and in downloadable form accessible from the website, educational information about overdose reversal agents as set forth in subsection (b) below.

(2) The educational information required under this subsection must be written at or below a sixth (6th) grade reading level in English, Spanish, and [any other language that the commissioner determines is the primary language of a significant number of individuals in the state].

(3) For each language used, at least one downloadable version of the educational information must be in a form and length suitable for physically giving to an individual or posting publicly.

(4) The [state department of health and/or other appropriate state agencies or departments] are encouraged to use existing federal educational resources to provide the information required by this section and tailor it as needed for the specifics of [state] law.

(b) Contents of educational information.—The educational information developed pursuant to subsection (a) shall include, at a minimum, the following topics:

(1) Recognizing the signs and symptoms of an overdose;

(2) How to perform rescue breathing and resuscitation;

(3) The importance of calling 911 immediately after administering an overdose reversal agent;

(4) What to do if overdose reversal agent is not available;

(5) Protections provided by [the state Good Samaritan fatal overdose protection law];

(6) How to administer nasal spray and injectable overdose reversal agents;

(7) Appropriate care of an individual believed to be experiencing an overdose after administration of an overdose reversal agent;

(8) Where to obtain overdose reversal agents throughout the state;

(9) De-stigmatizing the possession of an overdose reversal agent; and

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(10) [State] laws limiting a person or entity's liability for prescribing, dispensing, selling, transferring, distributing, or administering overdose reversal agents.

(c) Required dissemination of information.—

(1) Any person or entity required by Section V to offer an overdose reversal agent to an individual must contemporaneously provide that individual with the educational information developed pursuant to subsection (a) in writing, as a posted display, orally, or in another accessible form for an individual with a disability.

(2) Each of the following locations shall post the educational information developed pursuant to subsection (a) on or near the location of the overdose reversal agent in the language or languages spoken in the community in which such secured machine is installed:

(A) A vending machine containing an ORA;

(B) A secured machine containing an ORA; and

(C) Each location specified in Section VI(b).

(d) Encouraged dissemination of information.—The following persons or entities are strongly encouraged to provide the information developed pursuant to subsection (a) in writing, an accessible posting, orally, or in another accessible form for an individual with a disability:

(1) Any person or entity who gives or donates one or more overdose reversal agents to any individual without charge; and

(2) Any healthcare provider who prescribes or dispenses an overdose reversal agent in a circumstance not covered by Section V(a).

(e) Training programs.—

(1) The [state department of health], in conjunction with [other appropriate departments and persons or entities providing harm reduction], shall establish in-person or online training programs covering the information described in subsection (b).

(2) Such training programs shall be tailored to the unique needs of each of the following groups:

(A) Individuals who use drugs and their family and friends;

(B) Healthcare providers;

(C) First responders;

(D) Bystanders;

(E) Correctional setting employees;

(F) Educational institution employees;

(G) Employers required by Section VI to provide access to an overdose reversal agent; and

(H) [Any other group that legislators wish to add].

(3) The persons or entities establishing training programs are encouraged to use existing federal educational resources to develop the programs to the extent those resources meet the requirements of this section.

Commentary

Many of the subject matter experts in the working group involved with the 2021 Model Act discussed the importance of educating prescribers and dispensers on the availability of ORAs, ORAs' role in reducing the effects of the overdose crisis, and the laws applicable to ORA access. This section, which is based on educational and training provisions directed at differing groups scattered throughout the 2021 Model Act, aims to provide a comprehensive source of education and training programs so that prescribers, dispensers, and the public have the information and knowledge needed to make informed decisions regarding ORAs.

Together, subsections (a) and (b) require the state department of health (and/or other appropriate state agencies) to develop educational information covering the identified subject areas. This Act, in various places, requires certain people or entities to provide this information to individuals offered, or receiving, ORAs. Because the information must be physically given to, or viewable by, that individual, at least one version of the information needs to be in a concise, downloadable form. For that reason, the drafters included subsection (a)(3). The Act does not prevent the state department of health from making more thorough education also publicly available. Subsection (a)(4) further provides that the state agencies develop educational information should use already available federal resources to the extent possible as opposed to "reinventing the wheel." Entities developing training programs should also look to already existing federal resources, per subsection (e)(3).

In the 2021 Model Act, each of the various group-specific provisions covering educational information provided that, in the steps for responding to a drug overdose, an individual should call 911 for help and then administer the ORA. The 2021 Act's drafters based this order of operations on the Substance Abuse and Mental Health Services Administration's

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(SAMHSA's) *Opioid Overdose Prevention Toolkit: Five Essential Steps for First Responders*.[70] Recently, the drafters of this Act received a comment from a stakeholder that the directions for use of Narcan® provide that an individual should administer a first dose of ORA and then call 911.[71] As a practical matter, the order of actions may not matter much, so long as each is done contemporaneously with the other. The language in subsection (b)(3), however, reflects the order set forth by FDA-approved labeling on non-prescription ORAs.

Pursuant to earlier sections of this Act, the information developed pursuant to subsection (a) must be posted on or near: (1) a vending machine with ORAs; (2) a secured machine with ORAs; and (3) the location of the ORA required under Section VI to be available for use in case of emergency. Subsection (c)(2) restates this requirement. Likewise, the individuals or entities required under Section V to offer ORAs must also provide this information at those times. Subsection (c)(1) restates this requirement. Subsection (d) addresses other situations where information about ORAs could be provided. At present, the language does not mandate this, although state policymakers could easily adjust the wording to make it a requirement. Subsection (d)(1) covers the situation where a person or entity (state or local agency, organization providing harm reduction) gives/donates an ORA to someone. Subsection (d)(2) covers any situation where a healthcare provider prescribes or dispenses an ORA that is not already covered in Section V(a). The drafters concluded that providing information when an individual makes an out-of-pocket purchase of a non-prescription ORA at a retail store is unneeded, as that cuts against the anonymity of that transaction. As a result, that situation is not covered by the provisions described above in this paragraph.

SECTION X. INSURANCE COVERAGE.

(a) [State Medicaid program name].—

(1) Prescription overdose reversal agents and non-prescription overdose reversal agents shall both be a no-cost covered benefit under [state Medicaid program], up to a maximum provided benefit of [x doses] per insured per year.

(2) The coverage provided under subsection (a)(1) shall not be subject to prior authorization requirements.

(b) Other types of insurance coverage.—

(1) Except for federally administered health plans or programs, every public or private individual or group health insurance contract, plan, or policy not falling under subsection (a) that provides prescription drug coverage that is delivered, issued for

[70] *Opioid Overdose Prevention TOOLKIT: Five Essential Steps for First Responders*, SUBSTANCE ABUSE & MENTAL HEALTH SVS. ADMIN. 1-2, (last accessed May 16, 2024), https://store.samhsa.gov/sites/default/files/d7/priv/five-essential-steps-for-first-responders.pdf.

[71] *See*, *FAQs: How Does Narcan® Nasal Spray Work?*, NARCAN® (last accessed June 27, 2024), https://narcan.com/frequently-asked-questions.

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delivery, amended, or renewed in [state] on or after [effective date of this Act], shall cover both prescription overdose reversal agents and non-prescription overdose reversal agents, up to a maximum provided benefit of [x doses] per insured per year.

(2) The coverage provided under subsection (b)(1) shall not:

(A) Be subject to prior authorization requirements;

(B) Be subject to the insurance contract, plan, or policy's deductible requirements; or

(C) Impose a copayment upon the insured of more than [$10] for any individual unit purchased.

(c) Coverage for individuals other than the insured.—The coverage mandated by this section shall include overdose reversal agents intended for use on an individual other than the insured.

Commentary

Legal authorization for an individual to possess or administer ORAs is of limited value unless the individual can obtain the ORA. Certainly, there are many circumstances in which an individual can obtain an ORA, or at least have access to one in an emergency, at no cost. For example, state and local governmental entities and other entities providing harm reduction services routinely distribute ORAs at no cost to the recipient including by mail order for home delivery. [72] Likewise, Section VI requires ORAs to be kept at numerous locations for use in the case of an emergency without cost to the user.

Outside of these situations, however, an individual going to a pharmacy, other retail store, or a vending machine will need to pay for the ORA with health insurance coverage and/or out-of-pocket funds (*i.e.*, either the insurance coinsurance/copayment or non-prescription retail cost). Moreover, in cases where a healthcare provider gives an ORA to an individual at risk of an overdose as a means of providing health care, it makes sense for an individual's health insurance to cover some of or all of the cost. As of October 2023, 13 states and Puerto Rico place some type of requirement on Medicaid and/or other health insurers regarding insurance coverage for ORAs.[73] The requirements vary by state and include, but are not limited to, requiring coverage of ORAs, not requiring prior authorization for ORAs, and placing at least one ORA formulation on the lowest tier of the insurer's drug formulary. Each of these laws, however, originally predated the emergence of non-prescription ORAs in the marketplace.

[72] Although the end recipient gets the ORA "for free," the entity providing the ORA (or some entity further up the chain of ORA distribution) often faces a cost in obtaining the ORA, either through direct purchase or use of grant/appropriated funds that could go towards other things (or disappear).
[73] *See Opioid Antagonist Access: Summary of State laws*, *supra* note 13, at 10.

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The existence of non-prescription ORAs complicates this analysis. The default rule is that prescription drug coverage does not include non-prescription drugs. Both public and private health insurers, however, can choose to provide insurance coverage for non-prescription drugs, but there are administrative steps to do this. In terms of state Medicaid programs, several states took, or plan to take, these steps. In 2023, as part of its annual survey of state programs, the Kaiser Family Foundation (KFF) asked states about Medicaid coverage for non-prescription ORAs. According to KFF, "at least one-third of states have or plan to add OTC Narcan to FFS Medicaid OTC formularies."[74] In the past year, at least one private insurer announced that it will cover non-prescription ORAs (with no copayment) for all insureds.[75]

Concerns remain, however, about health insurance coverage for non-prescription ORAs generally. Indeed, the Congressional U.S. House Committee on Energy and Commerce very recently asked the Government Accountability Office to "analyze federal health insurance plans, to the extent data are available, including traditional Medicare and Medicare Advantage, Medicaid and Medicaid managed care, and private group and individual health plans" and answer a number of questions about ORAs including "How are opioid overdose reversal agents currently covered by selected federal and private health plans?" and "Can naloxone be covered as an over-the-counter drug for individuals[?]."[76]

After the FDA approved non-prescription ORA products in March 2023, there have been several state legislative proposals that would expressly require health insurers to provide insurance coverage for both non-prescription and prescription ORAs.[77] To date, none are enacted. However, although it does not expressly mention non-prescription ORAs, an Illinois law that took effect in 2023 provides that "no individual or group policy of accident and health insurance amended, delivered, issued, or renewed after January 1, 2024 that provides coverage for naloxone hydrochloride shall impose a copayment on the coverage provided." [78]

Despite the lack of success, considering this Act's primary goal is to provide a model to states, Section X requires insurance coverage for both prescription and non-prescription ORAs under all public or private health insurance policies in the state (including Medicaid) other than federally administered health plans that are not subject to state law restrictions on coverage.

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[74] Heather Saunders and Kathy Gifford, *State Approaches to Addressing the Opioid Epidemic: Findings from a Survey of State Medicaid Programs*, KAISER FAMILY FOUNDATION (Feb. 6, 2024), https://www.kff.org/medicaid/issue-brief/state-approaches-to-addressing-the-opioid-epidemic-findings-from-a-survey-of-state-medicaid-programs/.

[75] *Blue Cross Blue Shield of Massachusetts to Cover Over-the-counter Narcan at No Cost to Members*, BLUE CROSS MA. (Aug. 29, 2023), https://newsroom.bluecrossma.com/2023-08-29-BLUE-CROSS-BLUE-SHIELD-OF-MASSACHUSETTS-TO-COVER-OVER-THE-COUNTER-NARCAN-AT-NO-COST-TO-MEMBERS.

[76] Letter to the Hon. Gene Dodaro, U.S. HOUSE COMMITTEE ON ENERGY & COMMERCE (May 16, 2024), https://kuster.house.gov/uploadedfiles/050124_naloxone_affordability_gao_request_final.pdf.

[77] *See, e.g.,* A.B. 1060, 2023-2024 Reg. Sess. (Cal. 2023); A.B. 2271, 2023-2024 Reg. Sess. (Cal. 2024); H.B. 736, 446th Sess., Gen. Assem. (Md. 2024); S.B. 497, 446th Sess., Gen. Assem. (Md. 2024); H.B. 4743, 193rd Gen, Court (Mass. 2024).

[78] 215 ILL. COMP. STAT. ANN. 5/356z.23(a-5) (West 2024). The statute notes that the no copayment requirement does not apply if it would disqualify a high-deductible health plan from certain health savings account eligibility under the Internal Revenue Code.

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Section X's form, other than the express reference to non-prescription ORAs, resembles that of the insurance provisions in the 2021 Model Act (Section VIII) as well as some states with health insurance-related laws enacted before 2023.

Under typical prescription drug insurance coverage, the insurance company's coverage is not unlimited. Rather, the insurance company will cover a 30, 60, or 90-day supply of a drug and then will not cover a refill until that supply is near its end. The same quantity limits hold true for a prescription for drug used only in an emergency, such as an epinephrine injector ("epipen"). A policyholder cannot obtain prescription drug coverage for an unlimited supply of epipens. For this reason, Section X includes provisions in both subsection (a) (Medicaid) and subsection (b) (other health insurance) that insurance coverage will apply to a maximum number of doses per year, with the number of doses up to individual state legislative decision. The 2021 Model Act contained a quantity limit as well.

SECTION XI. DISCRIMINATION BY LIFE INSURANCE COMPANY PROHIBITED.

(a) Limitations on coverage.—Any company engaged in the business of providing life insurance that is authorized to do business within [state] shall not limit coverage, or refuse to issue or renew coverage, for an individual under any policy due to the fact that the individual:

(1) Has or had a prescription for an overdose reversal agent; or

(2) Purchased, or otherwise possessed, an overdose reversal agent.

(b) Rates.—Any company engaged in the business of providing life insurance that is authorized to do business within [state] shall not, when determining the premium rate for coverage of an individual under a policy issued or renewed by the company, consider the fact that the individual:

(1) Has or had a prescription for an overdose reversal agent; or

(2) Purchased or otherwise possessed an overdose reversal agent.

(c) Other discrimination.—Any company engaged in the business of providing life insurance that is authorized to do business within [state] shall not otherwise discriminate in the offering, issuance, cancellation, amount of coverage, premium, or any other condition of an insurance policy issued by the company based solely upon the fact that an individual:

(1) Has or had a prescription for an overdose reversal agent; or

(2) Purchased or otherwise possessed an overdose reversal agent.

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Commentary

This section protects individuals who possess an ORA or receive a prescription for an ORA from discrimination when seeking life insurance coverage. While this problem may not be widely prevalent, it is pervasive enough that as of October 2023 six states enacted laws prohibiting this type of discrimination.[79] In New York, the General Assembly enacted the law after lobbying by organizations like the state nurses' association and other healthcare practitioners who reported that their members were denied life insurance coverage because their active medication list contained an ORA.[80]

This section does not prevent life insurance companies from relying on an applicant's history of a substance use disorder or opioid use disorder in making coverage or rating decisions. This section simply bars the insurer from discriminating against individuals (whether or not they suffer from substance use disorder) solely because they receive a prescription for or possess an ORA.

SECTION XII. BULK OVERDOSE REVERSAL AGENT PURCHASING FUND.

(a) In general.—There is hereby created a bulk overdose reversal agent purchasing fund ("the fund") in the [state treasury] which shall be funded by the following sources and cannot revert back to the [general fund]:

(1) Payments made to the [state department of health] by the eligible persons or entities specified in subsection (e);

(2) Gifts, grants, donations, and federal funds credited to the fund pursuant to subsection (b);

(3) Payments made for violations pursuant to Sections IV(l), VI(e), and VII(f); and

(4) Any money that the [state legislature] may appropriate or transfer to the fund.

(b) Gifts, donations, and federal funds.—The single state authority:

(1) May seek, accept, and expend gifts, grants, or donations from private or public sources for the purposes of this section;

(2) May pursue federal funding, matching funds, grants, and foundation funding for the purposes of this section; and

[79] CONN. GEN. STAT. ANN. § 38a-447a (West 2024); ME. REV. STAT. ANN. tit. 24-A, § 2159-E (West 2024); N.H. REV. STAT. ANN. § 417:4(VIII)(h) (West 2024); N.Y. INS. LAW § 2617 (McKinney 2024); R.I. GEN. LAWS ANN. § 27-4-1.1 (West 2024); TEX. INS. CODE ANN. § 1101.253 (West 2024).

[80] Rachel Silberstein, *Nurses Say They are Denied Life Insurance for Carrying Naloxone*, TIMES UNION (May 7, 2019, 2:04 PM), https://www.timesunion.com/news/article/Nurses-say-they-are-denied-life-insurance-for-13822183.php.

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(3) Shall transmit all money received through sources identified in subsection (b)(1) and (b)(2) to the [state treasurer], who shall credit the money to the fund.

(c) Interest.— The [state treasurer] shall credit all interest and income derived from the deposit and investment of money in the fund to the fund.

(d) Appropriation.— For the [20XX to 20YY] state fiscal year, the [state legislature] shall appropriate [$XX] from [the general fund, opioid litigation proceeds fund, etc.] to the fund.

(e) Eligibility.—The following persons or entities are eligible to purchase one or more overdose reversal agents from the fund so long as the purchased overdose reversal agent is used for the specified purpose:

(1) Any person or entity required by this Act to offer an overdose reversal agent to an individual;

(2) Any person or entity required by this Act to provide access to an overdose reversal agent for use in an emergency; and

(3) Any person or entity who transfers an overdose reversal agent to an individual without charge.

(f) Priority.—The [state department of health and/or the single state authority] may prioritize the purchase of overdose reversal agents by eligible persons or entities based on the need of the person or entity and the availability of overdose reversal agents, as determined by the [state department of health and/or the single state authority].

(g) Regulations.—The [state department of health] shall promulgate regulations specifying the amount an eligible person or entity must pay to obtain overdose reversal agents from the fund.

(h) Report.—No later than [month/day/year] and every [month/day] thereafter, the [state department of health] shall report to the [house and senate appropriations committees, or their successor committees] on the fund's activity.

Commentary

The purpose of the bulk overdose reversal agent purchasing fund in Section XII is to reduce the financial burden of purchasing ORAs. Ideally, using the money put into the fund, the state department of health can purchase ORAs at a highly discounted rate and then provide them

to eligible entities at little or no cost. This section is extensively based on Colorado law[81] although at least four other states also have bulk ORA purchasing mechanisms.[82] As provided in subsection (g), Colorado's statutory language does not require the bulk fund to provide no cost ORAs to eligible entities.[83] As a practical matter, however, Colorado does not charge eligible entities to obtain ORAs from the fund.[84]

The single state authority (SSA) is the entity designated by the governor or chief executive officer as the single state administrative authority responsible for the planning, development, implementation, monitoring, regulation, and evaluation of substance use disorder services (see definition in Section III). In most states, the SSA receives SAMHSA Block and State Opioid Response grant funds and transmits money for things like purchasing ORAs directly to organizations. Because the SSA may not be housed in a state department of health, subsection (b) directs the SSA to perform the listed activities rather than the health department.

Subsection (e) contains the list of entities eligible to use the fund. The language is broad and covers every person or entity required by this Act to offer an ORA or provide access to an ORA. It also covers people or entities who distribute ORAs to others without charge.

The drafters leave it to state policymakers to decide the appropriation amount in subsection (d). In the Colorado law that serves as the basis for Section XII, the law directs the state's general assembly, for the 2022-23 fiscal year, to appropriate $19.7 million from the state's behavioral and mental health cash fund to the bulk purchasing fund.[85]

SECTION XIII. OTHER FUNDING PROVISIONS.

(a) In general.—With respect to funding the initial start-up and ongoing state agency activities and local-specific activities related to overdose reversal agent access services provided as part of this Act, other than the bulk overdose reversal agent purchasing fund established under Section XII:

(1) The [legislature] shall appropriate [*$*] to the [state department of health and/or other appropriate department or agency];

(2) The [state department of health and/or other appropriate department or agency] shall

[81] COLO. REV. STAT. ANN. § 25-1.5-115(6)(a) (West 2024). *See also*, *Opiate Antagonist (Naloxone) Bulk Purchase Fund – 2023 Legislative Report*, COLO. DEP'T OF PUB. HEALTH & ENVIRONMENT (Oct. 1, 2023), available at https://cdphe.colorado.gov/naloxone-bulk-purchase-fund.
[82] *See, e.g.,* CONN. GEN. STAT. ANN. § 17a-674h (West 2024); MASS. GEN. LAWS ANN. ch. 29, § 2RRRR (West 2024); NEV. REV. STAT. § 458.102 (West 2024); WASH. REV. CODE ANN. § 70.14.170 (West 2024).
[83] COLO. REV. STAT. ANN. § 25-1.5-115(3) (West 2024).
[84] *Opiate Antagonist (Naloxone) Bulk Purchase Fund – 2023 Legislative Report*, supra note 81 at 7 ("This funding will support ongoing life-saving measures by providing naloxone at no cost to eligible entities.").
[85] COLO. REV. STAT. ANN. § 25-1.5-115(6)(a) (West 2024). Note that the cited provision pertaining to the 2022-23 fiscal year "is repealed, effective July 1, 2024." COLO. REV. STAT. ANN. § 25-1.5-115(6)(b) (West 2024).

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pursue federal funding, matching funds, grants, and foundation funding; and

(3) The [state department of health and/or other appropriate department or agency] may receive such gifts, grants, and endowments from public or private sources as may be made from time to time, in trust or otherwise, for the use and benefit of the purposes of the Act and expand the same or any income derived from it according to the term of the gifts, grants, or endowments.

(b) Guidelines and requirements.—Funding shall be made available to support both new and existing overdose reversal agent access programs in a broad spectrum of geographic regions within the state, including urban, suburban, rural, and tribal communities.

Commentary

There are various avenues that states may pursue to fund increased access to ORAs within their communities. This includes partnering with private companies that make and distribute overdose reversal agents or seeking out and obtaining federal funding. For example, SAMHSA administers the formula-based Substance Abuse Prevention and Treatment Block Grant to help provide funding to states, territories, and tribes. In a publication issued about the block grant, SAMHSA noted that state agencies may use this funding for opioid education.[86] Moreover, there is no explicit restriction on using these funds for the purchase of ORAs.[87]

In addition, some states may be able to fund increased access to ORAs through opioid settlement funds.[88] In Massachusetts, for example, the state created the Municipal Naloxone Bulk Purchase Fund after reaching a settlement with one of the manufacturers of naloxone.[89] This fund allows municipalities to purchase naloxone for use by first responders at a heavily discounted rate.[90] Legislators and policymakers should consider allocating opioid settlement funds to cover costs associated with expanding access to ORAs within the state.

[86] *Expansion of Naloxone in the Prevention of Opioid Overdose FAQS*, SUBSTANCE ABUSE AND MENTAL HEALTH SERV. ADMIN. 1, (last accessed June 27, 2024), https://www.samhsa.gov/sites/default/files/programs_campaigns/medication_assisted/expansion-of-naloxone-faq.pdf.
[87] *Id*.
[88] Opioid settlement funds are funds recovered by a state through litigation against the pharmaceutical industry, including pharmaceutical manufacturers or distributors; Katie Zezima, *Ohio Tries an Unusual Tactic Toward Opioid Settlement: Working Together*, WASH. POST (Feb. 4, 2020), https://www.washingtonpost.com/national/ohio-tries-an-unusual-tactic-toward-opioid-settlement-workingtogether/2020/02/24/d5923faa-4c48-11ea-9b5c-eac5b16dafaa_story.html.
[89] *Narcan Fund*, MASS.GOV (last accessed June 27, 2024), https://www.mass.gov/service-details/narcan-fund.
[90] *Id.*

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SECTION XIV. RULES AND REGULATIONS.

Within six (6) months of the effective date of this Act, the [state department of health, state department of corrections, state board of pharmacy, and/or any other appropriate department or agency] shall promulgate such rules and regulations as are necessary to implement this Act.

SECTION XV. SEVERABILITY.

If any provision of this Act or application thereof to any individual or circumstance is held invalid, the remaining provisions of this Act shall not be affected nor diminished.

SECTION XVI. EFFECTIVE DATE.

This Act shall be effective on [specific date or reference to standard state method of determination of the effect].

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ABOUT THE LEGISLATIVE ANALYSIS AND PUBLIC POLICY ASSOCIATION

The Legislative Analysis and Public Policy Association (LAPPA) is a 501(c)(3) nonprofit organization whose mission is to conduct legal and legislative research and analysis and draft legislation on effective law and policy in the areas of public safety and health, substance use disorders, and the criminal justice system.

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