

### Model Universal Access to Naloxone Act

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## Model Universal Access to Naloxone Act

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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").1

#### 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>2</sup> Naloxone can be administered easily by nearly anyone, with minimal instruction.<sup>3</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>4</sup> Moreover, the distribution of naloxone for administration by non-medical experts

<sup>&</sup>lt;sup>1</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." NAMSDL 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. NAMSDL, 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>&</sup>lt;sup>2</sup> See <a href="https://www.narcan.com/faqs">https://www.narcan.com/faqs</a>. 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."), <a href="https://www.drugabuse.gov/naloxone-opioid-overdose-life-saving-science">https://www.drugabuse.gov/naloxone-opioid-overdose-life-saving-science</a>.

<sup>&</sup>lt;sup>3</sup> Doe-Simkins *et al.* BMC Public Health 2014, 14:297 <a href="http://www.biomedcentral.com/1471-2458/14/297">http://www.biomedcentral.com/1471-2458/14/297</a>; 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>&</sup>lt;sup>4</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

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can be highly cost-effective.<sup>5</sup>

- (d) All 50 states and the District of Columbia have enacted laws designed to improve access to naloxone. Studies show that implementation of these laws reduce overdose deaths. In April 2018, the U.S. Surgeon General issued an advisory urging 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.
- (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>9</sup>

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), <a href="https://www.cincinnati.com/story/news/2018/06/14/naloxone-treatment-push-contributes-plummeting-od-deaths/697336002/">https://www.cincinnati.com/story/news/2018/06/14/naloxone-treatment-push-contributes-plummeting-od-deaths/697336002/</a>.

<sup>&</sup>lt;sup>5</sup> Coffin, Phillip, et al. Cost-effectiveness of Distributing Naloxone to Heroin Users for Lay Overdose Reversal. Annuals 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>&</sup>lt;sup>6</sup> The Network for Public Health Law. *Legal Interventions to Reduce Overdose Mortality: Naloxone Access and Overdose Good Samaritan Laws*, (July 2017), <a href="https://www.networkforphl.org/">https://www.networkforphl.org/</a> <a href="mailto:asset/qz5pvn/legal-interventions-to-reduce-overdose.pdf">https://www.networkforphl.org/</a> <a href="mailto:asset/qz5pvn/legal-interventions-to-reduce-overdose.pdf">https://www.net

<sup>&</sup>lt;sup>7</sup> McClellan, Chandler, Lambdin, Barrot H., et al., Opioid-overdose laws association with opioid use and overdose mortality, Addictive Behaviors (March 19, 2018).

<sup>8</sup> https://www.surgeongeneral.gov/priorities/opioid-overdose-prevention/naloxone-advisory.html.

<sup>&</sup>lt;sup>9</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.

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#### **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. In so doing, the Act creates the broadest possible access to the life-saving medication. 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.

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.

- (a) "Co-prescribe" means, with respect to naloxone, the practice of prescribing the drug in conjunction with an opioid prescription.
- (b) "Community-focused organization" means any organization or health agency that seeks to distribute naloxone to community members.
- (c) "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.
- (d) "Drug" means: (1) an article recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (2) an article intended for use in the diagnosis, cure,

<sup>&</sup>lt;sup>10</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.

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mitigation, treatment, or prevention of disease in man or other animals; (3) an article (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) an article intended for use as a component of any article specified in clause (1), (2), or (3). The term does not include devices or their components, parts or accessories.

- (e) "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" 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-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.
- (h) "Prescriber" means an individual licensed, certified, or otherwise authorized by [state] to prescribe prescription drugs, including naloxone.
- (i) "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 individuals.

#### SECTION V. CO-PRESCRIBING OF NALOXONE.

Whenever prescribing a schedule II, III, or IV opioid to a patient, prescribers within [state] shall co-prescribe naloxone if any of the following risk factors are present: (1) a history of substance use disorder; (2) high dose or cumulative prescriptions that result in over 50 morphine milligram equivalents (MME) per day; (3) concurrent use of opioids and benzodiazepine or non-benzodiazepine sedative hypnotics; or (4) other factors, such as drug using friends/family, which is consistent with the recommendations in the Centers for Disease Control and Prevention

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#### SECTION VI. STATEWIDE STANDING ORDERS

- (a) 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]. Standing orders issued under this section shall authorize individuals, recovery community and other community-focused organizations to obtain, store, and distribute naloxone, as provided for by this Act. Standing orders issued under this section are for a legitimate medical purpose in the usual course of professional practice.
- (b) The standing order under subsection (a) shall specify, at a minimum:
  - (1) The naloxone formulations that are FDA-approved for community use, and means of administration for dispensing, distribution, and administration;
  - (2) Any recommended instruction for the individuals to whom the naloxone is dispensed or distributed; and
  - (3) Information about:
    - (i) signs and symptoms of an opioid-related overdose;
    - (ii) proper administration of naloxone;
    - (iii) proper care of an individual to whom naloxone has been administered;
    - (iv) procedures for summoning emergency medical assistance.<sup>12</sup>
- (c) Any standing order issued pursuant to subsection (a) shall remain in effect for two (2) years from the date of issuance. Prior to the end of the two-year period of any standing order, the

<sup>&</sup>lt;sup>11</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 (≥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: <a href="http://dx.doi.org/10.15585/mmwr.rr6501e1">http://dx.doi.org/10.15585/mmwr.rr6501e1</a>. This Act takes the next step by requiring co-prescription of naloxone in those circumstances, as opposed to only recommending consideration of it.

<sup>&</sup>lt;sup>12</sup> For example, Substance Abuse and Mental Health Services Administration, *Opioid Overdose Prevention Toolkit: Five Essential Steps for First Responders, supra* note 11.

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[appropriate state medical professional with prescribing authority] shall renew the order for two (2) additional years, unless the [appropriate state medical professional with prescribing authority] publicly certifies to the [state legislature] that: (1) the rate of opioid-related overdose death in the state is equal to or lower than it was in 2000; and (2) there is no longer any significant public health benefit for renewal.

#### SECTION VII. DIRECT PRESCRIBING AND DISPENSING NALOXONE.

- (a) 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) 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
  - (4) procedures for summoning emergency medical assistance.

#### SECTION VIII. DISTRIBUTION OF NALOXONE BY FIRST RESPONDERS.

State and municipal first responders may distribute naloxone approved by the FDA for community use to an individual or to the individual's responsible 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 substantial risk of experiencing an opioid overdose. In doing so, 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.

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

- (a) 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. If it is permitted 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. 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.
- (b) 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.
- (c) Individuals who summon emergency medical assistance contemporaneously with administering naloxone pursuant to subsection (b) 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.

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 seven (7) days of the request. 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,

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safety, or welfare and is not required to provide a finding of emergency for a rule promulgated under this subsection.

#### SECTION XI. IMMUNITY.

- (a) 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) 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) Any individual, 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.

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:

- (a) 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;
- (b) promote the safe and effective distribution, use, and administration of naloxone by all [state] residents, as set forth in this Act;
- (c) 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;

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- (d) 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;
- (e) 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>13</sup> and
- (f) establish or promote the development of recovery community or other communityfocused 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.

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

- (a) There is established in the [state Department of Health] 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] to fund the Grant Program.
- (b) The [Department of Health] 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>14</sup>

<sup>&</sup>lt;sup>13</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>&</sup>lt;sup>14</sup> For example, in 2015, the Pennsylvania Department of Drug & Alcohol Programs raised over \$500,000 to help provide naloxone for local police departments from several of the major state health insurers in the state.

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#### 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.

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

- (a) 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) 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 in compliance with applicable privacy and confidentiality laws and regulations.<sup>15</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
  - (5) any policies or regulations of the single state authority on drugs and alcohol governing the care of protection of client information.

<sup>&</sup>lt;sup>15</sup> See <a href="https://www.hhs.gov/sites/default/files/hipaa-opioid-crisis.pdf">https://www.hhs.gov/sites/default/files/hipaa-opioid-crisis.pdf</a>, 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.

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

- (a) All state Medicaid programs shall provide coverage for naloxone in a community use indication currently available as a nasal spray, an auto-injector, or both.
- (b) 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 [], shall provide coverage for naloxone in a community use indication currently available as a nasal spray, an auto-injector, or both.
- (c) 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) The coverage provided under this section shall not be subject to prior authorization, and shall not be subject to the insurance plan's deductible requirements.
- (e) The coverage mandated by this section shall include naloxone intended for use on individuals other than the insured.

#### SECTION XVII. DATA COLLECTION AND EVALUATION.

- (a) 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 and administration of naloxone as provided for in this section.
- (b) Collection of naloxone dispensing data. 16
  - (1) Effective [date], all dispensers within [state] must submit naloxone dispensing information to the [state prescription drug monitoring program] as described further

<sup>&</sup>lt;sup>16</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 patient identifiable and should be aggregated by the geographic unit at the county level or below.

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in this section.

- (2) 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) 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) Collection of naloxone administration data.<sup>17</sup>
  - (1) Effective [date], all agencies employing first responders within [state] must submit naloxone administration information to the [state prescription drug monitoring program] as described further in this section.
  - (2) In any case where a first responder encounters someone that he or she believes is undergoing, has just experienced, or has died of, an opioid-related drug overdose, the first responder's agency shall report to the [state prescription drug monitoring program] all of the following:
    - i. The name and date of birth of all of the following, if applicable:
      - (A) The individual who experienced an opioid-related drug overdose;
      - (B) The individual who died as a result of using a narcotic drug;
      - (C) The individual for whom a prescription drug related to an event under (A) or (B) was prescribed;
    - ii. The name of the prescriber, the prescription number, and the name of the drug as it appears on the prescription order or prescription medicine container if the prescription medicine container was in the vicinity of the suspected drug

<sup>&</sup>lt;sup>17</sup> Healthcare professionals want naloxone administration data because it can be clinically relevant to decisions regarding a patient's care. In order to be useful, the data must be patient identifiable, and ideally, would be included in a tool that the practitioner uses as part of their clinical decision-making process. While a prescription monitoring program is one of several such tools, it presents the most established interface between law enforcement / first responders and healthcare professionals.

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overdose, or death.

- (3) 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 agencies employing first responders to submit this information. The information collected shall be used by prescribers and dispensers on a need-to-know basis for purposes including improving patient health care by facilitating early identification of, and intervention with, patients who may be at risk for addiction, or who may be using, misusing, or diverting drugs for unlawful or otherwise unauthorized purposes.
- (4) The collection and submission of this information to the [state prescription drug monitoring program] by agencies employing first responders does not afford such agencies any additional access to the [prescription drug monitoring program] information other than what is allowed pursuant to [state law laying out access rights to PMP information].
- (d) The collection and submission of information by dispensers and agencies employing first responders to the [state prescription monitoring program] 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 administration of naloxone.
- (e) The [insert appropriate state health department/agency] shall evaluate the 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.]