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Overview of State	Legislation to Incre	ase Access to Treatm	ent for Opioid Overdose
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Overview of State Legislation to Increase Access to Treatment for Opioid Overdose

Preface

The following document discusses laws that States have enacted to increase access to treatment for opioid overdose, and in turn, to reduce fatal opioid overdose. These policies do not represent the full menu of options available in the States, but rather capture the most common policies that have been incorporated into State legislation related to treating overdose. With that being said, these strategies should be considered only one part of a comprehensive strategy that includes prevention efforts, access to treatment, and recovery support services. To learn more about some of the other efforts that States are using to address opioid overdose, please see NASADAD's 2012 Report: <u>State Substance Abuse</u> <u>Agencies and Prescription Drug Misuse and Abuse: Results from a NASADAD Membership Inquiry</u>.

Opioid overdose in the United States

The rate of fatal overdose in the U.S. has tripled since 1991. Opioid-related drug overdose, and particularly opioid pain relievers, account for most of that increase. In response, some States have enacted various policies that seek to reduce fatal opioid overdose. This brief summarizes some of the policies legislated by States to reduce opioid overdose deaths through improving access to naloxone to reverse opioid overdose.

- 911 Good Samaritan laws
- Naloxone prescribing and administration protections
- Naloxone distribution programs

The following policies cover a spectrum of approaches, though do not necessarily encompass all of the various strategies and programs that States have implemented in response to the increase in opioid-related overdose deaths. The policies are divided into two categories: calling 911 and naloxone access. An explanation of each category and policy is provided below. For additional information regarding these and other potential strategies, please refer to the Additional Resources section at the end of this brief.

Calling 911

The pace at which opioid use can escalate to a fatal overdose is relatively slow. Rather than an immediate reaction, opioids gradually depress respiration until the person stops breathing, a process that can take hours. 3,4,5,6 This offers a window of time in which victims can receive medical attention to reverse the overdose before significant brain damage or death occurs. Moreover, most opioid overdoses occur in the presence of someone else, such as a friend or family member. However, witnesses often do not call 911 during an overdose. 9,10,11,12 This is particularly true among witnesses of a heroin overdose who cite fear of police involvement as the most common reason that they do not call 911. 13,14,15,16 This is not entirely surprising given that in many States, both the caller and the victim may be arrested for possession of illegal substances, drug paraphernalia, or other offenses. This fear of police involvement among witnesses could potentially extend to users of other drugs, particularly unauthorized users of prescription opioid pain medication, given the potential for arrest and/or criminal charges. However, the current literature has yet to fully explore this population's overdose response behaviors. Fear of calling for help also increases the likelihood that witnesses will attempt common, yet ineffective revival strategies, such as shaking the victim, submerging them in cold water, or injecting them with salt, potentially worsening their condition. We condition. Sieven the recent rise in overdose deaths, some States have opted to enact policies that



attempt to reduce witnesses' fear of calling 911 and encourage them to call 911 during an overdose. These laws vary in scope, but are referred to as "911 Good Samaritan" laws. Given the current literature, these Good Samaritan laws are best positioned to overcome the fears of heroin users and witnesses of heroin overdoses and to encourage the use of emergency medical services. However, it would be valuable to evaluate the effect of these laws on other populations.

911 Good Samaritan laws

As of December 2013, 14 States and the District of Columbia have enacted 911 Good Samaritan laws. In broad terms, these laws provide immunity for victims and witnesses who "act in good faith" to seek medical assistance when they believe an overdose is occurring. These laws provide immunity for minor drug offenses that are discovered as a result of the Good Samaritan seeking medical assistance. These include immunity against arrest and/or prosecution for possessing a controlled substance or drug paraphernalia. Some States also provide protections for underage persons in possession of or under the influence of alcohol, among other protections. This limited immunity does not extend to more serious offenses such as drug trafficking or violent crime. There may be some concern that by removing the threat of criminal action, these policies would increase illegal drug use. The literature on this particular issue is limited, but early evaluation results from Washington State's 2010 Good Samaritan law have not found evidence for this kind of negative effect. Early results do show that 88% of users surveyed in Washington State said they would be more likely to call 911 during an overdose because of the new Good Samaritan law. For a list of the States with 911 Good Samaritan policies, please see Figure 2 on page 8.

A variant of the Good Samaritan law is to allow witnesses who call 911 (in good faith) to cite that action during criminal prosecution. The act of calling 911 would be cited in the hopes of reducing or mitigating any sentencing that follows. This does not guarantee that such an action would mitigate sentencing, but rather allows judges the discretion to utilize or consider it if deemed appropriate. This policy is often attached to a broader 911 Good Samaritan law, but it can also be passed as an independent policy, as in the case of Alaska and Maryland. To date, 10 States allow calling 911 during an overdose to serve as a mitigating factor in criminal prosecution. For a list of the States with this policy, please see Figure 2 on page 8.

Naloxone

As previously discussed, the pace of an opioid overdose generally allows time for victims to receive emergency medical care before the overdose becomes fatal. In the case of opioids, administering naloxone has long been a standard of care in emergency rooms and with paramedics throughout the United States. Naloxone is a prescription medication that reverses the effects of an opioid overdose. Administered most often via intramuscular injection or intranasally—naloxone binds to the opioid receptors in the brain, reviving the victim and restoring normal breathing. Naloxone is not a controlled substance, has no potential for abuse, and has no effect on the body in the absence of an opioid. Despite naloxone's high degree of effectiveness in reversing opioid overdose, thousands of opioid overdose victims fail to get timely access to this life-saving medication. Some of this can be explained by witnesses' reluctance to seek medical attention (discussed above). Another issue is that emergency medical personnel often do not arrive in time to administer naloxone. This may be a result of the time it takes witnesses to recognize that an overdose is occurring or a delay in emergency response times due to location or other issues. These factors suggest that with proper training, witnesses of an overdose, such



as friends or family members, may be better positioned to administer naloxone in a timely manner than first responders. Over the last decade, many community-based programs and 17 States have taken steps to make naloxone more readily available in the community. In addition, the American Medical Association, American Public Health Association, and the Office of National Drug Control Policy have endorsed expanding access to naloxone as a strategy to prevent fatal overdose. ^{32,33,34} Traditionally, efforts to increase naloxone access have focused on the heroin user population. However, as prescriptions for opioid pain relievers have increased, some particularly affected communities have begun educating providers about and encouraging them to co-prescribe naloxone with opioid pain relievers. The extent to which this approach is being utilized is still largely unknown, and as a result, the literature evaluating its efficacy is limited. However, an evaluation of one program, Project Lazarus in Wilkes County, North Carolina (a region with particularly heavy opioid pain reliever use and overdose rates), found a 42% reduction in fatal overdose rates. ³⁵ As communities evaluate the scope of their individual opioid overdose problems, there may be room to innovate different methods of expanding naloxone based on the individual population's needs. These methods should be rigorously evaluated to expand the body of literature concerning naloxone access and fatal opioid overdose.

Despite its growing acceptance, there are still several concerns that are commonly raised in response to expanding access to naloxone. One concern is about the safety of allowing lay persons to administer medical care. This is partially why many naloxone distribution programs involve a training component to ensure that witnesses can respond safely and effectively. In addition, some States have mandated that lay people who obtain and intend to administer naloxone receive overdose training. 36 However, as in the case of other medical emergencies such as a severe allergic reaction, the current literature suggests that trained bystanders can safely and effectively administer injections like naloxone. ^{37,38,39} Another concern is that naloxone has a shorter half-life than many opioids, meaning that in some cases, the naloxone may wear off and the victim return to an overdose/depressed respiratory state. 40 This situation rarely appears in the literature, though if it did, a second dose of naloxone would be required. There are concerns as to whether a lay person would be equipped to recognize this and administer a second dose in a timely fashion, particularly if he or she is intoxicated. 41 In addition, because naloxone blocks the opioid receptors, revived victims may experience acute withdrawal symptoms. This may cause the victim to attempt to use more opioids, even though doing so would be dangerous. However, there is preliminary evidence in the literature from naloxone distribution programs that peers are able to successfully administer a second dose when needed and prevent victims from using additional opioids, although evaluation of these programs is still in the early stages. 42 The final, and perhaps most common, concern about naloxone distribution is that by removing the threat of overdose, people will increase their drug use. 43 The current literature finds no evidence that this phenomenon is occurring. 44,45,46,47

As stated previously, 17 States have passed laws that in some way expand the availability of naloxone. The following sections explain the most common provisions from those laws: third party prescription, standing orders, liability protections, naloxone distribution programs, educational strategies, and overthe-counter naloxone. While these are discussed individually, they are interrelated in many ways and are often implemented in combination with one another.

Third party prescription

This refers to a law which allows a prescription for naloxone to be written for a friend or family member of someone considered at risk of opioid overdose. Naloxone is currently only approved by



the FDA as a prescription medication. ⁴⁸ However, due to the nature of naloxone, this creates a number of issues for prescribers and for patients. Firstly, potential overdose victims may be uncomfortable asking their physician for a naloxone prescription. ⁴⁹ In addition, overdose victims are generally unable to administer naloxone to themselves, creating some uncertainty for prescribers. State laws governing medical practice generally require that physicians only write prescriptions for the person who will actually take the medication. ⁵⁰ However, in the case of naloxone, the prescription and instructions on administering the drug may be better suited in the hands of a friend or family member who may be more likely to witness an overdose and to administer naloxone. This idea of prescribing a medication to someone other than the person receiving the drug is called "third party prescription." ⁵¹ Fourteen States have passed laws that enable physicians to write naloxone prescriptions to friends and family members of opioid users so that they may administer naloxone in the event of an opioid overdose. ⁵² For a list of the States that allow third party prescription, please see Figure 2 on page 8.

Standing orders

A "standing order" is an order that prescribers write allowing a prescription medication to be dispensed to a patient that they have not examined who meets a certain set of criteria.⁵³ For example, a community-based organization may have an affiliated physician write a standing order for naloxone so that they can distribute it to anyone who meets the criteria. For naloxone, the criteria may be as simple as someone who may be in a position to reverse an opioid overdose or someone who has received overdose training. This is not entirely unprecedented given that many paramedics currently operate under standing orders to be able to administer naloxone prior to arriving at the emergency room.⁵⁴ Six States that have passed overdose prevention legislation have explicitly allowed physicians to write standing orders for naloxone. However, some community-based naloxone distribution programs have received standing orders for naloxone in States that have not passed legislation that explicitly allows them. This is not surprising given that standing orders are commonly used in a variety of medical settings. However, using a standing order to increase access to naloxone may raise liability concerns for some physicians. Providing legal clarity may be preferred for physicians and community programs to avoid potential liability issues and encourage broader use. For a list of the States where overdose prevention laws allow standing orders, please see Figure 2 on page 8. Please note that Figure 2 does not capture all of the States where standing orders are in use, as there are at least 11 States where standing orders have been used without legislation since 2008.⁵⁵

Liability protections

These are laws that provide legal protection for physicians that prescribe naloxone or laypersons that administer it "in good faith." Regardless of their desire to prescribe naloxone, some physicians are concerned about potential liability issues. ⁵⁶ Most prescription drugs are taken orally, either in pill or liquid form. Naloxone, on the other hand, is often administered with an intramuscular injection — though other forms are available. Some physicians are concerned that if they prescribe naloxone to a lay person and something goes wrong, they will be held liable. In response, 8 States have enacted laws that provide protections for prescribers from civil and/or criminal liability. Also, some States provide liability protections for lay people who administer naloxone in good faith (14 States) or who have received overdose prevention information (7 States). These protections are specific to naloxone and are included in 17 States' overdose prevention policies in varying degrees. For a list of the States that provide liability protections, please see Figure 2 on page 8.



Naloxone distribution programs

These are entities that make naloxone and education about its use available to opioid users and/or their families and/or friends. Naloxone distribution programs are perhaps the oldest response to rising opioid overdose rates and exist throughout the United States. As of 2010, 188 distribution programs exist in 15 States and DC.⁵⁷ From 1996 to 2010, those programs distributed naloxone to roughly 53,000 people and reported more than 10,000 successful overdose reversals.⁵⁸ More recently, an evaluation of Massachusetts's distribution program revealed that overdose deaths decreased in those communities where the program was implemented compared to communities without the program. According to published reports, in September 2013, the program reversed their 2,000th overdose since the State began distributing naloxone in 2007. 59,60 Early evidence also suggests that naloxone distribution programs targeting heroin users are a cost-effective strategy, though this body of literature is still developing. ⁶¹ Naloxone distribution programs vary widely. It is outside the scope of this brief to describe all of the various training and educational components of each or how they receive their funding and support. With that said, 9 States explicitly provided support for naloxone distribution programs in their overdose prevention policies. 62 In some cases, relevant agencies were authorized to distribute grants to distribution programs and others authorized the creation of a Staterun program. For a list of the States that included naloxone distribution programs in their overdose prevention policies, please see Figure 2 on page 8.

Educational strategies

Education and training are often included in discussions of expanding lay naloxone access. While education and training are embedded in many naloxone distribution programs, 6 States included separate requirements for educational campaigns or grant making related to educational work in their overdose prevention legislation. These requirements range from offering grants to organizations that provide educational materials around overdose to creating physician trainings on how to use online prescription tracking systems to creating a prescription pain medication awareness program. These 6 States are only a few of the many States that engage in these types of educational efforts. In a 2012 NASADAD survey of State Substance Abuse Agencies (SSAs), 83% of the respondents (representing 46 states and the District of Columbia) were engaging in some kind of educational campaign regarding prescription drug abuse. These activities varied among providing printed materials, creating an internet campaign, or running radio or television advertisements, to name a few. For a list of the States that included educational components in their overdose prevention policies, please see Figure 2 on page 8.

Over-the-Counter Naloxone

Given the safety and effectiveness of naloxone, many public health advocates question why naloxone is not available over-the-counter. The prospects for changing naloxone's FDA status are complex and unlikely to happen in the short-term. Two important issues are that there is only one pharmaceutical company currently selling naloxone in the United States, and naloxone has a relatively small market value compared to most pharmaceutical products (roughly \$22 million vs. an estimated \$640 million for the auto-injector or "EpiPen" of the allergy rescue medication epinephrine). ^{64,65} US law does not allow the same active ingredient to be marketed as both prescription and over-the-counter if there is not a "clinically meaningful" difference between the two, so the two products could not be intended for the same population, for the same health issue, in identical dosage and delivery forms. ⁶⁶ Given this, the manufacturer would need to present the drug in a new way: a new formulation, delivery



method, etc. and file a "new drug application" for over-the-counter approval. However, undertaking a new drug application requires years and a significant financial investment from the drug company in the form of a user fee and requirements for extensive clinical trials and other research. Between the substantial financial investment and naloxone's limited market size, it is not likely that the owner will submit an application.

Public health advocates could also file a citizen petition to ask the FDA to change the rules surrounding naloxone's status. This would not require a user fee from the manufacturer, but would require that the petitioners submit the same research and clinical trial data that a new drug application would require. If this data does not exist or is not accessible to private citizens, petitioners would need to work with scientists to conduct such trials which would be incredibly expensive. 67

Concluding thoughts

There are a variety of public health tools available for States to address fatal opioid drug overdose. The provisions discussed in this document are primarily intended to improve access to treatment with naloxone for opioid overdose, but do not encompass all of the possible policy responses that exist. As fatal drug overdoses have increased, there has been growing activity among States to come up with overdose prevention strategies. The timeline in Figure 1 below illustrates the pacing of overdose treatment legislation since New Mexico passed the first of its kind (dealing with naloxone distribution and liability protections) in 2001. Another 10 States passed related legislation between 2006 and 2011, with 8 States passing legislation in 2012 and 11 in 2013. Please click on each State's legislative citation in the table on page 8 to see a copy of the law text. You can also find a more detailed description of the provisions in each State's law in The Network for Public Health Law's report: Legal interventions to reduce overdose mortality: naloxone access and overdose good Samaritan laws. For additional information, please see the Additional Resources section at the end of this brief.

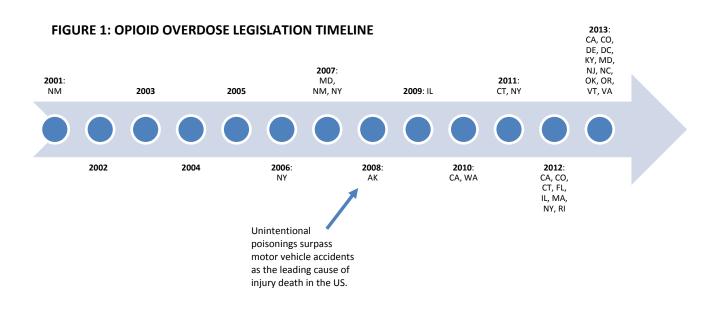




FIGURE 2: OVERVIEW OF RECENT ENACTED STATE OPIOID OVERDOSE LEGISLATION

States	Year	Citation	Good Samaritan	911 as Mitigating	3 rd Party Prescription	Standing Orders	Liability Protections	Naloxone Program	Educational Strategies
# States		20	15	10	14	6	17	9	6
Alaska	2008	Stat.		X					
	2010	12.55.155 AB 2145		,			Х	Х	
California	2012	AB 472	Х				Λ	Λ	
	2013	AB 635			Х	Х	X		
Colorado	2012	SB 12-020	Х						
	2013	SB 13-014			Х		Х		
Connecticut	2011	<u>Public Act</u> <u>No. 11-210</u>	Х						
Connecticut	2012	Public Act No. 12-159					X		
Delaware	2013	SB No. 116	Х						
DC	2013	<u>B19-0754</u>	Χ	X			X		X
Florida	2012	SB No. 278	Χ						
Illinois	2009	Public Act 096-0361			X	X	X	X	X
	2012	Public Act 097-0678	Χ	Χ					
Kentucky	2013	<u>HB 366</u>			Х	Χ	X		
Maryland	2009	<u>Crim. Proc.</u> <u>1-210</u>		Х					
	2013	<u>SB 610</u>			X		X	Χ	
Massachusetts	2012	Ses. Law, Chap. 192, Sects 32 & 11	X	X	X		X		
New Jersey	2013	<u>SB 2082</u>	Χ		X	Χ	X	Χ	X
New Mexico	2001	Stat. Ann. 24- 23-1; NMAC 7.32.7-10					X	Χ	
	2007	<u>SB 0200</u>	Χ	Χ					
	2006	Public Health Law 3309					X	Χ	
New York	2007	Tit. 10, 80.138 (Regulation)			X				
	2011	<u>\$4454-B</u>	Χ	Х					
	2012	<u>A10623</u>							Χ
North Carolina	2013	<u>SB 20</u>	Х		X	Х	Х		
Oklahoma	2013	HB 1782			X				
	2013	HB 1419							Х
Oregon	2013	<u>SB 384</u>			X		X	X	
Rhode Island	2012	H 7248	Х	Х			Х		
Vermont	2013	Act No. 71: Act No. 75	X	X	Χ	X	X	Χ	X
Virginia	2013	HB 1672			Χ		X	X	
Washington	2010	<u>SB 5516</u>	X	X	Х		X		

NOTE: This table provides a general overview of the types of provisions covered by each statute. For more detailed information, please refer to: the legislative text or Davis, C. (2013). Legal interventions to reduce overdose mortality: naloxone access and overdose good Samaritan laws. The Network for Public Health Law. (Additional Resources Section)



Additional Resources

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- FDA PowerPoint on Potential OTC (over the counter) Naloxone (presented at the FDA on April 12, 2012), http://www.fda.gov/drugs/newsEvents/ucm277119.htm
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Endnotes

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