LEGISLATIVE ANALYSIS AND PUBLIC POLICY ASSOCIATION

MODEL EXPANDED ACCESS TO EMERGENCY OPIOID ANTAGONISTS ACT





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SECTION I. TITLE.

This Act may be cited as the "Model Expanded Access to Emergency Opioid Antagonists Act," "Model Act," or "the Act."

SECTION II. LEGISLATIVE FINDINGS AND PURPOSE.

- (a) Legislative findings.—The [Legislature]¹ finds that:
 - The United States and the state of [insert name of state] are in the midst of the worst opioid epidemic in history;
 - (2) In the United States, researchers estimate that over 934,000 individuals died from a fatal overdose involving an opioid between 1999 and 2020;²
 - (3) Experts believe that this staggering number of overdose deaths is based on several factors, including an increase in illicitly manufactured fentanyl and other synthetic opioids;³
 - (4) Opioid antagonists, such as naloxone, can be used during emergencies to reverse opioid overdoses and are effective at preventing fatal drug overdoses;
 - (5) The Centers for Disease Control and Prevention reported that despite an increase in prescriptions for emergency opioid antagonists, not enough of the medication is getting into the hands of those who need it most;⁴

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

² This number was determined by combining the 841,000 overdose deaths reported by the CDC between 1999 and 2019 and the recently reported number of 93,000 people who died due to drug overdose in 2020. *Overdose Death Rates*, NAT'L INST. ON DRUG ABUSE (Jan. 29, 2021), <u>https://www.drugabuse.gov/drug-topics/trends-statistics/overdose-death-</u>

rates#:~:text=Opioid%2Dinvolved%20overdose%20deaths%20rose,2019%20to%2049%2C860%20overdose%20de aths. See also Lenny Bernstein and Joel Achenbach, Drug Overdose Deaths Soared to a Record 93,000 this Year, WASHINGTON POST (July 14, 2021, 10:00 AM), <u>https://www.washingtonpost.com/health/2021/07/14/drug-</u>overdoses-pandemic-2020/ and state-specific numbers related to drug overdose mortality, Drug Overdose Mortality

overdoses-pandemic-2020 and state-specific numbers related to drug overdose mortality, Drug Overdose Mortality by State, CENTERS FOR DISEASE CONTROL AND PREVENTION, (Feb. 12, 2021),

https://www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm. ³ Brian Mann, *Drug Overdose Deaths Spiked to 88,000 During the Pandemic, White House Says*, NPR.ORG (April 1, 2021, 2:16 PM), https://www.npr.org/2021/04/01/983414684/white-house-says-drug-overdose-deaths-spiked-to-88-000-during-the-pandemic.

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 (August 6, 2019), https://www.cdc.gov/media/releases/2019/p0806-naloxone.html.

- (6) Expanding access to emergency opioid antagonists and encouraging citizens of [state] to obtain emergency opioid antagonists are in [state's] best interests.
- (b) Purpose.—It is the intent of the [Legislature] through this Act to:
 - Potentially save the lives of individuals who experience an opioid overdose by expanding access to, and availability of, emergency opioid antagonists within the state;
 - (2) Address the critical need to provide uniformity in the ability of citizens of [insert state] to access emergency opioid antagonists;
 - (3) Encourage citizens to obtain emergency opioid antagonists;
 - (4) Grant immunity to individuals administering opioid antagonists;
 - (5) Require co-prescribing of an emergency opioid antagonist when a person is prescribed an opioid;
 - (6) Require health insurance coverage of emergency opioid antagonists like naloxone and prohibit discriminatory life and health insurance practices related to the possession of naloxone;
 - (7) Provide increased access to opioid antagonists in educational institutions and correctional settings;
 - (8) Establish a pilot program for bystander access; and
 - (9) Promote initiatives that educate citizens on the life-saving potential of emergency opioid antagonists.

The numbers are stark – drug overdoses are killing people in the United States (U.S.) at a record rate. In 2020, over 93,000 people died from a fatal overdose in the U.S., the highest number of overdoses ever recorded.⁵ Opioids are the cause of the majority of these deadly overdoses.⁶ However, if naloxone, 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 opioid overdose can be reversed. Such medications (hereafter called "emergency opioid

https://www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm.

⁵ Lenny Bernstein and Joel Achenbach, *Drug Overdose Deaths Soared to a Record 93,000 This Year*, WASHINGTON POST (July 14, 2021, 10:00 AM), <u>https://www.washingtonpost.com/health/2021/07/14/drug-overdoses-pandemic-2020/</u>. *See* state-specific numbers related to drug overdose mortality, *Drug Overdose Mortality by State*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Feb. 12, 2021),

⁶ Drug Overdose Deaths, CENTERS FOR DISEASE CONTROL AND PREVENTION (last reviewed March 3, 2021), https://www.cdc.gov/drugoverdose/deaths/index.html.

antagonists") are safe, non-addictive drugs that work to interrupt an opioid overdose and save a person's life. Studies show that overdose deaths decrease when emergency opioid antagonists and overdose education are available to community members.⁷ The use of emergency opioid antagonists to stop or prevent an opioid overdose is a crucial tool in controlling the opioid overdose epidemic within the United States.

This Act provides an evidence-based approach to increasing citizen access to emergency opioid antagonists. While all 50 states, the District of Columbia, and the Commonwealth of Puerto Rico allow specific individuals to obtain emergency opioid antagonists without a patient-specific prescription, these laws vary significantly between jurisdictions.⁸ There is a need for uniformity regarding access to and use of emergency opioid antagonists to save lives in an increasingly mobile society.

The goal of a model act should be to provide a template of suggested legislative provisions that can be followed efficiently and achieve the act's stated purposes. To that end, the Model Expanded Access to Emergency Opioid Antagonists Act gives legislators and policymakers the means to implement mechanisms that increase the ability of citizens in every state to access and use emergency opioid antagonists to save lives. This Act is comprehensive and will enable an enacting jurisdiction to either completely replace any existing legislation on emergency opioid antagonists with this Act or simply use the sections that best address the needs of the state.

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 the direct application of an emergency opioid antagonist by a person authorized pursuant to this Act to the body of an individual suffering, or believed to be suffering, an opioid overdose, whether by injection,

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⁷ U.S. Surgeon General's Advisory on Naloxone and Opioid Overdose, U.S. DEP'T OF HEALTH & HUM. SERVICES (April 5, 2018), <u>https://www.hhs.gov/surgeongeneral/priorities/opioids-and-addiction/naloxone-advisory/index.html</u>, citing to Alexander Y. Walley et al., *Opioid Overdose Rates and Implementation of Overdose Education and Nasal Naloxone Distribution in Massachusetts: Interrupted Time Series Analysis*, BMJ 2013;346:f174.

⁸ "Thirty-three states have a statewide standing order for naloxone. In 14 states and the District of Columbia, a prescriber and a pharmacist can enter into a standing order agreement for naloxone but must do so on their own terms as there is no statewide standing order. In Idaho and Oregon, pharmacists have authority to prescribe and dispense naloxone to individuals who do not otherwise have a prescription. Oklahoma law directly authorizes pharmacists to dispense naloxone without a prescription. Additionally, in March 2019, Puerto Rico's Department of Health announced that naloxone could be sold without a prescription." *Naloxone Access: Summary of State Laws*, LEGIS. ANALYSIS AND PUB. POL'Y ASS'N, 9 (Oct. 2020), <u>https://legislativeanalysis.org/wp-content/uploads/2021/05/Naloxone-Access-Summary-of-State-Laws-Final.pdf</u>.

inhalation, ingestion, or any other means;9

- (b) Community-based organization.—"Community-based organization" means a public or private organization that is representative of a community or significant segments of a community that provides educational, health, or social services to individuals in the community. This definition also includes local health departments;
- (c) Co-prescribe.—"Co-prescribe" means the practice of prescribing or dispensing an emergency opioid antagonist in conjunction with an opioid prescription;
- (d) Correctional setting.—…"Correctional setting" means a jail, prison, adult or juvenile detention center, or other environment in which a state or local entity confines a person;
- (e) Dispenser.—"Dispenser" means any individual or entity that is licensed, registered, certified, or otherwise authorized by [state] to dispense prescription drugs, including emergency opioid antagonists. "Dispenser" includes pharmacists, pharmacies, and dispensing practitioners;
- (f) Emergency opioid antagonist.—"Emergency opioid antagonist" means a drug, including but not limited to naloxone, approved by the United States Food and Drug Administration for the complete or partial reversal of an opioid overdose;
- (g) First responder.—"First responder" means a state or local law enforcement officer, firefighter, emergency medical services provider, or other individual who, in an official capacity, responds to an emergency or critical incident. This includes individuals working in an official or volunteer capacity;
- (h) Health care practitioner.—"Health care practitioner" means a person licensed, registered, certified, or otherwise authorized by [state] to provide health care to individuals;
- (i) Life insurance.—"Life insurance" means insurance upon the lives of human beings. "Life insurance" 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

⁹ The definition of "administer" is adapted from KY. REV. STAT. ANN. § 218A.010 (West 2021) (effective June 29, 2021).

benefits to provide for educational loans, and additional benefits providing specified disease coverage, limited benefit health coverage, or accident and sickness coverage;¹⁰

- (j) Opioid.—"Opioid" means natural, synthetic, or semi-synthetic chemicals that interact with opioid receptors on nerve cells in the body and brain and reduce the intensity of pain signals and feelings of pain. This class of drugs includes heroin, synthetic opioids such as fentanyl, and opioid analgesics, such as oxycodone, hydrocodone, codeine, and morphine;
- (k) Opioid analgesics.—"Opioid analgesics," commonly referred to as prescription opioids, means natural, semi-synthetic, or synthetic medications used pursuant to a prescription to treat moderate to severe pain;
- Opioid overdose.—"Opioid overdose" means an acute condition evidenced by symptoms including, but not limited to, physical illness, coma, decreased level of consciousness, or respiratory depression, resulting from the consumption or use of an opioid or another substance with which an opioid is combined;
- (m) Prescriber.—"Prescriber" means an individual licensed, registered, certified, or otherwise authorized by [state] to prescribe prescription drugs, including emergency opioid antagonists;
- (n) Risk management officer.—"Risk management officer" means a person who facilitates, manages, and coordinates access to emergency opioid antagonists and oversees the possession, stocking, or administration of emergency opioid antagonists on the premises of a state educational institution or state correctional setting; and
- (o) Standing order.—"Standing order" means a prewritten, non-individual specific order issued by a prescriber that authorizes the dispensing of a drug to, or administration of the drug by, any individual.

Commentary

The definitions in this section are adapted, in part, from the Centers for Disease Control and Prevention (CDC) website "Opioid Basics."¹¹

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¹⁰ See VA. CODE ANN. § 38.2-102 (West 2021) (effective July 1, 2012).

¹¹ *Opioid Basics*, CENTERS FOR DISEASE CONTROL AND PREVENTION (March 16, 2021), https://www.cdc.gov/opioids/basics/terms.html.

SECTION IV. STATEWIDE STANDING ORDER.

- (a) In general.—Within thirty (30) days of the effective date of this Act, the [state department of health or other appropriate department] shall designate a physician, licensed in this state and in good standing, to issue a statewide standing order for emergency opioid antagonists pursuant to the provisions of this section.
- (b) Requirements.—Within thirty (30) days of being designated pursuant to subsection (a) of this section, the physician shall issue a standing order that:
 - (1) Authorizes any prescriber or dispenser to prescribe or dispense emergency opioid antagonists to any person or entity within [state] upon request; and
 - (2) Allows for the possession, storage, distribution, and administration of emergency opioid antagonists by any individual or entity within [state].
- (c) Effective period.—The standing order issued pursuant to this section shall remain in effect until the FDA classifies at least one emergency opioid antagonist as an over-thecounter (OTC) drug.

Commentary

Pursuant to current federal law, an emergency opioid antagonist must either be dispensed in accordance with a prescription or by a pharmacist under a pharmacy-specific protocol.¹² The standing order language provided in this section is intentionally broad. The goal is to allow for the issuance of a standing order that will act as a prescription within the state and will enable any person, within the parameters of this Act, to dispense, possess, store, distribute, or administer an emergency opioid antagonist without the risk of violating federal or state law. All 50 states, the District of Columbia, and Puerto Rico allow specific individuals to obtain emergency opioid antagonists without a patient-specific prescription in some capacity. As of 2020, 33 states have a statewide standing order for an emergency opioid antagonist.¹³ In 14 states and the District of Columbia, while there is no statewide standing order, a prescriber and pharmacist can independently enter into a standing order agreement to dispense an emergency opioid antagonist.¹⁴ For example, in South Carolina, the state board of medical examiners and the state board of pharmacy entered into a joint protocol to dispense emergency opioid antagonists without a prescription.¹⁵ In Oklahoma and the Commonwealth of Puerto Rico, pharmacists may dispense emergency opioid antagonists without a prescription.¹⁶

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¹² Kirk E. Evoy, Lucas G. Hill, & Corey S. Davis, *Considering the Potential Benefits of Over-the-Counter Naloxone*, INTEGRATED PHARMACY RSCH. AND PRAC., Feb. 15, 2021, at 2.

¹³ LEGIS. ANALYSIS AND PUB. POL'Y ASS'N, *Naloxone Access, supra* note 8, at 9.
¹⁴ Id.

¹⁵ S.C. Code Ann. § 44-130-40 (effective June 5, 2016).

¹⁶ *Id.* LEGIS. ANALYSIS AND PUB. POL'Y ASS'N, *Naloxone Access, supra* note 8, at 9.

There was a suggestion by some reviewers that the Act grant direct, prescriptive authority to pharmacists in place of a standing order provision. This idea is not without merit. One study suggests that direct pharmacy prescriptive authority is associated with "significant reductions in fatal overdoses . . . " as opposed to a statewide standing order provision. ¹⁷ However, there are a few crucial differences in the existing statewide standing orders that the study reviewed and the standing order language provided in this section. First, the study noted that many of the standing order laws passed provided only limited immunity to pharmacists specifically.¹⁸ By contrast, this Act explicitly provides immunity to pharmacists (dispensers) directly, with the goal being to prevent any hesitancy the pharmacist may have about dispensing an emergency opioid antagonist without direct, prescriptive authority. Second, the study found that in some states that have implemented standing order language, the standing order only applies in limited settings, usually emergency departments.¹⁹ That is not the case here. The language of the standing order provided in this section is intended to cover all instances in which an emergency opioid antagonist might need to be dispensed or administered.

As the opioid epidemic continues in the United States, there is a growing call from clinicians and policymakers for the FDA to reclassify emergency opioid antagonists as OTC drugs.²⁰ Some argue that classifying emergency opioid antagonists as an OTC drug would further increase its accessibility and get it into the hands of individuals. There is growing support for this reclassification and strong indication from the FDA that this will happen at some point in the next few years.²¹ Thus, this section includes language that removes the necessity of a standing order once at least one emergency opioid antagonist is classified as an OTC drug.

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¹⁷ Rahi Abouk, PhD, Rosalie Liccardo Pacula, PhD, and David Powell, PhD, Association Between State Laws Facilitating Pharmacy Distribution of Naloxone and Risk of Fatal Overdose, JAMA Intern Med. June 2019, at 805-811., 805, doi: 10.1001/jamainternmed.2019.0272.

¹⁸ Id. at 809.

¹⁹ Id.

²⁰ Evoy et al., *supra* note 12.

²¹ In September 2019, the U.S. Food and Drug Administration (FDA) published a statement on continued efforts to increase availability of all forms of naloxone. In this statement, Acting Commissioner of the FDA Norman Sharpless, M.D. noted, "Making naloxone more widely available in every pharmacy as an approved over-the-counter (OTC) product would also be an important public health advancement – one we have been working on at the FDA. In January, we took an unprecedented step in helping to encourage development of OTC naloxone products. To encourage drug companies to enter the OTC market, the FDA designed, tested and validated the key labeling requirements necessary to approve an OTC version of naloxone." *Statement on Continued Efforts to Increase Availability of All Forms of Naloxone to Help Reduce Opioid Overdose Deaths*, U.S. FOOD AND DRUG ADMIN. (Sept. 20, 2019), <u>https://www.fda.gov/news-events/press-announcements/statement-continued-efforts-increase-availability-all-forms-naloxone-help-reduce-opioid-overdose.</u>

SECTION V. GENERAL ACCESS TO AN EMERGENCY OPIOID ANTAGONIST.

- (a) Prescribers.—Notwithstanding the presence or lack of a statewide standing order, prescribers may issue a prescription for an emergency opioid antagonist to any individual, first responder, or community-based organization upon request.
- (b) Dispensers.—Authorized dispensers in this state shall dispense emergency opioid antagonists directly to any individual, first responder, or community-based organization upon request.
- (c) Administer.—Any person may administer an emergency opioid antagonist to a recipient located in this state if the person believes, in good faith, that the recipient is experiencing an opioid overdose.
- (d) First responders and community-based organizations.—Upon request, first responders and community-based organizations may distribute an emergency opioid antagonist to any person within the state.
- (e) Duty to inform.—Any prescriber, dispenser, first responder, or community-based organization who prescribes, dispenses, or distributes an emergency opioid antagonist pursuant to this Act shall provide the recipient with information, either in writing or orally, or other accessible instructional materials for an individual with a disability, regarding:
 - The importance of emergency opioid antagonists in preventing deaths from opioid overdoses;
 - (2) How to recognize the signs and symptoms of a drug overdose;
 - (3) The essential steps in responding to a drug overdose, including:
 - (A) Evaluate for signs of an opioid overdose;
 - (B) Call 911 for help;
 - (C) Administer an emergency opioid antagonist;
 - (D) Support the person's breathing; and
 - (E) Monitor the person's response;
 - (4) Where to obtain emergency opioid antagonists throughout the state;
 - (5) De-stigmatizing the possession of an emergency opioid antagonist; and
 - (6) State laws limiting a person's civil and criminal liability for prescribing, dispensing,

distributing, or administering emergency opioid antagonists.

(f) Possession.—Notwithstanding any other law or regulation to the contrary, any individual, community-based organization, entity, or first responder within this state may possess or store an emergency opioid antagonist.

Commentary

In April 2018, then U.S. Surgeon General Jerome Adams called for heightened awareness and availability of emergency opioid antagonists to reverse the effects of opioid overdose to help prevent such overdoses.²² Specifically, General Adams called for increasing availability and targeted distribution of emergency opioid antagonists as a critical component in reducing opioidrelated overdose deaths.²³ Following those guidelines, this section aims to make emergency opioid antagonists as easy to obtain as possible. As noted earlier, all 50 states now allow access to an emergency opioid antagonist without an individual-specific prescription in some form or another.²⁴ Thus, this section seeks to erase as many of the barriers, both actual and perceived, as possible, mainly by including explicit statutory permission for any person within the state to administer an emergency opioid antagonist to an individual that they believe is experiencing an opioid overdose.

Multiple subject matter experts of this Act noted in discussion that there are still many unknowns regarding best practices surrounding de-stigmatizing, possessing, administering, or accessing emergency opioid antagonists. "[The] area of effective stigma interventions for harm reduction interventions specifically (as opposed to stigma toward people who use drugs, which is a related, but different kind of stigma), is very limited at the moment. Most studies document that stigma exists but have not tested interventions to reduce that stigma."²⁵ The drafters of this Act recognize that data is limited on this topic and that education alone will not de-stigmatize possession, administering, or accessing emergency opioid antagonists to the public. Accordingly, the goal of the drafter is to make both education *and* accessibility the driving forces behind the language of this Act. This Act aims to make emergency opioid antagonists as accessible as possible while educating the public about how crucial emergency opioid antagonists are to curbing the opioid overdose crisis and saving lives in the hope that this will help de-stigmatize emergency opioid antagonists in the eyes of the public.

The language in subsection (e)(3) listing the five essential steps to take in response to a suspected opioid overdose are taken directly from the Substance Abuse and Mental Health

²² U.S. DEP'T OF HEALTH & HUM. SERVICES, *supra*_note 7.

²³ Id.

²⁴ LEGIS. ANALYSIS AND PUB. POL'Y ASS'N, *Naloxone Access, supra* note 8, at 8.

²⁵ Email from Erin Madden, PhD., MPH, Assistant Professor, Department of Family Medicine and Public Health Sciences, Wayne State University School of Medicine, to author (Friday, September 10, 2021 12:11 PM, EST) (on file with author).

Services Administration's (SAMHSA) Opioid Overdose Prevention Toolkit: Five Essential Steps for First Responders.²⁶

SECTION VI. IMMUNITY FROM CIVIL AND CRIMINAL LIABILITY.

- (a) Prescribers.—Any prescriber who, in good faith and the absence of gross negligence, malice, or criminal intent, issues a prescription for an emergency opioid antagonist shall be 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) Dispensers.—Any dispenser who, in good faith and the absence of gross negligence, malice, or criminal intent, dispenses an emergency opioid antagonist shall be immune from civil or criminal liability and shall not be subject to administrative action for the dispensing of an emergency opioid antagonist or the ultimate outcome of such dispensing.
- (c) Distributor.—Any individual, community-based organization, entity, or first responder who, in good faith and the absence of gross negligence, malice, or criminal intent, distributes an emergency opioid antagonist shall be immune from civil or criminal liability and shall not be subject to administrative action for distributing an emergency opioid antagonist or the ultimate outcome of such distribution.
- (d) Administrator.—Any person who, in good faith and the absence of gross negligence, malice, or criminal intent, administers an emergency opioid antagonist to a person suffering, or believed to be suffering, an opioid overdose, shall be immune from civil or criminal liability and shall not be subject to administrative action for administering an emergency opioid antagonist or the ultimate outcome of such administration.
- (e) Good Samaritan protections.—Individuals who summon emergency medical assistance contemporaneously with administering an emergency opioid antagonist shall, in addition to the protections afforded under subsection (d), receive the protections afforded by [insert citation to appropriate state Good Samaritan provisions pertaining to overdoses]

²⁶ Opioid Overdose Prevention TOOLKIT: Five Essential Steps for First Responders, SAMHSA (last accessed August 23, 2021) https://store.samhsa.gov/sites/default/files/d7/priv/five-essential-steps-for-first-responders.pdf.

This section aims to build on existing laws and provide uniform civil and criminal immunity to all appropriate individuals involved in the prescribing, dispensing, distributing or administering emergency opioid antagonists, thus helping to encourage individuals to obtain and use emergency opioid antagonists. Currently, state laws vary regarding the level of immunity provided to those prescribing, dispensing, distributing, or administering emergency opioid antagonists. Twenty-eight states offer immunity from civil liability, criminal liability, and professional disciplinary actions for those prescribing emergency opioid antagonists.²⁷ Twentynine states provide immunity from civil and criminal liability and professional actions for persons dispensing emergency opioid antagonists.²⁸ Finally, over (35) states have enacted Good Samaritan laws which offer some form of both civil and criminal immunity from liability for people who act in good faith to administer an emergency opioid antagonist to an individual believed to be experiencing an opioid overdose.²⁹ These laws run the gamut, from protecting a caller from arrest to informing sentencing, which means the caller can still be arrested, charged, and sentenced.³⁰ This section aims to build on these laws and provide uniform civil and criminal immunity to all appropriate individuals involved in the prescribing, dispensing, distributing or administering emergency opioid antagonists, thus helping to encourage individuals to obtain and use emergency opioid antagonists. Legislators and policymakers should also strongly consider strengthening or revising existing Good Samaritan laws to encompass situations in which individuals on probation or parole administer an emergency opioid antagonist to persons experiencing a suspected overdose or who contact emergency services or law enforcement in instances of a suspected overdose.

On a final note, this section does not provide immunity for prescribers or dispensers for failure to prescribe or dispense an emergency opioid antagonist. While the drafters considered the possibility of including a provision exempting individuals from such liability, it was ultimately determined that language providing coverage in those situations would be, in effect, "a solution in search of a problem" that could hinder the ultimate goal of this Act - to expand access to emergency opioid antagonists.

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²⁷ LEGIS. ANALYSIS AND PUB. POL'Y ASS'N, *Naloxone Access, supra* note 8, at 5.

 $^{^{28}}$ *Id*. at 6.

²⁹ *Id*. at 7.

³⁰ Andra Wilkson, *Inconsistent State Policies Complicate Response To Opioid Epidemic*, CHILDTRENDS (June 12, 2018), https://www.childtrends.org/blog/state-response-opioid-epidemic-complicated-inconsistent-naloxone-good-samaritan-laws.

SECTION VII. MANDATORY CO-PRESCRIBING.

- (a) In general.—Any prescriber issuing an initial or renewal prescription to an individual for an opioid analgesic in this state shall co-prescribe an emergency opioid antagonist.
- (b) Patient education.—Upon issuing an initial prescription for an opioid analgesic, and at least once every [n] months thereafter as long as such opioid analgesic remains a part of patient care, the prescriber shall provide educational materials to the patient, in writing, or other accessible instructional materials for an individual with a disability, regarding:
 - The importance of emergency opioid antagonists in preventing deaths from opioid overdoses;
 - (2) How to recognize the signs and symptoms of a drug overdose;
 - (3) The essential steps in responding to a drug overdose, including:
 - (A) Evaluate for signs of an opioid overdose;
 - (B) Call 911 for help;
 - (C) Administer an emergency opioid antagonist;
 - (D) Support the person's breathing; and
 - (E) Monitor the person's response;
 - (4) Where to obtain emergency opioid antagonists throughout the state;
 - (5) De-stigmatizing the possession of an emergency opioid antagonist; and
 - (6) State laws limiting a person's civil and criminal liability for prescribing, dispensing, distributing, or administering emergency opioid antagonists.

Commentary

In 2016, the CDC recommended that health care practitioners prescribe naloxone concurrently with opioid prescriptions.³¹ Subsequently, in a drug safety communication, the FDA announced that drug manufacturers should update labels for opioid pain medicine and medications used to treat opioid use disorder to recommend that health care professionals discuss the availability of naloxone with patients and caregivers, both when beginning and when renewing these medicines.³² This section expands on the CDC recommendations and goes one

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³¹ DEBORAH DOWELL, M.D., TAMARA M. HAEGERICH, PHD, & ROGER CHOU, M.D., *CDC Guideline for Prescribing Opioids for Chronic Pain* — *United States, 2016*, MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1.

³² FDA Requiring Labeling Changes for Opioid Pain Medicines, Opioid Use Disorder Medicines Regarding Naloxone, U.S. FOOD & DRUG ADMIN. (July 23, 2020), <u>https://www.fda.gov/news-events/press-announcements/fda-</u>requiring-labeling-changes-opioid-pain-medicines-opioid-use-disorder-medicines-regarding.

step further; no matter the amount or type of opioid, or the risk factors associated with the patient, any person prescribed an opioid in the state must also receive a prescription for an emergency opioid antagonist. Co-prescribing is a crucial step in saving lives. Recent research indicates that when clinicians prescribe emergency opioid antagonists in conjunction with an opioid, the risk of opioid overdose decreases even if the emergency opioid antagonist prescription does not get filled.³³ The CDC reported that nearly nine million more naloxone prescriptions could have been dispensed in 2018 if every patient with a high-dose opioid prescription was offered an emergency opioid antagonist.³⁴

Several states have laws in place that either allow or require co-prescribing of an emergency opioid antagonist if a person is prescribed an opioid. In some states, a health care practitioner must co-prescribe an emergency opioid antagonist if certain conditions exist. For example, in Vermont, prescribers must co-prescribe naloxone or document that the patient has a valid prescription or is in possession of naloxone if the patient is receiving a daily opioid dose of 90 morphine milligram equivalents (MMEs) or more or a prescription that results in concurrent use of an opioid and benzodiazepines.³⁵ In New Mexico, health care providers must co-prescribe an opioid antagonist if the amount of the opioid analgesic being prescribed is at least a 5 day supply.³⁶ In other states, co-prescribing an opioid antagonist along with an opioid analgesic prescription is merely permissive. In Oregon, for example, pharmacists may co-prescribe naloxone with an opioid prescription.³⁷ This permissive setup is similar to Maryland, where licensed health care providers may co-prescribe an opioid antagonist if an individual is at an elevated risk of experiencing an opioid overdose.³⁸

The emergency opioid antagonist prescription appears to serve as an essential educational strategy. The Act's drafters discussed whether issuance of an emergency opioid antagonist prescription should be required only for every second or third opioid prescription or perhaps once every 90 days. However, given that patients who are prescribed opioids under this section are not required to *fill* the emergency opioid antagonist prescription but merely are allowed to do so, the drafters determined that it would be most beneficial to issue a prescription for an emergency opioid antagonist with each opioid prescription.

³⁶ *Id.* at 104.

³³ Naloxone for Opioid Overdose: Life-Saving Science, NAT'L INST. ON DRUG ABUSE (June 2021), https://www.drugabuse.gov/publications/naloxone-opioid-overdose-life-saving-science.

³⁴ *Still Not Enough Naloxone Where It's Most Needed*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Aug. 6, 2019), <u>https://www.cdc.gov/media/releases/2019/p0806-naloxone.html</u>.

³⁵ LEGIS. ANALYSIS AND PUB. POL'Y ASS'N, *Naloxone Access, supra* note 8, at 147.

³⁷ *Id.* at 121

³⁸ *Id.* at 73.

SECTION VIII. INSURANCE COVERAGE.

- (a) In general.—All state Medicaid programs, Medicare programs, and health insurance programs shall provide prescription coverage of emergency opioid antagonists and associated devices to all participants.
- (b) Private insurance.—Every individual or group health insurance contract, plan, or policy that provides prescription coverage that is delivered, issued for delivery, amended, or renewed in this state on or after the effective date of this Act, shall provide coverage for at least one nasal spray or auto-injector form of emergency opioid antagonist and devices per year to all policyholders.
- (c) Coverage requirements.—The coverage provided under subsections (a) and (b) shall include the emergency opioid antagonist product itself, any refills for expired or utilized drugs, and any reasonable pharmacy administration fees related to the dispensing of emergency opioid antagonists and provision of overdose prevention consultation.
- (d) Prior authorization.—Subject to the provisions of subsection (g), the coverage provided under this section shall not be subject to prior authorization.
- (e) Deductible.—The coverage provided under this section shall not be subject to the insurance plan's deductible requirements.
- (f) Coverage for individuals other than the insured.—The coverage mandated by this section shall include emergency opioid antagonists intended for use on individuals other than the insured.
- (g) Generic formulations.—Once at least one generic nasal spray or auto-injector form of emergency opioid antagonist becomes available for sale in [state], the provisions of subsection (d) covering prior authorization will only apply to the generic form or forms of the emergency opioid antagonist.
- (h) Coverage parameters.—As used in this section, "coverage" shall mean at a minimum that insurance companies may fully cover the total cost of the various forms of an emergency opioid antagonist or may require a co-pay as part of that coverage.

As of October 2020, 18 states place some type of requirement on insurers regarding emergency opioid antagonists.³⁹ This section aims to make it easier for individuals to obtain emergency opioid antagonists by removing barriers that could potentially be presented by insurance entities.⁴⁰ Increased access to emergency opioid antagonists must go hand in hand with the ability of citizens within the state to obtain emergency opioid antagonists. More than half of people with an opioid use disorder have incomes below 200 percent of the federal poverty line, or \$24,120 for an individual.⁴¹ This is why Medicaid, the health insurance program for low-income adults, children, and individuals with disabilities, is a critical tool in allowing "financial access to naloxone."⁴² As of 2020, all 50 state Medicaid programs cover emergency opioid antagonists.⁴³ This section seeks to take that coverage one step further and require that all approved formularies of emergency opioid antagonists be covered by Medicaid, thereby expanding access.

This section also requires private insurers to cover emergency opioid antagonists for the same policy reasons - to ensure that citizens within this state cannot just access an emergency opioid antagonist in theory but actually obtain it and have it on hand in practice.

SECTION IX. 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 emergency opioid antagonist; or

(2) Purchased, or otherwise possessed an emergency opioid antagonist;

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³⁹ *Id.* at 8.

⁴⁰ The wording of this section is taken directly from Rhode Island law. R.I. GEN. LAWS ANN. § 27-41-86 (West 2021).

⁴¹ Kendal Orgera & Jennifer Tolbert, *The Opioid Epidemic and Medicaid's Role in Facilitating Access to Treatment*, KAISER FAMILY FOUND. (May 24, 2019), <u>https://www.kff.org/medicaid/issue-brief/the-opioid-epidemic-and-</u>medicaids-role-in-facilitating-access-to-treatment/.

 ⁴² Richard G. Frank & Carrie Fry, *Medicaid Expands Access to Lifesaving Naloxone*, THE COMMONWEALTH FUND (July 5, 2017), <u>https://www.commonwealthfund.org/blog/2017/medicaid-expands-access-lifesaving-naloxone</u>.
 ⁴³ Id.

- (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, use the fact that the individual:
 - (1) Has or had a prescription for an emergency opioid antagonist; or
 - (2) Purchased or otherwise possessed an emergency opioid antagonist.
- (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 emergency opioid antagonist; or
 - (2) Purchased, or otherwise possessed an emergency opioid antagonist.

This section protects persons who possess an emergency opioid antagonist or receive a prescription for an emergency opioid antagonist from discrimination when seeking life insurance coverage. While this problem may not be widely prevalent, it is a pervasive enough issue that states like New York and Maine have passed laws prohibiting this type of discrimination.⁴⁴ In New York, the General Assembly enacted similar legislation after lobbying by organizations like the state nurse's association and other health care practitioners who reported that their members were denied life insurance coverage because their active medication list contained an emergency opioid antagonist.⁴⁵

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 someone (whether or not they suffer from substance use disorder) solely because they are prescribed or possess an emergency opioid antagonist.

⁴⁴ N.Y. INS. LAW § 2617 (McKinney 2021) (effective Oct. 6, 2020); *See also* ME. REV. STAT. ANN. tit. 24-A, § 2159-E (West 2021) (effective Sept. 19, 2019).

⁴⁵ Rachel Silberstein, *Nurses Say They are Denied Life Insurance for Carrying Naloxone*, TIMES UNION (May 7, 2019, 2:04 PM), <u>https://www.timesunion.com/news/article/Nurses-say-they-are-denied-life-insurance-for-13822183.php</u>.

SECTION X. CORRECTIONAL SETTINGS.

- (a) In general.—All state and local correctional settings shall make the following information available to both correctional staff and incarcerated individuals:
 - The importance of emergency opioid antagonists in preventing deaths from opioid overdoses;
 - (2) How to recognize the signs and symptoms of a drug overdose;
 - (3) The essential steps in responding to a drug overdose, including:
 - (A) Evaluate for signs of an opioid overdose;
 - (B) Call 911 for help;
 - (C) Administer an emergency opioid antagonist;
 - (D) Support the person's breathing; and
 - (E) Monitor the person's response;
 - (4) Where to obtain emergency opioid antagonists throughout the state;
 - (5) De-stigmatizing the possession of an emergency opioid antagonist; and
 - (6) State laws limiting a person's civil and criminal liability for prescribing, dispensing, distributing, or administering emergency opioid antagonists.
- (b) Training.—Staff members, employees, and volunteers of state and local correctional settings may take part in training offered pursuant to Section XII of this Act.
- (c) Storage.—State and local correctional settings are hereby authorized to possess, stock, dispense, and administer emergency opioid antagonists on their premises and shall keep emergency opioid antagonists in stock pursuant to the prisoner release program established in subsection (e) of this section.
- (d) Risk management officer.—All state and local correctional settings shall designate a risk management officer to oversee the possession, stocking, or administration of emergency opioid antagonists on its premises.
- (e) Prisoner release.—At all state and local correctional settings, on the day of an individual's release from the correctional setting, correctional staff are required to:
 - (1) Offer an emergency opioid antagonist;
 - (2) Provide the individual with instructions on the use of emergency opioid antagonists in the form of a written pamphlet or other accessible instructional materials for an

individual with a disability;

- (3) Require the individual to sign a written form indicating that they have been given the opportunity to receive an emergency opioid antagonist; and
- (4) Provide the individual with information regarding where and how to obtain additional emergency opioid antagonist doses locally.
- (f) Amount.—When offering an emergency opioid antagonist to a soon-to-be-released incarcerated individual, the individual shall be given as much of the emergency opioid antagonist as they request and is available at the correctional setting.
- (g) Purchase agreement.—A state or local correctional setting may enter into a purchase agreement with a private entity or organization to purchase a supply of emergency opioid antagonists for use pursuant to this section.
- (h) Guidelines.—Within six (6) months of the effective date of this Act, the [department of health or other appropriate departments] shall develop and make available to the department of corrections and state and local correctional settings guidelines for the training referenced in this section.

Commentary

Studies indicate that as many as 65 percent of incarcerated individuals have an active substance use disorder.⁴⁶ The prevalence of those in state correctional settings with a substance use disorder mandates that, in addition to receiving appropriate treatment, incarcerated people also be given access to education about emergency opioid antagonists.⁴⁷ Furthermore, research shows that opioid overdose education and emergency opioid antagonist distribution programs in prisons and jails reduce mortality.⁴⁸

This section requires that any person released from a state correctional setting be provided an emergency opioid antagonist if they wish to receive it.⁴⁹ This provision is imperative

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⁴⁶ Criminal Justice Drug Facts, NAT'L INST. ON DRUG ABUSE (June 2020), https://www.drugabuse.gov/publications/drugfacts/criminal-justice.

⁴⁷ This idea is taken directly from a presentation by Kathleen Manseau, MN BS/ARNP-C, given at the Rx Drug Abuse & Heroin Summit in 2021. In her presentation, Ms. Manseau discussed the impact of a pilot program created in conjunction with Robert Childs that offers naloxone to individuals released from local jails in central Washington. Robert Childs, Patty Collins, & Kathleen Manseau, MN, BS/ARNP-C, Presentation at the RX Summit: Planning and Implementing a Rural Jail-Based Naloxone Program During COVID-19: Lessons Learned from Georgia and Washington Part 2: Rural Central Washington State Experience (April 2021).

⁴⁸ Trevor Bennett & Katy Holloway, *The Impact of Take-home Naloxone Distribution and Training on Opiate Overdose Knowledge and Response: An Evaluation of the THN Project in Wales*, Drugs: Educ., Prevention and Pol'y, 19, (2012), 320-328, DOI: 10.3109/09687637.2012.658104.

⁴⁹ Childs, Collins, & Manseau, *supra* note 47.

as drug overdose is the leading cause of death after release from prison.⁵⁰ In light of this, the aim of providing emergency opioid antagonists upon release is simple—give individuals leaving a correctional facility the tools to prevent death from an opioid overdose, either their own or someone else's. In Scotland, for example, a study found that providing naloxone to people leaving prison reduced drug-related deaths by 36 percent in the weeks following their release.⁵¹

There was a great deal of discussion among subject matter experts regarding subsection (e) of this section. This section provides that the soon-to-be-released incarcerated person may be given as much of an emergency opioid antagonist as they request. Valid concerns were raised that including this provision might lead to a correctional setting's stock of emergency opioid antagonists being depleted and that, given the cost of these drugs, it would be cost-prohibitive to allow this. However, the drafters ultimately determined that the possible risk of stock depletion is outweighed by the value of allowing a person with a potentially increased risk of opioid overdose access to as much of this potentially life-saving drug as possible. Multiple doses of an emergency opioid antagonist may be necessary if an overdose involves a highly potent synthetic opioid such as fentanyl or large quantities of opioids⁵² or if the overdosing individual's respiratory function does not improve after administration of the initial dose.⁵³ The cost of life-saving emergency opioid antagonists is also likely to go down in the future, which may ease some of the financial concerns raised of potential stock depletion.⁵⁴

SECTION XI. PUBLIC EDUCATIONAL INSTITUTIONS AND UNIVERSITIES.

- (a) In general.—All public educational institutions and universities within [state] shall make the following information available to students, staff, and employees regarding emergency opioid antagonists:
 - The importance of emergency opioid antagonists in preventing deaths from opioid overdose;
 - (2) How to recognize the signs and symptoms of a drug overdose;

⁵¹ Sheila M. Bird, Andrew McAuley, Samantha Perry, & Carole Hunter, *Effectiveness of Scotland's National Naloxone Programme for Reducing Opioid-related Deaths: A Before (2006–10) Versus After (2011–13) Comparison*, 111 ADDICTION 5, 883-891 (Dec. 2015), <u>https://onlinelibrary.wiley.com/doi/10.1111/add.13265</u>.

⁵⁰ Ingrid A. Binswanger, Marc F. Stern, Richard A. Deyo, Patrick J. Heagerty, Allen Cheadle, Joann G. Elmore, & Thomas D. Koepsell, *Release from Prison — A High Risk of Death for Former Inmate*, N Engl J Med. 157-165 (January 11, 2097) doi:10.1056/NEJMsa064115.

⁵² Ronald B. Moss & Dennis J. Carlo, *Higher Doses of Naloxone are Needed in the Synthetic Opioid Era*. 14 SUBSTANCE ABUSE TREATMENT, PREVENTION, AND POL'Y, Feb. 18, 2019, at 4, <u>https://doi.org/10.1186/s13011-019-0195-4</u>.

⁵³Id.

⁵⁴ The FDA has made it clear that it will likely approve an OTC version of an emergency opioid antagonist as soon it is feasible to do so, indicating it is likely the cost of this life-saving drug will continue to be reduced. U.S. FOOD & DRUG ADMIN., *Statement on Continued Efforts, supra* note 21; *see also supra* text accompanying note 21.

- (3) The essential steps in responding to a drug overdose, including:
 - (A) Evaluate for signs of an opioid overdose;
 - (B) Call 911 for help;
 - (C) Administer an emergency opioid antagonist;
 - (D) Support the person's breathing; and
 - (E) Monitor the person's response;
- (4) Where to obtain emergency opioid antagonists throughout the state;
- (5) De-stigmatizing the possession of an emergency opioid antagonist; and
- (6) State laws limiting a person's civil and criminal liability for prescribing, dispensing, distributing, or administering emergency opioid antagonists; and
- (7) Any applicable educational institution policies and guidelines regarding medical amnesty for students who administer an emergency opioid antagonist or contact law enforcement for persons experiencing a suspected overdose.
- (b) Storage.—Public educational institutions and universities in this state are authorized to possess, stock, and administer emergency opioid antagonists on their premises.
- (c) Risk management officer.—All public schools and universities that possess or stock emergency opioid antagonists on the premises shall designate a school official as a risk management officer to oversee the possession, stocking, or administration of emergency opioid antagonists.
- (d) Training.—All staff, employees, and volunteers at public educational institutions or universities that possess or stock emergency opioid antagonists on the premises may take part in training offered through the [department of health or other appropriate departments] on the use and administration of emergency opioid antagonists pursuant to Section XII of this Act.
- (e) Private schools and universities.—Any private school or university within the state may:
 - Possess or stock emergency opioid antagonist subject to the exact requirements provided in this section for public educational institutions; and
 - (2) Take part in training offered through the [department of health or other appropriate departments] as referenced in subsection (d) of this section.

- (f) Guidelines.—Within six (6) months of the effective date of this Act, the [department of health or other appropriate departments] shall develop and make available to both public and private educational institutions and universities guidelines for the training referenced in this section.
- (g) Purchase agreement.—A public educational institution or university may enter into a purchase agreement with a private entity or organization to purchase a supply of emergency opioid antagonists for use pursuant to this section.

In 2019, over 3,000 people between the ages of 15 and 24 died from an opioid overdose.⁵⁵ Among 12th graders, close to 2 in 10 reported using prescription medicine without a prescription.⁵⁶ On university campuses, "the strongest danger of overdose in college students may be from non-medical use of illicit pills or stimulants like cocaine and methamphetamine tainted with strong synthetic opioids."⁵⁷ It is clear that the opioid epidemic impacts everyone, including children and young adults. This section aims to improve the ability of educational institutions to save lives. By offering educational programs to students and staff on the life-saving abilities of an emergency opioid antagonist, the state can exponentially increase the number of people who may be in a position and have the knowledge and ability to save the life of a person experiencing an opioid overdose. In addition, encouraging and allowing schools and universities to stock and possess emergency opioid antagonists on campus increases the likelihood that emergency opioid antagonists will be on hand and, more importantly, be administered to someone who experiences an opioid overdose while on school or university premises.

This section also requires educational institutions to inform students of any applicable medical amnesty policies and guidelines. "Most colleges have medical amnesty policies in place to protect students from university discipline when they call emergency services, according to Students for Sensible Drug Policy, an organization that promotes student health and safety over law enforcement."⁵⁸ However, students may not be aware of these policies. This provision is intended to encourage students to contact emergency services in instances of suspected drug overdoses.

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⁵⁵ Drug Overdoses in Youth, NAT'L INST. ON DRUG ABUSE, <u>https://teens.drugabuse.gov/drug-facts/drug-overdoses-youth</u> (last accessed April 22, 2021).

⁵⁶ Teen Substance Use & Risks, CENTERS FOR DISEASE CONTROL AND PREVENTION, (last reviewed Feb. 10, 2020), https://www.cdc.gov/ncbddd/fasd/features/teen-substance-use.html.

⁵⁷ Allison Smith, Senior Program Adm'r, La. Bd. of Regents, & Cece Spitznas, Senior Pol'y Analyst, Off. of Nat'l Drug Control Pol'y, Presentation at RX Summit: Improving Overdose Prevention and Naloxone Availability in Higher Education Settings (April 5, 2021).

⁵⁸ *Get Help or Let Them Die?*, INSIDE HIGHER ED., <u>https://www.insidehighered.com/news/2019/12/06/medical-amnesty-policies-encourage-students-call-911</u> (last accessed August 24, 2021).

The bulk of this section is inspired by Maine's recently enacted law expanding access to an emergency opioid antagonist in schools.⁵⁹ However, the idea that training and discussion surrounding emergency opioid antagonists and their use should be encouraged, if not required, in state schools and universities is taken directly from a presentation given by Allison Smith, Ph.D., Senior Program Administrator for the Louisiana Board of Regents.⁶⁰ Dr. Smith discussed how policymakers can teach prevention and encourage the use of emergency opioid antagonists by individuals on campus and in the surrounding community.⁶¹ Training programs like GenerationRx are entirely free and offer training and education programs on the "... potential dangers of misusing prescription medications."⁶² Online training programs like this are also beneficial considering the COVID-19 pandemic and potential social distancing requirements. There are also programs like the one at the University of Texas at Austin, where pharmacy students work to train undergraduates on campus to perform overdose rescues, or the National Institute of Health's Heal Initiative, where, in collaboration with Columbia University and other key community stakeholders, practitioners and those with lived experience work to increase overdose education and the distribution of emergency opioid antagonists.⁶³ These are programs in which state legislators, policymakers, educators, and university administrators should consider collaborating or bringing to their own states.

SECTION XII. EDUCATION AND PROMOTION OF INFORMATION.

- (a) Publicly available information.—Within six (6) months of the effective date of this Act, the [department of health or other appropriate departments] shall publish on its website, the following information at or below a sixth (6th) grade reading level:
 - The importance of emergency opioid antagonists in preventing deaths from opioid overdoses;
 - (2) How to recognize the signs and symptoms of a drug overdose;
 - (3) The essential steps in responding to a drug overdose, including:

(A) Evaluate for signs of an opioid overdose;

- (B) Call 911 for help;
- (C) Administer an emergency opioid antagonist;
- (D) Support the person's breathing; and
- (E) Monitor the person's response;

⁵⁹ L.D. 772, 130th Leg., 1st Spec. Sess. (Me. 2021).

⁶⁰ Smith & Spitznas, *supra* note 57.

⁶¹*Id.* Dr. Smith's presentation focused on college and university campuses and students; however, the drafters of this Act believe that the overall discussion and the concerns raised are directly applicable to younger persons. ⁶² *Mission*, GENERATIONRX, https://generationrx.org/about/mission/ (last accessed August 24, 2021).

⁶³*Id. See also State Snapshot*, NIH HEAL INITIATIVE, <u>https://healingcommunitiesstudy.org/sites/new_york.html</u>, (last accessed April 5, 2021).

- (4) Where to obtain emergency opioid antagonists throughout the state
- (5) De-stigmatizing the possession of an emergency opioid antagonist; and
- (6) State laws limiting a person's civil and criminal liability for prescribing, dispensing, distributing, or administering emergency opioid antagonists.
- (b) Education programs.—The [department of health or other appropriate departments] shall establish a statewide educational initiative in conjunction with community-based organizations that promote:
 - The importance of emergency opioid antagonists in preventing deaths from opioid overdoses;
 - (2) How to recognize the signs and symptoms of a drug overdose;
 - (3) The essential steps in responding to a drug overdose, including:
 - (A) Evaluate for signs of an opioid overdose;
 - (B) Call 911 for help;
 - (C) Administer an emergency opioid antagonist;
 - (D) Support the person's breathing; and
 - (E) Monitor the person's response;
 - (4) Where to obtain emergency opioid antagonists throughout the state;
 - (5) De-stigmatizing the possession of an emergency opioid antagonist;
 - (6) State laws limiting a person's civil and criminal liability for prescribing, dispensing, distributing, or administering emergency opioid antagonists; and
 - (7) Any additional measures that promote the safe distribution, use, and administration of emergency opioid antagonists by persons within the state.
- (c) Training.—The [department of health or other appropriate department] shall establish training programs that are tailored to the unique needs of each of the following groups:
 - Any person who may potentially administer an emergency opioid antagonist to a person exhibiting the signs of an overdose;
 - (2) Prescribers;
 - (3) Dispensers, including pharmacists;
 - (4) Laypeople and bystanders;
 - (5) Educational institutions and universities;

- (6) First responders;
- (7) Correctional setting staff; and
- (8) Community-based organizations.

Many of our subject matter experts discussed the importance of educating prescribers and dispensers on the availability of emergency opioid antagonists, their role in curbing the opioid overdose crisis, and the laws applicable to dispensing emergency opioid antagonists. This section aims to provide education and access to training so that prescribers, dispensers, distributors, and the general public have the information and knowledge needed to make informed decisions regarding emergency opioid antagonists. Policymakers should also consider including public service announcements and other tools tailored to share information with the community via local newspapers and radio and television stations as a part of the statewide education initiative. As noted earlier, studies show that when emergency opioid antagonists and overdose education are available to communities, overdose deaths decrease.⁶⁴ Thus, it is crucial that the citizens of this state have access to, and be provided with, information and training on the emergency opioid antagonist.

SECTION XIII. PILOT PROGRAM ESTABLISHING BYSTANDER ACCESS.

- (a) Advisory committee.—There is hereby created an emergency opioid antagonist bystander access advisory committee under the authority of the [department of health or other appropriate department], which shall oversee the creation and implementation of an emergency opioid antagonist bystander access pilot program.
- (b) Committee appointment.—Subject to the provisions of subsections (c) and (d), the [Secretary of the department of health or other appropriate department] shall appoint members of the committee within sixty (60) days of the effective date of this Act.
- (c) Membership generally.—The advisory committee of the emergency opioid antagonist bystander access pilot program shall include, but not be limited to, the following members:
 - The Secretary of [the department of health], or their designee, who shall serve as the chair of the committee;
 - (2) [Representative(s) of other appropriate regulatory body or bodies];

⁶⁴ U.S. DEP'T OF HEALTH & HUM. SERVICES, U.S. Surgeon General's Advisory, supra note 7. <u>Return to Table of Contents</u>

- (3) At least one representative from local health departments;
- (4) At least one person with experience working in the field of addiction;
- (5) At least one representative from community-based organizations; and
- (6) Any other entity or person as determined by the committee, including but not limited to:
 - (A) People engaged in research at academic institutions; or
 - (B) Advocates who work in the field of substance use treatment.
- (d) Membership considerations.—When selecting the members pursuant to subsection (c), the [Secretary of the department of health or other appropriate departments] shall choose individuals who serve and are representative of the racial, ethnic, and socioeconomic diversity of the citizens of the state and, to the extent possible, underserved communities within the state or areas of the state with limited access to treatment for substance use disorders.
- (e) Powers and duties.—The advisory committee shall:
 - Establish the emergency opioid antagonist access bystander pilot program, which shall involve establishing one or more publicly accessible emergency opioid antagonist locations within the state;
 - (2) Determine the potential location or locations of publicly accessible emergency opioid antagonists;
 - (3) Monitor the use of such publicly accessible emergency opioid antagonist locations;
 - (4) Create and distribute opioid overdose response toolkits that include an emergency opioid antagonist for distribution to participating private businesses to be kept onsite; and
 - (5) Research and apply for additional funding through the federal government or private entities, or both.
- (f) Term of membership.—The term of each member appointed to the committee shall be [number] years or the length of the emergency opioid antagonist bystander access pilot program as provided in subsection (a) of this section.
- (g) Vacancy.—Vacancies in the committee's membership shall be filled in the same manner provided by the original appointments.

- (h) Quorum.—The majority of the members of the committee shall constitute a quorum.
- (i) Compensation.—Members of the committee shall not receive compensation for their services as members of the committee; however, members may be reimbursed for actual expenses incurred in carrying out their duties as members of the advisory board pursuant to [statutory reference] or receive an honorarium.
- (j) Meetings.—The advisory committee shall convene at least [number] of times per year.
- (k) Report to legislature.—The advisory committee shall, within one year of the establishment of the first publicly accessible emergency opioid antagonist location, and at least annually thereafter, submit a report to the [appropriate Senate and House committees], and the Governor, that includes, but is not limited to, the following information:
 - Number and location of each site participating in the emergency opioid antagonist access bystander pilot program as of the date of the report;
 - (2) Number of emergency opioid antagonist doses provided to each location;
 - (3) Number of emergency opioid antagonist doses administered, if any, at each location;
 - (4) Number of expired emergency opioid antagonist doses required to be disposed of;
 - (5) The costs associated with the program in the twelve (12) months preceding the report;
 - (6) The committee's recommendation on whether the pilot program should be expanded, and if so, how the pilot program could best be expanded based on the experience and knowledge gained from the pilot program; and
 - (7) Any other information required by regulation.
- Duration.—The emergency opioid antagonist access bystander pilot program shall be active for three (3) years, commencing on the committee's first meeting established in this section.
- (m) Final report.—At the conclusion of the pilot program, the advisory committee shall submit a final report which shall include recommendations as to whether the program should be expanded and implemented statewide and the estimated cost of statewide implementation.

- (n) Permanent expansion of pilot program.—Based on the committee recommendations and findings provided in the final report on the emergency opioid antagonist access bystander pilot program, the Legislature shall determine whether the pilot program shall become permanent and implemented statewide across a broad spectrum of geographic locations within the state.
- (o) Website.—The committee, in conjunction with the [department of health or other appropriate departments], shall create and update a website to inform the public of the emergency opioid antagonist bystander access pilot program, the progress of the committee in establishing and implementing the pilot program, and any data collected from the pilot program.

This section provides a method by which the state can increase bystander access to emergency opioid antagonists and assess the effectiveness of the methods used by implementing a pilot program. Bystander (or layperson) use of an emergency opioid antagonist can potentially save lives. In Massachusetts, for example, one study found that layperson rescue with intranasal naloxone had a 98 percent success rate.⁶⁵ There is limited research on whether publicly accessible emergency opioid antagonists make it easier for bystanders (or laypeople) to save lives. Nevertheless, the available data is promising and provides a roadmap for states crafting their own pilot programs. In 2017, the Rhode Island Department of Health created an overdose prevention pilot program through funding provided by the CDC.⁶⁶ The pilot involved collaboration between a doctor and an expert in industrial design⁶⁷ to create "NaloxBoxes" distributed throughout several communities.⁶⁸ Each NaloxBox contains multiple doses of naloxone and is equipped with electronics to notify staff employed at that location if someone opens the box.⁶⁹ In the first five months of the program, multiple agencies installed 47 NaloxBoxes.⁷⁰ In 2018, a follow-up study found none of the installed units were vandalized, two units needed restocking, and one confirmed successful NaloxBox involved rescue.⁷¹ Since that time, the creators of the NaloxBox expanded the initiative and now offer NaloxBoxes outside of

⁶⁵ Geoffrey A. Capraro & Claudia B. Rebola, *The NaloxBox Program in Rhode Island: A Model for Community-Access Naloxone*, 108 AM. J. PUB. HEALTH, 1649 (Dec. 2018), citing Alexander Y. Walley et al., *Opioid Overdose Rates and Implementation of Overdose Education and Nasal Naloxone Distribution in Massachusetts: Interrupted Time Series Analysis*, BMJ 2013;346:f174.

⁶⁶ *Id.* at 1649.

⁶⁷ "Industrial design is the professional practice of designing products, devices, objects, and services used by millions of people around the world every day." *What is Industrial Design*, INDUS. DESIGNERS SOC'Y OF AM., <u>https://www.idsa.org/what-industrial-design</u>, (last accessed July 23, 2021).

⁶⁸Capraro & Rebola, *supra* note 65, at 1649.

⁶⁹ Id.

⁷⁰ *Id.* at 1650.

⁷¹ Id.

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Rhode Island, including in the Akron-Canton, Ohio airport, and Canada.⁷²

Other public and private organizations also created pilot programs to test the efficacy of publicly accessible emergency opioid antagonists. In Ohio, for example, the Alcohol, Drug Addiction, and Mental Health Services Board of Cuyahoga County and Metro Health, a private hospital, are collaborating to install over 100 NaloxBoxes throughout the community.⁷³ In addition to making emergency opioid antagonists readily available, pilot programs like this may also help de-stigmatize the use of emergency opioid antagonists to save lives. Metro Health's Director of Opioid Safety, Dr. Joan Papp, notes that she hopes that one day seeing an opioid response kit will be just as normal as seeing an automated external defibrillator.⁷⁴ According to Dr. Papp, "putting these boxes in public spaces is definitely going to make it more visual for people that this is a real problem and that is just as important and devastating as cardiac arrest."⁷⁵

SECTION XIV. FUNDING.

(a) In general.—The Legislature shall appropriate:

- (1) [\$ _____] to the [department of health or other appropriate departments] for funding services provided as part of increasing access and obtaining emergency opioid antagonists pursuant to this Act; and
- (2) [\$ _____] to the [department of health or other appropriate departments] as part of emergency opioid antagonist access within state and local educational institutions and state and local correctional settings as applicable.
- (b) Federal funds.—The [state department of health] shall pursue federal funding, matching funds, grants, and foundation funding for the initial start-up and ongoing activities required under this Act, both for funding for state agency activities and local-specific activities related to emergency opioid antagonist access.
- (c) Grant program.—There is established in the [department of health or other appropriate departments] an Emergency Opioid Antagonist Access Grant Program to incentivize emergency opioid antagonist access through statewide initiatives, community programs, and pilot programs developed pursuant to this Act. The Legislature shall appropriate the amount of [\$] to the [department of health or other appropriate departments] to

⁷² NALOXBOX, <u>https://naloxbox.org/</u> (last visited April 7, 2021).

⁷³ Abigail Bottar, *New Program Aims to Destigmatize Addiction by Making Naloxone More Available*, WKSU.ORG (July 7, 2021, 5:00 AM), <u>https://www.wksu.org/health-science/2021-07-07/new-program-aims-to-destigmatize-addiction-by-making-naloxone-more-available</u>.

⁷⁴ Id. ⁷⁵ Id.

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fund the Emergency Opioid Antagonist Access Grant Program.

- (d) Guidelines and requirements.—Funding shall be made available to support both new and existing emergency opioid antagonist access programs in a broad spectrum of geographic regions within the state, including urban, suburban, and rural communities.
- (e) Additional sources.—The [department of health or other appropriate department] may also 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 Emergency Opioid Antagonist Access Grant Program and expand the same or any income derived from it according to the term of the gifts, grants, or endowments.

Commentary

There are various avenues that states may pursue to fund increased access to emergency opioid antagonists within their communities. This includes partnering with private companies that make and distribute emergency opioid antagonists or seeking out and obtaining federal funding. For example, the Substance Abuse and Mental Health Services Administration (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.⁷⁶ Moreover, there is no explicit restriction on using these funds regarding the purchase of emergency opioid antagonists.⁷⁷

In addition, some states may be able to fund increased access to emergency opioid antagonists through opioid settlement funds. Opioid settlement funds are funds recovered by a state through litigation against the pharmaceutical industry, including pharmaceutical manufacturers or distributors.⁷⁸In Massachusetts, for example, the state created the Municipal Naloxone Bulk Purchase Fund after reaching a settlement with one of the manufacturers of naloxone.⁷⁹ This fund allows municipalities to purchase naloxone for use by first responders at a heavily discounted rate. ⁸⁰Legislators and policymakers should consider allocating opioid settlement funds to cover costs associated with expanding access to emergency opioid antagonists within the state.

⁷⁶ Expansion of Naloxone in the Prevention of Opioid Overdose FAQS, SUBSTANCE ABUSE AND MENTAL HEALTH SERV. ADMIN. 1, (last accessed August 5, 2021)1,

<u>https://www.samhsa.gov/sites/default/files/programs_campaigns/medication_assisted/expansion-of-naloxone-faq.pdf.</u>

⁷⁷ Id.

⁷⁸ Katie Zezima, Ohio Tries an Unusual Tactic Toward Opioid Settlement: Working Together, WASH. POST (Feb. 4, 2020), <u>https://www.washingtonpost.com/national/ohio-tries-an-unusual-tactic-toward-opioid-settlement-workingtogether/2020/02/24/d5923faa-4c48-11ea-9b5c-eac5b16dafaa_story.html.</u>

 ⁷⁹ Narcan Fund, MASS.GOV (last accessed August 23, 2021), <u>https://www.mass.gov/service-details/narcan-fund</u>.
 ⁸⁰ Id.

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SECTION XV. RULES AND REGULATIONS.

[Relevant state agencies and officials] shall promulgate such rules and regulations as are necessary to effectuate this Act within twelve (12) months of the date of enactment.

SECTION XVI. 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 XVII. EFFECTIVE DATE.

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

ABOUT THE LEGISLATIVE ANALYSIS AND PUBLIC POLICY ASSOCIATION

Based in Washington D.C., and led by and comprised of experienced attorneys, the Legislative Analysis and Public Policy Association 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.

LAPPA produces timely model laws and policies that can be used by national, state, and local public health, public safety, and substance use disorder practitioners who want the latest comprehensive information on law and policy as well as up-to-theminute comparative analyses, publications, educational brochures, and other tools ranging from podcasts to fact sheets. Examples of topics on which LAPPA has assisted stakeholders include naloxone laws, law enforcement/community engagement, alternatives to incarceration for those with substance use disorders, medication-assisted treatment in correctional settings, and the involuntary commitment and guardianship of individuals with alcohol or substance use disorders.

