



# Model Universal Access to Naloxone Act (Third Edition)

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# Model Universal Access to Naloxone Act (Third Edition)<sup>1</sup>

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## SECTION I. SHORT TITLE.

This Act is known and may be cited as the “Model Universal Access to Naloxone Act” (the “Act”).<sup>2</sup>

## SECTION II. LEGISLATIVE FINDINGS.

- (a) The United States and [name of state] is encountering the worst opioid overdose epidemic in its history.
- (b) Many opioid-related overdose deaths are preventable if naloxone, a U.S. Food and Drug Administration (FDA)-approved opioid overdose reversal medication, is readily available to, and carried by, all first responders and a greater number of other residents of [state].
- (c) In use for more than 40 years, naloxone is non-addictive and has no known potential for abuse.<sup>3</sup> Naloxone can be administered easily by nearly anyone, with minimal instruction.<sup>4</sup> Overdose education and naloxone distribution programs that train residents in identifying overdoses and responding with naloxone can effectively reduce opioid overdose death rates.<sup>5</sup> Moreover, the distribution of naloxone for administration by non-medical experts

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<sup>2</sup> As of 2018, many state laws providing increased access to naloxone refer to the drug in terms other than “naloxone” or “naloxone hydrochloride.” Such terms include “opioid antagonist”, “opiate antagonist”, “opioid antidote”, “opioid overdose drug”, “opioid overdose medication”, and “overdose intervention drug.” NAMSDDL uses “naloxone” in this Model Act because naloxone itself has been the exclusively used opioid overdose reversal drug for 40 years. Presumably, states using a term other than naloxone do so to avoid a need to amend their laws if a reversal drug other than naloxone becomes widely used. NAMSDDL, however, believes that the benefit of introducing a new, and potentially confusing, term is outweighed by simplicity and the wide public awareness of naloxone. Moreover, the term “opioid antagonist” appears to be overbroad, since it would also include naltrexone, which is not used to reverse opioid overdoses. The term “opiate antagonist” is, in addition to being overbroad for that reason, is also too narrow since many overdoses are due to synthetic opioids, not opiates. Finally, Section XIV of the Model Act provides that in the event that a new opioid overdose reversal drug is approved, the provisions of the Act are applicable to such drug for a period of two years.

<sup>3</sup> See <https://www.narcan.com/faqs>. See also NIDA. *Naloxone for Opioid Overdose: Life-Saving Science*. National Institute on Drug Abuse, March 30, 2017 (“There is no evidence of significant adverse reactions to naloxone.”), <https://www.drugabuse.gov/naloxone-opioid-overdose-life-saving-science>.

<sup>4</sup> Doe-Simkins *et al.* BMC Public Health 2014, 14:297 <http://www.biomedcentral.com/1471-2458/14/297>; Behar, Emily, *et al.*, *Brief Overdose Education Is Sufficient for Naloxone Distribution to Opioid Users*, Drug and Alcohol Dependence, vol. 148, 2015, pp. 209–212., doi:10.1016/j.drugalcdep.2014.12.009.

<sup>5</sup> Wally, Alexander, *et al.*, *Opioid Overdose Rates and Implementation of Overdose Education and Nasal Naloxone Distribution in Massachusetts: interrupted Time Series Analysis*, BMJ 346:f174 doi:10.1136/bmj.f174 (January 31, 2013); Keane, Christopher, *et al.*, *Effects of naloxone distribution to likely bystanders: Results of an agent-based model*, International Journal of Drug Policy, vol. 55, 2018, pp. 61-69, <https://doi.org/10.1016/j.drugpo.2018.02.008>. In

can be highly cost-effective.<sup>6</sup>

- (d) All 50 states and the District of Columbia have enacted laws designed to improve access to naloxone.<sup>7</sup> Studies show that implementation of these laws reduce overdose deaths.<sup>8</sup> In 2018, the U.S. Surgeon General urged individuals who are personally at risk for an opioid overdose, the family and friends of such individuals, and any individuals who may encounter those experiencing opioid overdose, to keep doses of naloxone on hand at all times.<sup>9</sup>
- (e) Despite these efforts, too few community members are aware of the important role that naloxone plays in saving the lives of people suffering an opioid overdose. In addition, the cost of naloxone is a barrier to some individuals accessing the medication in an easily usable form.<sup>10</sup>

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addition, preliminary data arising out of a naloxone distribution collaborative formed in Hamilton County (Ohio) in late 2017 is positive. Over the first few months of 2018, the data shows a decrease in overall deaths, emergency medical service calls for overdoses, and emergency room visits for overdoses as compared to a similar timeframe in 2017. These decreases are coupled with an increase in patients seeking treatment for opioid addiction. Terry DeMio, *Huge Narcan influx, treatment boost contributes to OD death drop in Hamilton County*, The Cincinnati Inquirer (June 14, 2018), <https://www.cincinnati.com/story/news/2018/06/14/naloxone-treatment-push-contributes-plummeting-od-deaths/697336002/>.

<sup>6</sup> Coffin, Phillip, et al. *Cost-effectiveness of Distributing Naloxone to Heroin Users for Lay Overdose Reversal*. *Annals of Internal Medicine*, 158:1-9 (2013); Uyei, Jennifer, et al., *Effects of naloxone distribution alone or in combination with addiction treatment with or without pre-exposure prophylaxis for HIV prevention in people who inject drugs: a cost-effectiveness modelling study*, *The Lancet Public Health*, Volume 2, Issue 3, 2017, Pages e133-e140, <https://www.sciencedirect.com/science/article/pii/S2468266717300063#bib9>.

<sup>7</sup> The Network for Public Health Law. *Legal Interventions to Reduce Overdose Mortality: Naloxone Access and Overdose Good Samaritan Laws*, (July 2017), [https://www.networkforphl.org/\\_asset/qz5pvn/legal-interventions-to-reduce-overdose.pdf](https://www.networkforphl.org/_asset/qz5pvn/legal-interventions-to-reduce-overdose.pdf).

<sup>8</sup> McClellan, Chandler, Lambdin, Barrot H., et al., *Opioid-overdose laws association with opioid use and overdose mortality*, *Addictive Behaviors* (March 19, 2018).

<sup>9</sup> See U.S. Surgeon General's Advisory on Naloxone and Opioid Overdose (April 2018), available at <https://www.surgeongeneral.gov/priorities/opioid-overdose-prevention/naloxone-advisory.html> (last accessed May 15, 2019); U.S. Surgeon General's Digital Postcard (September 2018), available at <https://addiction.surgeongeneral.gov/sites/default/files/SG-Postcard.jpg> (last accessed May 15, 2019).

<sup>10</sup> In April 2018, several U.S. Senators called upon the Secretary of the U.S. Department of Health and Human Services to negotiate "a lower price for easy to administer naloxone combination products," noting that "Narcan, which delivers naloxone as a nasal spray, costs \$150 for a two pack and Evzio, a hand-held auto-injector, increased in price from \$690 in 2014 to more than \$4,000 today for a two pack." Letter to the Honorable Alex Azar from sixteen U.S. Senators (April 18, 2018), <https://www.peters.senate.gov/download/41818-letter-on-secretary-azar-on-naloxone-prices>.

### SECTION III. PURPOSE

The purpose of the Act is to help save the lives of individuals who have experienced opioid-related overdoses so that they can live and seek recovery. The Act requires the issuance of a standing order that authorizes the distribution to and administration of naloxone by everyone in [state], any of whom could find themselves in a position to assist an individual experiencing an opioid-related overdose.<sup>11</sup> In so doing, the Act creates the broadest possible access to the life-saving medication.<sup>12</sup> In addition, the Act ensures comprehensive financial support for the activities authorized by this Act under Medicaid, commercial insurance, and state funding mechanisms.

### SECTION IV. DEFINITIONS.

- (a) For the purposes of this Act, unless the context clearly indicates otherwise, the following words and phrases shall have the meanings given them in this Section.
- (b) Co-prescribe.— “Co-prescribe” means, with respect to naloxone, the practice of prescribing the drug in conjunction with an opioid prescription.
- (c) Community-focused organization.— “Community-focused organization” means any organization or health agency that seeks to distribute naloxone to community members.
- (d) Dispenser.— “Dispenser” means any entity that is licensed, certified, or otherwise authorized by [state] to dispense prescription drugs, including naloxone. Dispensers include pharmacists, pharmacies, and dispensing practitioners licensed, certified, or otherwise authorized by [state]. Dispensers, for purposes of this Act, do not include individuals, recovery community, or other community-focused organizations granted authority to store and distribute naloxone solely by authority of this Act.

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<sup>11</sup> It is important to note here that naloxone alone may not be sufficient to address all overdoses since multiple drugs, including non-opioid substances (*e.g.*, methamphetamine or cocaine) may be involved. Other lifesaving actions will be necessary at times. This is yet another reason why, as stated throughout the Act, it is *always* essential that emergency medical services be called.

<sup>12</sup> In addition to this Act, NAMSDL has promulgated the Model Act Providing for the Warm Hand-off of Overdose Survivors to Treatment. This Act provides for a collaborative and robust intervention mechanism to intervene with, assess, and refer overdose survivors to appropriate addiction treatment services. Likewise, NAMSDL has developed Good Samaritan legislation to encourage all individuals who witness an overdose to summon emergency assistance.

- (e) First responder.— “First responder” means a law enforcement officer, firefighter, emergency medical services provider, or other individual who, in an official capacity, responds rapidly to an emergency or critical incident. This includes such individual working in an official capacity on a volunteer basis.
- (f) Naloxone.— “Naloxone” means naloxone hydrochloride, which binds to an individual’s opioid receptors and blocks the effects of the opioid acting on those receptors, and is approved by the federal Food and Drug Administration (FDA) for the emergency treatment of a known or suspected opioid overdose.
- (g) Opioid.— “Opioid” means a class of drugs that: (1) are opiates or synthetic narcotics that resemble opiates; and (2) interact with opioid receptors on nerve cells in the body and brain.<sup>13</sup>
- (h) Opioid-related overdose.— “Opioid-related 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.
- (i) Prescriber.— “Prescriber” means an individual licensed, certified, or otherwise authorized by [state] to prescribe prescription drugs, including naloxone.
- (j) Public place.<sup>14</sup>— “Public place” means a physical location within [state]: (1) in which the public is invited or in which the public is permitted; and (2) whose owners or operators operate it as one or more of the following: bank, bar, restaurant, educational building, dorm, library, doctor’s office, dentist’s office, health care facility, laundromat, homeless shelter, fitness center, gym, grocery store, indoor arena, outdoor spectator venue, shopping mall, retail store, government office building, hotel, and theater.

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<sup>13</sup> Compare National Institute on Drug Abuse, Opioids: Summary of the Issue, available at <https://www.drugabuse.gov/drugs-abuse/opioids> (last accessed June 12, 2019).

<sup>14</sup> Compare the definition of “public place” found in Rhode Island House Bill 5551, 2019 session (“Naloxone Public Access Program”), in which “public place” is defined as “an enclosed area capable of holding one hundred (100) people or more and to which the public is invited or in which the public is permitted.” Using an enumerated list for the definition has the advantage of making the requirement in subsection X(b) apply by category of facility. Upon implementation at the state level, states may choose different terminology for the categories, based on common regional verbiage and desired scope of the requirement.

(k) Standing order.— “Standing order” means a prewritten, non-individual specific order issued by a prescriber that authorizes the dispensing, distribution or administration of a drug by any individuals.

## **SECTION V. STATEWIDE STANDING ORDERS.**

(a) In general.— The [insert appropriate state medical professional with prescribing authority, e.g., surgeon general, physician general] shall issue one or more standing orders for the dispensing, distribution, and administration of naloxone covering any individual seeking naloxone within [state].

(b) Purpose and authorization.— Standing orders issued under this section are for a legitimate medical purpose in the usual course of professional practice and shall authorize individuals, recovery community and other community-focused organizations to obtain, store, and distribute naloxone, as provided for by this Act.

(c) Order specification.— The standing order under subsection (a) shall specify, at a minimum:

- (1) The naloxone formulations that are FDA-approved for community use<sup>15</sup>;
- (2) Any recommended instruction for the individuals to whom the naloxone is dispensed or distributed; and
- (3) Information about:
  - (A) signs and symptoms of an opioid-related overdose;
  - (B) proper administration of naloxone;
  - (C) proper care of an individual to whom naloxone has been administered;

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<sup>15</sup> The phrase “FDA-approved for community use” refers to the terminology used by the FDA in recent presentations and press releases referring to the general public’s use of naloxone formulated as a nasal spray or auto-injector. As an example, page 17 of the FDA’s October 2016 presentation entitled “Clinical and Regulatory Perspectives on Naloxone Products Intended for Use in the Community,” (available at <https://www.fda.gov/media/100648/download>) describes nasal spray and auto-injector formulations as “naloxone products approved for community use.” This is in contrast to naloxone iterations administered in “off label” fashion, primarily via injectable syringe and atomizer. Our intent in using the “approved for community use” language in this Act is to require that standing orders specify, and insurers provide coverage for, naloxone formulations that require no special training for the public to use. Our use of this phrase does not suggest that a particular brand name naloxone formulation must be used, and in fact includes generic forms of nasal sprays and auto-injections as they become available.

(D) procedures for summoning emergency medical assistance.<sup>16</sup>

- (d) The [Pharmacy Board or other agency regulating pharmacies in the state] shall ensure that all pharmacies are notified of the legal requirements of this Act, and shall establish fines and fees for failure to recognize and fill a prescription for naloxone, either under an individual prescription or under the standing order set forth in this section, as provided for in Section X(a) of this Act (“Naloxone Supply and Location”).
- (e) Effective period.— Any standing order issued pursuant to subsection (a) shall remain in effect for two (2) years from the date of issuance.
- (f) Renewal.— Prior to the end of the two-year period of any standing order, the [appropriate state medical professional with prescribing authority] shall renew the order for two (2) additional years, unless there is no longer any significant public health benefit for renewal.

## **SECTION VI. CO-PRESCRIBING OF NALOXONE.**

- (a) Co-prescribing naloxone in conjunction with opioid prescription.—
- (1) In general.— Prescribers within [state] shall co-prescribe naloxone when prescribing a schedule II, III, or IV opioid to a patient if any of the risk factors in subsection (b) are present.
- (2) Risk factors.— Pursuant to subsection (a), naloxone must be co-prescribed to a patient if any of the following are present:
- (A) a history of substance use disorder;
  - (B) high dose or cumulative prescriptions that result in over 50 morphine milligram equivalents (MME) per day;
  - (C) concurrent use of opioids and benzodiazepine or non-benzodiazepine sedative hypnotics; or
  - (D) other factors, such as drug using friends/family, which is consistent with the recommendations in the Centers for Disease Control and Prevention Guideline for

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<sup>16</sup> For example, Substance Abuse and Mental Health Services Administration, *Opioid Overdose Prevention Toolkit: Five Essential Steps for First Responders*, *supra* note 11.

Prescribing Opioids for Chronic Pain (CDC Guideline).<sup>17</sup>

(b) Education.—

- (1) Medical, dental, nursing [and physician’s assistant] schools.— Each medical, dental, nursing [and physician’s assistant] school operating in [state] must require that all students who are training for health care positions with prescribing authority are trained on the co-prescribing of naloxone to patients with the risk factors identified in subsection (a).
- (2) Continuing medical education.— All prescribers in [state] must receive at least one (1) hour of training on the co-prescribing of naloxone to patients with the risk factors identified in subsection (a).

**SECTION VII. DIRECT PRESCRIBING AND DISPENSING OF NALOXONE.**

- (a) In general.— Notwithstanding the presence or lack of a statewide standing order as described in Section VI, prescribers may prescribe, and dispensers may dispense, naloxone formulations that are FDA-approved for community use directly to any individual, and recovery community or other community-focused organization. A prescription issued under this Section is for a legitimate medical purpose in the usual course of professional practice.
- (b) Provision of information.— A prescriber who directly prescribes or dispenses naloxone pursuant to subsection (a) shall provide that recipient with information regarding:
  - (1) signs and symptoms of an opioid-related overdose;
  - (2) proper administration of naloxone;
  - (3) proper care of an individual to whom naloxone has been administered; and

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<sup>17</sup> CDC Guideline 8 provides that “[c]linicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages ( $\geq 50$  MME/day), or concurrent benzodiazepine use, are present.” Dowell D, Haegerich TM, Chou R. 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>. This Act takes the next step by requiring co-prescription of naloxone in those circumstances, as opposed to only recommending consideration of it.

- (4) procedures for summoning emergency medical assistance.

## **SECTION VIII. DISTRIBUTION OF NALOXONE BY FIRST RESPONDERS AND CORRECTIONAL FACILITIES.**

- (a) In general.— State and municipal first responders may distribute naloxone in an FDA-approved indication currently available as a nasal spray, an auto-injector, or both, to an individual or to the individual’s family member, friend, or other person, along with instructions on the administration and use of the naloxone, to provide opioid overdose protection to the individual, if, in the good faith judgment of the first responder, the individual is at risk of experiencing an opioid overdose.
- (b) Good faith judgment.— In distributing naloxone pursuant to subsection (a), first responders shall exercise their good faith judgment based on their experience, training, knowledge, observations, and information provided by the individual or by the individual's family, friend, or others with knowledge of the individual's opioid use.
- (c) Availability of naloxone in correctional facilities.— All state and county correctional officers shall have naloxone readily available at all times while on duty, and shall be trained in the following:
  - (1) signs and symptoms of an opioid-related overdose;
  - (2) proper administration of naloxone;
  - (3) proper care of an individual to whom naloxone has been administered; and
  - (4) procedures for summoning emergency medical assistance.
- (d) Release of inmates with substance use disorder.— Prior to the release of any state correctional or county jail inmate with a history of substance use disorder, the inmate and his or her immediate family member must be offered naloxone and instruction on the administration and use of the naloxone. The inmate’s or the family’s decision to accept such naloxone and instruction, and the providing of such naloxone and instruction, may not delay, in any way, the date and time the inmate otherwise would be released.

- (e) Bulk purchasing programs.—Naloxone manufacturers and distributors doing business in [state] must establish a discounted bulk purchasing rate for FDA-approved naloxone currently available as a nasal spray, an auto-injector, or both, with the [state department of health, single state authority for drugs and alcohol, or other appropriate entity] in order to facilitate the distribution of naloxone by first responders, state correctional facilities and others.

## **SECTION IX. POSSESSION, DISTRIBUTION AND ADMINISTRATION OF NALOXONE BY INDIVIDUALS AND RECOVERY COMMUNITY OR OTHER COMMUNITY-FOCUSED ORGANIZATIONS.**

- (a) Possession of naloxone.— Notwithstanding any other law or regulation to the contrary, individuals and recovery community or other community-focused organizations receiving naloxone may possess and store the drug.
- (b) Distribution of naloxone.— Under any standing order or prescription issued pursuant to this Act, recovery communities or other community-focused organizations that possess naloxone may distribute the drug to other individuals. When doing so, recovery communities or other community-focused organizations may not require recipients to provide personal identifying information about those who receive the naloxone.
- (c) State storage laws.—The storage of naloxone pursuant to this section is not subject to [state] pharmacy practice laws or other [state] requirements that apply to the storage of drugs or medications.
- (d) Administration of naloxone.— An individual to whom naloxone is dispensed or distributed pursuant to this Act may administer the drug to anyone that the recipient reasonably believes to be experiencing an opioid-related overdose. The individual administering naloxone shall be immune from civil and criminal liability, and is not subject to adverse professional action, for the good faith administration of the drug.
- (e) Medical assistance.— Individuals who summon emergency medical assistance contemporaneously with administering naloxone pursuant to subsection (d) shall, in addition to the protections afforded under that subsection, receive the protections

afforded by [insert citation to appropriate state Good Samaritan provisions pertaining to overdoses].

## **SECTION X. NALOXONE SUPPLY AND LOCATION.**

### **(a) Pharmacies.—**

- (1) In general.— All pharmacies licensed, certified, or otherwise authorized to do business in [state] shall dispense naloxone to an individual, recovery community, or community-focused organization pursuant to either a traditional or non-individual specific prescription within one (1) business day of the request.<sup>18</sup>
- (2) Prominent posting of standing order.— All pharmacies shall prominently post for public view notice that naloxone is available to all members of the public based on the standing order issued pursuant to Section V. Such postings shall be in English and in any other language commonly spoken by pharmacy customers. Such notices shall be approved by the [Pharmacy Board or other state agency regulating pharmacies]. The [Pharmacy Board or other state agency regulating pharmacies] shall establish a per-day fine for failure to post such notice in compliance with this Act.
- (3) Use on others.— When dispensing naloxone pursuant to paragraph (a)(1), no pharmacy licensed, certified, or otherwise authorized to do business in [state] may collect or require to be disclosed any information about the person or persons for whom the customer may be seeking to obtain naloxone.
- (4) Rules and regulations.— The [state department/agency that oversees pharmacies] shall implement appropriate rules and regulations to enforce this requirement.  
Notwithstanding [statutory section that describes the requirements for the administrative rule writing process], the [state department/agency that oversees pharmacies] is not required to provide evidence that promulgating a rule under this subsection as an emergency rule is necessary for the preservation of the public peace, health, safety, or welfare and is not required to provide a finding of emergency for a rule promulgated

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<sup>18</sup> An example of proposed state legislation requiring pharmacies to stock naloxone and penalizing them for failing to comply is New Jersey Senate Bill 3515, introduced in March 2019. The bill provides that a first offense is a warning (from the state board of pharmacy) followed by a civil penalty of \$250 for a second or subsequent offense (with each day constituting a separate offense).

under this subsection.

- (b) Public places<sup>19</sup>— Any person or entity who owns or operates a public place, as defined in this Act, is encouraged to provide and maintain:
- (1) On-site, functional naloxone boxes containing a supply of naloxone in quantities and types, deemed by [the state director of health] to be adequate, to ensure ready and appropriate public use during emergencies at or in the vicinity of the public place;<sup>20</sup> and
  - (2) At least one person in each public place who is trained in the administration of naloxone, or where the public place is not usually staffed, prominently posted instructions in the operation and use of naloxone. Such instructions shall be in the language or languages known by the operators of the public place to be in common use at that location.
- (c) Substance use disorder treatment programs and recovery homes.—
- (1) In general.— Any person or entity who owns or operates a substance use disorder treatment program or recovery home shall provide and maintain:
    - (A) On-site, functional naloxone in quantity and type, deemed by the [state substance use disorder treatment program licensing agency] or [the agency or entity that certifies recovery homes] to be adequate, to ensure ready and appropriate public use during emergencies at or in the vicinity of the treatment program or recovery home; and
    - (B) At least one person who is trained in the operation and use of naloxone.
  - (2) Discharge of patients.— Any person or entity who owns or operates a substance use disorder treatment program shall offer naloxone, and instructions for its use, to a patient in recovery from opioid use disorder at the time of the patient’s discharge from the program.

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<sup>19</sup> Subsection (b) and the framework of subsection (c) are conceptually derived from Rhode Island House Bill 5551, 2019 session (“Naloxone Public Access Program”). At this time, the Act does not *require* “public places” to carry naloxone for public use. However, states could consider a mandatory supply provision for some more high-risk categories listed under the “public place” definition.

<sup>20</sup> There are anecdotal reports of facilities refusing to allow their naloxone to be used by individuals outside the facility who are overdosing. Given that such individuals are at grave risk of death, this Act strongly encourages the use of naloxone whenever and wherever it is needed and discourages the morally reprehensible refusal to use one’s available naloxone while a fellow human in the vicinity may be dying of an overdose.

- (d) Registration.— Upon providing and maintaining naloxone supplies as required by subsections (b) and (c), the person or entity who owns or operates the public place, substance use disorder treatment program or recovery home shall register the location or locations of naloxone in, and actively participate with, the computer or phone application designated pursuant to Section XII(b)(5) (“Public Education Programs.”) including providing the hours the public place is open, the address and site coordinates of the public place, and where available, a contact person at the public place.
- (e) Naloxone supply.— The [state department of health, single state authority for drugs and alcohol or other appropriate agency] is directed to provide, or prioritize funding for, the naloxone supplies utilized pursuant to subsections (b) and (c) of this section.

## **SECTION XI. IMMUNITY.**

- (a) Prescriber.— Any prescriber issuing a prescription for naloxone pursuant to this Act is immune from civil and criminal liability, and is not subject to adverse professional action, for: (1) the prescribing of naloxone; or (2) for any ultimate outcomes of such prescribing.
- (b) Dispenser.— Any dispenser dispensing naloxone pursuant to this Act is immune from civil and criminal liability, and is not subject to adverse professional action, for: (1) the dispensing of naloxone; or (2) for any ultimate outcomes of such dispensing.
- (c) Distributors and dispensers.— Any individual or entity that possesses or makes available naloxone, recovery community or other community-focused organization, or first responder who distributes or administers naloxone pursuant to this Act is immune from civil and criminal liability, and is not subject to adverse professional action, for: (1) the distributing of naloxone; (2) the administration of naloxone; or (3) for any ultimate outcomes of such distribution or administration.

## **SECTION XII. PUBLIC EDUCATION PROGRAMS.**

- (a) In general.—In conjunction with the issuance of a statewide standing order under this Act, the [state health department, single state authority on drugs and alcohol, and/or other appropriate party] shall develop public education programs as described in this

section.

- (b) Elements of program.— The educational program or programs developed pursuant to subsection (a), using culturally and linguistically appropriate materials, shall:
- (1) establish prescriber and dispenser training in the necessity of educating patients about the risks of opioids, the even greater risk involved with combining opioids and benzodiazepines, and the role of naloxone as an antidote to opioid overdose;
  - (2) promote the safe and effective distribution, use, and administration of naloxone by all [state] residents, particularly by families with someone with substance use disorder or on a long-term use of prescription opioids;
  - (3) post information on naloxone access inside pharmacies located in [state];
  - (4) maintain, on a state government webpage, an online directory of locations where naloxone is distributed, with such directory including physical address, contact information, services offered, special populations served, insurance providers accepted, hours of operation, any other information deemed necessary by the [state health department, single state authority on drugs and alcohol, and/or other appropriate party];
  - (5) maintain on a state government webpage, and educate the public about, one widely used computer or phone application for use in the state that enables persons carrying naloxone to register their location, and allows persons in immediate need of naloxone to use that computer or phone application to locate and directly communicate with a nearby naloxone carriers, and to locate public places where naloxone is available pursuant to Section X(d);
  - (6) identify resources for and develop a public education program that trains all [state] residents about the use, misuse and risks of opioid drugs, the need to carry naloxone, how to identify an overdose, the process for administering naloxone, and the necessity of immediately calling 911 upon encountering an overdose. Such program also will include instruction for students in grades seven and above concerning the above;
  - (7) identify resources for and develop an educational program that trains all [state] law enforcement, probation, parole, and correctional officers on the importance of encouraging individuals to call 911 upon encountering an overdose, including utilizing discretion in arresting and charging such individuals for minor crimes and offenses so as

- to not deter 911 calls;
- (8) identify resources for and develop an educational program addressing the recommended procedures to limit first responders' potential exposure to the drug(s) involved in an underlying overdose;<sup>21</sup>
  - (9) establish or promote the development of recovery community or other community-focused organization naloxone access and distribution programs. At a minimum, such access programs shall offer participants an approved training and education program as part of the program of naloxone distribution; and
  - (10) include direct outreach to populations at higher risk of overdose.

### **SECTION XIII. NALOXONE ACCESS GRANT PROGRAM.**

- (a) In general.— There is established in the [state Department of Health/single state drug and alcohol authority] a Naloxone Access Grant Program for the purpose of incentivizing the development of successful naloxone access initiatives developed pursuant to this Act. An amount of [\$] for fiscal years [20\_\_ - 20\_\_] shall be appropriated to the [Department of Health/single state drug and alcohol authority] to fund the Grant Program.
- (b) Receipt of funds.—The [Department of Health/single state drug and alcohol authority] 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 Naloxone Access Grant Program and expand the same or any income derived from it according to the term of the gifts, grants, or endowments. In addition, the [Department of Health] shall aggressively pursue all federal funding, matching funds, and foundation funding for the Naloxone Access Grant Program.<sup>22</sup>
- (c) Prioritized funding.—The [Department of Health/single state drug and alcohol authority]

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<sup>21</sup> Recommended procedures should address both first responders and service animals working for first responders who may also come into contact with the drug(s) causing the overdose.

<sup>22</sup> For example, in 2015, the Pennsylvania Department of Drug & Alcohol Programs raised over \$500,000 from several of the major state health insurers in the state to help provide naloxone for local police departments.

shall prioritize funding from the Naloxone Access Grant Program for naloxone provided and maintained pursuant to Sections X(b) and X(c) of this Act.

#### **SECTION XIV. NEW OPIOID OVERDOSE REVERSAL DRUG.**

In the event that the Food and Drug Administration (FDA) approves a new opioid overdose reversal drug, the provisions of this Act shall be applicable to such drug.<sup>23</sup>

#### **SECTION XV. CONSENTS.**

- (a) In general.—The attending physician in an emergency department, or the physician’s designee, shall make reasonable efforts to obtain a signed patient consent to disclose information about the patient’s opioid-related overdose to family members or other medical professionals involved in the patient’s health care.
- (b) Consent impractical.— If consent cannot practicably be provided because of the patient’s incapacity or a serious and imminent threat to a patient’s health or safety, the physician, or physician’s designee, may disclose information about a patient’s opioid-related overdose, so long as such disclosure is compliant with applicable privacy and confidentiality laws and regulations.<sup>24</sup> Such laws include:
- (1) the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191 (Aug. 21, 1996);
  - (2) 45 C.F.R. parts 160 and 164 (HIPAA Privacy and Security Rules);
  - (3) federal confidentiality law and regulations, 42 U.S.C. § 290dd-2, 42 C.F.R. Part 2;
  - (4) any relevant state law related to the privacy, confidentiality, and disclosure of protected health information; and

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<sup>23</sup> Presently, the U.S. Department of Health and Human Services (HHS) is working with a pharmaceutical company “to develop a fast-acting, long-lasting intranasal, potentially improved form of an opioid overdose drug,” called nalmeffene. *HHS Sponsors Development of Intranasal Form of Long-acting Opioid Overdose Drug* (Sept. 20, 2018), available at <https://www.hhs.gov/about/news/2018/09/20/hhs-sponsors-development-intranasal-form-long-acting-opioid-overdose-drug.html> (last accessed May 15, 2019). News reports suggest the possibility that a new drug application to the FDA could be made as early as 2020.

<sup>24</sup> See <https://www.hhs.gov/sites/default/files/hipaa-opioid-crisis.pdf>, describing how Health Insurance Portability and Accountability Act of 1996 regulations allow health professionals to share health information to certain individuals in emergency or dangerous situations.

- (5) any policies or regulations of the single state authority on drugs and alcohol governing the care of protection of client information.

## **SECTION XVI. INSURANCE COVERAGE FOR NALOXONE.**

- (a) Medicaid.—All state Medicaid programs shall provide coverage for naloxone in a FDA-approved community use indication currently available as a nasal spray, an auto-injector, or both.
- (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 [date ], shall provide coverage for naloxone in a FDA-approved community use indication currently available as a nasal spray, an auto-injector, or both.
- (c) Coverage included.—The coverage provided under subsections (a) and (b) shall include the naloxone product itself and any reasonable pharmacy administration fees related to the dispensing of naloxone and provision of overdose prevention consultation. This coverage also must include refills for expired or utilized drugs.
- (d) No prior authorization or co-payment.— The coverage provided under this section shall not be subject to prior authorization, shall not be subject to the insurance plan’s deductible or co-payment requirements, and shall cover the insured’s full cost of the naloxone.<sup>25</sup>
- (e) Use on others covered.— The coverage mandated by this section shall include naloxone intended for use on individuals other than the insured provided, however, that the insurer may not collect or require to be disclosed any identifying information about such other person or persons.

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<sup>25</sup> Subsection (d) should not be read to discourage insurers from negotiating with naloxone manufacturers for lower prices. Rather, the intent of (d) is for insureds to pay no out-of-pocket cost for obtaining naloxone.

(f) Prohibited actions.<sup>26</sup>—

- (1) In general.— No insurer, including but not limited to those providing life insurance, health insurance, disability or unemployment insurance, and no health care center, hospital service corporation, medical service corporation, fraternal benefit society or other entity that delivers, issues for delivery, renews, amends or continues an individual or group insurance policy in this state, shall take any adverse action against an individual based on an individual’s prior or current obtaining of, prescription for, or claim for, naloxone.
- (2) Actions prohibited.— The prohibition contained in paragraph (1) covers the following:
  - (A) denying or canceling insurance coverage to the individual;
  - (B) limiting the amount, extent or kind of coverage available to the individual;
  - (C) charging the individual, or a group to which the individual belongs, a rate that is different from the rate charged to other individuals or groups, respectively, for the same coverage, without any additional actuarial justification unrelated to the need to carry naloxone;
  - (D) refusing to supply naloxone; or
  - (E) collecting or requiring to be disclosed any information about the person or persons for whom the customer may be seeking to obtain naloxone.
- (3) Unfair discrimination.— Actions prohibited under this section constitute unfair discrimination pursuant to [state insurance law prohibiting unlawful discrimination] subject to penalties provided by [state insurance law providing penalty for unlawful

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<sup>26</sup> Within the past year, there have been anecdotal reports of individuals being unable to purchase life insurance because of their prior purchase of naloxone for family members. See Martha Bebinger, *Why You May Be Denied Life Insurance For Carrying Naloxone* (Dec. 5, 2018), available at <https://www.wbur.org/commonhealth/2018/12/05/narcain-insurance-prescription> (last accessed June 11, 2019). In reaction to this emerging practice, legislators in several states introduced bills similar to subsection (f) during the 2019 legislative session. To date, laws have been enacted in Maine (2019 Public Laws, Chapter 203; "An Act To Prohibit Consideration of Naloxone Purchases in Life Insurance Underwriting") and Texas (Senate Bill 437; "An act relating to prohibited practices by a life insurance company relating to an individual's prescription for or obtainment of an opioid antagonist"). In Massachusetts earlier this year, the state commissioner of insurance issued an advisory to "Insurers Offering Individual Accident and Sickness Policies, Life Insurance Policies and Annuity Contracts in Massachusetts" that stated "[i]t would defeat the Commonwealth's important public health efforts if applications for individual accident and sickness insurance policies, life insurance policies and annuity contracts were unfavorably impacted solely because the applicant had obtained naloxone or some other opioid antagonist to address opioid overdoses of other persons or had a prescription written to prevent illness or disease." Through subsection (f) of this Act, we believe that expanding these protections to health, disability and unemployment insurance is warranted and in the interest of promoting public health.

discrimination].

## SECTION XVII. DATA COLLECTION AND EVALUATION.

- (a) In general.—Notwithstanding any other law or regulation to the contrary, it is hereby directed that the [state prescription drug monitoring program] is authorized and required to collect certain information about the dispensing of naloxone as provided for in this section.
- (b) Collection of naloxone dispensing data.—<sup>27 28</sup>
- (1) In general.—Effective [date], all dispensers within [state] must submit naloxone dispensing information to the [state prescription drug monitoring program] as described further in this section.
- (2) Rules and regulations.—The [state agency that regulates prescription drug monitoring programs] is directed to promulgate rules and regulations [by date] that will govern the methods and procedures for dispensers to submit this information.
- (3) Limitation of purpose.—The information collected regarding dispensing of naloxone shall be for statistical, research, or educational purposes only. The rules and regulations developed pursuant to subdivision (b)(2) shall require the removal of patient, recipient, or prescriber information that could be used to identify individual patients or recipients of naloxone.
- (c) Good Samaritan protections.—The collection and submission of information by dispensers does not in any way diminish the protections afforded by this Act and [state Good Samaritan law(s)] to individuals suffering overdoses and individuals who call 911 or assist in the

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<sup>27</sup> State health departments and agencies implementing statewide standing orders want naloxone dispensing information in order to determine the effectiveness of the standing order as well as to identify locations that lack pharmacies dispensing naloxone. For these purposes, the data does not need to be, and should not be, patient identifiable and should be aggregated by the geographic unit at the county level or below.

<sup>28</sup> The second edition of this Act (published September 2018) contained a provision relating to the collection of naloxone administration data in the state prescription monitoring program. In preparing the third edition of this Act, we decided that a statutory provision addressing the collection of naloxone administration data would best be included as part of statutory language covering the collection of overdose information generally. Future NAMSDDL model law projects, including an update to our Model Prescription Monitoring Program Act, will address this issue, balancing the needs for critical information to ensure safer prescribing with the need to avoid possible stigmatization of those suffering with substance use disorders.

administration of naloxone.

- (d) Annual report.—The [insert appropriate state health department/agency] shall evaluate de-identified data collected pursuant to this section in conjunction with other applicable, available data, and annually report to [insert appropriate state policy bodies, e.g., governor’s office, state legislature] all findings and recommendations relevant to the development and implementation of state policy regarding opioid-related overdoses, naloxone access and distribution, opioid prescribing, prescription drug misuse, substance use disorders, diversion, substance use disorder treatment and other evidence-based public health interventions.

### **SECTION XVIII. RULES AND REGULATIONS.**

State agencies and officials shall promulgate rules and regulations necessary to implement their responsibilities under this Act.

### **SECTION XIX. SEVERABILITY.**

If any provision of this Act or application thereof to any individual or circumstance is held invalid, the invalidity does not affect other provisions or applications of the Act that can be given effect without the invalid provisions or applications, and to this end, the provisions of this Act are severable.

### **SECTION XX. EFFECTIVE DATE.**

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