

RxLegal

Increasing Access to Naloxone and Legal Issues

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According to the Centers for Disease Control and Prevention (CDC), drug overdose deaths in the United States reached a record high in 2014 and more than 28,000 individuals died due to an overdose involving an opioid.¹ Of these deaths, more than 50% were related to prescription opioids. Fatalities from prescription opioid overdose have quadrupled since 1999 in the United States, along with a corresponding increase in the prescribing of opioid medications.² The US Food and Drug Administration (FDA) initially observed a sharp increase in overdose and death related to prescription opioids in the early 2000s and commenced a series of actions to curb this emerging epidemic, including implementing risk evaluation and mitigation strategies (REMS); launching educational initiatives to ensure safe prescribing, use, and disposal of opioids; and encouraging the development of abuse-deterrent opioid formulations.³ On the state level, prescription drug monitoring programs were implemented to collect, monitor, and analyze electronically transmitted opioid prescribing and dispensing data submitted by pharmacies and dispensing practitioners.⁴ Additionally, community-based opioid overdose prevention programs increasingly provided naloxone to individuals experiencing an overdose.⁵ More recently, there has been a major push to expand access to naloxone in the community pharmacy setting. This push has been supported by many national medical and pharmacy organizations not only as a method to potentially reduce overdose deaths, but also as a way to expand the role of pharmacists in direct patient care.

As a result of this movement toward increasing naloxone access, state laws have been passed that revolve around authorized dispensing methods; providing civil, criminal, or disciplinary immunity for the prescriber or dispenser; and training, certification, and/or education requirements.⁶ One action that a majority of states has taken is to permit third party prescribing in a potential opioid overdose situation.

The purpose of such laws is to basically waive the general requirement that a prescriber must have a relationship with the patient for whom a medication is prescribed. This in turn allows for naloxone to be prescribed to a patient (parent, caregiver, friend) for administration to other individuals who may be at an overdose risk. Additionally, many states have enacted laws authorizing the use of standing orders for naloxone administration and dispensing. Standing orders, in which a prescriber authorizes the provision of medication to a person who meets predetermined criteria, are fairly common in medical practice and are used in a variety of settings such as by emergency medical system (EMS) personnel or pharmacists who administer vaccinations. Standing orders may also be part of a collaborative practice agreement involving an individual physician or on a statewide basis that allows pharmacists to prescribe naloxone to at-risk individuals. A minority of states has enacted laws that permit some or all pharmacists to prescribe naloxone on their own authority versus dispensing pursuant to an agreement with another prescriber. When this situation occurs, the pharmacist is generally held to the same standard of care and requirements that apply to physicians and other prescribers.

Efforts to expand naloxone access have resulted in increased liability concerns for some providers, whether genuine or misplaced.⁶ To address these concerns, a majority of states has altered laws to provide limited civil immunity to prescribers, dispensers, and administrators of naloxone. While the provisions within these laws vary, most require that the individual prescribing, dispensing, or administering naloxone does not act with gross negligence or reckless indifference to harm. Many of these laws also provide immunity from criminal sanction and prevent state licensing or regulatory board agencies from pursuing disciplinary actions for engaging in actions permitted by law. Due to these provisions, the prescribing, dispensing, and administration of naloxone in most

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states carries lower legal risk than the same actions taken with any other prescription medication.

The passage of good samaritan laws at the state level is another important legal topic related to increasing access to naloxone. Individuals who witness an opioid overdose are often hesitant to get involved and report the situation due to fear of being arrested themselves for a drug-related crime.⁶ As such, the majority of states have now modified laws to encourage people who witness an overdose to call for emergency responders. Most of these laws provide a person who calls for emergency responders in good faith protection from prosecution for minor drug possessions, and many also protect the caller from being arrested for those crimes. Nearly all of these laws extend the protection to the victim of the overdose as well as the individual who called for an emergency response. Some good samaritan laws go even further protecting individuals from probation or parole violations or even other drug-related crimes.

As noted in this column, pharmacists need to be aware of many legal issues related to expanding naloxone access. Of note, current in-depth resources are available to pharmacists that may be very useful in determining the applicable laws within a pharmacist's state of practice. *Pharmacy Times* hosts the Naloxone Pharmacist Resource center that contains an interactive map that allows pharmacists to review naloxone laws in their state (<https://www.pharmacytimes.org/resource-center/opioid-overdose-rescue>). Additionally, Prescribe to Prevent (<http://prescribetoprevent.org/>) contains information that is needed to start

prescribing and dispensing naloxone, including information on legal issues. Finally, the LawAtlas Policy Surveillance Portal contains information on naloxone overdose prevention laws by state as well as related resources (<http://lawatlas.org/query?dataset=laws-regulating-administration-of-naloxone>). Pharmacists should consult with these resources when questions arise regarding the appropriate prescribing, dispensing, and administration of naloxone.

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