pennsylvania
DEPARTMENT OF HEALTH
PRESCRIPTION DRUG MONITORING PROGRAM

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State Regulation of Naloxone Access & Use

Introduction

Opioids affect the part of the brain that regulates breathing. When used in high doses, opioids may cause respiratory depression and death. During an overdose, the gradual slowing of an individual's breathing leaves time for an individual to intervene and reverse the effects of the drug before it causes death.[1] Naloxone is a medication that quickly reverses opioid overdoses. As an opioid antagonist, naloxone binds to receptors to block and reverse the effects of other opioids that may be present in an individual's body. When naloxone is administered to an opioid user, it immediately sends the individual into withdrawal. Side effects of naloxone include dizziness, nausea, shaking and sweating, which – although unpleasant – are rarely dangerous. If an individual has not used opioids and is given any form of naloxone, the individual will not feel any negative or positive effects from the drug. Naloxone is available as an injectable, which requires professional training to administer; an auto injectable, which requires no training and can be administered by anyone; and as a prepackaged nasal spray, which also requires no training for administration.[2]

While naloxone has clear benefits, there is some disagreement between states and the federal government when it comes to regulating its availability and use. Naloxone is a potentially life-saving intervention available to those suffering from opioid dependence, those living with someone suffering from dependence, and for individuals living in an area where they may witness an overdose. However, many politicians and community activists disagree on the benefits of making naloxone widely available. Critics argue that by making naloxone more available, people will be more likely to abuse opioids. They believe that naloxone provides both illicit and prescription drug users a safety net, allowing them to take more risks because of its widespread availability.[3] Research has shown otherwise; harm reduction by means of naloxone intervention has not been shown to increase drug use.[4] Moreover, by saving a user from an opioid overdose with naloxone, the user is granted a new opportunity to seek treatment for opioid dependence.

The federal government, all 50 states and the District of Columbia have passed laws increasing naloxone access.[5] While Pennsylvania's law is similar to laws in other states, there are some key differences that may highlight opportunities for improvement.

Federal Policy

Federal law regarding naloxone is scarce, deferring regulation of the drug largely to the states. The Food and Drug Administration first approved the use of naloxone in 2002.[6] While many laws have addressed funding for research into naloxone, few have stipulated requirements for naloxone access on a state level. Federal policy related to naloxone originates largely from the Comprehensive Addiction and Recovery Act of 2016, which calls for federal grants to be awarded to states with the goal of expanding access to and education about naloxone.[7] The Act also called for a review of state and local Good

Samaritan laws which grant immunity to administrators of naloxone and underlines the benefit of authorizing third party prescriptions of naloxone.[8] While the Act does touch on many of the issues addressed by the various state laws concerning access to naloxone, it does not provide a unified federal policy.

Pennsylvania Policy and the National Landscape

Regulation of Prescribing & Dispensing Naloxone

While the leading federal law on naloxone access was not enacted until 2016, many states have had naloxone access laws on the books for years.[9] Pennsylvania enacted its first and current naloxone access law, the Drug Overdose Response Immunity Act, in 2014.[10] Like the majority of states' naloxone access laws, Pennsylvania's law addresses the key issues of third party prescriptions, non-patient-specific prescriptions, and immunity for the various parties involved.[11] Under Pennsylvania's law, prescribers of naloxone have immunity from criminal prosecution for prescribing, dispensing, or distributing naloxone to laypersons, and immunity is not conditioned upon participation in a naloxone administration program nor a showing that the prescriber was acting with reasonable care.[12] Thirty-four states and D.C. offer immunity from criminal liability to prescribers, though 14 states (up from four states in 2014) now require prescribers to have been acting with reasonable care. Similarly, under Pennsylvania's law, prescribers also have immunity from civil liability and from professional sanctions, and there is neither a naloxone administering program requirement nor a reasonable care requirement to secure civil immunity.[13] Thirty-two states and D.C. grant prescribers immunity from professional sanctions, and 38 states and D.C. grant civil immunity to prescribers. As of 2016, 12 states have implemented a reasonable care requirement that limits prescribers' civil immunity.

Under the Pennsylvania law, naloxone dispensers are granted the same immunities as prescribers. Dispensers, like prescribers, also have no reasonable care or program participation requirements attached to their civil or criminal immunity. To date, 32 states and D.C. offer criminal immunity to dispensers and 37 states and D.C. offer civil immunity. However, 13 states (up from two in 2014) now require a showing of reasonable care for dispensers to be granted criminal immunity, and 12 states (up from three in 2014) require it for civil immunity. In total, 31 states and D.C. offer immunity to dispensers from professional sanctions.

For third party prescriptions and non-patient specific prescriptions, Pennsylvania's law aligns with most state laws. Under Pennsylvania's law, prescriptions for naloxone are authorized to third parties with no further requirements. Similarly, pharmacists are allowed to use a standing order to dispense naloxone without a patient-specific prescription from another medical professional. Forty-three states and D.C. allow for third party prescriptions of naloxone; however, 14 states (up from three in 2014) have implemented a reasonable care requirement, and two states (down from four in 2014) require participation in a naloxone program for third party prescriptions to be authorized. Meanwhile, 45 states and D.C. allow for non-patient specific prescriptions. Of the jurisdictions that allow for non-patient specific prescriptions, 39 states and D.C. require that the prescriptions be dispensed using a standing order.

Regulation of Naloxone Administration

Laypersons who administer naloxone to third parties are granted immunity from both civil and criminal liability under Pennsylvania's law. While the majority of other states also provided layperson immunity, Pennsylvania's law makes layperson immunity contingent on a showing of reasonable care. Pennsylvania's law does not provide a definition of reasonable care, nor have any cases been litigated regarding this provision of the law. Restatement (Second) of Torts § 298 defines reasonable care as "the care which the actor is required to exercise to avoid being negligent in the doing of the act is that which a reasonable man in his position, with his information and competence, would recognize as necessary to prevent the act from creating an unreasonable risk of harm to another."[14] Of the 34 states and D.C that grant criminal immunity to laypersons, and the 42 states and D.C which grant civil immunity to laypersons, only 18 have a reasonable care requirement. Due to the nature of opioid overdoses, third party laypersons are often most immediately available to administer naloxone. There is broad concern that including a reasonable care requirement for layperson immunity may cause bystanders to be reluctant to assist someone who is overdosing, for fear of not assisting to an amorphous "reasonable care" standard and/or of exposing their own drug-related crimes.[15]

Regulation of Naloxone Possession

The final issue addressed by naloxone access laws is how to regulate possession of naloxone without a prescription. Pennsylvania and 32 other states have not decriminalized possession of naloxone without a prescription. In Pennsylvania, a standing order permits "eligible persons," as defined in the standing order, to obtain and lawfully possess naloxone without an individual prescription.[16] When Pennsylvania first implemented its naloxone access law in 2014, only six states and D.C. had decriminalized non-prescribed possession of naloxone. As of 2017, nine more states have followed suit.

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[1] Maia Szalavitz. "Naloxone Debate: FDA Hears Testimony About Making an Overdose Antidote Nonprescription," *Time Magazine*, April 13, 2012, http://healthland.time.com/2012/04/13/naloxone-debate-fda-hears-testimony-about-making-an-overdose-antidote-nonprescription/.

[2] "Administering Naloxone, Overdose Response," *Harm Reduction Coalition*, http://harmreduction.org/issues/overdose-prevention/overview/overdose-basics/responding-to-opioid-overdose/administer-naloxone/.

[3] Carrie Arnold, "The Fight for the Overdose Drug," *The Atlantic*, December 29, 2014 athttps://www.theatlantic.com/health/archive/2014/12/the-fight-for-the-overdose-drug/383467/.

[4] Gabay, M. (2016). Increasing Access to Naloxone and Legal Issues. Hospital Pharmacy, 51(8), 633–634. http://doi.org/10.1310/hpj5108-633

[5] Davis, C., "Naloxone Overdose Prevention Laws," 2017, Prescription Drug Abuse Policy System. http://pdaps.org/dataset/overview/laws-regulating-administration-of-naloxone/592493ecd42e07d567ee64e2.

[6] FDA APPROVAL OF BUPRENORPHINE/NALOXONE, 148 Cong Rec S 10655, 10656 (2002).

[7] Comprehensive Addiction and Recovery Act of 2016, 114 P.L. 198 § 110 (2016).

[8] *Id.*

[9] For more detailed information on laws referenced here in Pennsylvania and other states, please see Corey Davis, "Naloxone Overdose Prevention Laws," 2017, Prescription Drug Abuse Policy System. Available at: http://pdaps.org/dataset/overview/laws-regulating-administration-of-naloxone/592493ecd42e07d567ee64e2

[10] 35 P.S. § 780-113.8.
[11] Drug Overdose Response Immunity Act. 2014 Pa. ALS 139, (2014).
[12] 35 Pa. Stat. Ann. § 780-113.8, (2014).
[13] *Id.*
[14] Restatement (Second) of Torts § 298.
[15] Gabay, M. (2016). Increasing Access to Naloxone and Legal Issues. Hospital Pharmacy, 51(8), 633–634. http://doi.org/10.1310/hpj5108-633.
[16] Standing Order DOH-002-207: Naloxone Prescription for Overdose Prevention. Pennsylvania Department of Health. Available at: http://www.health.pa.gov/My%20Health/Diseases%20and%20Conditions/M-P/opioids/Documents/Naloxone%20Standing%20Order%20DOH%20Public%20April%202017.pdf.