



Model Universal Access to Naloxone Act

Published _____ 2018 (original version published August 2016).

This project was supported by Grant No. G1799ONDCP03A, awarded by the Office of National Drug Control Policy. Points of view or opinions in this document are those of the author and do not necessarily represent the official position or policies of the Office of National Drug Control Policy or the United States Government.

Model Universal Access to Naloxone Act

Table of Contents

4	Section I – <i>Short Title</i>
4	Section II – <i>Legislative Findings</i>
7	Section III – <i>Purpose</i>
8	Section IV – <i>Definitions</i>
9	Section V – <i>Co-Prescribing of Naloxone</i>
9	Section VI – <i>Statewide Standing Orders</i>
10	Section VII – <i>Direct Prescribing and Dispensing Naloxone</i>
11	Section VIII – <i>Possession and Administration of Naloxone by Individuals and Community-Focused Organizations</i>
12	Section IX – <i>Naloxone Supply</i>
12	Section X - <i>Immunity</i>
13	Section XI – <i>Public Education Programs</i>
13	Section XII – <i>New Opioid Overdose Reversal Drug</i>
14	Section XIII – <i>Consents</i>
14	Section XIV – <i>Insurance Coverage for Naloxone</i>

- 15 Section XV – *Data Collection and Evaluation*
- 17 Section XVI – *Rules and Regulations*
- 17 Section XVII - *Severability*
- 17 Section XVIII – *Effective Date*

SECTION I. SHORT TITLE.

This Act shall be known and may be cited as the “Model Universal Access to Naloxone Act” (“Model Act”).¹

SECTION II. LEGISLATIVE FINDINGS.

- (a) From 1999 to 2016, the United State age-adjusted drug overdose rate more than tripled, from 6.2 to 19.8 deaths per 100,000 persons.² The rate of increase itself grew from 3% per year between 2006 and 2014 to 18% per year from 2014 to 2016.³
- (b) When combined with the increase in U.S. population over the same timeframe, this terrible surge in drug overdose death rate equates to a nearly four-fold increase in actual deaths, from less than 18,000 in 1999 to nearly 64,000 in 2016.⁴ Preliminary estimates indicate a projected increase to nearly 70,000 deaths in 2017, making drug overdoses the second deadliest health epidemic in the nation’s history, exceeded only by the flu pandemic of 1918.⁵
- (c) [State statistics mirroring (a) or (b) above.]
- (d) 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

¹ 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 customary. Section XII 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.

² Hedegaard H, Warner M, Miniño AM. Drug overdose deaths in the United States, 1999–2016. NCHS Data Brief, no 294. Hyattsville, MD: National Center for Health Statistics. December 2017. Available at <https://www.cdc.gov/nchs/data/databriefs/db294.pdf>.

³ *Id.*

⁴ National Center for Health Statistics, Provisional Drug Overdose Death Counts, available at <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>.

⁵ <https://www.forbes.com/sites/niallmccarthy/2017/09/11/u-s-heroin-deaths-have-increased-533-since-2002-infographic/#3bed6e7331ab>.

to, and carried by, all first responders and a greater number of other residents of [state]. Indeed, given the rate that overdoses are occurring, no [state] resident can be sure that he or she will never be in a position to encounter an opioid-based overdose.

- (e) Naloxone is a medication that, when administered to an individual experiencing an opioid-related overdose, blocks the effects of the opioid by reversing the depression of the central nervous system and respiratory system caused by opioids. Naloxone is the only opioid overdose reversal drug available at this time and it is classified by FDA as a prescription medication.
- (f) In use for more than 40 years, naloxone is non-addictive and has no known potential for abuse.⁶ Naloxone can be administered easily by nearly anyone, with minimal instruction.⁷
- (g) Overdose education and naloxone distribution programs that train [state] residents in identifying overdoses and responding with naloxone can effectively reduce opioid overdose death rates.⁸ Moreover, the distribution of naloxone for administration by non-medical experts can be highly cost-effective.⁹

⁶ See <https://www.narcan.com/faqs>. See also NIDA. *Naloxone for Opioid Overdose: Life-Saving Science*. National Institute on Drug Abuse, 30 Mar. 2017, <https://www.drugabuse.gov/naloxone-opioid-overdose-life-saving-science>. Accessed 24 May 2018 (“There is no evidence of significant adverse reactions to naloxone.”).

⁷ Doe-Simkins *et al.* *BMC Public Health* 2014, 14:297, available at <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.

⁸ 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 (Published 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>

⁹ 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>.

- (h) As of July 2017, all 50 states and the District of Columbia have enacted laws designed to improve access to naloxone.¹⁰ These laws have been shown to reduce overdose deaths.¹¹ Moreover, in April 2018, the U.S. Surgeon General released an advisory urging individuals who are personally at risk for an opioid overdose, the family and friends of such persons, and any individuals who may encounter those experiencing opioid overdose, to keep doses of naloxone on hand at all times.¹²
- (i) An opioid-related overdose is a life-threatening medical emergency. It is critical to summon emergency medical assistance before, or immediately after, administering naloxone, usually by calling 911.¹³ However, individuals who witness an overdose are sometimes reluctant to call 911 for fear of being arrested and prosecuted for a crime. As of January 2018, 41 states and the District of Columbia have enacted “Good Samaritan” laws providing varying levels of limited immunity to individuals who call for help when someone has experienced an opioid-related overdose.¹⁴ In most states, this immunity also applies to the individual experiencing the overdose. These laws have also been shown to be associated with reductions in drug-related overdose.¹⁵
- (j) Help should not end with reversing a person’s overdose and getting the person medical assistance, however. Recent statistics confirm that many individuals who die from drug overdoses previously survived at least one overdose.^{16 17}

¹⁰ The Network for Public Health Law. *Legal Interventions to Reduce Overdose Mortality: Naloxone Access and Overdose Good Samaritan Laws*. P.2 (July 2017), available at https://www.networkforphl.org/_asset/qz5pvn/legal-interventions-to-reduce-overdose.pdf.

¹¹ McClellan, Chandler, Lambdin, Barrot H., *et al.* *Opioid-overdose laws association with opioid use and overdose mortality*. Addictive Behaviors. March 19, 2018.

¹² <https://www.surgeongeneral.gov/priorities/opioid-overdose-prevention/naloxone-advisory.html>.

¹³ According to the Substance Abuse and Mental Health Services Administration, the first step for anyone encountering a potential opioid overdose is to call 911. Substance Abuse and Mental Health Services Administration, *Opioid Overdose Prevention Toolkit: Five Essential Steps for First Responders*. HHS Publication No. (-SMA) 13-4742. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

¹⁴ Network for Public Health Law, *supra* note 10, reporting 40 states plus D.C. as of July 2017. Arizona became the 41st state with such a law in January 2018 (effective April 2018).

¹⁵ McClellan, *et al.*, *supra* note 11.

¹⁶ Nearly 10% of Massachusetts residents who survived a nonfatal overdose between 2011 and 2015 suffered a fatal

- (k) The cost of naloxone can be a barrier to some individuals from accessing the medication in an easily usable form.¹⁸ Requiring Medicaid and private health insurers to cover the cost of naloxone without prior authorization or any other non-quantitative limitation restrictions can help remove this barrier to access.¹⁹

SECTION III. PURPOSE

The Model Universal Access to Naloxone Act (Act) is designed to save the lives of individuals who have experienced opioid-related overdoses and to create the opportunity for individuals who wish to access appropriate, state-licensed addiction treatment to do so. The Act requires the issuance of a standing order that authorizes the distribution 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

opioid-related overdose within two years. Massachusetts Department of Health, *An Assessment of Opioid-Related Overdoses in Massachusetts 2011-2015* (August 2017). West Virginia found that 71% of individuals who died of a drug overdose in 2016 previously had used emergency medical services within 12 months of their death. West Virginia Violence and Injury Prevention Center. (2017) *West Virginia Drug Overdose Deaths in 2016: Healthcare Systems Utilization, Risk Factors, and Opportunities for Intervention*.

¹⁷ States must therefore develop and implement a collaborative strategy promoting the clinical assessment for drug and alcohol addiction in patients treated for opioid-related overdoses after medical stabilization. The strategy should take all reasonable steps to encourage and facilitate immediate transfer to treatment in accordance with an individualized clinical assessment and application of appropriate patient placement criteria. A prevention, intervention, and addiction treatment strategy developed specifically for overdose survivors will save lives, cut utilization of emergency rooms, encourage demand reduction, and save money for insurers. To this end, NAMSDL recommends adoption of The Model Act Providing for Warm Hand-off of Overdose Survivors to Treatment (“Model Warm Hand-off Act”), which directs state agencies or departments to develop this strategy.

¹⁸ 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), available at <https://www.peters.senate.gov/download/41818-letter-on-secretary-azar-on-naloxone-prices>.

¹⁹ In June 2017, the Medicaid and CHIP Payment and Access Commission (“MACPAC”) reported to Congress that all state Medicaid programs cover naloxone and that “26 state Medicaid programs listed naloxone on their preferred drug lists or made at least one formulation available without prior authorization.” Medicaid and CHIP Payment and Access Commission. 2017. Chapter 2: Medicaid and the Opioid Epidemic. In Report to the Congress on Medicaid and CHIP. June 2017. Washington, DC. Moreover, the laws of several states, including Connecticut, Illinois, Maryland, and Rhode Island, require private insurers to cover one or more formulations of naloxone without prior authorization requirements. C.G.S.A. § 38a-510b; C.G.S.A. §38a-544b; 215 ILCS 5/356z.23; MD Code, Insurance, § 15-850; R.I. Gen.Laws, § 27-18-82; R.I. Gen.Laws, § 27-19-73; R.I. Gen.Laws, § 27-20-69; R.I. Gen.Laws, § 27-41-86.

to the life-saving medication.²⁰ In addition, the Act includes language designed to ensure comprehensive financial support under Medicaid, commercial insurance, and state funding mechanisms for the activities authorized by this Act.

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 do not include individuals or community-focused organizations who are granted authority to store and distribute naloxone solely through 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, 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

²⁰ As described in footnote 17 above, NAMSDL recommends adoption of the Warm Hand-off Act in order to develop a collaborative and robust intervention mechanism to intervene with, assess and refer overdose survivors to appropriate addiction treatment services. Likewise, NAMSDL supports comprehensive overdose Good Samaritan legislation to encourage all individuals who witness an overdose to summon emergency assistance.

emergency or critical incident. This includes such person working in an official capacity on a volunteer basis.

- (f) “Naloxone” means naloxone hydrochloride, which binds to a person’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-person 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.

All prescribers within [state] shall co-prescribe naloxone whenever they prescribe a schedule II, III, or IV opioid to a patient. Where the prescriber has issued to the same patient a co-prescription for naloxone within the past 12 months, the prescriber may, but is not required to, issue an additional co-prescription for naloxone.

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 person seeking naloxone within [state]. Standing orders issued under this section shall authorize individuals and 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 formulation and means of administration that are approved for dispensing, distribution, and administration;
 - (2) Any recommended instruction for the persons 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.²¹
- (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 [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 and any necessary supplies for administering the drug directly or by standing order to any individual or any community-focused organization. A prescription issued under this Section is for a legitimate medical purpose in the usual course of professional practice.

²¹ For example, Substance Abuse and Mental Health Services Administration, *Opioid Overdose Prevention Toolkit: Five Essential Steps for First Responders*, *supra* note 11.

- (b) A prescriber who directly prescribes or dispenses naloxone and any necessary supplies for administering the drug 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. POSSESSION AND ADMINISTRATION OF NALOXONE BY INDIVIDUALS AND COMMUNITY-FOCUSED ORGANIZATIONS

- (a) Notwithstanding any other law or regulation to the contrary, individuals and community-focused organizations receiving naloxone, and any necessary supplies for administering the drug, may possess and store the drug and such supplies. If it is permitted under any standing order or prescription issued pursuant to this Act, community-focused organizations that possess naloxone may distribute the drug to other individuals. The storage of naloxone and supplies to administer it 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) A person 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 person 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) Persons 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 IX. NALOXONE SUPPLY.

All pharmacies licensed, certified, or otherwise authorized to do business in [state] shall dispense naloxone to an individual or community-focused organization pursuant to either a traditional or non-person 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, safety, or welfare and is not required to provide a finding of emergency for a rule promulgated under this subsection

SECTION X. 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 and any necessary supplies for administering the drug; 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 and any necessary supplies for administering the drug; or (2) for any ultimate outcomes of such dispensing.
- (c) Any individual or community-focused organization who distributes or administers naloxone pursuant to this Act or is immune from civil and criminal liability, and is not subject to adverse professional action, for: (1) the distributing of naloxone and any necessary supplies for administering the drug; (2) the administration of naloxone; or (3) for any ultimate outcomes of such distribution or administration.

SECTION XI. 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) Promote the safe and effective use and administration of naloxone by all [state] residents, as set forth in this Act;
- (b) Identify resources for and develop a public education program that trains all [state] residents about 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;
- (c) 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;
- (d) 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;²² and
- (e) Establish or promote the development of community-focused organization naloxone access programs. At a minimum, such access program shall offer participants an approved training and education program as part of the program of naloxone distribution.

SECTION XII. 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.

²² 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.

SECTION XIII. 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.²³ 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; and
 - (4) any relevant state law related to the privacy, confidentiality, and disclosure of protected health information.

SECTION XIV. INSURANCE COVERAGE FOR NALOXONE.

- (a) 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 _____, including both state Medicaid programs and private health insurance plans, shall provide coverage for naloxone, as a nasal spray, an auto-injector, or both.
- (b) The coverage provided under subsection (a) shall include both the naloxone product itself, any necessary administration supplies, 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.

²³ 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.

- (c) The coverage provided under this section shall not be subject to prior authorization.
- (d) The coverage mandated by this section shall include naloxone that is intended for use on persons other than the insured.

SECTION XV. 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.²⁴

(1) 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) 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.

²⁴ 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.

(c) Collection of naloxone administration data.²⁵

- (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: (1) is undergoing, or has immediately prior experienced, an opioid-related drug overdose; or (2) died as a result of using a narcotic drug; 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 a prescription medicine container was in the vicinity of the suspected drug 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.

²⁵ 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.

DRAFT

- (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 change 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, prescription drug abuse, addiction, and diversion, and evidence-based public health interventions.

SECTION XVI. RULES AND REGULATIONS.

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

SECTION XVII. SEVERABILITY.

If any provision of this Act or application thereof to any person 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 XVIII. EFFECTIVE DATE.

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