Preventing the Consequences of Opioid Overdose: Understanding Naloxone Access Laws

Naloxone is a prescription medication that reverses the effects of an opioid overdose.[1] It has become an essential tool for providers and prevention programs aiming to prevent overdose death and disability.

All 50 states allow medical providers to prescribe naloxone to patients who are risk for an opioid overdose,[2] including those in outpatient treatment for opioid misuse or who take high doses of prescription opioids for medical conditions.[3-7] However, many individuals who are most at risk for an opioid overdose do not have regular contact with health professionals and would benefit from alternative means of obtaining naloxone.[8]

Naloxone access laws make naloxone easier to obtain by expanding how the medication can be distributed beyond traditional prescriptions.[9] This document describes the aims of naloxone access laws and the various forms they can take. It also includes examples of distribution programs that prevention practitioners have implemented in the context of their own states' naloxone access laws, and a chart that compares the three primary naloxone prescription models.

BEYOND TRADITIONAL PRESCRIPTIONS

Professionals have used naloxone to reverse opioid overdoses in medical settings since the early 1970s. Before any state had passed naloxone access laws, all had permitted **traditional naloxone prescriptions.** Under the traditional prescription model:

- **Providers can prescribe naloxone to individual patients under their care who are at high risk of opioid overdose.** These patients might be at high risk because they have been prescribed high doses of opioids, have health conditions that limit breathing, have a history of substance use-related problems, use non-prescription opioids, and/or receive medication-assisted treatment.[3-7]
- **Only pharmacists or physicians can distribute naloxone.** This means that most people who receive a naloxone prescription must go to a pharmacy to obtain the rescue medication (with the exception being people who receive it directly from the physician through a community-based program).

Recently, experts and advocates have recognized the need for naloxone to be in the hands of those individuals most likely to respond to an overdose.[9-10] These first responders include family, friends,

harm reduction program staff, law enforcement officers, emergency medical technicians (EMTs), and others.[9] New naloxone access laws expand access to these individuals by:

- **Expanding who can receive naloxone** beyond those directly at risk of an overdose[9,11-12]
- **Expanding who can distribute naloxone** beyond pharmacists. [9,11-12]
- **Simplifying the process of obtaining naloxone**, that is, removing the need to go to a prescriber and/or pharmacy. [9,11-12]

State laws vary in terms of the extent to which they broaden naloxone access and the ways they do so.[11-12] The sections below describe the two broad types of naloxone prescriptions that access laws address—**third-party prescriptions** and **non-patient-specific prescriptions**.

THIRD-PARTY PRESCRIPTIONS

Many states' naloxone access laws permit third-party prescriptions—that is, prescriptions issued to a third party who is not at risk of overdose for use on someone else. Here are some important things to know about third-party prescriptions:

- **Prescribers can write naloxone prescriptions for people who are likely to encounter an overdosing person.** In most states, this includes friends, family members, or professionals who work with at-risk individuals.[9]
- **Some states have extra requirements before third parties can obtain naloxone.** These include receiving trainings or instructional materials on how to use the medication.[11-12]
- **Nearly all states provide specific legal protections for those who distribute, carry, and/or administer naloxone as permitted by law**. However, these protections are generally not *needed.* By definition, it is not a crime for professionals or laypeople to distribute, carry, and/or administer naloxone in accordance with state law.[11-12]

THE ROLE OF PREVENTION: TRAINING AND PRESCRIBING NALOXONE TO THIRD PARTIES

Prevention Point Pittsburgh (PPP): A public health advocacy and needle exchange program, PPP targets clients who use opioids and frequently report encountering overdoses. PPP has operated a naloxone access program since 2005, initially providing naloxone training and distribution solely to people who use opioids. In 2015, state law was changed to permit the program to include anyone in a position to respond to an opioid-related overdose. From 2005 to 2014, PPP trained approximately 125 people per year in preventing and identifying opioid overdoses, as well as administering naloxone. With the expansion of the potential number of naloxone recipients, this number jumped to 864 in 2015.[13-15]

Originally, many laws permitting third-party prescriptions required that the third party interact with a prescriber before obtaining the naloxone. More recently, states with laws that permit non-patient

specific prescriptions have removed this requirement.[16] Non-patient-specific prescriptions are described further below.

NON-PATIENT-SPECIFIC PRESCRIPTIONS

Non-patient-specific prescriptions authorize naloxone distribution to individuals and organizations that meets specific criteria without needing to interact with a prescriber beforehand.[917] These non-patient-specific prescriptions are especially useful for individuals who are at high risk for an opioid overdose, but unwilling or unable to see a medical provider due to factors such as insurance status (underinsured or uninsured), stigma, and lack of transportation.

Here are some important things to know about non-patient-specific prescriptions:

- Non-patient-specific prescriptions provide the most flexibility in terms of who has access to naloxone and where naloxone can be obtained. They also show the greatest potential for wide-scale distribution.[18]
- Similar to third party prescriptions, state laws protect professionals and laypeople who distribute, carry, or administer naloxone obtained from non-patient-specific prescriptions.[9,11-12,17,19-20]
- In most states, anyone at risk for an opioid overdose or likely to be in a position to assist in the event of an overdose is eligible to receive naloxone via a non-patient-specific prescription.[17]
- Several states require that individuals who prescribe, distribute, or receive naloxone through non-patient-specific prescriptions obtain training or instructional materials beforehand.[11-12,17]

A variety of models have emerged for non-patient-specific prescriptions, based on the state's particular naloxone access laws and regulations. These include the following:

Expanding pharmaceutical distribution of naloxone. Several types of non-patient-specific prescriptions allow pharmacies to dispense naloxone to individuals who request it without their own prescription from a provider. These types differ based on who authorizes them (that is, a prescriber vs. a medical agency) and the types of formal agreements on which they are based. They include:

- **Standing orders.** Written by prescribers, these orders authorize pharmacies to dispense naloxone to patients without a prescription from a provider.[9,17,21] For example, community prescribers can sign a standing order to authorize local pharmacies, or state-level physicians (that is, the physician general, secretary of health and human services) can authorize all pharmacies in the state.

THE ROLE OF PREVENTION: PHARMACIST DISTRIBUTION OF NALOXONE TO RELEASED INMATES

Overdose Education and Naloxone Distribution (OEND) in Southern Maryland Detention Centers: In December 2015, Maryland's Deputy Secretary for the Department of Health and Mental Health issued a statewide standing order authorizing pharmacists to dispense naloxone to individuals trained and certified under the state's Overdose Response Program.[22] Subsequently, three local health departments partnered with local detention centers and used Department funding to support overdose response education to inmates and provide them with naloxone from the detention center medical provider upon release. These former inmates were also able to obtain naloxone from a pharmacy if needed again in the future.[23]

- **Protocol orders.** These are similar to a standing order except the authorization to dispense naloxone comes from a state board of health or pharmacy licensing board instead of a licensed prescriber.[17] Protocol orders are always written at the state level, meaning that any pharmacist in the state who follows the requirements of the order (which typically involves receiving training on naloxone) can become eligible to dispense naloxone without a patient-specific prescription. Protocol orders are permitted in several states, however, in Kansas and West Virginia they are the only mechanism through which pharmacists are permitted to dispense or distribute naloxone without a patient-specific prescription (as of October 2017).[12]

THE ROLE OF PREVENTION: PROTOCOL ORDERS FOR NALOXONE DISTRIBUTION IN PHARMACIES

In **New Mexico and California,** pharmacists can complete a specified training protocol and obtain the authority to distribute naloxone directly to patients without a prescription from an outside provider.[12] In both of these states, the Medical Board and Board of Pharmacy developed and approved the protocol; in New Mexico, the state Nursing Board was also involved.

- **Collaborative practice agreements.** These are another type of formal agreement between prescribers and specific pharmacies or pharmacy chains within a state. Like standing and protocol orders, they permit the pharmacist to dispense naloxone without the patient first seeing a prescriber. Only a few states use this type of agreement.[17]

THE ROLE OF PREVENTION: COLLABORATIVE PRACTICE AGREEMENTS FOR NALOXONE DISTRIBUTION IN PHARMACIES

Rhode Island Board of Pharmacy Collaborative Practice Agreement: From January 2014 to May 2015, Rhode Island pharmacies dispensed 572 naloxone kits via collaborative practice agreements, representing 25% of all naloxone distributed in the state. Experts believe this contributed to a much smaller increase in opioid overdose deaths (7) between 2013 and 2014 compared to surrounding states such as Massachusetts and New Hampshire (at least 40).[22]

- **Pharmacist prescriptive authority.** This approach allows pharmacists to prescribe naloxone without an order or agreement from a physician, pharmaceutical board, or board of health. As of October 2017, only a handful of states permitted this practice[12] and in most of them, pharmacists are required to complete an approved training, record each time they distribute naloxone, and provide training or informational materials to patients receiving naloxone. From the patients' perspective, obtaining naloxone from a pharmacist with prescriptive authority is no different from obtaining naloxone from a pharmacist who can distribute under an order or agreement.

While it is important for pharmacies to know the particulars of their own state's requirements and the models that dictate distribution, from the standpoint of the patient these different types of non-patient-specific prescriptions are largely non-distinguishable.

Permitting distribution of naloxone in community settings. Many states have passed legislation that allows non-medical professionals to distribute naloxone within community settings even if they are not otherwise permitted to distribute prescription medications. This is especially useful for community-based Overdose Education and Naloxone Distribution (OEND) programs. OEND programs aim to educate lay individuals in the community on identifying and responding to overdoses, in addition to providing naloxone at little to no cost. Allowing these programs to distribute naloxone without needing a licensed prescriber on the premises saves resources and increases access. Official permission for these programs is granted by a **standing order** from a prescriber.[9,24-29]

THE ROLE OF PREVENTION: USING STANDING ORDERS TO DISTRIBUTE NALOXONE IN COMMUNITY SETTINGS

Massachusetts Community Bystander OEND Program: This program was implemented via a collaboration between the Massachusetts Department of Public Health Commissioner's Office, Office of HIV/AIDS, and Bureau of Substance Abuse Services. It was made possible by a standing order from a state-level medical director who authorized overdose prevention trainers to provide training and distribute naloxone to potential overdose bystanders within various community agencies. Between 2007 and 2016, these trainers trained and distributed naloxone to 48,222 individuals, including opioid users, social service agency workers, friends/families of opioid users, and others. A total of 8,149 overdose reversals occurred using OEND program naloxone.[22-24]

Naloxone Distribution in New Mexico: In March 2016, legislation went into effect in New Mexico that expanded community-based access to naloxone. The law permits "any person" acting under a physician standing order to store or distribute naloxone (e.g., pharmacists may distribute naloxone to staff at overdose prevention programs who are permitted to distribute under a standing order). As a result, prevention efforts have focused on training and distributing naloxone to laypeople (e.g., people who use opioids and their friends and families) who would be in a position to respond to an overdose prior to the arrival of fire/emergency medical services, or law enforcement. Since the statute was passed, the state epidemiologist has issued a separate standing order permitting law enforcement officers to carry and administer naloxone.[25,29]

COMPARING PRESCRIPTION MODELS: PROS AND CONS

Prescription Model	Benefits for Prevention Efforts	Drawbacks for Prevention Efforts	Which States Permit this Model?*
Traditional	• Can prescribe naloxone to patients with opioid addiction, including individuals on medication-assisted treatment (e.g., methadone). • Can prescribe naloxone with opiate analgesics to individuals who use them as prescribed but are vulnerable to overdose	• Obtaining naloxone is a two-step process (see provider, then fill Rx at pharmacy) • Time, money, lack of insurance, and stigma act as barriers to seeking/filling Rx • Patient may not be around someone who is willing/able to administer naloxone • Does not improve access for certain first responders (e.g., EMS, law enforcement officers, firefighters)	• All 50 states and the District of Columbia (D.C.)
Third Party	• People not at personal risk may be more comfortable accessing healthcare for this medication (less stigma) • Takes the responsibility out of hands of individuals who may have little access to healthcare	• May still require a visit to a prescriber in communities not covered by a non-patient-specific prescription • Doesn't make it easier for those most at risk to obtain naloxone	• 45 states and D.C. permit third-party Rx's. • States that do not: DE, MN, KS, MO, VA
Non-patient-specific - Standing Orders - Collaborative practice agreements - Protocol Orders	• Shows the most promise in terms of contributing to broad expansion of naloxone access • Naloxone distribution without need for prescriber visits • Lower threshold for receiving naloxone	• Lack of awareness around ability to distribute naloxone without liability • Limited resources or funding for programs to purchase and distribute naloxone (with lay distribution)	• 49 states and D.C. permit some model of non-patient-specific prescriptions • States that do not: NE • 26 states also have statutes

Prescription Model	Benefits for Prevention Efforts	Drawbacks for Prevention Efforts	Which States Permit this Model?*
Non-patient-specific (cont.)	• Often permits naloxone to be distributed in community settings and by lay individuals	• May require a special training before distributing or receiving naloxone	permitting lay distribution

*As of July 2017

WHERE TO LEARN MORE ABOUT NALOXONE ACCESS LAWS

For general information about your state's policies regarding naloxone, see the following online resources:

- **Naloxone Overdose Prevention Laws Database; Database from the Prescription Drug Abuse Policy System website.**

  This database, in the form of an interactive US map from the Prescription Drug Abuse Policy System website, allows users to look up naloxone access laws by state. As of October 2017, the site covers laws passed from 1/1/01 to 7/1/17.

- **Legal Interventions to Reduce Overdose Mortality: Naloxone Access and Overdose Good Samaritan Laws.**

  This fact sheet, from the Network for Public Health Law website, provides a comprehensive table of naloxone access policies by state as of July 15, 2017.

For more detailed information regarding what is permitted in your state, contact the following:

- **The Network for Public Health Law.**

  The Network for Public Health Law's website provides helpful resources regarding the development, evaluation, and enforcement of law and policy to improve health outcomes. The network also offers no-cost technical assistance and training and collaborates with public health practitioners; local, tribe, state, and federal officials; policy makers; public health advocates; and others.

- **State-level practitioners in your state's health departments and on your state's pharmacy board.**

  See this page from the Centers for Disease Control and Prevention to look up Health Departments by state or territory.

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