

Best Practices in Naloxone Treatment Programs for Opioid Overdose

Policy Report
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Center for Evidence-based Policy Medicaid Evidence-based Decisions Project (MED)

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Key Findings

Opioid overdose is a leading cause of preventable death in the United States (U.S.). Naloxone is an opioid antagonist which can safely and reliably reverse the respiratory depression associated with opioid overdose and can be administered by bystanders with minimal training. Expanding the availability of naloxone rescue kits to bystanders and first responders is a crucial element of the strategy to reduce opioid overdose deaths. Over the past five years, naloxone treatment programs have grown rapidly. However, challenges remain regarding the interface between public health and Medicaid programs and disparate coverage practices. This report examines naloxone programs in various stages of development in three states and summarizes Medicaid coverage policies in ten states.

Several key findings were identified by staff in preparing this report:

General Considerations:

- Legal protections from civil and criminal liability for those who prescribe or administer naloxone are prerequisites for naloxone distribution. Some states also offer some form of protection from criminal prosecution under controlled substance acts for those who contact emergency services to report an opioid overdose. Third party prescriptions are also permitted by most states with naloxone treatment programs.
- A short training (10 to 20 minutes, various formats) in recognizing the signs of opioid overdose and the use of the naloxone rescue kit appears to be adequate for safe bystander use of the medication. The shorter training curricula can also be delivered to potential naloxone users in a greater diversity of settings, including on the street.
- Access to naloxone rescue kits has traditionally been provided through community distribution sites like needle exchange programs. Pharmacies are increasingly providing naloxone rescue kits, and efforts to streamline prescribing and dispensing, including standing orders and pharmacist prescribing, have improved access through this route.

• Medicaid Coverage Considerations:

Intramuscular and intranasal naloxone are both acceptable delivery routes and are commonly covered by Medicaid programs. The mucosal atomization device needed for intranasal delivery can be covered through a unique National Drug Code, as a durable medical equipment benefit, or by enhanced reimbursement of the naloxone pre-filled syringe. Where the mucosal atomization device is not covered, linking Medicaid naloxone coverage to community partners that

- provide the mucosal atomization device should be considered. The cost of a single mucosal atomization device is generally between \$3 and \$7.
- Eligible provider time spent in counseling or education for naloxone rescue kits can be billed using existing codes for substance abuse screening, brief intervention, and referral for treatment (HCPCS code H0050).
- States may wish to consider allowing public health entities to seek reimbursement for naloxone kits distributed to Medicaid beneficiaries through community naloxone programs, as New Mexico does.
- In states with preexisting public health programs for naloxone distribution, Medicaid beneficiaries have been slow to make use of Medicaid coverage of naloxone through pharmacies, especially when those beneficiaries have previously received naloxone through community sites.
- States may need to collaborate with pharmacies (either through agreements with large pharmacy chains or by targeting pharmacies in areas with large numbers of people at risk for opioid overdose) in order to ensure that naloxone is routinely stocked and available to be dispensed.
- Although there is less evidence and experience to inform these practices, several states have linked naloxone distribution programs to medication assisted substance use treatment programs (i.e. methadone programs) and to re-entry services for people at high-risk for opioid overdose after release from incarceration.
- States generally require prior authorization for EVZIO® due to its high cost relative to other naloxone formulations and usually cover it only when patientspecific circumstances prohibit the use of the other formulations.

Objectives

The objectives of this report are threefold. First, the report will summarize information on community overdose prevention programs using naloxone by examining three exemplary state programs designed to increase the availability and use of naloxone rescue kits. Second, the report will review Medicaid coverage policies in 10 states for naloxone and highlight linkages between community overdose prevention programs and Medicaid policy. Third, the report will review how state statutes regarding criminal and civil liability have changed to encourage the wider use of naloxone treatment for overdose.

Background

Opiates and their synthetic congeners (collectively referred to as opioids), are a group of compounds that bind to opioid receptors throughout the human body. Opioids have been used for centuries for their pain relieving properties, and morphine is included on the List of Essential

Medicines by the World Health Organization. Opioids are also known to reliably produce myriad adverse effects including tolerance, dependence, addiction, respiratory depression, and death.

In 2013, there were more than 24,000 overdose deaths from prescription and illicit opioid drugs in the U.S., an increase of more than 300% since 1999. Among people between the ages of 25 to 64, overdoses are the leading cause of injury deaths, now exceeding traffic fatalities. The societal costs of prescription opioid abuse alone are substantial. A study from 2011 estimated the combined costs of prescription opioid abuse in 2007 at over \$55 billion with one-fifth of that total attributable to premature death (Birnbaum et al., 2011).

Factors associated with an increased risk of opioid overdose include prescribed opioid doses greater than 100 morphine-equivalent milligrams (mg) per day (Bohnert et al., 2011), previous opioid overdose (Darke et al., 2007), concomitant use of opioids and benzodiazepines or alcohol (Gudin, Mogali, Jones, & Comer, 2013), high-risk medication filling behaviors (Baumblatt et al., 2014), and loss of opioid tolerance due to periods of abstinence (i.e. incarceration) (Moller et al., 2010). The presence of adverse social conditions like poverty, unemployment, uninsurance, and illicit drug use are also correlated with an increased risk of opioid overdose-related death (Johnson et al., 2013). Additionally, in a study conducted in Washington, the age-adjusted risk of opioid overdose death was nearly six times greater among Medicaid enrollees compared with those not in enrolled in Medicaid (Coolen, Best, Lima, Sabel, & Paulozzi, 2009).

As efforts to limit the use of prescription opioids for chronic non-cancer pain have gained momentum, the use of heroin has increased nationally. In addition to the rise in fatal overdoses, non-fatal overdoses also appear to be increasing with one study from 2006 estimating that approximately 65% of drug users had witnessed an overdose and approximately 35% had personally experienced an overdose (Lagu, Anderson, & Stein, 2006). The high prevalence of witnessed overdoses suggests a possible role for bystander interventions to prevent overdose deaths.

Naloxone

Naloxone, also commonly known by the trade name Narcan®, is an opioid antagonist that rapidly reverses the effects, including respiratory depression, of opioid drugs by competitively occupying the opioid receptor site. Naloxone has been used in healthcare facilities for decades, and it is increasingly being used in community settings as an antidote to opioid overdoses. A 2015 report by the Centers for Disease Control and Prevention (CDC), estimated that community naloxone programs have distributed more than 150,000 doses of naloxone and have effected over 26,000 overdose reversals.

Naloxone can be administered by multiple routes including intravenously, subcutaneously, intramuscularly, or intranasally. The intranasal route substitutes a mucosal atomization device

(atomizer) for the needle which is required for the other delivery routes. Although intranasal use of naloxone remains an off-label use, a randomized controlled trial comparing intranasal and intramuscular naloxone use concluded that they are similarly effective in treating heroin overdose (Kerr, Kelly, Dietze, Jolley, & Barger, 2009). Intranasal naloxone use has gained wide acceptance and is even considered first-line treatment for opioid overdose in many areas (Doe-Simkins, Walley, Epstein, & Moyer, 2009). One proprietary drug and drug delivery combination, known as EVZIO®, delivers step-by-step instructions (similar to automated external defibrillators) for delivering an intramuscular dose of naloxone using an auto-injector. EVZIO® was approved by the Food and Drug Administration (FDA) in April 2014 (FDA, 2014). The price of the single use EVZIO® device has been reported at about \$350 (Hayes Inc., 2014). By comparison, the current cost of a naloxone 2 mg/2 ml prefilled syringe for intranasal use is estimated at about \$28. This represents an increase of nearly 100% over the 2013 cost, which has led members of Congress to investigate pricing information from the manufacturer, Amphastar Pharmaceuticals, Inc. (Silverman, 2015).

States have developed a variety of programs to encourage the prescribing, distribution, and use of naloxone by laypersons. Many community naloxone programs are affiliated with other harm reduction services like needle exchanges (Piper et al., 2008). Other programs focus on the highrisk period after release from prison (Strang, Bird, & Parmar, 2013). In states where prescription opioid overdoses predominate, county health agencies, nonprofit organizations, and prescribers have developed partnerships to encourage naloxone prescription and education for high-risk patient groups at the point of care (Albert et al., 2011). Finally, several states are encouraging wider distribution of naloxone by revising prescribing laws to allow third-party prescriptions (i.e. prescriptions to those for whom the medication is not necessarily intended for use), collaborative prescribing agreements with standing physician orders to pharmacies, or pharmacists to dispense naloxone without a prescription (Bailey & Wermeling, 2014).

Community naloxone programs operate in a complex legal and regulatory environment. State laws pertaining to the prescribing and use of naloxone have been changing to afford greater civil and criminal liability protection for prescribers and lay people who administer naloxone. Additionally, some states have amended their controlled substance and paraphernalia possession laws to limit or eliminate criminal sanctions for bystanders who render aid to people experiencing an overdose (Davis, Chang, & Carr, 2015). In a survey of opioid users conducted in Washington state after the passage of the "911 Good Samaritan Overdose Law," 88% of respondents indicated that they would be more likely to summon emergency services in an overdose situation because of the legal protection afforded under the law (Banta-Green, Kuszler, Coffin, & Schoeppe, 2011).

As the number of community programs designed to expand the use of naloxone by bystanders has grown, many states have also permitted emergency medical services (EMS) personnel with lower levels of training (i.e. EMS technicians with basic life support certification) to administer naloxone. This is especially important in rural areas where the burden of prescription opioid misuse is high and the availability of EMS personnel with advanced certifications is limited (Davis, Southwell, Niehaus, Walley, & Dailey, 2014). Another approach to expanding the availability and use of naloxone rescue kits has been to train first responders from law enforcement agencies to carry and administer naloxone. Law enforcement training and participation has been a centerpiece of Massachusetts' efforts to decrease opioid overdose deaths, and the U.S. Department of Justice announced a plan for some federal law enforcement officers to begin carrying naloxone in July 2014 (Department of Justice, 2014).

Effectiveness and Safety of Naloxone Distribution Programs

Naloxone distribution programs appear to be safe and effective, though the evidence is limited due to the lack of data from randomized trials. An analysis of data from the Drug Overdose Prevention and Education Project in San Francisco, one of the first naloxone prescription program in the U.S., found that between September 2003 and December 2009 naloxone was used to reverse nearly 400 overdose events with a 90% success rate and a negligible rate of serious adverse events (Enteen et al., 2010). A more recent interrupted time series study from Massachusetts examined the effects of an Overdose Education and Naloxone Distribution (OEND) program by comparing overdose death rates in counties with variable rates of OEND program uptake (Walley, Xuan, et al., 2013). The authors concluded that communities with higher rates of OEND implementation had lower rates of opioid overdose death.

A recent systematic review of community opioid overdose prevention and naloxone distribution programs concluded that "bystanders (mostly opioid users) can and will use naloxone to reverse opioid overdoses when properly trained..." (Clark, Wilder, & Winstanley, 2014, p. 153). Similarly, a systematic review of take-home naloxone programs conducted by the European Monitoring Centre for Drugs and Drug Addiction (2015) concluded that take-home naloxone programs reduce overdose-related deaths. Additionally, a recent cost-effectiveness analysis showed that distribution of naloxone to heroin users appears to be cost-effective across a wide range of assumptions and well below broadly accepted willingness-to-pay thresholds (Coffin & Sullivan, 2013).

The Substance Abuse and Mental Health Services Administration (SAMHSA) of the U.S. Department of Health & Human Services has endorsed expanding community availability of naloxone (SAMHSA, 2013). Community naloxone programs are also supported by the American Society of Addiction Medicine (2014) and the American Medical Association (2012).

Report Approach

Center for Evidence-based Policy (Center) staff conducted interviews with representatives of naloxone treatment programs in three states: New Mexico, Massachusetts, and Vermont. These states were selected to capture information about naloxone programs in various stages of development. The interview guide and detailed information about the contacts in each state are available in Appendix A. Except where otherwise cited, the information presented in the case studies was obtained in the course of these interviews.

For state-specific policy, a search of state websites, provider manuals, and relevant laws and regulations was conducted for the following states: California, Maryland, Massachusetts, Minnesota, New Mexico, New York, North Carolina, Rhode Island, Vermont, and Washington. In some cases, Center staff also contacted state pharmacy program staff to clarify areas of uncertainty in the coverage provisions.

In addition, a comprehensive Google search was conducted using the terms "naloxone Medicaid coverage," "naloxone rescue programs," "opioid antagonist Medicaid coverage," and "opioid antagonist programs" to identify relevant literature, clinical guidelines, policy briefs, press releases, and media reports. Reference lists from key sources were reviewed.

State Case Studies

New Mexico

The first naloxone treatment programs in New Mexico were established in 2001 after state law was changed to permit third-party prescriptions and to protect prescribers and users from civil and criminal liability. At the same time, New Mexico also became the first state to permit naloxone administration by all levels of EMS responders. The original naloxone programs were coordinated through existing community needle exchange programs and included three hours of training on recognizing signs of opioid overdose and the proper assembly and use of intranasal naloxone for reversal. New Mexico Department of Health (NMDOH) staff estimates that approximately 50 people were trained each year in the initial programs. In 2004, in order to reach more people, the training was shortened to 15 to 20 minutes and was modified so that it could be delivered outside a classroom environment (i.e. on the street).

In 2013, New Mexico further expanded their efforts by allowing pharmacist dispensing of naloxone rescue kits without a prescription. Participating pharmacists must complete a prescriptive authority training certification and complete two hours of continuing education on this topic every two years. New Mexico developed patient screening criteria to establish an increased risk of overdose (Appendix D), although naloxone dispensing is ultimately left to the

discretion of the pharmacist. Pharmacists must obtain and document the recipient's informed consent for providing the naloxone rescue kit (the New Mexico Pharmacists Association form is included in Appendix E), and the pharmacist should notify the recipient's primary care provider (when feasible) within 15 days of the original prescription. Finally, the state asks pharmacists to complete a naloxone prescription reporting form (Appendix F) to help track the initial prescription, use, and refill of naloxone rescue kits.

The standard naloxone rescue kit used in New Mexico contains two 2 mg/2 ml prefilled syringes, two mucosal atomization devices, and overdose prevention education materials. The New Mexico Medicaid program (both through its fee-for-service and managed care organizations) reimburses pharmacies for the naloxone rescue kit and for the pharmacist's time spent training rescue kit recipients. Medicaid claims for naloxone rescue kits are submitted under NDC 76329-3369-01 (naloxone pre-filled syringe) which authorizes an additional dispensing fee to account for the cost of the atomizer, educational materials, and training. In addition, when a Medicaid beneficiary receives a naloxone rescue kit through a community-based distribution program, that information is provided to the NMDOH which is then able to seek reimbursement from New Mexico Medicaid.

New Mexico currently has four co-prescription pilot projects operating in Taos, Santa Fe, Roswell, and Albuquerque. In these co-prescription programs, providers identify patients at high-risk for opioid overdose and provide an internal referral for overdose prevention education and provision of a naloxone rescue kit (filled at the participating clinic or at a partner pharmacy in the community). Additionally, the University of New Mexico School of Medicine chronic pain clinic is currently engaged in a study offering naloxone rescue kits to all patients on opioid therapy without overdose risk screening. The co-prescription pilot sites have worked closely with healthcare licensing boards, medical societies and professional organizations, and large medical groups to encourage co-prescribing of naloxone with opioids.

New Mexico is also seeking to expand naloxone access through law enforcement first responders in a pilot program that is operating in municipal police departments in Española and Santa Fe, as well as the Santa Fe County Sheriff's office. After completing a brief training course focused on recognizing the signs and symptoms of opioid overdose, the officers are provided with intranasal naloxone rescue kits.

A final pilot project involving community distribution of EVZIO® from a single community site is also underway. This program is being funded by kaléo®, the manufacturer of EVZIO®.

The NMDOH Hepatitis and Harm Reduction Program presented preliminary data to state stakeholders regarding the naloxone overdose prevention program in 2015 (Swatek, 2015 [unpublished]). Between 2011 and 2014, there were approximately 4,700 enrollments, over

13,000 distributed naloxone doses, 2,900 records of naloxone use, and 2,138 instances in which the naloxone recipient was reported to be "okay" on the record of use. Among the key findings was a decrease in the overdose mortality rate from a peak of 25 per 100,000 in 2008 to 21 per 100,000 in 2013.

The NMDOH staff emphasized that Medicaid coverage and consolidated reimbursement for the components of the naloxone rescue kit and brief training performed by pharmacists was one of the keys to the program's success. They highlighted that reimbursement for Medicaid beneficiaries has allowed them to spend additional public health and private funds on reaching other groups of patients that may not be eligible for Medicaid coverage (e.g., undocumented immigrants). Agency staff also reported that the development of shorter training sessions allowed them to reach more potential naloxone users while simultaneously conveying the simplicity and ease of use of intranasal naloxone.

The NMDOH staff identified several barriers to expanding naloxone distribution in their model. First, they noted that relatively few pharmacies have elected to participate in the pharmacist dispensing program. The NMDOH staff estimated that fewer than 10 pharmacies have enrolled in the program and fewer than 50 pharmacists have received the training. The reasons for lagging enrollment are unclear. The NMDOH is working with large chain pharmacies to try to expand access. Finally, NMDOH staff cited a lack of awareness about naloxone among patients and providers and a more general absence of public concern over opioid overdose deaths as additional barriers to wider distribution and use.

Massachusetts

The first naloxone treatment programs in Massachusetts were established in 2006 when the Boston Public Health Commission authorized naloxone distribution through mobile needle exchange programs. The Massachusetts Department of Health expanded naloxone treatment programs in 2007 with the creation of the OEND program. In addition to overdose prevention education and referral to substance abuse treatment services, the OEND program provides free intranasal naloxone rescue kits to potential opioid overdose bystanders (individuals most likely to witness an overdose). Initial pilot programs were authorized under Massachusetts Drug Control Program regulations. The OEND medical director issued a standing order for naloxone distribution to potential bystanders, thus bypassing the need for traditional prescriptions.

In 2010, based on experience with intranasal naloxone administration at the community level, the Massachusetts Department of Health began piloting programs to allow first responders (EMS, police, and fire departments) to carry and administer naloxone rescue kits. In 2012, state law was changed to allow third-party prescriptions and to protect prescribers and users from criminal liability. This favorable legal environment allowed for further expansion of both

bystander and first-responder pilot programs, as well as naloxone prescribing through traditional routes with distribution by pharmacists.

In 2014, Massachusetts Governor Deval Patrick declared opioid overdoses a public health emergency. As a result, the fiscal year 2015 Massachusetts state budget included a \$1 million appropriation for communities to administer naloxone treatment programs and purchase naloxone rescue kits. Regulatory restrictions on first-responder programs were also reduced. Prior to the FY2015 appropriation, the OEND program supported 31 bystander distribution sites and five first-responder pilot programs. The additional funding was accompanied by a mandate to expand the OEND program by at least seven new bystander distribution sites and 10 first-responder pilot programs.

In addition to needle exchange programs, training sites now include human immunodeficiency virus (HIV) education drop-in centers, addiction treatment programs, emergency and primary healthcare settings, and community support groups. Trainers with the OEND program complete a four-hour course with a knowledge test and train two bystanders while being supervised by a master trainer. These OEND trainers then train naloxone treatment program participants in 10 to 60 minutes, depending on the knowledge base and needs of the participant. The standard naloxone rescue kit used in Massachusetts contains two 2 mg/2 ml prefilled syringes, two mucosal atomization devices, and instructions. The OEND program uses a standard reporting form for community partners to provide feedback regarding naloxone distribution and reported overdose reversals.

Since creation of the OEND program, Amphastar Pharmaceuticals, Inc., the sole manufacturer of the naloxone formulation for intranasal use, has increased the price of the naloxone rescue kit from approximately \$30 to \$75. The Massachusetts Department of Health pays the cost of these kits when they are distributed by OEND programs. In 2014, kaléo® donated 2,000 cartons of EVZIO® (equivalent to 4,000 naloxone doses) to the OEND program. Donated EVZIO® was distributed among first-responder pilot sites in order to offset the cost of purchasing standard naloxone rescue kits.

Pharmacies with established standing orders for naloxone are permitted to prescribe and distribute naloxone rescue kits without traditional prescriptions. Several pharmacies have also partnered with substance use treatment programs to improve naloxone access. Naloxone rescue kits are reimbursed by the Massachusetts Medicaid program without refill limits. Medicaid claims for naloxone are submitted under NDC 76329-3369-1 (naloxone pre-filled syringe). Individuals who receive a naloxone rescue kit from a pharmacy may be subject to a copay depending on their health insurance and are typically responsible for the cost of the atomization device (generally between \$3 to \$7). Pharmacists are not separately reimbursed for time spent training recipients on use of the kit.

As of January 2015, the OEND program had provided 31,827 individuals with training and naloxone rescue kits resulting in 4,033 reported overdose reversals. An early study of the OEND program found that in 19 Massachusetts communities with at least five fatal opioid overdoses between 2004 to 2006, communities with access to OEND programs from 2006 to 2009 had significantly reduced opioid overdose death rates compared to communities where OEND programs were not implemented (Walley, Doe-Simkins, et al., 2013).

The OEND program staff attributes the success of the program to the support of Massachusetts policymakers, as well as key partnerships with community-based organizations. In particular, the Massachusetts Department of Health has partnered with Learn to Cope, an advocacy organization for families dealing with addiction. Learn to Cope family support meetings account for more than a third of the OEND program's bystander distribution sites.

Demand for training and free naloxone rescue kits at both the community and first-responder level now exceeds supply. The OEND program is attempting to increase naloxone distribution by pharmacies as a means of shifting some of the costs to the Medicaid program. The OEND program staff note that a barrier to broader naloxone distribution by pharmacies has been the expectation on the part of naloxone users that rescue kits are provided for free through community-based programs rather than through traditional provider venues. This aspect of the Massachusetts experience highlights one of the challenges of expanding naloxone treatment programs beyond a public health model.

Vermont

Compared with the well-established programs in New Mexico and Massachusetts, the Vermont naloxone distribution program is relatively new. However, several features of the Vermont program, including its community partnerships and novel funding mechanism, warrant mention.

In 2013, the Vermont legislature adopted a naloxone statute that permitted third-party prescriptions, established civil and criminal liability protections, and mandated the development of a statewide opioid antagonist pilot program. The naloxone pilot program is administered through the Vermont Department of Health Division of Alcohol and Drug Abuse Programs. In the pilot phase, they are focusing on three types of sites for distribution: needle exchanges, medication-assisted treatment programs for substance abuse, and substance abuse recovery centers. Naloxone rescue kits, consisting of two prefilled 2 mg/2 ml syringes, two mucosal atomization devices, and instructions for use (adapted from materials produced by the Harm Reduction Coalition) are now being distributed by eight community partners throughout the state that act as "regional treatment hubs." The program is funded through the Vermont Evidence-based Education and Advertising Fund. This special fund was established by statute in 2007 as a source of financing for projects related to surveillance of pharmaceutical marketing

activities, the state prescription drug monitoring database, evidence-based education for providers, and opioid antagonist education and distribution. The revenue for this fund is derived primarily from a pharmaceutical manufacturer fee that is based on volume of sales, but also through grants and contributions.

In addition to the community distribution efforts, the Vermont board of pharmacy has recently promulgated rules and regulation which will allow pharmacist dispensing protocols for naloxone without a provider prescription. However, a prescription is still required for Medicaid coverage of the dispensed naloxone rescue kit. Staff at the Department of Health noted that the issues related to low-volume of prescribing and the shelf-life of the products are major barriers to increasing access. Staff at the Department of Health are planning to focus on a small number of pharmacies in high-impact areas that expect to dispense greater numbers of naloxone rescue kits.

Additional measures in Vermont have included expanded training and availability of naloxone rescue kits with EMS first responders, prescriber education on both chronic opioid therapy and the role of naloxone rescue kits for high-risk patients, and a statutory requirement that providers refer all patients who have been administered naloxone to substance abuse treatment services.

Based on preliminary data from December 2013 to April 2015 released by the Vermont Department of Health (2015), more than 2,000 naloxone rescue kits have been distributed. More than 800 of those kits have been provided as refills with reports that 204 of the kits were used on 146 unique people experiencing an overdose. The remaining kits were thought to be lost or stolen. The vast majority of the kits were used in the setting of heroin overdose, and a call to 911 was placed in fewer than one-third of cases.

State Naloxone Policy

The state policy environment is crucial to the creation and success of naloxone treatment programs. At the statutory level, civil and criminal liability protections for those who prescribe and administer naloxone are essential. In addition, legislation or regulatory changes to streamline the prescribing and dispensing of naloxone rescue kits through standing orders with collaborative practice agreements or by permitting pharmacists to dispense the kits at their discretion have been an important development in expanding the availability of naloxone. Statues or regulation to expand the use of naloxone rescue kits to all levels of EMS providers and other first responders (police and firefighters) have become common. The relevant statutes from the included states are detailed in Appendix C.

State Medicaid programs vary widely with regard to coverage of naloxone and the other components of the rescue kits. Some states cover all three formulations of naloxone

(intramuscular, intranasal, and auto-injector), while others cover one or two formulations. Although it is not FDA-approved for intranasal use, the 2 mg/2ml prefilled syringe for use with a mucosal atomization device for intranasal delivery is commonly covered. Where the auto-injector (EVZIO®) is covered by Medicaid, a prior authorization is generally required to document that the beneficiary has physical or cognitive impairments that would prevent the use of the less expensive intramuscular or intranasal formulations.

Medicaid programs have taken a variety of approaches to coverage of the mucosal atomization device. Some states do not cover the device, and the modest cost (\$3 to \$7) for it is borne by the pharmacy or the patient. New Mexico, Massachusetts, and other states provide enhanced reimbursement for claims for naloxone that are intended to account for the cost of the mucosal atomization device to the pharmacy. Minnesota has assigned a National Drug Code to the mucosal atomization device, while Maryland and California both provide coverage under level 2 Healthcare Common Procedure Coding System (HCPCS) codes. Finally, both California and North Carolina have collaborative programs in which the Medicaid program covers naloxone for beneficiaries while the mucosal atomization device is purchased with public health or private funds and distributed by community partners.

In states with both fee-for-service and managed care Medicaid, naloxone coverage is generally required within both programs, though California and Maryland have notably carved-out this benefit for coverage in their fee-for-service programs.

A variety of freely available educational modules on recognizing opioid overdose and administering naloxone exist, and many of these resources are used by state naloxone programs. One commonly used tool, prescribetoprevent.org, is an online resource created by overdose prevention researchers and advocates that includes educational modules for prescribers, pharmacists, and patients. In some states, provider or pharmacist time devoted to educating patients on the use of naloxone can be billed under the HCPCS code (H0050) that is used for screening, brief intervention, and referral to treatment (SBIRT) after a drug abuse screening test (i.e. DAST-10) is performed. Alternatively, enhancing reimbursements for naloxone National Drug Codes is another approach to reimbursing providers for time spent educating patients on the use of the naloxone rescue kit.

While Center staff did not identify any specific Medicaid policies linking naloxone distribution to methadone maintenance programs or medication assisted therapy programs, public health efforts in several states including Vermont and Massachusetts have focused on these sites in addition to traditional harm reduction venues like needle exchanges. Similarly, Center staff did not identify mandatory naloxone co-prescribing requirements for those at increased risk of overdose from prescribed opioids, though several states have encouraged co-prescribing

through smaller pilot programs and collaboration with local professional boards to educate providers about the availability of naloxone rescue kits.

Naloxone distribution programs in many states are supported through a combination of public health and Medicaid funds, but there are few linkages between these programs. Among the states included in this report, only New Mexico has a mechanism in which naloxone kits distributed to Medicaid beneficiaries by community partners (i.e. outside the usual pharmacy dispensing route) can be paid as claims to the New Mexico Department of Health, and these funds are then used to purchase more naloxone rescue kits for the community distribution sites. The other linkage staff identified relates to the separate provision of the naloxone prefilled syringes and the mucosal atomization device. Project Lazarus in North Carolina and certain municipalities in California purchase and distribute the mucosal atomization device to Medicaid beneficiaries who have obtained the drug through their pharmacy benefit.

The Medicaid policies of the ten included states are detailed in Appendix B.

Conclusions

In the U.S., opioid overdose is a leading cause of preventable death. Programs to encourage the wider distribution and use of naloxone are growing and these programs show promise in reducing opioid overdose deaths. Naloxone rescue programs have been enabled by changes in state laws that afford legal protections to those who prescribe and administer naloxone. Additional changes to limit the criminal liability under controlled substances laws for those who render aid and contact emergency services are also common. However, challenges remain regarding the interface between public health and Medicaid programs and disparate coverage practices.

Among the best practices that states may wish to consider in naloxone programs are:

- Shortening training programs for bystanders and providing this training in nontraditional venues may increase the number of people able and willing to use a naloxone rescue kit in an overdose situation.
- Both intramuscular and intranasal naloxone are acceptable delivery routes for trained bystanders. Ensuring the availability of mucosal atomization devices to enable intranasal use can be achieved through Medicaid coverage or through partnerships with community naloxone programs.
- Collaboration between public health agencies, community distribution sites, Medicaid programs, and local pharmacies can help to improve access to naloxone rescue kits.

- Allowing public health entities to seek reimbursement for naloxone kits distributed to Medicaid beneficiaries through community naloxone programs (as New Mexico does) may promote the sustainability and growth of these community programs.
- Although there is less evidence and experience to inform these practices, several states have linked naloxone distribution programs to medication assisted substance abuse treatment programs (i.e. methadone programs) and to re-entry services to people at high-risk for opioid overdose after release from incarceration.

In conclusion, wider availability of naloxone is likely to reduce the number of opioid overdose deaths and state laws and policies to encourage its distribution and use are essential.

Appendix A: Structured Interview Guide and Interview Contacts

Structured Interview Guide

What is the state's approach to increasing naloxone availability and use?

- 1. Pharmacist prescribing?
 - a. Special training or certification?
 - b. Number/proportion of participating pharmacies?
- 2. Collaborative prescribing agreements?
- 3. Community distribution?
 - a. What locations?
- 4. Training/education requirements for patients/family
- 5. Funding sources

How has the state Medicaid agency supported this program through coverage/reimbursement policy or other means?

- 1. Naloxone coverage? Preferred Drug List status?
- 2. Delivery devices and supplies? EVZIO®?
- 3. Prior authorization? Criteria?
- 4. Refill limits?
- 5. Annual limits?
- 6. Co-pays?
- 7. Differences between fee-for-service and managed care?

How could the state Medicaid agency better support the naloxone distribution program?

How has the state changed the legal context regarding the use of naloxone?

- 1. Third-party prescriptions?
- 2. Civil and criminal liability protections?
- 3. Controlled substance and paraphernalia statutes?

Has the state made any changes to emergency medical services policy with respect to what level of provider may administer naloxone?

In creating the naloxone distribution program what were the barriers to implementation and adoption? What helped facilitate implementation and adoption?

How would you characterize the effects of the program? What are the perceived successes or failures to date?

What advice would you give to other states looking at expanding naloxone availability?

Interview Contacts

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Appendix B: Medicaid Naloxone Coverage Provisions in Selected States

California

Formulation and delivery	Naloxone available as
	 0.4mg/1ml IM injection 2mg/2ml prefilled syringe with mucosal atomizer device (MAD) nasal adapter 0.4mg auto-injector (EVZIO®)
Take-home naloxone permitted	Yes
Prior authorization	Not required with the exception of EVZIO® which requires a treatment authorization request
	Claims for mucosal atomizer device (MAD) nasal adapter require an approved Treatment Authorization Request or Service Authorization Request justifying the medical necessity for the use of the FDA unapproved route of administration. The device must be billed as a miscellaneous medical supply using HCPCS code T5999 (supply, not otherwise specified). Claims require documentation of product cost (an invoice, manufacturer's catalog page or price list), as an attachment to the claim, for reimbursement.
Number of refills	No limit noted
Prescriber requirements	None identified
	California law permits pharmacist dispensing
Linkages to methadone programs	No information found
Relevant HCPCS Level 2 Codes	J2310: Naloxone HCl injection per 1 mg
	H0050: Alcohol and/or drug services, brief intervention, per 15 minutes
NDC code(s) (pharmacy benefit) -	Intramuscular: Hospira NDC 00409-1215-01, Mylan NDC 67457-292-00 Intranasal: Amphastar NDC 76329-3369-01 Auto-injector (Evzio): NDC 60842-030-01
Co-pay	No information found
Notes	Naloxone and associated supplies are carved-out and all claims are submitted to the Medi-Cal fee-for-service program. Some municipalities purchase and provide atomizers.

Maryland

Formulation and delivery	Naloxone available as:
	 0.4mg/1ml vial for IM use with 3 ml syringes and 23 gauge 1 inch needles 2mg/2ml prefilled syringe with mucosal atomizer device (MAD) nasal adapter 0.4 mg auto-injector (EVZIO®)
Take-home naloxone permitted	Yes
Prior authorization	Not required with the exception of EVZIO® which requires PA documenting why generic naloxone cannot be used
Number of refills	No limit noted
Prescriber requirements	None noted
Linkages to methadone programs	No information found
Relevant HCPCS Level 2 Codes	A4208: Syringe w/ needle, 3 cc
	A4210: Needle free injection device used for Narcan/Naloxone
	H0050: Alcohol and/or drug services, brief intervention, per 15 minutes
NDC code(s) (pharmacy benefit) -	Intramuscular: Hospira NDC 00409-1215-01, Mylan NDC 67457-292- 00, Hospira NDC 0409-1782-69
	Intranasal: Amphastar NDC 76329-3369-01
	Auto-injector (Evzio): NDC 60842-030-01
Со-рау	\$1 co-pay for naloxone; however Maryland regulations state that pharmacies may not deny service if beneficiaries are unable to pay the co-pay
Notes	Claims for the associated equipment (syringe and needle for IM delivery and atomizer device for IN delivery) are covered under the durable medical supplies benefit. Both the medications and the DME have been carved-out and all claims are submitted to the Medicaid fee-for service program

Massachusetts

Formulation and delivery	Naloxone available as:
Take-home naloxone permitted	Yes
Prior authorization	Not required except for EVZIO®
Number of refills	No limit
Prescriber requirements	None noted
Linkages to methadone programs	No information found
Relevant HCPCS Level 2 Codes	No information found
NDC code(s) (pharmacy benefit) -	Intranasal: Amphastar NDC 76329-3369-01
Co-pay	MassHealth has a tiered co-payment system with most generic medications having a co-pay of \$3.65 with a \$250 annual co-pay cap. The co-pay does not apply to certain groups including: age <19 years, pregnancy, and hospice. Additionally, pharmacies cannot refuse service to members who cannot pay the co-pay.
Notes	MassHealth provides an enhanced reimbursement for naloxone claims in order to defray the cost of the atomizer (Taglieri, 2014).

Minnesota

Formulation and delivery	Naloxone available as
	 2mg/2mL Naloxone prefilled syringe for intranasal use with the LMA mucosal atomization device 0.4mg auto-injector (EVZIO®)
Take-home naloxone permitted	Yes
Prior authorization	Not required for the components of the intranasal naloxone rescue kit
	PA is required for Evzio with the following criteria:
	 Patient has a diagnosis of opiate dependency or addiction, and
	 Prescriber provides detailed reasoning why the standard intranasal naloxone rescue kit cannot be used
Number of refills	Quantity limit of two syringes (2 mL each) and two nasal mucosal atomization devices; no limit on refills noted
Prescriber requirements	Basic patient education and counseling is required
Linkages to methadone programs	No information found
Relevant HCPCS Level 2 Codes	No information found
NDC code(s) (pharmacy benefit)	Intranasal:
	2mg/2mL naloxone syringe: NDC 76329-3369-01
	LMA MAD Nasal Mucosal Atomization Device without syringe: NDC 00042-2718-02
Co-pay	No information found
Notes	Minnesota has assigned an NDC code to the mucosal atomization device to allow coverage.

New Mexico

Formulation and delivery	Naloxone available as:
	 2mg/2mL prefilled syringe for intranasal use with one of two commercially available atomizers
Take-home naloxone permitted	Yes
Prior authorization	Not required with the exception of EVZIO® which requires PA with the following criteria: • Diagnosis of opioid overdose prevention/reversal; and
	 Medical necessity for the auto-injection formulation as noted by one of the following as it pertains to the caregiver: Physical disability; or Visual impairment; or Cognitive impairment; and Request is for ≤ 1 auto-injection
Number of refills	No limit noted
Prescriber requirements	None noted
Linkages to methadone programs	No information found
Relevant HCPCS Level 2 Codes	None identified
NDC code(s) (pharmacy benefit) -	Intranasal: Amphastar NDC 76329-3369-01
	Auto-injector (EVZIO®): NDC 60842-030-01
Co-pay	There are no co-pays for generic drugs in the standard Medicaid benefit package. Beneficiaries in the alternative benefit plan (i.e. those between 101%-138% of the federal poverty level) have a copay of \$3 per drug with a number of exempted groups or categories.
Notes	All components of the naloxone rescue kit are covered under a single reimbursement and paid at a rate of \$40 (New Mexico Department of Human Services, 2014). This coverage is mandated in both the fee-for-service and managed care programs.

New York

Formulation and delivery	Naloxone available as:
	0.4 mg/ml vial
	0.4 mg/ml syringe
Take-home naloxone permitted	Yes
Prior authorization	Not required with the exception of EVZIO® which requires PA
Number of refills	Quantity limit of 2 single-use vials or pre-filled syringes
	5 refills per 6 months
Prescriber requirements	No – dispensed pursuant to prescription
Linkages to methadone programs	No information found
Relevant HCPCS Level 2 Codes	None identified
NDC code(s) (pharmacy benefit) -	Intramuscular:
	Hospira NDC 00409-1782-69
	Hospira NDC 00409-1215-01
	Hospira/Nova+ NDC 00409-1215-25
	Mylan NDC 67457-0292-00
	Mylan NDC 67457-0292-02
	Mylan NDC 67457-0599-00
	Mylan NDC 67457-0599-02
Со-рау	The standard generic drug co-pay of \$1 applies.
Notes	New York Medicaid covers parenteral preparations of naloxone for intramuscular use. EVZIO® is listed as requiring PA on the preferred drug list, but clinical criteria are not provided.

North Carolina

Formulation and delivery	Naloxone available as:
	 0.4mg/1ml vial for IM injection with 3 ml syringes and 23 gauge 1 inch needles 2mg/2ml prefilled syringe with mucosal atomizer device (MAD) nasal adapter
Take-home naloxone permitted	Yes
Prior authorization	Not required
Number of refills	No limit noted
Prescriber requirements	Patients should be shown a 20 minute educational video on recognizing opioid overdose and using the naloxone rescue kit
Linkages to methadone programs	No information found
Relevant HCPCS Level 2 Codes	None identified
NDC code(s) (pharmacy benefit) -	Intramuscular: Hospira NDC 00409-1215-01
	Intranasal: Amphastar NDC 76329-3369-01
Со-рау	There is a standard drug co-pay of \$3 for members age 21 and older
Notes	Patients can obtain the nasal atomizer through a collaboration with Project Lazarus. The Project Lazarus rescue kits contain 2 atomizers, step-by-step instructions in English and Spanish, and an overdose prevention DVD. The project is funded by the Kate B. Reynold Charitable Trust and the North Carolina Office of Rural Health and Community Care

Rhode Island

Formulation and delivery	Naloxone available as:
	 2mg/2mL prefilled syringe for intranasal use
Take-home naloxone permitted	Yes
Prior authorization	Not required
Number of refills	All prescriptions in the fee-for-service program are limited to 5 refills before a new prescription is needed
Prescriber requirements	None noted
Linkages to methadone programs	No information found
Relevant HCPCS Level 2 Codes	J2310: Naloxone HCl injection per 1 mg
NDC code(s) (pharmacy benefit) -	Intranasal: Amphastar NDC 76329-3369-01
Со-рау	There is no co-pay.
Notes	Through a collaborative prescribing agreement, CVS and Walgreens pharmacies are able to dispense naloxone rescue kits without a prescription (Borg, 2014).

Vermont

Formulation and delivery	Naloxone available as:
	 2 mg/2 ml prefilled syringe
	 0.4mg auto-injector (EVZIO®)
Take-home naloxone permitted	Yes
Prior authorization	EVZIO® requires prior authorization.
Number of refills	No limit noted
Prescriber requirements	None noted
Linkages to methadone programs	Naloxone distribution has been linked to medication assisted therapy through the regional hubs established by the Vermont Department of Health.
Relevant HCPCS Level 2 Codes	No information found
NDC code(s) (pharmacy benefit) -	Intranasal: Amphastar NDC 76329-3369-01
Со-рау	The standard copay of \$1 for drugs that cost less than \$30 applies.
Notes	Vermont Medicaid covers purchase of the prefilled 2 mg/2 ml syringe. The mucosal atomization device is not covered but is distributed by community partners.

Washington

Formulation and delivery	Naloxone available as: • 2 mg/2 ml prefilled syringe
	0.4 mg/ml vial
	0.4 mg/ml syringe
Take-home naloxone permitted	Yes
Prior authorization	No PA for 1 st fill through the pharmacy point-of-sale system with 365 days, if requested a 2 nd time within 365 days of the first fill the 2 nd fill will require PA
Number of refills	Limited to one refill (without seeing physician or pharmacist again)
Prescriber requirements	None noted
Linkages to methadone programs	No information found
Relevant HCPCS Level 2 Codes	J2310: Naloxone HCl injection per 1 mg
NDC code(s) (pharmacy benefit) -	Intramuscular:
	Hospira NDC 00409-1782-69
	Hospira NDC 00409-1215-01
	Hospira/Nova+ NDC 00409-1215-25
	Mylan NDC 67457-0292-00
	Mylan NDC 67457-0292-02
	Mylan NDC 67457-0599-00
	Mylan NDC 67457-0599-02
	Dispensing Solutions NDC 55045-3515-01
	Physician Total Care Inc NDC 54868-2062-0
	Intranasal:
	Amphastar NDC 76329-3369-01
	International Medical Systems NDC 76329-1469-1
Со-рау	There is no co-pay required.
Notes	Washington allows "collaborative practice" model in which pharmacists may directly dispense take-home naloxone so that patients may obtain it without a visit to a physician.

Appendix C: Relevant Opioid Antagonist Statutes

State	Relevant Opioid Antagonist Statutes
California	Excerpted from California Codes (2014)

liable in a civil action, or be subject to criminal prosecution for this administration.

Section 1797.170 of the Health and Safety Code

- (a) The authority shall develop and, after approval by the commission pursuant to Section 1799.50, adopt regulations for the training and scope of practice for EMT-I certification.
- (b) Any individual certified as an EMT-I pursuant to this division shall be recognized as an EMT-I on a statewide basis, and recertification shall be based on statewide standards.
- (c) Effective July 1, 1990, any individual certified as an EMT-I pursuant to this act shall complete a course of training on the nature of sudden infant death syndrome which is developed by the California SIDS program in the State Department of Public Health in consultation with experts in the field of sudden infant death syndrome.
- (d) On or before July 1, 2016, the authority shall develop and, after approval by the commission pursuant to Section 1799.50, adopt regulations to include the administration of naloxone hydrochloride in the training and scope of practice of EMT-I certification. These regulations shall be substantially similar to existing regulations set forth in Chapter 3 (commencing with Section 100101) of Division 9 of Title 22 of the California Code of Regulations that authorize an EMT-I to receive EMT-II training in the administration of naloxone hydrochloride without having to complete the entire EMT-II certification course. This subdivision shall be implemented in accordance with Chapter 5 (commencing with Section 1798).

1797.197 of the Health and Safety Code

- (a) The authority shall establish training and standards for all prehospital emergency medical care personnel, as defined in paragraph (2) of subdivision (a) of Section 1797.189, regarding the characteristics and method of assessment and treatment of anaphylactic reactions and the use of epinephrine. The authority shall promulgate regulations regarding these matters for use by all prehospital emergency medical care personnel.
- (b) (1) The authority shall develop and, after approval by the commission pursuant to Section 1799.50, adopt training and standards for all prehospital emergency medical care personnel, as defined in paragraph (2) of subdivision (a) of Section 1797.189, regarding the use and administration of naloxone hydrochloride and other opioid antagonists. The authority shall promulgate regulations regarding these matters for use by all prehospital emergency medical care personnel. The authority may adopt existing training and standards for prehospital emergency medical care personnel regarding the statewide use and administration of naloxone hydrochloride or another opioid antagonist to satisfy the requirements of this section.
- (2) The medical director of a local EMS agency may, pursuant to Section 1797.221, approve or conduct a trial study of the use and administration of naloxone hydrochloride or other opioid antagonists by any level of prehospital emergency medical care personnel. Training received by prehospital emergency medical care personnel specific to the use and administration of naloxone hydrochloride or another opioid antagonist during this trial study may be used towards satisfying the training requirements established pursuant to paragraph (1) regarding the use and administration of naloxone hydrochloride and other opioid antagonists by prehospital emergency medical care personnel.

(3) The training described in paragraphs (1) and (2) shall satisfy the requirements of paragraph (1) of subdivision (d) of Section 1714.22 of the Civil Code.

Section 4052.01 of the Business and Professions Code

- (a) Notwithstanding any other provision of law, a pharmacist may furnish naloxone hydrochloride in accordance with standardized procedures or protocols developed and approved by both the board and the Medical Board of California, in consultation with the California Society of Addiction Medicine, the California Pharmacists Association, and other appropriate entities. In developing those standardized procedures or protocols, the board and the Medical Board of California shall include the following:
- (1) Procedures to ensure education of the person to whom the drug is furnished, including, but not limited to, opioid overdose prevention, recognition, and response, safe administration of naloxone hydrochloride, potential side effects or adverse events, and the imperative to seek emergency medical care for the patient.
- (2) Procedures to ensure the education of the person to whom the drug is furnished regarding the availability of drug treatment programs.
- (3) Procedures for the notification of the patient's primary care provider with patient consent of any drugs or devices furnished to the patient, or entry of appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider, and with patient consent.
- (b) A pharmacist furnishing naloxone hydrochloride pursuant to this section shall not permit the person to whom the drug is furnished to waive the consultation required by the board and the Medical Board of California.
- (c) Prior to performing a procedure authorized under this section, a pharmacist shall complete a training program on the use of opioid antagonists that consists of at least one hour of approved continuing education on the use of naloxone hydrochloride.
- (d) The board and the Medical Board of California are each authorized to ensure compliance with this section. Each board is specifically charged with enforcing this section with respect to its respective licensees. This section does not expand the authority of a pharmacist to prescribe any prescription medication.
- (e) The board may adopt emergency regulations to establish the standardized procedures or protocols. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The emergency regulations authorized by this subdivision are exempt from review by the Office of Administrative Law. The emergency regulations authorized by this subdivision shall be submitted to the Office of Administrative Law for filing with the Secretary of State and shall remain in effect until the earlier of 180 days following their effective date or the effective date of regulations adopted pursuant to subdivision (a).

Maryland

Excerpted from Maryland Statutes (2013)

§13–3101. (a) In this subtitle the following words have the meanings indicated. (b) "Certificate" means a certificate issued by a private or public entity to administer naloxone. (c) "Private or public entity" means a health care provider, local health department, community—based organization, substance abuse treatment organization, or other person that addresses medical or social issues related to drug addiction. (d) "Program" means an Overdose Response Program.

§13–3102. An Overdose Response Program is a program overseen by the Department for the purpose of providing a means of authorizing certain individuals to administer naloxone to an individual experiencing, or believed to be experiencing, opioid overdose to help prevent a fatality when medical services are not immediately available.

§13–3103. (a) The Department shall adopt regulations necessary for the administration of the Program. (b) The Department may: (1) Collect fees necessary for the administration of the Program; (2) Authorize private or public entities to issue and renew certificates to persons meeting the requirements of this subtitle; (3) (i) Authorize private or public entities to conduct educational training programs described in § 13–3104 of this subtitle; and (ii) Develop guidance regarding the content of educational training programs conducted by private or public entities; and (4) Collect and report data on the operation and results of the programs.

§13-3104. (a) To qualify for a certificate, an individual shall meet the requirements of this section. (b) The applicant shall be at least 18 years old. 2 (c) The applicant shall have, or reasonably expect to have, as a result of the individual's occupation or volunteer, family, or social status, the ability to assist an individual who is experiencing an opioid overdose. (d) (1) The applicant shall successfully complete an educational training program offered by a private or public entity authorized by the Department. (2) An educational training program required under this subsection shall: (i) Be conducted by: 1. A physician licensed to practice medicine under Title 14 of the Health Occupations Article; 2. A nurse practitioner licensed to practice registered nursing under Title 8 of the Health Occupations Article and certified as a nurse practitioner by the State Board of Nursing; or 3. An employee or a volunteer of a private or public entity that maintains a written agreement with a supervisory physician or nurse practitioner that includes: A. Procedures for providing patient overdose information; B. Information as to how the employee or volunteer providing the information will be trained; and C. Standards for documenting the provision of patient overdose information to patients; and (ii) Include training in: 1. The recognition of the symptoms of opioid overdose; 2. The proper administration of naloxone; 3. The importance of contacting emergency medical services; 4. The care of an individual after the administration of naloxone; and 5. Any other topics required by the Department.

§13–3105. An applicant for a certificate shall submit an application to a private or public entity authorized by the Department on the form that the Department requires.

§13–3106. (a) A private or public entity authorized by the Department shall issue a certificate to any applicant who meets the requirements of this subtitle. (b) Each certificate shall include: (1) A statement that the holder is authorized to administer naloxone in accordance with this subtitle; 3 (2) The full name of the certificate holder; and (3) A serial number. (c) A replacement certificate may be issued to replace a lost, destroyed, or mutilated certificate. (d) (1) The certificate shall be valid for 2 years and may be renewed. (2) In order to renew a certificate, the certificate holder shall: (i) Successfully complete a refresher training program conducted by an authorized private or public entity; or (ii) Demonstrate proficiency to the private or public entity issuing certificates under this subtitle.

§13–3107. An individual who is certified may: (1) On presentment of a certificate, receive from any physician licensed to practice medicine in the State, or any nurse practitioner licensed to practice nursing in the State, a prescription for naloxone and the necessary supplies for the administration of naloxone; (2) Possess prescribed naloxone and the necessary supplies for the administration of naloxone; and (3) In an emergency situation when medical services are not immediately available, administer naloxone to an individual experiencing or believed by the certificate holder to be experiencing an opioid overdose.

§13–3108. A physician or nurse practitioner may prescribe and dispense naloxone to a certificate holder.

§13–3109. (a) A certificate holder who, in accordance with this subtitle, is administering naloxone to an individual experiencing or believed by the certificate holder to be experiencing an opioid overdose may not be considered to be practicing medicine for the purposes of Title 14 of the Health Occupations Article. (b) A physician who prescribes or dispenses naloxone to a certificate holder in a manner consistent with the protocol established by the authorized private or public entity may not be subject to any disciplinary action under Title 14 of the Health Occupations Article solely for the act of prescribing or dispensing naloxone to the certificate holder.

Massachusetts

Excerpted from Massachusetts General Laws (2014)

Chapter 94C Controlled Substances Act

Section 19

(d) Naloxone or other opioid antagonist may lawfully be prescribed and dispensed to a person at risk of experiencing an opiate-related overdose or a family member, friend or other person in a position to assist a person at risk of experiencing an opiate-related overdose. For purposes of this chapter and chapter 112, any such prescription shall be regarded as being issued for a legitimate medical purpose in the usual course of professional practice.

Section 34A.

- (a) A person who, in good faith, seeks medical assistance for someone experiencing a drug-related overdose shall not be charged or prosecuted for possession of a controlled substance under sections 34 or 35 if the evidence for the charge of possession of a controlled substance was gained as a result of the seeking of medical assistance.
- (b) A person who experiences a drug-related overdose and is in need of medical assistance and, in good faith, seeks such medical assistance, or is the subject of such a good faith request for medical assistance, shall not be charged or prosecuted for possession of a controlled substance under said sections 34 or 35 if the evidence for the charge of possession of a controlled substance was gained as a result of the

overdose and the need for medical assistance.

- (c) The act of seeking medical assistance for someone who is experiencing a drug-related overdose may be used as a mitigating factor in a criminal prosecution under the Controlled Substance Act, 1970 P.L. 91-513, 21 U.S.C. section 801, et seq.
- (d) Nothing contained in this section shall prevent anyone from being charged with trafficking, distribution or possession of a controlled substance with intent to distribute.
- (e) A person acting in good faith may receive a naloxone prescription, possess naloxone and administer naloxone to an individual appearing to experience an opiate-related overdose.

Minnesota

Excerpted from 2014 Minnesota Statutes (2014)

151.37 LEGEND DRUGS, WHO MAY PRESCRIBE, POSSESS.

Subd. 12. Administration of opiate antagonists for drug overdose.

- (a) A licensed physician, a licensed advanced practice registered nurse authorized to prescribe drugs pursuant to section <u>148.235</u>, or a licensed physician assistant authorized to prescribe drugs pursuant to section <u>147A.18</u> may authorize the following individuals to administer opiate antagonists, as defined in section <u>604A.04</u>, <u>subdivision</u> <u>1</u>:
 - (1) an emergency medical responder registered pursuant to section 144E.27;
- (2) a peace officer as defined in section $\underline{626.84}$, subdivision $\underline{1}$, paragraphs (c) and (d); and
- (3) staff of community-based health disease prevention or social service programs.
- (b) For the purposes of this subdivision, opiate antagonists may be administered by one of these individuals only if:
- (1) the licensed physician, licensed physician assistant, or licensed advanced practice registered nurse has issued a standing order to, or entered into a protocol with, the individual; and
- (2) the individual has training in the recognition of signs of opiate overdose and the use of opiate antagonists as part of the emergency response to opiate overdose.
- (c) Nothing in this section prohibits the possession and administration of naloxone pursuant to section 604A.04.

604A.04 GOOD SAMARITAN OVERDOSE PREVENTION.

Subdivision 1. Definitions; opiate antagonist.

For purposes of this section, "opiate antagonist" means naloxone hydrochloride

or any similarly acting drug approved by the federal Food and Drug Administration for the treatment of a drug overdose.

Subd. 2. Authority to possess and administer opiate antagonists; release from liability.

- (a) A person who is not a health care professional may possess or administer an opiate antagonist that is prescribed, dispensed, or distributed by a licensed health care professional pursuant to subdivision 3.
- (b) A person who is not a health care professional who acts in good faith in administering an opiate antagonist to another person whom the person believes in good faith to be suffering a drug overdose is immune from criminal prosecution for the act and is not liable for any civil damages for acts or omissions resulting from the act.

Subd. 3. Health care professionals; release from liability.

A licensed health care professional who is permitted by law to prescribe an opiate antagonist, if acting in good faith, may directly or by standing order prescribe, dispense, distribute, or administer an opiate antagonist to a person without being subject to civil liability or criminal prosecution for the act. This immunity applies even when the opiate antagonist is eventually administered in either or both of the following instances: (1) by someone other than the person to whom it is prescribed; or (2) to someone other than the person to whom it is prescribed.

604A.05 GOOD SAMARITAN OVERDOSE MEDICAL ASSISTANCE.

Subdivision 1. Person seeking medical assistance; immunity from prosecution.

A person acting in good faith who seeks medical assistance for another person who is experiencing a drug-related overdose may not be charged or prosecuted for the possession, sharing, or use of a controlled substance under section 152.023, subdivision 2, clauses (4) and (6), 152.024, or 152.025, or possession of drug paraphernalia. A person qualifies for the immunities provided in this subdivision only if:

- (1) the evidence for the charge or prosecution was obtained as a result of the person's seeking medical assistance for another person; and
- (2) the person seeks medical assistance for another person who is in need of medical assistance for an immediate health or safety concern, provided that the person who seeks the medical assistance is the first person to seek the assistance, provides a name and contact information, remains on the scene until assistance arrives or is provided, and cooperates with the authorities.

Good faith does not include seeking medical assistance during the course of the execution of an arrest warrant or search warrant or a lawful search.

Subd. 2. Person experiencing an overdose; immunity from prosecution.

A person who experiences a drug-related overdose and is in need of medical assistance may not be charged or prosecuted for possession of a controlled substance under section <u>152.023</u>, <u>subdivision 2</u>, clauses (4) and (6), <u>152.024</u>, or <u>152.025</u>, or possession of drug paraphernalia. A person qualifies for the immunities provided in this

subdivision only if the evidence for the charge or prosecution was obtained as a result of the drug-related overdose and the need for medical assistance.

Subd. 3. Persons on probation or release.

A person's pretrial release, probation, furlough, supervised release, or parole shall not be revoked based on an incident for which the person would be immune from prosecution under subdivision 1 or 2.

Subd. 4. Effect on other criminal prosecutions.

- (a) The act of providing first aid or other medical assistance to someone who is experiencing a drug-related overdose may be used as a mitigating factor in a criminal prosecution for which immunity is not provided.
 - (b) Nothing in this section shall:
- (1) be construed to bar the admissibility of any evidence obtained in connection with the investigation and prosecution of other crimes or violations committed by a person who otherwise qualifies for limited immunity under this section;
- (2) preclude prosecution of a person on the basis of evidence obtained from an independent source;
- (3) be construed to limit, modify, or remove any immunity from liability currently available to public entities, public employees by law, or prosecutors; or
- (4) prevent probation officers from conducting drug testing of persons on pretrial release, probation, furlough, supervised release, or parole.

Subd. 5. Drug-related overdose defined.

As used in this section, "drug-related overdose" means an acute condition, including mania, hysteria, extreme physical illness, or coma, resulting from the consumption or use of a controlled substance, or another substance with which a controlled substance was combined, and that a layperson would reasonably believe to be a drug overdose that requires immediate medical assistance.

New Mexico

New Mexico Statutes Chapter 24 Health and Safety (2001)

- 24-23-1. Authority to administer opioid antagonists; release from liability.
- A. A person authorized under federal, state or local government regulations, other than a licensed health care professional permitted by law to administer an opioid antagonist, may administer an opioid antagonist to another person if:
- (1) he, in good faith, believes the other person is experiencing a drug overdose; and
- (2) he acts with reasonable care in administering the drug to the other person.
- B. A person who administers an opioid antagonist to another person pursuant to Subsection A of this section shall not be subject to civil liability or criminal prosecution

as a result of the administration of the drug.

24-23-2. Health care professionals; release from liability.

A licensed health care professional who is permitted by law to prescribe an opioid antagonist, if acting with reasonable care, may prescribe, dispense, distribute or administer an opioid antagonist without being subject to civil liability or criminal prosecution.

Chapter 30 Criminal Offenses

30-31-27.1. Overdose prevention; limited immunity.

- A. A person who, in good faith, seeks medical assistance for someone experiencing a drug-related overdose shall not be charged or prosecuted for possession of a controlled substance pursuant to the provisions of Section 30-31-23 NMSA 1978 if the evidence for the charge of possession of a controlled substance was gained as a result of the seeking of medical assistance.
- B. A person who experiences a drug-related overdose and is in need of medical assistance shall not be charged or prosecuted for possession of a controlled substance pursuant to the provisions of Section 30-31-23 NMSA 1978 if the evidence for the charge of possession of a controlled substance was gained as a result of the overdose and the need for medical assistance.
- C. The act of seeking medical assistance for someone who is experiencing a drugrelated overdose may be used as a mitigating factor in a criminal prosecution pursuant to the Controlled Substances Act.

New York

Excerpted from New York Consolidated Laws (2014)

Public Health Law Section 3309 1. The commissioner is authorized

- to establish standards for approval of any opioid overdose prevention program, and opioid antagonist prescribing, dispensing, distribution,
- program, and opioid antagonist prescribing, dispensing, distribution, possession and administration pursuant to this section which may include, but not be limited to, standards for program directors, appropriate clinical oversight, training, record keeping and reporting.
- 2. Notwithstanding any inconsistent provisions of section sixty-five hundred twelve of the education law or any other law, the purchase, acquisition, possession or use of an opioid antagonist pursuant to this section shall not constitute the unlawful practice of a profession or other violation under title eight of the education law or this article.
- 3. (a) As used in this section:
- (i) "Opioid antagonist" means a drug approved by the Food and Drug Administration that, when administered, negates or neutralizes in whole

- or in part the pharmacological effects of an opioid in the body. "Opioid antagonist" shall be limited to naloxone and other medications approved by the department for such purpose.
- (ii) "Health care professional" means a person licensed, registered or authorized pursuant to title eight of the education law to prescribe prescription drugs.
- (iii) "Pharmacist" means a person licensed or authorized to practice pharmacy pursuant to article one hundred thirty-seven of the education law.
- (iv) "Opioid antagonist recipient" or "recipient" means a person at risk of experiencing an opioid-related overdose, or a family member, friend or other person in a position to assist a person experiencing or at risk of experiencing an opioid-related overdose, or an organization registered as an opioid overdose prevention program pursuant to this section
- (iv) "Opioid antagonist recipient" or "recipient" means a person at risk of experiencing an opioid-related overdose, or a family member, friend or other person in a position to assist a person experiencing or at risk of experiencing an opioid-related overdose, or an organization registered as an opioid overdose prevention program pursuant to this section or a school district, board of cooperative educational services, county vocational education and extension board, charter school, non-public elementary and/or secondary school in this state or any person employed by such district, board or school.
- (b)(i) A health care professional may prescribe by a patient-specific or non-patient-specific prescription, dispense or distribute, directly or indirectly, an opioid antagonist to an opioid antagonist recipient.
- (ii) A pharmacist may dispense an opioid antagonist, through a patient-specific or non-patient-specific prescription pursuant to this paragraph, to an opioid antagonist recipient.
- (iii) An opioid antagonist recipient may possess an opioid antagonist obtained pursuant to this paragraph, may distribute such opioid antagonist to a recipient, and may administer such opioid antagonist to a person the recipient reasonably believes is experiencing an opioid overdose.
- (iv) The provisions of this paragraph shall not be deemed to require a prescription for any opioid antagonist that does not otherwise require a prescription; nor shall it be deemed to limit the authority of a health care professional to prescribe, dispense or distribute, or of a pharmacist to dispense, an opioid antagonist under any other provision of law.
- 3. Any distribution of opioid antagonists through this program shall include an informational card or sheet. The informational card or sheet shall include, at a minimum, information on:
 - (a) how to recognize symptoms of an opioid overdose;
- (b) steps to take prior to and after an opioid antagonist is administered, including calling first responders;
- (c) the number for the toll free office of alcoholism and substance

abuse services HOPE line;

- (d) how to access the office of alcoholism and substance abuse services' website; and
- (e) any other information deemed relevant by the commissioner. The educational card shall be provided in languages other than English as deemed appropriate by the commissioner. The department shall make such informational cards available to the opioid overdose prevention programs.
- 3-a. Any distribution of opioid antagonists through this program shall include an informational card or sheet. The informational card or sheet shall include, at a minimum, information on:
 - (a) how to recognize symptoms of an opioid overdose;
- (b) steps to take prior to and after an opioid antagonist is administered, including calling first responders;
- (c) the number for the toll free office of alcoholism and substance abuse services HOPE line;
- (d) how to access the office of alcoholism and substance abuse services' website; and
- (e) any other information deemed relevant by the commissioner. The educational card shall be provided in languages other than English as deemed appropriate by the commissioner. The department shall make such informational cards available to the opioid overdose prevention programs.
- 4. Use of an opioid antagonist pursuant to this section shall be considered first aid or emergency treatment for the purpose of any statute relating to liability.

A recipient or opioid overdose prevention program under this section, acting reasonably and in good faith in compliance with this section, shall not be subject to criminal, civil or administrative liability solely by reason of such action.

4. Use of an opioid antagonist pursuant to this section shall be considered first aid or emergency treatment for the purpose of any statute relating to liability.

A recipient, opioid overdose prevention program, school district, board of cooperative educational services, county vocational education and extension board, charter school, non-public elementary school and/or secondary school in the state, or any person employed by such district, board or school under this section, acting reasonably and in good faith in compliance with this section, shall not be subject to criminal, civil or administrative liability solely by reason of such action.

5. The commissioner shall publish findings on statewide opioid overdose data that reviews overdose death rates and other information to ascertain changes in the cause and rates of fatal opioid overdoses. The report may be part of existing state mortality reports issued by the department, and shall be submitted annually to the governor, the temporary president of the senate, the speaker of the assembly, and the chairs of the senate and assembly health committees. The report shall include, at a minimum, the following information:

- (a) information on opioid overdose deaths, including age, gender, ethnicity, and geographic location;
- (b) data on emergency room utilization for the treatment of opioid overdose;
- (c) data on utilization of pre-hospital services;
- (d) data on utilization of opioid antagonists; and
- (e) any other information necessary to ascertain the success of the program and ways to further reduce overdoses.

Education Law Section 922

- 1. School districts, boards of
- cooperative educational services, county vocational education and extension boards, charter schools, and non-public elementary and secondary schools in this state may provide and maintain on-site in each instructional school facility opioid antagonists, as defined in section three thousand three hundred nine of the public health law, in quantities and types deemed by the commissioner, in consultation with the commissioner of health, to be adequate to ensure ready and appropriate access for use during emergencies to any student or staff suspected of having opioid overdose whether or not there is a previous history of opioid abuse.
- 2. School districts, boards of cooperative educational services, county vocational education and extension boards, charter schools, and non-public elementary and secondary schools in this state may elect to participate as an opioid antagonist recipient and any person employed by any such entity that has elected to participate may administer an opioid antagonist in the event of an emergency, provided that such person shall have been trained by a program approved under section three thousand three hundred nine of the public health law. Any school district, board of cooperative educational services, county vocational education and extension board, charter school, and non-public elementary and secondary school that has employees trained in accordance with this section shall comply with the requirements of section three thousand three hundred nine of the public health law including, but not limited to, appropriate clinical oversight, record keeping and reporting. No person shall be required to participate in the program and any participation by an individual shall be voluntary.

Penal Law Section 220.78

1. A person who, in good faith, seeks health care for someone who is experiencing a drug or alcohol overdose or other life threatening medical emergency shall not be charged or prosecuted for a controlled substance offense under article two hundred twenty or a marihuana offense under article two hundred twenty-one of this title, other than an offense involving sale for consideration or other benefit or gain, or charged or prosecuted for possession of alcohol by a person under age twenty-one years under section sixty-five-c of the alcoholic beverage control law, or for possession of drug paraphernalia under article thirty-nine of the general business law, with

- respect to any controlled substance, marihuana, alcohol or paraphernalia that was obtained as a result of such seeking or receiving of health care.
- 2. A person who is experiencing a drug or alcohol overdose or other life threatening medical emergency and, in good faith, seeks health care for himself or herself or is the subject of such a good faith request for health care, shall not be charged or prosecuted for a controlled substance offense under this article or a marihuana offense under article two hundred twenty-one of this title, other than an offense involving sale for consideration or other benefit or gain, or charged or prosecuted for possession of alcohol by a person under age twenty-one years under section sixty-five-c of the alcoholic beverage control law, or for possession of drug paraphernalia under article thirty-nine of the general business law, with respect to any substance, marihuana, alcohol or paraphernalia that was obtained as a result of such seeking or receiving of health care.
- 3. Definitions. As used in this section the following terms shall have the following meanings:
- (a) "Drug or alcohol overdose" or "overdose" means an acute condition including, but not limited to, physical illness, coma, mania, hysteria or death, which is the result of consumption or use of a controlled substance or alcohol and relates to an adverse reaction to or the quantity of the controlled substance or alcohol or a substance with which the controlled substance or alcohol was combined; provided that a patient's condition shall be deemed to be a drug or alcohol overdose if a prudent layperson, possessing an average knowledge of medicine and health, could reasonably believe that the condition is in fact a drug or alcohol overdose and (except as to death) requires health care.
- (b) "Health care" means the professional services provided to a person experiencing a drug or alcohol overdose by a health care professional licensed, registered or certified under title eight of the education law or article thirty of the public health law who, acting within his or her lawful scope of practice, may provide diagnosis, treatment or emergency services for a person experiencing a drug or alcohol overdose.
- 4. It shall be an affirmative defense to a criminal sale controlled substance offense under this article or a criminal sale of marihuana offense under article two hundred twenty-one of this title, not covered by subdivision one or two of this section, with respect to any controlled substance or marihuana which was obtained as a result of such seeking or receiving of health care, that:
- (a) the defendant, in good faith, seeks health care for someone or for him or herself who is experiencing a drug or alcohol overdose or other life threatening medical emergency; and
- (b) the defendant has no prior conviction for the commission or attempted commission of a class A-I, A-II or B felony under this article.
- 5. Nothing in this section shall be construed to bar the admissibility of any evidence in connection with the investigation and prosecution of a crime with regard to another defendant who does not independently qualify for the bar to prosecution or for the affirmative defense; nor with regard to other crimes committed by a person who otherwise qualifies under this section; nor shall anything in this section be construed to bar any seizure pursuant to law, including but not limited to pursuant to section thirty-three hundred eighty-seven of the public health law.
- 6. The bar to prosecution described in subdivisions one and two of this section shall not apply to the prosecution of a class A-I felony under this article, and the affirmative

defense described in subdivision four of this section shall not apply to the prosecution of a class A-I or A-II felony under this article

North Carolina

Excerpted from North Carolina General Statutes (2013)

Chapter 90

§ 90-96.2. Drug-related overdose treatment; limited immunity. (a) As used in this section, "drug-related overdose" means an acute condition, including mania, hysteria, extreme physical illness, coma, or death resulting from the consumption or use of a controlled substance, or another substance with which a controlled substance was combined, and that a layperson would reasonably believe to be a drug overdose that requires medical assistance. (b) A person acting in good faith who seeks medical assistance for an individual experiencing a drug-related overdose shall not be prosecuted for (i) a misdemeanor violation of G.S. 90-95(a)(3), (ii) a felony violation of G.S. 90-95(a)(3) for possession of less than one gram of cocaine, (iii) a felony violation of G.S. 90-95(a)(3) for possession of less than one gram of heroin, or (iv) a violation of G.S. 90-113.22 if the evidence for prosecution under those sections was obtained as a result of the person seeking medical assistance for the drug-related overdose. (c) A person who experiences a drug-related overdose and is in need of medical assistance shall not be prosecuted for (i) a misdemeanor violation of G.S. 90-95(a)(3), (ii) a felony violation of G.S. 90-95(a)(3) for possession of less than one gram of cocaine, (iii) a felony violation of G.S. 90-95(a)(3) for possession of less than one gram of heroin, or (iv) a violation of G.S. 90-113.22 if the evidence for prosecution under those sections was obtained as a result of the drug-related overdose and need for medical assistance. (d) Nothing in this section shall be construed to bar the admissibility of any evidence obtained in connection with the investigation and prosecution of other crimes committed by a person who otherwise qualifies for limited immunity under this section.

§ 90-106.2. Treatment of overdose with opioid antagonist; immunity. (a) As used in this section, "opioid antagonist" means naloxone hydrochloride that is approved by the federal Food and Drug Administration for the treatment of a drug overdose. (b) A practitioner acting in good faith and exercising reasonable care may directly or by standing order prescribe an opioid antagonist to (i) a person at risk of experiencing an opiate-related overdose or (ii) a family member, friend, or other person in a position to assist a person at risk of experiencing an opiate-related overdose. As an indicator of good faith, the practitioner, prior to prescribing an opioid under this subsection, may require receipt of a written communication that provides a factual basis for a reasonable conclusion as to either of the following: (1) The person seeking the opioid antagonist is at risk of experiencing an opiate-related overdose. (2) The person other than the person who is at risk of experiencing an opiate-related overdose, and who is seeking the opioid antagonist, is in relation to the person at risk of experiencing an opiate-related overdose: a. A family member, friend, or other person, b. In the position to assist a person at risk of experiencing an opiate-related overdose. (c) A person who receives an opioid antagonist that was prescribed pursuant to subsection (b) of this section may administer an opioid antagonist to another person if (i) the person has a

good faith belief that the other person is experiencing a drug-related overdose and (ii) the person exercises reasonable care in administering the drug to the other person. Evidence of the use of reasonable care in administering the drug shall include the receipt of basic instruction and information on how to administer the opioid antagonist. (d) All of the following individuals are immune from any civil or criminal liability for actions authorized by this section: (1) Any practitioner who prescribes an opioid antagonist pursuant to subsection (b) of this section. (2) Any person who administers an opioid antagonist pursuant to subsection (c) of this section.

Chapter 18

§ 18B-302.2. Medical treatment; limited immunity. Notwithstanding any other provision of law, a person under the age of 21 shall not be prosecuted for a violation of G.S. 18B-302 for the possession or consumption of alcoholic beverages if law enforcement, including campus safety police, became aware of the possession or consumption of alcohol by the person solely because the person was seeking medical assistance for another individual. This section shall apply if, when seeking medical assistance on behalf of another, the person did all of the following: (1) Acted in good faith, upon a reasonable belief that he or she was the first to call for assistance. (2) Used his or her own name when contacting authorities. (3) Remained with the individual needing medical assistance until help arrived.

Rhode Island

Excerpted from Rhode Island General Laws (2012)

21-28.8-1. Short title. – This chapter shall be known and may be cited as "The Good Samaritan Overdose Prevention Act".

21-28.8-2. Definition. – "Opioid antagonist" is a drug which is a competitive antagonist

that binds to the opioid receptors with higher affinity than agonists but does not activate the

receptors, effectively blocking the receptor, preventing the human body from making use of opiates and endorphins.

- 21-28.8-3. Authority to administer opioid antagonists Release from liability. (a) A person may administer an opioid antagonist to another person if:
- (1) He or she, in good faith, believes the other person is experiencing a drug overdose;

and

- (2) He or she acts with reasonable care in administering the drug to the other person.
- (b) A person who administers an opioid antagonist to another person pursuant to this

section shall not be subject to civil liability or criminal prosecution as a result of the administration of the drug.

21-28.8-4. Emergency overdose care – Immunity from legal repercussions. – (a) Any person who, in good faith, without malice and in the absence of evidence of an intent to defraud,

seeks medical assistance for someone experiencing a drug overdose or other drug-

related medical

emergency shall not be charged or prosecuted for any crime under RIGL 21-28 or 21-28.5, except

for a crime involving the manufacture or possession with the intent to manufacture a controlled

substance or possession with intent to deliver a controlled substance, if the evidence for the

charge was gained as a result of the seeking of medical assistance.

(b) A person who experiences a drug overdose or other drug-related medical emergency

and is in need of medical assistance shall not be charged or prosecuted for any crime under RIGL

21-28 or 21-28.5, except for a crime involving the manufacture or possession with the intent to

manufacture a controlled substance or possession with intent to deliver a controlled substance, if

the evidence for the charge was gained as a result of the overdose and the need for medical

assistance.

(c) The act of providing first aid or other medical assistance to someone who is experiencing a drug overdose or other drug-related medical emergency may be used as a

mitigating factor in a criminal prosecution pursuant to the controlled substances act.

21-28.8-5. Law enforcement reports. – In the first week of January, 2013 and each year

thereafter, the attorney general shall, in cooperation with local law enforcement agencies and the

state police, submit to the general assembly a report summarizing the impact of this chapter on

law enforcement. The report shall include any incidents in which a law enforcement agency was

barred, due to the immunity provisions of subsection 21-28.8-4(a), from charging or prosecuting a

person under Rhode Island general law 21-28 or 21-28.5 who would have otherwise been so

charged or prosecuted, and indicating whether the person was charged with, or prosecuted for,

any other criminal offense resulting from the agency's response to the request for medical assistance.

Vermont

Vermont Statutes Title 18 (2013)

§ 4240. Prevention and treatment of opioid-related overdoses

- (a) As used in this section:
- (1) "Health care professional" means a physician licensed pursuant to 26 V.S.A. chapter 23 or 33, a physician's assistant certified to prescribe and dispense prescription drugs pursuant to 26 V.S.A. chapter 31, or an advanced practice registered nurse authorized to prescribe and dispense prescription drugs pursuant to 26 V.S.A. chapter 28.
- (2) "Opioid antagonist" means a drug that, when administered, negates or neutralizes in whole or part the pharmacological effects of an opioid in the body.
- (3) "Victim" means the person who has overdosed on an opioid drug or who is believed to have overdosed on an opiate drug.
- (b) For the purpose of addressing prescription and nonprescription opioid overdoses in Vermont, the Department shall develop and implement a prevention, intervention, and response strategy, depending on available resources, that shall:
- (1) provide educational materials on opioid overdose prevention to the public free of charge, including to substance abuse treatment providers, health care providers, opioid users, and family members of opioid users;
- (2) increase community-based prevention programs aimed at reducing risk factors that lead to opioid overdoses;
- (3) increase timely access to treatment services for opioid users, including medication-assisted treatment;
- (4)(A) educate substance abuse treatment providers on methods to prevent opioid overdoses;
- (B) provide education and training on overdose prevention, intervention, and response to individuals living with addiction and participating in opioid treatment programs, syringe exchange programs, residential drug treatment programs, or correctional services;
- (5) facilitate overdose prevention, drug treatment, and addiction recovery services by implementing and expanding hospital referral services for individuals treated for an opioid overdose; and

- (6) develop a statewide opioid antagonist pilot program that emphasizes access to opioid antagonists to and for the benefit of individuals with a history of opioid use.
- (c)(1) A health care professional acting in good faith may directly or by standing order prescribe, dispense, and distribute an opioid antagonist to the following persons, provided the person has been educated about opioid-related overdose prevention and treatment in a manner approved by the Department:
- (A) a person at risk of experiencing an opioid-related overdose; or
- (B) a family member, friend, or other person in a position to assist a person at risk of experiencing an opioid-related overdose.
- (2) A health care professional who prescribes, dispenses, or distributes an opioid antagonist in accordance with subdivision (1) of this subsection shall be immune from civil or criminal liability with regard to the subsequent use of the opioid antagonist, unless the health professional's actions with regard to prescribing, dispensing, or distributing the opioid antagonist constituted recklessness, gross negligence, or intentional misconduct. The immunity granted in this subdivision shall apply whether or not the opioid antagonist is administered by or to a person other than the person for whom it was prescribed.
- (d)(1) A person may administer an opioid antagonist to a victim if he or she believes, in good faith, that the victim is experiencing an opioid-related overdose.
- (2) After a person has administered an opioid antagonist pursuant to subdivision (1) of this subsection (d), he or she shall immediately call for emergency medical services if medical assistance has not yet been sought or is not yet present.
- (3) A person shall be immune from civil or criminal liability for administering an opioid antagonist to a victim pursuant to subdivision (1) of this subsection unless the person's actions constituted recklessness, gross negligence, or intentional misconduct. The immunity granted in this subdivision shall apply whether or not the opioid antagonist is administered by or to a person other than the person for whom it was prescribed.
- (e) A person acting on behalf of a community-based overdose prevention program shall be immune from civil or criminal liability for providing education on opioid-related overdose prevention or for purchasing, acquiring, distributing, or possessing an opioid

antagonist unless the person's actions constituted recklessness, gross negligence, or intentional misconduct.

(f) Any health care professional who treats a victim and who has knowledge that the victim has been administered an opioid antagonist within the preceding 30 days shall refer the victim to professional substance abuse treatment services.

Washington

Excerpted from Washington 2015 Engrossed Substitute House Bill 1671

NEW SECTION. Sec. 1. (1) The legislature intends to reduce the number of lives lost to drug overdoses by encouraging the prescription, dispensing, and administration of opioid overdose medications. (2) Overdoses of opioids, such as heroin and prescription painkillers, cause brain injury and death by slowing and eventually stopping a person's breathing. Since 2012, drug poisoning deaths in the United States have risen six percent, and deaths involving heroin have increased a staggering thirty-nine percent. In Washington state, the annual number of deaths involving heroin or prescription opiates increased from two hundred fifty-eight in 1995 to six hundred fifty- one in 2013. Over this period, a total of nine thousand four hundred thirty-nine people died from opioid-related drug overdoses. Opioid-related drug overdoses are a statewide phenomenon. (3) When administered to a person experiencing an opioid-related drug overdose, an opioid overdose medication can save the person's life by restoring respiration. Increased access to opioid overdose medications reduced the time between when a victim is discovered and when he or she receives lifesaving assistance. Between 1996 and 2010, lay people across the country reversed over ten thousand overdoses. (4) The legislature intends to increase access to opioid overdose medications by permitting health care practitioners to administer, prescribe, and dispense, directly or by collaborative drug therapy agreement or standing order, opioid overdose medication to any person who may be present at an overdose - law enforcement, emergency medical technicians, family members, or service providers and to permit those individuals to possess and administer opioid overdose medications prescribed by an authorized health care provider. NEW SECTION. Sec. 2. A new section is added to chapter 69.41 RCW to read as follows: (1)(a) A practitioner may prescribe, dispense, distribute, and deliver an opioid overdose medication: (i) Directly to a person at risk of experiencing an opioid-related overdose; or (ii) by collaborative drug therapy agreement, standing order, or protocol to a first responder, family member, or other person or entity in a position to assist a person at risk of experiencing an opioid-related overdose. Any such prescription or protocol order is issued for a legitimate medical purpose in the usual course of professional practice. (b) At the time of prescribing, dispensing, distributing, or delivering the opioid overdose medication, the practitioner shall inform the recipient that as soon as possible after administration of the opioid overdose medication, the person at risk of experiencing an opioid-related overdose should be transported to a hospital or a first responder should be summoned. (2) A pharmacist may dispense an opioid overdose medication pursuant to a prescription issued in accordance with this section and may administer an opioid overdose medication to a person at risk of experiencing an

opioid-related overdose. At the time of dispensing an opioid overdose medication, a pharmacist shall provide written instructions on the proper response to an opioidrelated overdose, including instructions for seeking immediate medical attention. The instructions to seek immediate medication attention must be conspicuously displayed. (3) Any person or entity may lawfully possess, store, deliver, distribute, or administer an opioid overdose medication pursuant to a prescription or order issued by a practitioner in accordance with this section. (4) The following individuals, if acting in good faith and with reasonable care, are not subject to criminal or civil liability or disciplinary action under chapter 18.130 RCW for any actions authorized by this section or the outcomes of any actions authorized by this section: (a) A practitioner who prescribes, dispenses, distributes, or delivers an opioid overdose medication pursuant to subsection (1) of this section; (b) A pharmacist who dispenses an opioid overdose medication pursuant to subsection (2) of this section; (c) A person who possesses, stores, distributes, or administers an opioid overdose medication pursuant to subsection (3) of this section. (5) For purposes of this section, the following terms have the following meanings unless the context clearly requires otherwise: (a) "First responder" means: (i) A career or volunteer firefighter, law enforcement officer, paramedic as defined in RCW 18.71.200, or first responder or emergency medical technician as defined in RCW 18.73.030; and (ii) an entity that employs or supervises an individual listed in (a)(i) of this subsection, including a volunteer fire department. (b) "Opioid overdose medication" means any drug used to reverse an opioid overdose that binds to opioid receptors and blocks or inhibits the effects of opioids acting on those receptors. It does not include intentional administration via the intravenous route. (c) "Opioid-related overdose" means a condition including, but not limited to, extreme physical illness, decreased level of consciousness, respiratory depression, coma, or death that: (i) Results from the consumption or use of an opioid or another substance with which an opioid was combined; or (ii) a lay person would reasonably believe to be an opioid-related overdose requiring medical assistance. (d) "Practitioner" means a health care practitioner who is authorized under RCW 69.41.030 to prescribe legend drugs. (e) "Standing order" or "protocol" means written or electronically recorded instructions, prepared by a prescriber, for distribution and administration of a drug by designated and trained staff or volunteers of an organization or entity, as well as other actions and interventions to be used upon the occurrence of clearly defined clinical events in order to improve patients' timely access to treatment. Sec. 3. RCW 69.41.040 and 2003 c 53 s 324 are each amended to read as follows: (1) A prescription, in order to be effective in legalizing the possession of legend drugs, must be issued for a legitimate medical purpose by one authorized to prescribe the use of such legend drugs. Except as provided in section 2 of this act, an order purporting to be a prescription issued to a drug abuser or habitual user of legend drugs, not in the course of professional treatment, is not a prescription within the meaning and intent of this section; and the person who knows or should know that he or she is filling such an order, as well as the person issuing it, may be charged with violation of this chapter. A legitimate medical purpose shall include use in the course of a bona fide research program in conjunction with a hospital or university. (2) A violation of this section is a class B felony punishable according to chapter 9A.20 RCW.21 22 Sec. 4. RCW 69.50.315 and 2010 c 9 s 2 are each amended to read as follows: (1)(((a))) A person acting in good faith who seeks medical assistance for someone experiencing a drug-related overdose shall not be charged or prosecuted for

possession of a controlled substance pursuant to RCW 69.50.4013, or penalized under RCW 69.50.4014, if the evidence for the charge of possession of a controlled substance was obtained as a result of the person seeking medical assistance. (((b) A person acting in good faith may receive a naloxone prescription, possess naloxone, and administer naloxone to an individual suffering from an apparent opiate-related overdose.)) (2) A person who experiences a drug-related overdose and is in need of medical assistance shall not be charged or prosecuted for possession of a controlled substance pursuant to RCW 69.50.4013, or penalized under RCW 69.50.4014, if the evidence for the charge of possession of a controlled substance was obtained as a result of the overdose and the need for medical assistance. (3) The protection in this section from prosecution for possession crimes under RCW 69.50.4013 shall not be grounds for suppression of evidence in other criminal charges. NEW SECTION. Sec. 5. RCW 18.130.345 (Naloxone—Administering, 5 dispensing, prescribing, purchasing, acquisition, possession, or use—Opiate-related overdose) and 2010 c 9 s 3 are each repealed.

Appendix D: New Mexico Opioid Overdose Risk Categories

NEW MEXICO HEALTHCARE PROFESSIONALS:

PRESCRIBE NALOXONE NOW!

Naloxone is the antidote for an opioid overdose. It has been used for decades to reverse respiratory depression associated with toxic exposure to opioids. Naloxone is not a controlled substance and can be prescribed routinely to patients at risk of an opioid overdose.

PATIENTS WHO COULD BENEFIT FROM NALOXONE PRESCRIPTION INCLUDE THOSE WHO:

- 1. Have received emergency medical care for opioid detoxification or overdose
- 2. Have just been released from incarceration or institutionalization with a history of opioid addiction
- 3. Have a reported or suspected history of substance abuse or nonmedical opioid use
- 4. Have a known severe psychiatric illness or history of suicide attempt
- 5. Are on medication assisted therapy for opiate addiction (such as methadone or buprenorphine)
- Are prescribed long-acting opioid (oxycodone ER, oxymorphone ER, morphine ER, transdermal fentanyl, methadone or buprenorphine).
- 7. Are on a higher dose (>50 mg morphine equivalent/day) opioid prescription or have used opioids for greater than 30 days
- 8. Have history of or current polyopioid use
- 9. Have received opioid pain prescription plus:
 - a. Have rotated from one opioid to another because of possible incomplete cross-tolerance
 - b. Are smoking or have COPD, emphysema, asthma, sleep apnea, respiratory infection, other respiratory illness
 - c. Have been diagnosed with renal dysfunction, hepatic disease, cardiac illness, HIV/AIDS
 - d. Have known or suspected current alcohol use
 - Have concurrent prescription or OTC medication that could potentiate the CNS and respiratory depressant
 properties of opioid medications such as benzodiazepines or other sedative medications, antipsychotics,
 carisoprodol or antihistamine use
 - f. Have concurrent antidepressant prescription
- Have difficulty accessing emergency medical services (distance, remoteness, lack of transportation, homelessness and/or without phone services.)
- 11. Are from households with people at risk of overdose, such as children or someone with a substance use disorder
- 12. Are elderly (>65) receiving an opioid prescription
- 13. Are teens receiving an opioid prescription
- 14. Have requested naloxone

Retrieved from: http://www.nmmb.state.nm.us/docs/notices/NaloxoneProviderPatientInfo.pdf

Appendix E: New Mexico Informed Consent for Naloxone Rescue Kit

NEW MEXICO PHARMACISTS ASSOCIATION Pharmacist Prescribed Naloxone Rescue Kit Informed Consent Form

Informed Consent Form		
NameAddress	Birthdate Phone ()	
questions, we will be happy to discuss them with y	nd both the pros and cons of the naloxone rescue kit. If you have you. Do not sign your name at the end of this form until you have the pharmacist has answered your questions and can witness	
Contents:		
The naloxone rescue kit I will receive contain	S:	
 One to two needle-free syringes of n 	aloxone rescue medication	
 One to two nasal adaptors 		
 Patient handout with instructions how 	v to administer naloxone	

responding, and aftercare information including information on obtaining refills Overdose Antidote:

 I understand that I will be given naloxone because I am at risk for respiratory depression due to an opioid overdose.

Written material containing information on overdose prevention, recognizing overdose,

- I understand and can recognize the signs and symptoms of an overdose.
- I understand that naloxone is a drug that reverses an opioid overdose.
- I understand that naloxone can reverse an overdose, but does not treat abuse or addiction.
- I understand how to use and administer the naloxone to both myself and to someone else.
- I understand naloxone may cause withdrawal symptoms, including nausea, vomiting, sweating, tachycardia, increased blood pressure, & tremulousness.
- I understand that naloxone may cause withdrawal symptoms within minutes after administration, which can last for one to one and a half hours.
- I understand that most opioids remain in the body longer than naloxone, and that I could
 overdose again after the naloxone wears off.
- I understand that naloxone will reverse an overdose from opioids including morphine, codeine, OxyContin, Percocet, Vicodin, other prescription pain medications, heroin and methadone.
- I have been shown/understand how to put the naloxone together to use in case of emergency.
- I understand naloxone does not prevent deaths caused by other drugs such as benzodiazepines, bath salts, cocaine, methamphetamines or alcohol.

Additional Information:

- I understand I must return to the pharmacy to request a refill or to replace an expired medication.
- I have been counseled on how to avoid an overdose and what to do if an overdose occurs.
- I understand my pharmacist is available to provide info. on substance abuse/treatment & that I
 can ask questions at any time.
- I understand when to call 911 & the Poison Center (1-800-222-1222), which is free & anonymous.

Sharing Information:

- I understand it is strongly encouraged to share this treatment information with my family & friends.
- I understand it is strongly encouraged to teach family & friends how to respond to an overdose.
- I understand that my provider will be notified that I am obtaining naloxone.

		Phone Number a copy of the Notice of Privacy Practices, addressed
Printed Name	Signature	Date
Patient Name/Info:		Date Written:
Drug/Sig/Quantity:		Prescriber:

Retrieved from: http://www.nm-pharmacy.com/Naloxone Resources/Consentonepager-1-.pdf

Appendix F: New Mexico Naloxone Prescription Reporting Form

NEW MEXICO PHARMACIST NALOXONE PRESCRIPTION PROGRAM REPORTING FORM

For all naloxone prescriptions, please complete Sections I-III bel or providing information about prior use of naloxone, regardles			
DATE	Refill (check one)		
I. PATIENT INFORMATION			
(1) First letter of legal first name:	Is your patient Hispanic/Latino? ☐ Yes ☐ No Is your patient (please check all that apply)? ☐ Hispanic/Latino? ☐ Black ☐ American Indian/Alaskan Native ☐ Asian/Pacific Islander ☐ White ☐ Unknown ☐ Other ZIP code:		
II. PHARMACY INFORMATION			
Pharmacy Name:	Pharmacy Zip Code:		
□Rx for high-dose opioid	□Current poly-opioid use		
□Rx for long-term opioid (any ME dose)	☐History of Opioid Abuse		
$\square Rx$ for opioid with concurrent benzodiazepine use	□Patient request for Naloxone		
□Rx for opioid with known/suspected alcohol use	□Other		
III. PRESCRIPTION INFORMATION_(Ask about other drug use to Which, if any, of the following drugs does the patient currently			
□Alcohol □Prescription Painkillers □Marijuana □Methadon			
\square Benzodiazepines(e.g., Xanax or Valium) \square Buprenorphine (e.	g., Suboxone) Prescription Sleep Medicine		
Naloxone Prescribed by a Pharmacist? \square Yes $\ \square$ No $\ $ Amount	prescribed: x 2.0 mg intranasal dosages		
IV. USE AND/OR REFILL INFORMATION (Complete only for refil	s or previous naloxone use)		
Was Naloxone administered to a person? □Yes□No			
If no, what happened to the naloxone? (stop after completing this question)			
□lost □expired □stolen □given to a friend or family	member 🗆 other		
If yes, was it administered to:			
□patient □adult family member □family member bel	• • •		
Date of Naloxone Use:(approximate month/year) An Which of the following drugs were used at time of the overdoon			
□Alcohol □Prescription Painkillers □Marijuana □Methadon	e □Cocaine □Methamphetamine □Heroin		
\square Benzodiazepines(e.g., Xanax or Valium) \square Buprenorphine (e.	g., Suboxone) Prescription Sleep Medicine		
Did someone do rescue breathing? □Yes □No □Unknown Did someone call 911? □Yes □No □Unknown			
What was the outcome? □Person OK □EMS □Emergency R	oom Hospitalization Deceased Unknown		

Please use the Naloxone Cover Sheet & fax completed forms to 505-272-5892

Retrieved from:

http://www.nmpharmacy.com/Pharmacist Prescribing/Naloxone Resources/naloxone reporting form FINAL6-314.pdf

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The Medicaid Evidence-based Decisions Project (MED) is housed at the Center. Its mission is to create an effective collaboration among Medicaid programs and their state partners for the purpose of making high-quality evidence analysis available to support benefit design and coverage decisions made by state programs. Further information about the MED Project and the Center is available at www.ohsu.edu/policycenter.

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