



MODEL NALOXONE ACCESS ACT

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MODEL NALOXONE ACCESS ACT

SECTION I. SHORT TITLE.

This Act shall be known and may be cited as the “Model Naloxone Access Act.”

SECTION II. LEGISLATIVE FINDINGS.

- (a) Drug overdose was the leading cause of injury death in 2013¹. Overdose deaths now exceed motor vehicle-related deaths in 36 states and the District of Columbia.² Since 2000, the drug overdose rate has increased 137%, **including a 200% increase in the rate of overdose deaths involving opioids.**³
- (b) [State statistics mirroring (a) and (b) above.]
- (c) Many opioid-related overdose deaths are preventable if the FDA approved overdose reversal medication, naloxone, is readily available to first responders, family members, and others in a position to help an individual experiencing an opioid-related overdose.
- (d) Naloxone is a prescription medication that when administered to an individual experiencing an opioid-related overdose restores the individual to consciousness and normal breathing. Naloxone is virtually always effective when administered correctly.
- (e) In use for more than thirty (30) years, naloxone is non-addictive and can easily be administered by someone who has training in overdose recognition and naloxone administration. People with such training identify opioid overdoses and indications for naloxone as well as medical experts do.⁴
- (f) Overdose education and naloxone distribution programs that train family members, friends, and others in a position to assist someone experiencing an opioid-related

¹ *Deaths: Final Data for 2013*. National Vital Statistics Reports. Centers for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics System. 64:2 (February 16, 2016). (2013 was most recent year data was available at time of CDC analysis).

² *The Facts Hurt: A State-by-State Injury Prevention Policy Report, Press Release*. Trust for America’s Health and Robert Wood Johnson Foundation. (June 17, 2015).

³ *Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014*. Morbidity and Mortality Weekly Report. Centers for Disease Control and Prevention. 64-50&51:1378-1382 (January 1, 2016).

⁴ Green, Traci C., et al. *Distinguishing Signs of Opioid Overdose and Indication for Naloxone: An Evaluation of Six Overdose Training and Naloxone Distribution Programs in the United States*. *Addiction*. 103(6):979-989. Doi:10.1111/j.1360-0443.2008.02182.x. (June 2008).

overdose can effectively reduce opioid overdose death rates.⁵ Moreover, naloxone distribution for administration by non-medical experts can be highly cost-effective.⁶

- (g) Forty-seven (47) states and the District of Columbia have naloxone access laws.⁷
- (h) An opioid-related overdose is a medical emergency. After naloxone administration, it is critical to summon emergency medical assistance. However, individuals who witness an overdose are sometimes reluctant to call 911 for fear of being arrested and prosecuted for a crime. Thirty-six (36) states and the District of Columbia passed laws providing limited immunity to individuals who call for help when someone has experienced an opioid-related overdose.⁸
- (i) Preliminary anecdotal research indicates that approximately 25% of those who die from drug overdoses likely have had at least one prior hospital admission for an overdose.⁹
- (j) Single State Authorities on Drugs and Alcohol must therefore develop and implement collaborative strategies to ensure that after medical stabilization, patients hospitalized for opioid-related overdoses are assessed for drug and alcohol addiction. The strategy should also ensure that where appropriate, the individual is transferred to intensive treatment in an addiction treatment program licensed by the state for this purpose. Because of the high potential of another, possible fatal overdose, intensive treatment in an inpatient addiction facility most likely will be required.
- (k) Hospitalization for an opioid-related overdose presents a key opportunity for intervention with an individual with a drug and/or alcohol problem and for the family. Such hospitalizations, if managed properly, can serve as a serious wake-up call for all involved. Whenever possible, family members, significant others, and close friends should be pulled together to develop and support the ongoing addiction treatment and recovery plan.
- (l) Prevention, intervention, and addiction treatment strategies developed specifically for overdose survivors will save lives, cut utilization of emergency rooms, save money for insurers and reduce the demand for drugs.

⁵ Wally MD., 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).

⁶ Coffin, MD., et al. *Cost-effectiveness of Distributing Naloxone to Heroin Users for Lay Overdose Reversal*. *Annals of Internal Medicine*. 158:1-9 (2013).

⁷The Network for Public Health Law. *Legal Interventions to Reduce Overdose Mortality: Naloxone Access and Overdose Good Samaritan Laws*. P.2 (June 2016).

⁸ Ibid.

⁹ Drug and Alcohol Service Providers Organization of Pennsylvania (DASPOP). For more information, please contact Deb Beck, President, DASPOP at ddasdbeck@hotmail.com

SECTION III. PURPOSE

The Model Naloxone Access Act (Act) is designed (1) to save the lives of individuals who have experienced opioid-related overdoses, and (2) to create the opportunity for the individuals to receive appropriate addiction treatment. The Act authorizes the dispensing of naloxone to and administration of naloxone by many people who are 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. Equally important, the Act establishes a collaborative intervention mechanism in emergency departments to assess the individuals and refer them to addiction treatment programs. This Act should be adopted in conjunction with appropriate state legislative and regulatory language that assures comprehensive financial support under Medicaid, commercial insurance, and state funding mechanisms for the activities authorized by this Act (See attached policy statement).

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) “Addiction treatment program” means any facility or treatment program that is [licensed], [certified], or [approved] by the state to provide alcohol or other drug addiction treatment on a hospital, non-hospital residential or out-patient basis.
- (b) “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.
- (c) “First responder” means a law enforcement officer, a firefighter, an emergency medical services provider or other individual who, in a professional capacity, responds rapidly to an emergency or critical incident and renders assistance.
- (d) “Health care professional” means an individual licensed, certified, or otherwise authorized by the state to prescribe drugs.
- (e) “Naloxone” means an opioid overdose reversal medication approved by the Food and Drug Administration (FDA) that binds to the opioid receptors and blocks the effects of the opioid acting on those receptors.
- (f) “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.

- (g) “Standing order” means a prewritten, non-person specific order issued by a health care professional that authorizes the dispensing of a drug to or administration of the drug by individuals who satisfy pre-determined criteria.

SECTION V. STATEWIDE STANDING ORDERS

- (a) The [insert appropriate state medical professional with prescribing authority, e.g., surgeon general, physician general] may prescribe naloxone by one or more standing orders to eligible recipients. Standing orders issued under this Section are for a legitimate medical purpose in the usual course of professional practice.

- (b) Eligible recipients shall include:

- (1) An individual who is at risk of experiencing an opioid-related overdose;
- (2) A family member, friend, or other individual who is in a position to assist someone who is at risk of experiencing an opioid-related overdose;
- (3) An offender with a history of drug and alcohol problems upon release from prison, jail or other confinement in a state or local correctional facility;
- (4) A first responder;
- (5) An addiction treatment program representative;
- (6) A representative of a community-based organization that provides services to individuals at high risk of an opioid-related overdose;
- (7) A school nurse or other school employee authorized to administer medication; and
- (8) A probation or parole officer.

- (c) A standing order under Subsection (a) shall specify, at a minimum:

- (1) The naloxone formulations and means of administration that are approved for dispensing;
- (2) The eligible recipients to whom naloxone may be dispensed;
- (3) Any required training for eligible recipients to whom naloxone is dispensed;
- (4) In the absence of required training, (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, and (D) procedures for summoning emergency medical assistance;
- (5) Any circumstances under which eligible recipients may dispense naloxone; and
- (6) The timeline for renewing and updating the order.

- (d) A standing order under Subsection (a):

- (1) Is superseded by an existing prescription that a health care professional issued directly or by standing order pursuant to Section VI;

- (2) Automatically terminates for an eligible recipient when a health care professional prescribes naloxone, directly or by standing order, to that recipient pursuant to Section VI.

SECTION VI. HEALTH CARE PROFESSIONALS' PRESCRIBING AND DISPENSING OF NALOXONE.

- (a) A health care professional may prescribe, directly or by standing order, or dispense, naloxone to an eligible recipient identified in Section V(b). A prescription issued under this Section is for a legitimate medical purpose in the usual course of professional practice.
- (b) A standing order shall satisfy the requirements of Section V(c).
- (c)(1) A health care professional who directly prescribes or dispenses naloxone to an eligible recipient shall provide that recipient with information regarding (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, and (D) procedures for summoning emergency medical assistance.
- (2) A health care professional may satisfy the requirement in paragraph (1) through a written agreement with an entity qualified to provide the required information to the eligible recipient. Such entity shall include, but not be limited to, a community-based organization that provides services to individuals at high risk of an opioid-related overdose, an addiction treatment program, or a state or county health agency.
- (d) A health care professional is immune from civil or criminal liability, and is not subject to adverse professional action, for the prescribing or dispensing of naloxone pursuant to this Section.

SECTION VII. POSSESSION AND ADMINISTRATION OF NALOXONE.

- (a) Eligible recipients to whom naloxone is prescribed or dispensed pursuant to Sections V and VI may possess and store naloxone. The storage of naloxone by such recipients is not subject to pharmacy practice laws or other requirements that apply to the storage of drugs or medications.
- (b) (1) An agency, program or organization regulated by the state that employs, contracts with, or has a criminal justice custodial or supervisory relationship with eligible recipients under Sections V and VI, shall develop procedures and enter into agreements to obtain (A) necessary supplies of naloxone for administration and dispensing, and (B) training required pursuant to Sections V and VI.
- (2) The procedures and agreements identified in paragraph (b)(1) shall be in effect no later than [insert applicable time frame] from the effective date of this Act.

- (c) Eligible recipients to whom naloxone is prescribed or dispensed pursuant to Sections V and VI may administer naloxone to individuals the recipients reasonably believe to be experiencing opioid-related overdoses. The recipients shall be immune from civil or criminal liability, and are not subject to adverse professional action, for the good faith administration of naloxone pursuant to this Subsection.
- (d) Eligible recipients to whom naloxone is prescribed or dispensed pursuant to Sections V and VI shall report, if required by the [insert appropriate state health department/agency], information to the [insert appropriate term, e.g., department, agency] about their administration and dispensing of naloxone or other naloxone-related activities.
- (e) Eligible recipients identified in Section V(b)(1) or (2) who summon emergency medical assistance after administering naloxone pursuant to Subsection (c) will receive the protections afforded by [insert citation to appropriate state Good Samaritan provisions].

SECTION VIII. INTERVENTION AND REFERRAL TO TREATMENT.

- (a) The attending physician in an emergency department, or a 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 others involved in the patient's health care.
- (b) If consent cannot practicably be provided because of the patient's incapacity or an emergency circumstance, the physician, or physician's designee, may disclose information about a patient's opioid-related overdose in compliance with applicable privacy and confidentiality laws. Such laws shall include the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191 (Aug. 21, 1996), 45 C.F.R. parts 160 and 164 (HIPAA Privacy and Security Rules); and the federal confidentiality law and regulations, 42 U.S.C. § 290dd-2, 42 C.F.R. Part 2.
- (c) Prior to the emergency department's discharge of a patient who experienced an opioid-related overdose, the attending physician, or physician's designee, shall provide the patient with educational materials about addiction, and a list of addiction treatment programs.
- (d) The [insert name of single state authority on drugs and alcohol] shall develop and implement a collaborative plan to assess emergency department patients who experienced opioid-related overdoses, and with their consent, transfer them to addiction treatment programs. Assessment and transfer services shall occur after medical stabilization of the patients.

SECTION IX. DATA COLLECTION AND EVALUATION.

- (a) The [insert appropriate state health department/agency] shall establish and maintain a registry or other collection mechanism to track de-identified data regarding:
 - (1) The amount of naloxone dispensed,
 - (2) The number of times naloxone was administered to an individual experiencing an opioid-related overdose,
 - (3) The number of times naloxone administration resulted in a reversal of an opioid-related overdose, and
 - (4) Any other naloxone activities deemed relevant to effective implementation of this Act.

- (b) The [insert appropriate state health department/agency] shall specify which eligible recipients to whom naloxone has been dispensed pursuant to Sections V and VI must report information to the [insert appropriate term, e.g., department, agency] for the data collection purposes stated in Subsection (a).

- (c) The [insert appropriate state health department/agency] shall evaluate the data collected pursuant to Subsection (a) 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 relevant to the development and implementation of state policy regarding opioid-related overdoses, and prescription drug abuse, addiction, and diversion.

SECTION X. RULES AND REGULATIONS.

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

SECTION XI. 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 which can be given effect without the invalid provisions or applications, and to this end the provisions of this Act are severable.

SECTION XII. EFFECTIVE DATE.

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

ATTACHMENT

NATIONAL ALLIANCE FOR MODEL STATE DRUG LAWS

MEDICAID AND PRIVATE HEALTH INSURANCE REIMBURSEMENT OF NALOXONE: REMOVING COST BARRIERS TO ACCESS

POLICY STATEMENT

The cost to obtain naloxone may seriously undermine a state's well-intended strategy to broadly distribute naloxone. Family members, friends, community organizations, and others in a position to assist someone experiencing an opioid-related overdose may simply be unable to afford the purchase price of the medication. As noted by experts on naloxone laws and policy, the cost of the medication has "increased drastically in the past several years..."¹⁰ According to Truven Health Analytics, an auto-injector version of naloxone increased from \$575 to \$3,750 per two-dose package between 2014 and 2016.¹¹ The cost of another product at the end of 2014 was almost double the price in 2013.¹² Recent times have seen companies new to the naloxone market offering community rates for community organizations purchasing bulk supplies of naloxone.¹³ While more products and more competition hold the promise of eventually decreasing prices, state officials must find ways to help people overcome the increasing prices they face in the here and now.

To prevent cost barriers from stopping robust implementation of a naloxone access strategy, state policymakers need to increase the resources available to pay for naloxone expenses. A critical step is to ensure state Medicaid programs and private health insurance plans provide reimbursement for the following items:

- **Take-home naloxone in intramuscular and intranasal formulations.** Some programs or plans may only cover naloxone directly administered in an emergency room or other medical setting. Coverage should include naloxone prescribed or dispensed to third parties in addition to individuals at risk of experiencing an opioid-related overdose.
- **Devices needed to administer the medication.** Atomizers needed for intranasal administration present special difficulties for coverage. Atomizers have no national drug code (NDC) that is used by Medicaid and private insurers to process reimbursements.¹⁴

¹⁰ Davis, C.S. et al. *Legal changes to increase access to naloxone for opioid overdose reversal in the United States*. Drug and Alcohol Dependence. 157:117. <http://dx.doi.org/10.1016/j.drugalcdep.2015.10.013> (2015).

¹¹ Sarah Karlin-Smith, *Price spikes for life-saving drug*, Politico, May 16, 2016. (Accessed online at www.politico.com/story/2016/05/drug-prices-addiction-223192.)

¹² Ibid.

¹³ For information on community rates, please contact Stephanie Galica, Director of Community Health Solutions, AdaptPharma, 100 Matsonford Rd., Bldg. 4, Suite 201, Radnor, PA 19087, 844-232-7811, ext. 207.

¹⁴ Seiler, N. et al. *Medicaid Reimbursement for Take-home Naloxone: A Toolkit for Advocates*, Milken Institute School of Public Health, The George Washington University, at 10. (2014).

- **Refills for naloxone that has expired or been administered.**
- **Pharmacy administration fees related to the dispensing of naloxone.**
- **Time spent counseling, training or educating people to whom naloxone is prescribed or dispensed** about (1) overdose recognition, (2) proper administration of naloxone, (3) care of an individual to whom naloxone has been administered, and (4) procedures for summoning emergency medical assistance.

Elimination of prior authorization requirements or similar restrictions will also streamline the reimbursement process. Numerous jurisdictions have begun to successfully expand coverage for naloxone, including California, Illinois, New Mexico, New York, North Carolina and Washington state.¹⁵ For a detailed discussion of state Medicaid reimbursement for naloxone, see *Medicaid Reimbursement for Take-home Naloxone: A Toolkit for Advocates* published by the Milken Institute School of Public Health at The George Washington University in Washington, D.C.

¹⁵ Seiler et al, supra note 2, at 13-19; IL H.B.1 (2015); New Mexico Department of Health, *Coverage of Naloxone Under Medicaid Announced*. <http://nmhealth.org/news/information/2014/6/?view=88> (June 18, 2014). (Accessed on March 23, 2016).