

NALOXONE ACCESS LAWS: WHAT DO WE KNOW ABOUT KENTUCKY?

By Elham Erfanian

For years, the opioid crisis in the United States has continued to be discussed as a nationwide concern with catastrophic consequences. In 1999, the number of opioid overdose deaths in the U.S. was 8,491. According to the Center for Disease Control (CDC), in 2018 this number rose to 56,199 (a more than six-fold increase). While the number of opioid overdose deaths may report differently based on the methodology used to define an opioid death, the rate of growth is undeniably alarming.

From lowering life expectancy to its influence on the labor market, to an increased burden on the healthcare system, opioid abuse continues to have a significant impact on the economy. Whether or not we accept the argument from the former Food and Drug Administration head David Kessler who remarked that an opioid epidemic is one of the greatest mistakes of modern medicine,¹ our response to the opioid crisis requires both demand-side and

supply-side approaches. Prescription Drug Monitoring Programs are among the supply-side approaches with a focus on controlling and decreasing the misuse of prescription drugs. Among demand-side policies is the state government law implemented in 2001 named the “naloxone access law,” which includes various provisions that will be explained in more detail later. This study provides an overview of the trends in the opioid overdose deaths and the naloxone access laws in Kentucky.

Before exploring the provisions of the naloxone access law in Kentucky, it is important to consider the opioid overdose deaths within the state relative to the U.S. and the region.² At the end of 1999, Kentucky ranked 17th in the nation with 1.6 opioid overdose deaths per 100,000 population. In 2018, opioid overdose deaths per 100,000 had increased to 25.5 per 100,000, changing Kentucky’s ranking from 17th to 41st. Looking at the long-term trends in

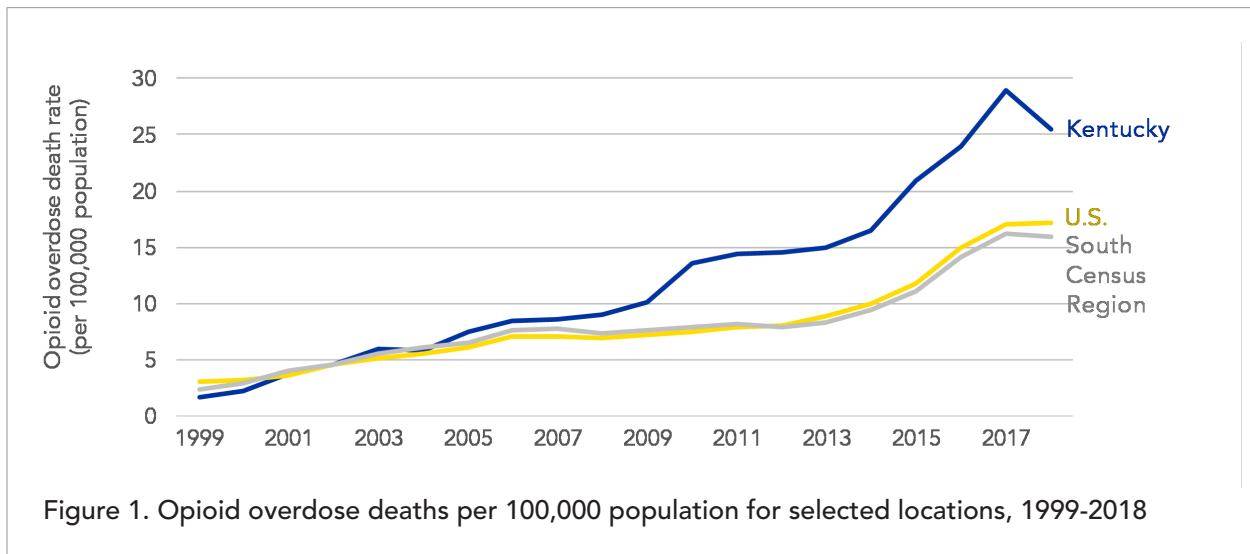


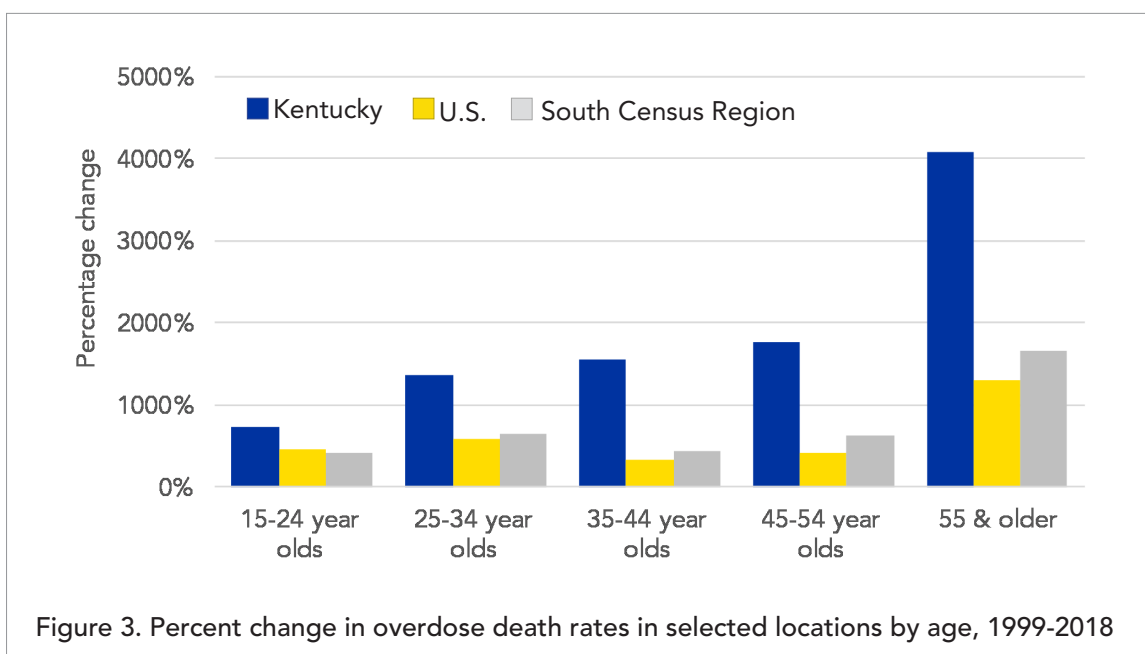
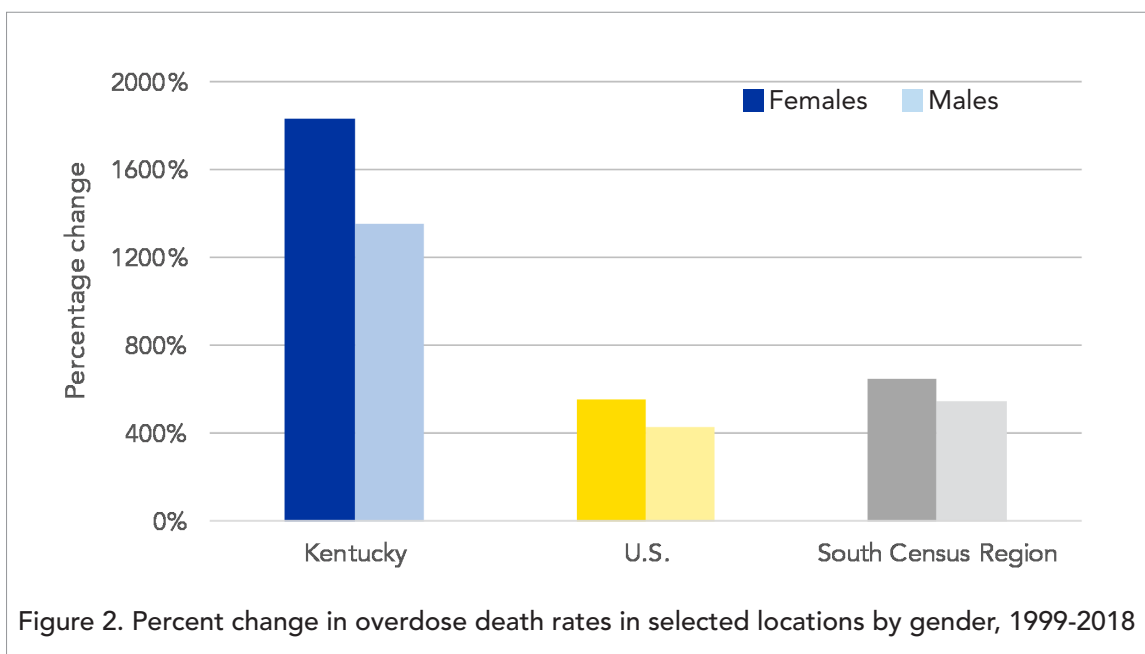
Figure 1. Opioid overdose deaths per 100,000 population for selected locations, 1999-2018

¹ Available at <https://www.cbsnews.com/news/former-fda-head-doctor-david-kessler-opioid-epidemic-one-of-great-mistakes-of-modern-medicine/>.

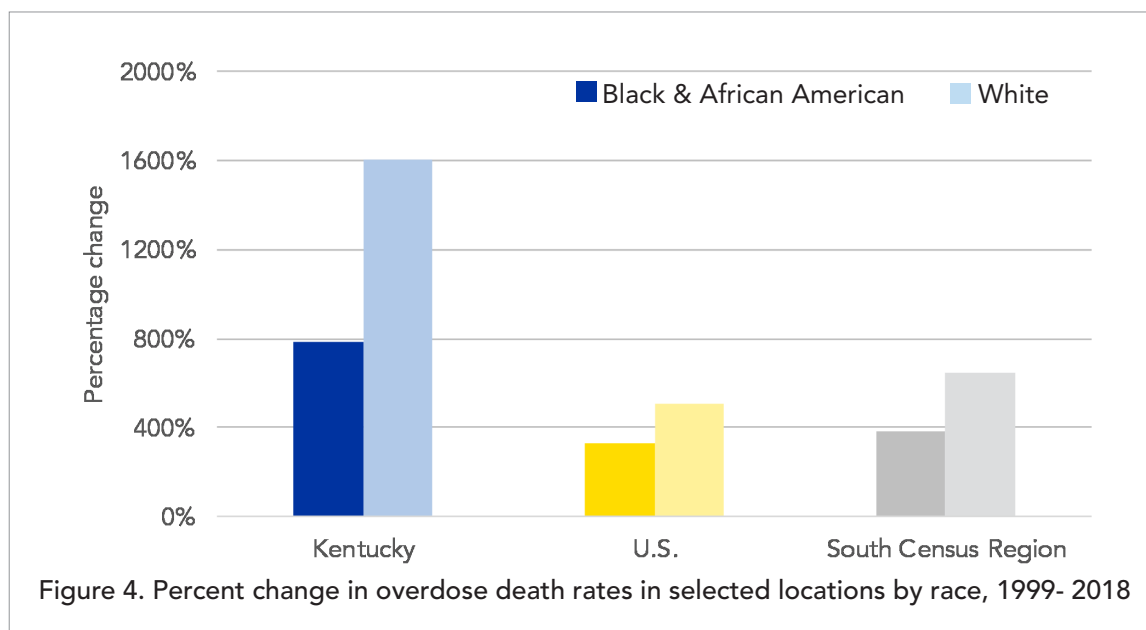
² For a list of states included in the South Census Region visit <https://www.bls.gov/regions/southeast/south.htm>

opioid overdose death per 100,000 population (OODR) in Kentucky, the U.S. and the South Census Region reveals an obvious pattern: the opioid overdose death rate is growing. Compared to the opioid overdose deaths³ in the U.S. and South, the death rate in Kentucky increased gradually at first and then more substantially after 2004 (Figure 1). After 2017, the OODR in Kentucky starts to decline rapidly.

Figures 2 to 4 illustrate the percentage change (1999-2018) in opioid overdose deaths by gender, age and race for Kentucky, U.S. and the South region. Overall, there is a gap between OODR in females and males for all three areas (Figure 2). In 1999, the OODR for males was 2.3 versus 0.9 for females in Kentucky. These numbers have grown to 33.4 and 17.8 in 2018, respectively. As a result, we see the OODR



³ For more information refer to the CDC guideline available at https://www.cdc.gov/drugoverdose/pdf/pdo_guide_to_icd-9-cm_and_icd-10_codes-a.pdf



for Kentuckian females has increased by more than 1,800 percent compared to more than 1,300 percent increase for Kentuckian males.

Across all age groups in Kentucky, individuals within the 35 to 44 age group are facing the highest OODR. The population of Kentuckians aged 25 to 34 is the second highest age group following by the 45 to 54 age group. For the 35 to 44 age group, the OODR has risen from 3.4 opioid overdose deaths per 100,000 in 1999, to 56.8 deaths in 2018. Kentuckians with the age group of 55 and above are experiencing the lowest rate of overdose deaths but the highest percentage change among all aged groups between 1999 and 2018 (Figure 3).

Another element of the opioid crisis is the frequency of death between races. As expected and following the same trend as other states in the region and the U.S., in Kentucky, the OODR among Whites is more prevalent than among Blacks and African Americans (Figure 4).

While the OODR in Kentucky among Blacks and African Americans in 1999 was higher than the OODR among Whites (1.9 versus 1.5), in 2018, these numbers changed to 17.5 for Blacks and African Americans versus

26.8 for Whites. In other words, in 2018, the OODR among Whites was 65% greater than that of Blacks and African Americans in Kentucky, while the same as the U.S. and the South between 1999 and 2018, compared to Blacks and African Americans, Whites suffer from a higher percentage change in OODR.

NALOXONE AND NALOXONE ACCESS LAWS

Naloxone (known as Narcan) is an opioid antagonist, nonscheduled (i.e., non-addictive) medication that has the ability to reverse an overdose. Injecting naloxone into a person who has opioids in their system allows them to breathe normally.⁴ Whether or not naloxone is a potential solution to the persistent opioid crisis remains a subject of intense debate. However, without question, it saves lives and provides an opportunity for users to move forward to treatment and recovery programs. To ease access to naloxone and provide more availability, states have started to implement different variations of naloxone access laws. The first state to implement the law was New Mexico (4/3/2001). As of 6/30/2017, all U.S. states have passed one or several provisions of naloxone access laws.⁵

Like other state level policies, naloxone access laws vary from state to state. According to

⁴ For more details see <https://harmreduction.org/issues/overdose-prevention/overview/overdose-basics/understanding-naloxone/>

⁵ For more details see <http://pdaps.org/datasets/laws-regulating-administration-of-naloxone-1501695139>

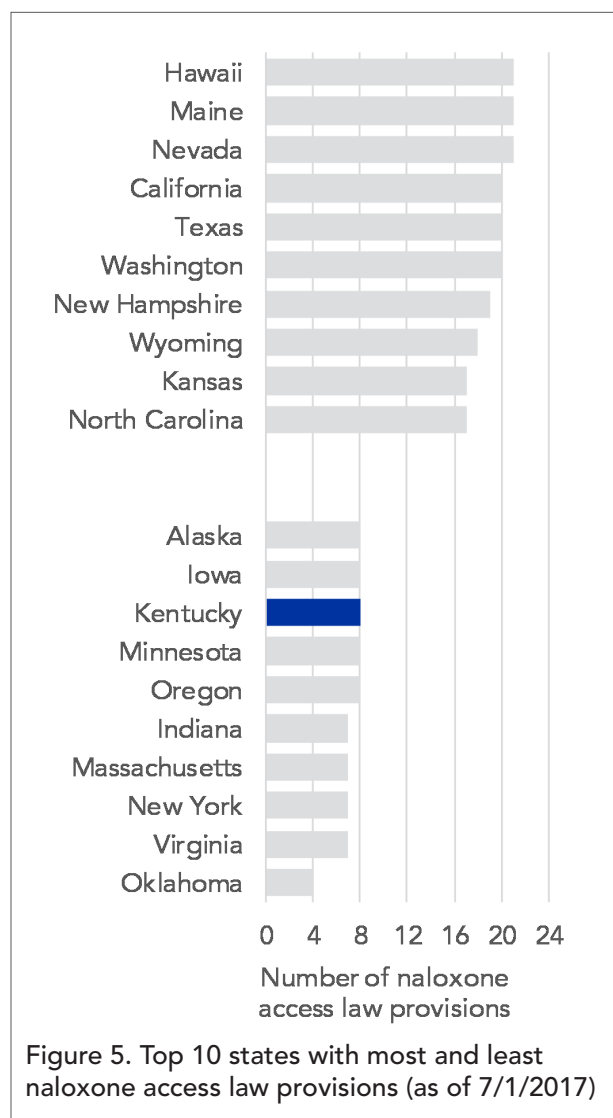
the Prescription Drug Abuse Policy System (PDAPS), as of 2017, there are 11 different provisions with 17 sub provisions in the U.S. The main provisions are listed below:

1. Prescribers' immunity from criminal prosecution for prescribing, dispensing or distributing naloxone to a layperson
2. Prescribers' immunity from civil liability for prescribing, dispensing or distributing naloxone to a layperson
3. Prescribers' immunity from professional sanctions for prescribing, dispensing, or distributing naloxone to a layperson
4. Dispensers' immunity from criminal prosecution for prescribing, dispensing, or distributing naloxone to a layperson
5. Dispensers' immunity from civil liability for prescribing, dispensing, or distributing naloxone to a layperson
6. Dispensers' immunity from professional sanctions for prescribing, dispensing, or distributing naloxone to a layperson
7. Authorizing prescriptions of naloxone to third parties
8. Allowing pharmacists to dispense or distribute naloxone without a patient-specific prescription from another medical professional
9. Laypersons' immunity from criminal liability when administering naloxone
10. Laypersons' immunity from civil liability when administering naloxone
11. Removing criminal liability for possession of naloxone without a prescription

Under provisions 1 to 6, there are three different types of immunities (from criminal prosecution, civil liability, and professional sanctions) for prescribers and/or dispensers. Provision 7 is authorizing naloxone to a third party; it allows certain people (a licensed health-care provider, firefighter, paramedic, etc.) to have the opportunity to inject naloxone. Provision 8 allows pharmacists to dispense naloxone without a patient-specific prescription. Provisions 9-10 provide immunity to laypeople from civil and criminal liabilities. Provision 11 provides immunity from criminal liability for possession of naloxone.

Provisions listed above include sub-provisions. Most of the sub-provisions are related to immunities. For instance, prescribers and dispensers' immunities from criminal prosecution or civil liability may be required as a condition of immunity. Provisions 3 and 6 do not have any sub provisions. All the sub provisions are listed below:

- 1.1. Participation in a naloxone administration program requires a condition of immunity
- 1.2. Prescribers are required to act with reasonable care
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- 4.1. Participation in a naloxone administration program requires a condition of immunity
- 4.2. Dispensers are required to act with reasonable care
- 5.1. Participation in a naloxone administration program requires a condition of immunity
- 5.2. Dispensers are required to act with reasonable care
- 7.1. Naloxone program participation required for a third party prescription
- 7.2. Prescribers are required to act with reasonable care
- 8.1. Pharmacists are allowed to dispense or distribute naloxone without a patient-specific prescription from another medical professional through standing order, protocol order, naloxone-specific collaboration practice agreement, and pharmacists' perspective authority, or directly authorized by legislature
- 9.1. Naloxone program participation required for a condition of immunity
- 9.2. Laypeople are required to act with reasonable care
- 10.1. Naloxone program participation requires a condition of immunity
- 10.2. Laypeople are required to act with reasonable care
- 11.1. Participation in a naloxone administration program required as a condition of immunity
- 11.2. Acting with reasonable care required as a condition of immunity



As of July 2017 (the most recently available year of data), Kentucky is among the states that have passed few provisions of naloxone access law (Figure 5). Hawaii, Maine and Nevada are among states with greater accessibility and availability of naloxone, while Oklahoma, Virginia and New York are among states with fewer naloxone access laws.

Since June 2013, Kentucky has implemented a strategy of moving toward greater availability and accessibility of naloxone in order to save lives. The law was amended in 2015. However, among 30 different provisions and sub-provisions, Kentucky has passed only a few of

⁶ Available at <https://apps.legislature.ky.gov/law/statutes/statute.aspx?id=49014>

them. As of 2015, immunity from professional sanction for prescribers as well as dispensers has been employed, while immunity from criminal prosecution and civil liability have not been implemented yet.

Third party authorization is one of the effective provisions in Kentucky. According to the Kentucky Legislature⁶, a peace officer, jailer, firefighter, paramedic, or emergency medical technician or a school employee authorized to administer medication under KRS 156.502 can receive a prescription for naloxone. An above-mentioned person may possess naloxone and any equipment needed for administering it. In addition, they may administer naloxone to an individual experiencing an overdose.

Another provision of naloxone access law in Kentucky is the availability of the standing order by pharmacists. With a “standing order,” pharmacists are allowed to dispense naloxone to an at-risk-person or to a person who is in a position to assist an at-risk-person who does not have a patient-specific prescription.

The last two implemented provisions in Kentucky are immunity from criminal and civil liability for a layperson. Due to these two immunities, any person (who acts in a good faith), administers naloxone shall be immune from any outcomes of administering naloxone.

SUMMARY AND CONCLUSIONS

Opioid overdoses are increasing at an alarming rate in the United States. Kentucky’s opioid overdose death rate is higher than the national level, as well as the south region. This study is not analyzing the causal relationship between naloxone access laws and opioid overdose deaths, but rather discusses the naloxone access laws and its provisions in Kentucky. As of 2017, the most recent year of data, Kentucky ranks among the less supportive states for naloxone accessibility and availability. Prescribers and dispensers are only immune against professional sanctions, not criminal prosecution nor civil liability. Criminal liability for possession of naloxone without a prescription has not yet been removed.

With regard to the persistent and high opioid overdose deaths in Kentucky, policies should be aimed at relaxing or removing obstacles that prevent the saving of lives should be viewed as strategies intended to provide an opportunity for individuals to gain a fresh start and enable them to pursue treatment and rehabilitation. Improving accessibility and availability of naloxone as an antidote for opioid overdoses through lessening the liabilities faced by prescribers, dispensers, laypeople, and other health-care providers who are eligible to dispense, deliver, and administer naloxone is a crucial step in tightening the opioid cycle. Steps like launching the online naloxone registry provided by the Kentucky Office of Drug Control Policy (ODCP)⁷ is encouraging, in that it allows at-risk individuals to locate pharmacists that dispense naloxone without a patient-specific prescription.

In conclusion, in order to more effectively combat and control the opioid crisis, a welcoming attitude toward providing more immunity to workers in our health-care system who are actively engaging with opioid patients, along with support for treatment and recovery programs will achieve the best outcomes.

⁷ Available at <https://www.pharmacytimes.com/publications/issue/2017/January2017/increasing-national-naloxone-access-kentucky-is-first-to-open-online-naloxone-registry>