

Expanding Access to Opioid and Heroin Overdose Reversal Agents (Naloxone)

According to the U.S. Centers for Disease Control and Prevention, the rate of deaths from drug overdoses has increased 137%, including a 200% increase in the rate of overdose deaths involving opioids (opioid pain relievers and heroin), since 2000.¹ Communities across the country are faced with the growing challenge of how to prevent overdose and assist those in an overdose situation. While 94% of prescription opioids are generic,¹ the Pharmaceutical Research and Manufacturers of America (PhRMA) and its members are committed to working with others to collectively address this complex public health challenge.

Opioids in high doses can lead to respiratory depression and death. The effects of opioid overdose can be reversed if the person receives basic life support and the timely administration of the medication naloxone. Naloxone products, sometimes referred to as “rescue drugs” or “overdose reversal agents,” are used to counter the effects of overdose from heroin and other opioids. These medications are not controlled substances, meaning there is not a potential for abuse. They only have an effect in a person that has opioids in his/her system.

Opioid overdose is a critical public health threat requiring a comprehensive strategy that includes the implementation of evidence-based approaches, including expansion of overdose education efforts and access to overdose reversal agents. We support public policies to:

- *Expand the scope of “first responders”* to include those who are most likely to be presented with the need to assist an overdose victim (e.g., law enforcement officers, firefighters, pharmacists, paramedics and emergency technicians, and family members and other loved ones). Some states, for example, allow access to naloxone products without a prescription, while others permit family members and caregivers in cases of emergency to possess and administer opioid reversal agents provided they have received training on the appropriate use of opioid reversal agents.
- *Provide training and education for first responders in overdose prevention and steps to assist an overdose victim.* Expanded education and training is needed for potential first responders, including family members, and should include how to identify overdose risk factors, signs and symptoms, the steps to assist in a potential overdose situation, the

¹ Among the most abused prescription medicines (opioids, CNS drugs, and stimulants) an estimated 94% of prescriptions at the retail level were for generic medicines in calendar year 2015 (including 94% of opioids). PhRMA analysis of IMS National Prescription Audit, April 29, 2016.

appropriate use of opioid reversal products, and the importance of seeking immediate medical care for the individual experiencing an overdose.

- *Assess whether and under what circumstances civil immunity could or should be granted to a prescriber providing the product to a first responder and to a person who aids those at peril who are otherwise incapacitated, on a voluntary basis in an emergency, by administering an opioid reversal agent.*
- *Identify and disseminate best practices for opioid overdose prevention strategies.* A growing body of research has documented the value of community-level pilot programs in addressing opioid overdose. Lessons learned and best practices from pilot and ongoing programs can help inform the development and implementation of comprehensive measures to prevent overdose deaths.

Questions and Answers About Overdose Reversal Agents

The following are answers to some of the commonly raised questions about overdose reversal agents:

Is naloxone effective only for overdose caused by opioids?

Yes. Naloxone only reverses the effects of prescription opioid analgesics and heroin. If someone overdoses on an illicit drug or prescription medicine that is not an opioid, naloxone will have no effect.

How and by whom are these products administered?

Naloxone is available for intravenous, intramuscular or subcutaneous use, and with a recent approval, it is now available as a nasal spray.

Depending on state law, the medication may be administered by a health care provider, pharmacist, emergency responder, a family member or caregiver who has received appropriate training. In some states, the medication is available without a prescription, and in some cases is purchased directly from the manufacturer, e.g., by emergency services.

Is naloxone only available by prescription?

Historically, access to naloxone products has been limited to circumstances in which there was a direct physician-patient relationship and providing the drug to anyone other than the patient was prohibited by law.

As noted above, many states have sought to update their laws to expand access to naloxone among those likely to be in a position as first responder such as paramedics and other emergency medical services personnel, law enforcement, pharmacists, parents and other caregivers.

Several states and pharmacy chains have made naloxone available over the counter without a prescription. For example, in February 2016, these products became available over-the-counter via a pharmacy chain in New York and will be available without a prescription in Indiana and Ohio.ⁱⁱ

In addition, direct sales of these products are occurring between manufacturers and community departments, such as emergency service providers, in states where these products are available without a prescription.

Is naloxone available in generic form?

Yes. Naloxone was first approved in the 1970s and has been widely available in generic form for decades.

What are “good samaritan” laws?

Often parents, caregivers and other “witnesses” are in the best position to administer naloxone to someone who may be having an overdose. To encourage people to seek medical attention for an overdose after naloxone has been administered, 34 states and the District of Columbia have enacted laws providing some form of immunity for those acting in “good faith” to assist someone experiencing an opioid overdose.ⁱⁱⁱ

ⁱ <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm>

ⁱⁱ Scutt, S. Walgreens To Sell Naloxone, Heroin And Prescription Pain Med Overdose Antidote, Over The Counter Medical Daily, 2/10/2016; <http://www.medicaldaily.com/walgreensnaloxone-overdose-antidote-over-counter-372980>

ⁱⁱⁱ National Conference of State Legislators. Drug overdose and Good Samaritan laws. 11/2015; <http://www.ncsl.org/research/civil-and-criminal-justice/drug-overdose-immunity-good-samaritan-laws.aspx>