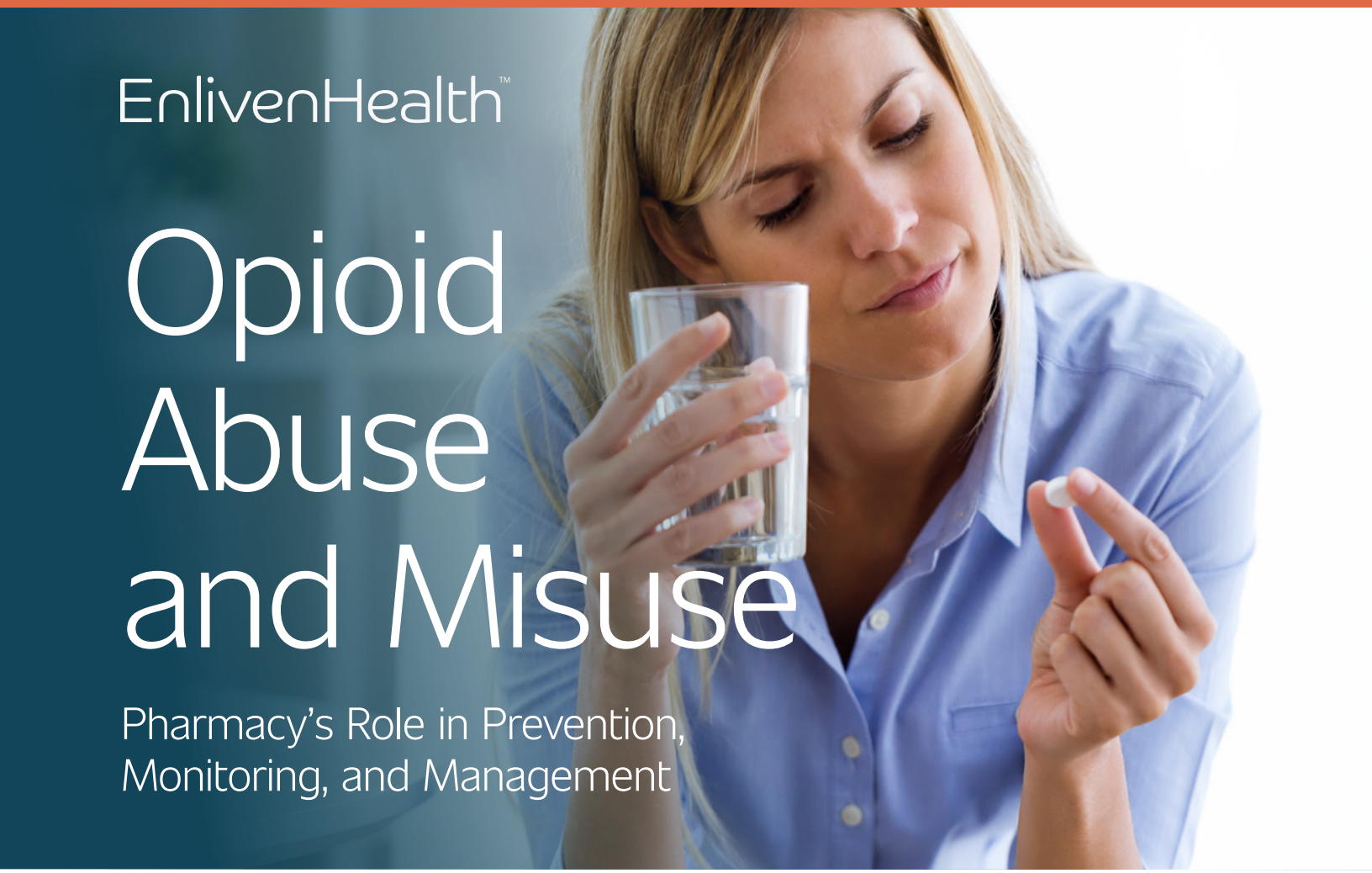
EnlivenHealth™

Opioid Abuse and Misuse

Pharmacy's Role in Prevention, Monitoring, and Management



Overview: The National Opioid Crisis

Background

This white paper provides an overview of the national opioid crisis and explores strategies to identify and provide education to patients at highest risk of opioid misuse and abuse through the most accessible healthcare provider — the pharmacist.

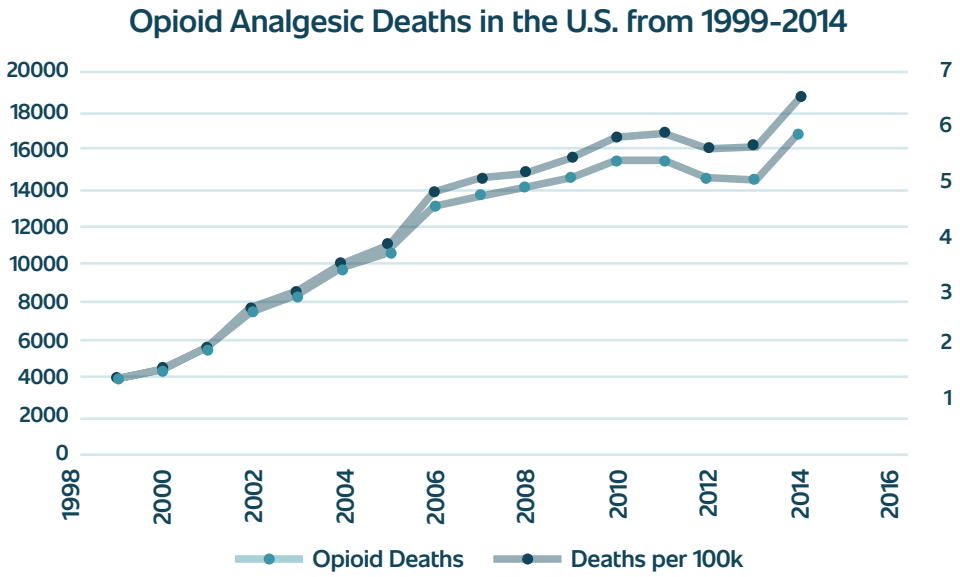
With two million people suffering from opioid addiction and 115 people dying from an opioid overdose every day in the U.S., the opioid crisis is unlike any situation the U.S. healthcare system has experienced to date.[1–3]

The sale of prescription opioid medications nearly quadrupled between 1999 and 2014. During this time, the amount of pain reported by Americans

CONTENTS

remained unchanged, while the number of deaths related to opioid overdose increased. In 2016, although the national opioid prescribing rate was at the lowest it had been in over 10 years, the rate was still 66.5 opioid prescriptions per 100 people.[3]

With increased exposure to opioids comes an increased risk of opioid abuse and accidental overdose. Prescription opioid deaths increased from 4,400 in 2000 to 18,893 in 2014, as shown right.[4]

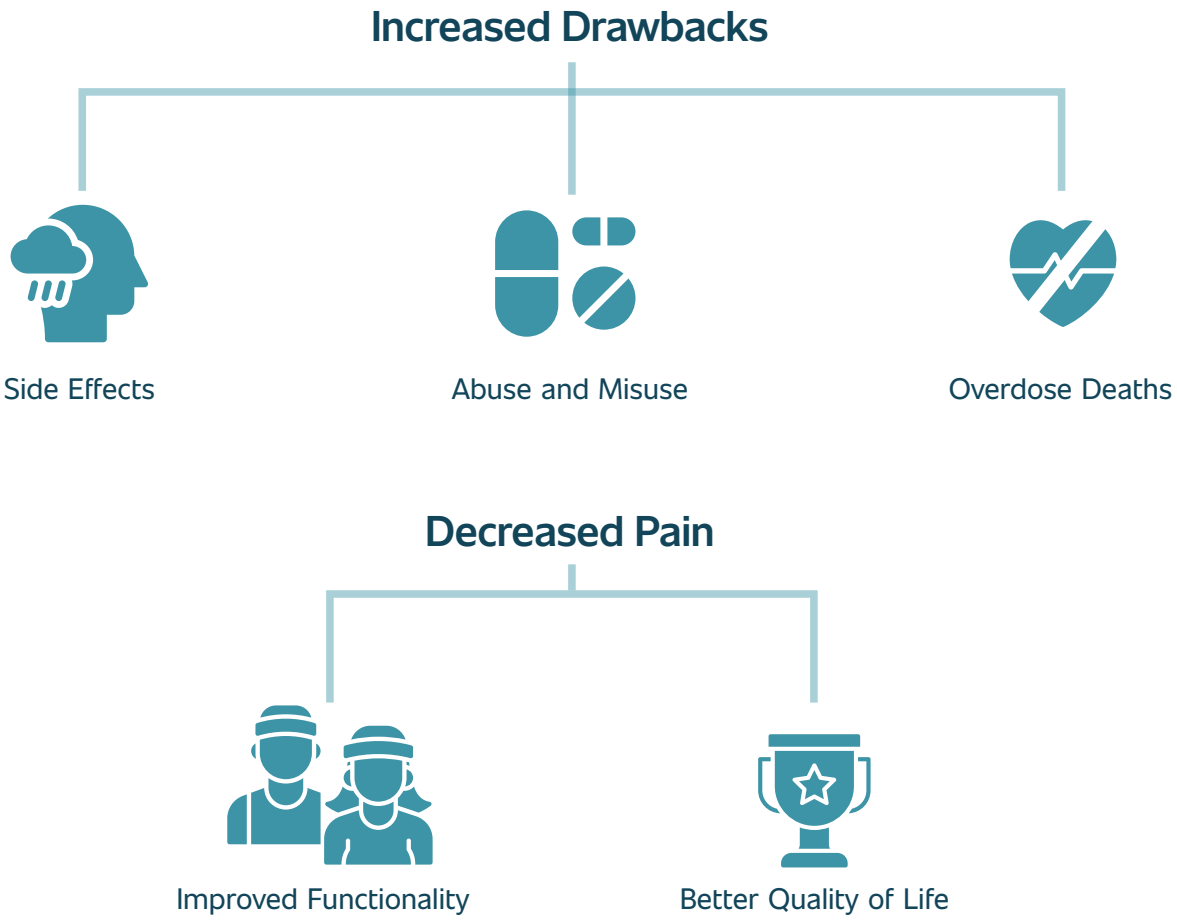


The Opioid Epidemic: A Growing Problem

Failing Healthcare Technology Projects

The growing opioid problem can partially be attributed to the lack of education regarding medications. A 2015 survey indicated that 45% of people who were prescribed pain medication did not know they were taking opioids or were unaware of their addictive properties.[5]

The treatment of pain is fundamental to the medical profession. If pain is not well controlled, the patient's quality of life decreases and detrimental long-term effects can follow. In the hospital setting, pain scores can even affect reimbursement. Opioids have the ability to be safely prescribed and used for pain, but the clinical benefit of opioids must be weighed against the health risks with patient-specific factors in mind. Furthermore, creating a culture of education around these medications is needed.



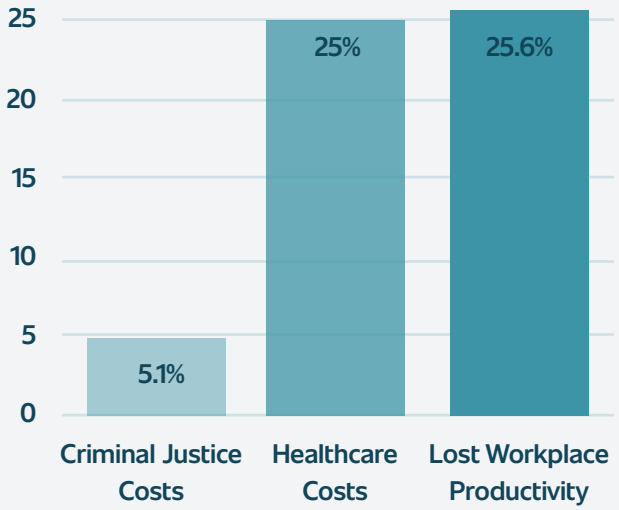
Impact of Opioid Misuse: Societal and Special Populations

Societal Impact of Opioid Misuse

In 2015, the opioid epidemic cost the U.S. $504 billion, a 542% increase from 2013 which was $78.5 billion.[6] Opioid abusers cost employers twice as much in healthcare expenses annually compared to non- abusers. Significant absenteeism (costs due to days lost at work) and presenteeism (lost productivity while at work) is linked to opioid abuse. In 2007, the American Society of Addiction Medicine (ASAM) estimated the total U.S. societal costs of prescription opioid abuse to be $55.7 billion, with $25.6 billion (46%) attributed to lost workplace productivity, $25 billion (45%) attributed to healthcare costs and $5.1 billion (9%) attributed to criminal justice costs.[7]

Opioid Abuse by the Numbers

Total U.S. Societal Costs ($B) of Prescription Opioid Abuse

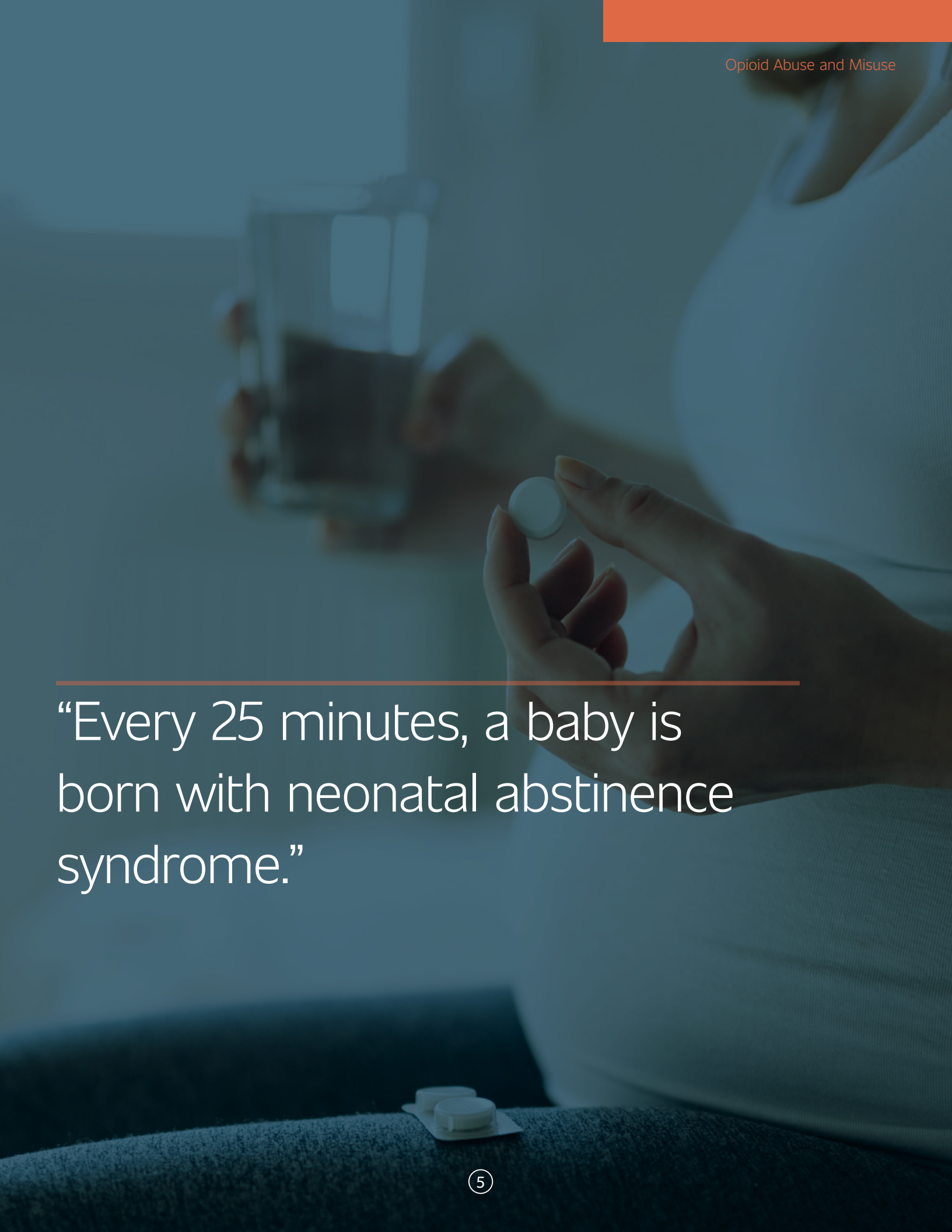


Impact on Special Populations

Pregnant Women. As opioid use disorder is increasing in women of reproductive age, use of opioids during pregnancy has also increased four-fold during 1999–2014, resulting in adverse maternal effects such as preterm labor, stillbirth, and maternal mortality.[9] Every 25 minutes, a baby is born with neonatal abstinence syndrome due to maternal use of opioids. This opioid withdrawal is responsible for life-threatening complications such as lower birthweights, respiratory deficiencies, seizures, and longer hospital stays.[10]

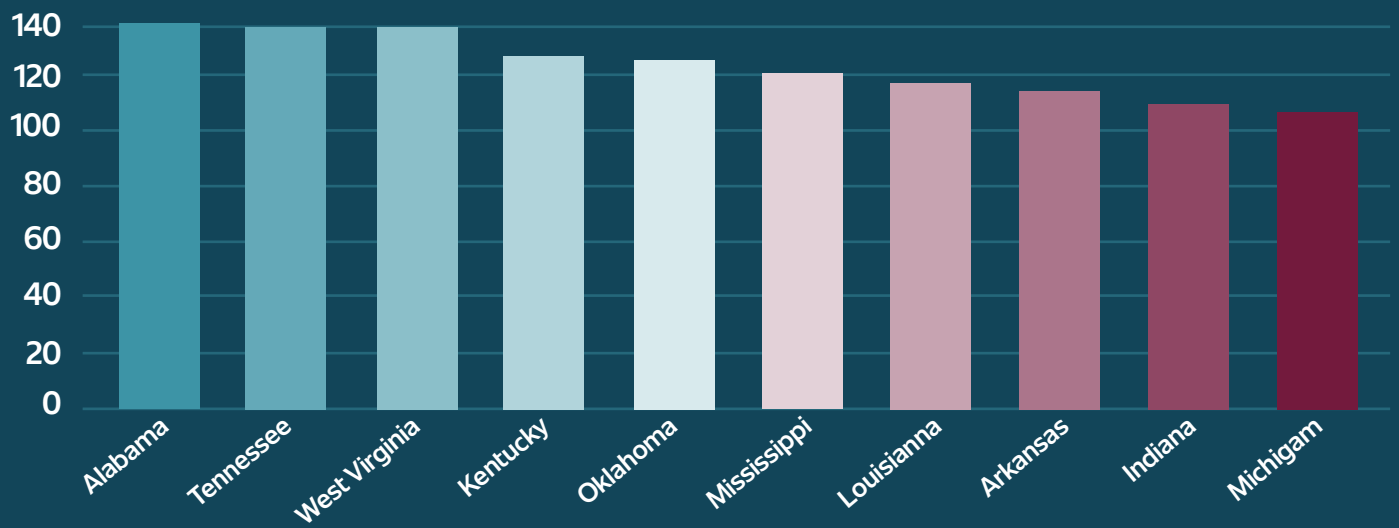
Older Adults. More than 40% of older adults report having chronic pain, leading to a higher use of prescription opioids in adults over 40, compared to adults 20–39 years of age. While misuse occurs in only 1% of adults 65 years and older and 4% of adults between 50–64 years, prescription opioids are reported to be misused more than any other type of prescription medications in this population.[3, 11]

Adolescents (12–17 years of age). Prescription opioids are usually given to adolescents by friends or relatives. However, initial exposure to opioids can often occur at home by accidental discovery. In 2015, 276,000 adolescents were using prescription opioids for non-medical reasons with almost half of them (122,000) suffering from addiction to these medications. Between 1994 and 2007, the volume of opioids prescribed for adolescents nearly doubled.[2, 12]



"Every 25 minutes, a baby is born with neonatal abstinence syndrome."

Number of Opioid Prescriptions per 100 Residents[13]



Risk Factors: Developing Abuse and Misuse

Factors Influencing Opioid Abuse and Misuse

Although opioid dependence does not discriminate between race and gender, some patients are at greater risk for developing abuse than others. It is crucial to be able to identify and educate these patients on the potential risks of taking opioids.

Patients taking prescription opioids are at increased risk for abuse and misuse if they have the following risk factors:

- Younger age (18–25 years)
- Male gender
- Multiple pain complaints
- Psychiatric disorders (e.g. depression, bipolar disorder)
- Exposure to violence of sexual assault
- History of substance use disorder
- Family history of substance use disorder
- Taking an extended-release product
- Taking > 120 mg morphine equivalent (MME) daily[14, 15]

Decreased Opioid Misuse: A Healthcare Imperative

The magnitude of the current opioid epidemic has drawn attention at federal, state, and local levels. Current national initiatives are aimed at (1) improving prescription practices, (2) expanding access to naloxone and, (3) improving treatment options for opioid use disorders.

CDC Prescribing Guidelines. In 2016, the CDC released guidelines and resources for prescribing opioids for chronic, non-cancer pain. This directive is geared towards primary care clinicians who are treating pain in the outpatient setting. These guidelines recommend when to initiate or continue opioids, which opioids to choose, and how to assess risk and harm of opioid use.[16]

Opioid-Related Quality Measures. In 2016, one in three Medicare Part D beneficiaries received a prescription opioid. About 500,000 of those beneficiaries received high amounts of opioids (greater than 120mg morphine equivalent dose) for at least 3 months.[18] To protect these patients from opioid abuse, the 2017 CMS Final Call letter outlined four display measures developed by the Pharmacy Quality Alliance (PQA). These measures were identified as additional measures under consideration for the 2019 Part D display page for payors.[19]

Measure 1	Measure 2	Measure 3	Measure 4
Concurrent Use of Opioids and Benzodiazepines	**Use of Opioids at High Dosage in Persons Without Cancer**	**Use of Opioids from Multiple Providers in Persons Without Cancer**	**Use of Opioids at High Dosage and from Multiple Providers in Persons Without Cancer**
Numerator Statement: The number of individuals from the denominator with ≥2 prescription claims for any benzodiazepines with different dates of service AND concurrent use of opioids and benzodiazepines for ≥30 cumulative days.	**Numerator Statement:** Individuals from the denominator with an average daily dosage ≥90 MME during the opioid episode.	**Numerator Statement:** Numerator Statement: Individuals from the denominator with opioid prescription claims from ≥4 prescribers AND ≥4 pharmacies within ≤180 days during the opioid episode.	**Numerator Statement:** Individuals from the denominator with an average daily dosage ≥90 MME during the opioid episode AND with opioid prescription claims from ≥4 prescribers AND ≥4 pharmacies within ≤180 days during the opioid episode.
Denominator Statement: Individuals with ≥2 prescription claims for opioid medications on different dates of service and with a of ≥15 cumulative days' supply during the measurement year.	**Denominator Statement:** Individuals ≥18 years of age with ≥2 prescription claims for opioid medications on different dates of service and with a cumulative days' supply ≥15 during the measurement year.	**Denominator Statement:** Individuals ≥18 years of age with ≥2 prescription claims for opioid medications on different dates of service and with a cumulative days' supply ≥15 during the measurement year.	**Denominator Statement:** Individuals ≥18 years of age with ≥2 prescription claims for opioid medications on different dates of service and with a cumulative days' supply ≥15 during the measurement year.

Healthcare providers wrote 259 million prescriptions for painkillers in 2012, enough for every American adult to have a bottle of pills.[17]

Three other opioid measures were also endorsed by PQA in 2019 focused on the initial prescribing of opioids

1. **Initial Opioid Prescribing at High Dosage**
2. **Initial Opioid Prescribing for Long Duration**
3. **Initial Opioid Prescribing for Long-Acting or Extended-Release Opioids**

Opportunities for Success: Pharmacy's Role

Potential for Pharmacists to Impact Opioid Epidemic

While pharmacists are highly accessible, they are the most underutilized members of the healthcare team. Pharmacists have access to patients' medication profiles, uniquely positioning them to identify patients at risk and initiate the conversation on prescription opioid abuse and misuse. This calls for a heightened level of vigilance on the part of pharmacists in prevention, monitoring, and management of opioid use in both acute and non-acute settings.

Lastly, they can provide naloxone to at-risk patients.

The appointment-based model (ABM), a model for patient-centered, outcome-focused care, would allow pharmacists to plan in advance to better facilitate the conversation with the patient.

Stratify population to identify at-risk patients

Plan for intervention with patient at monthly visit

Improve patient awareness; decrease likelihood of misuse

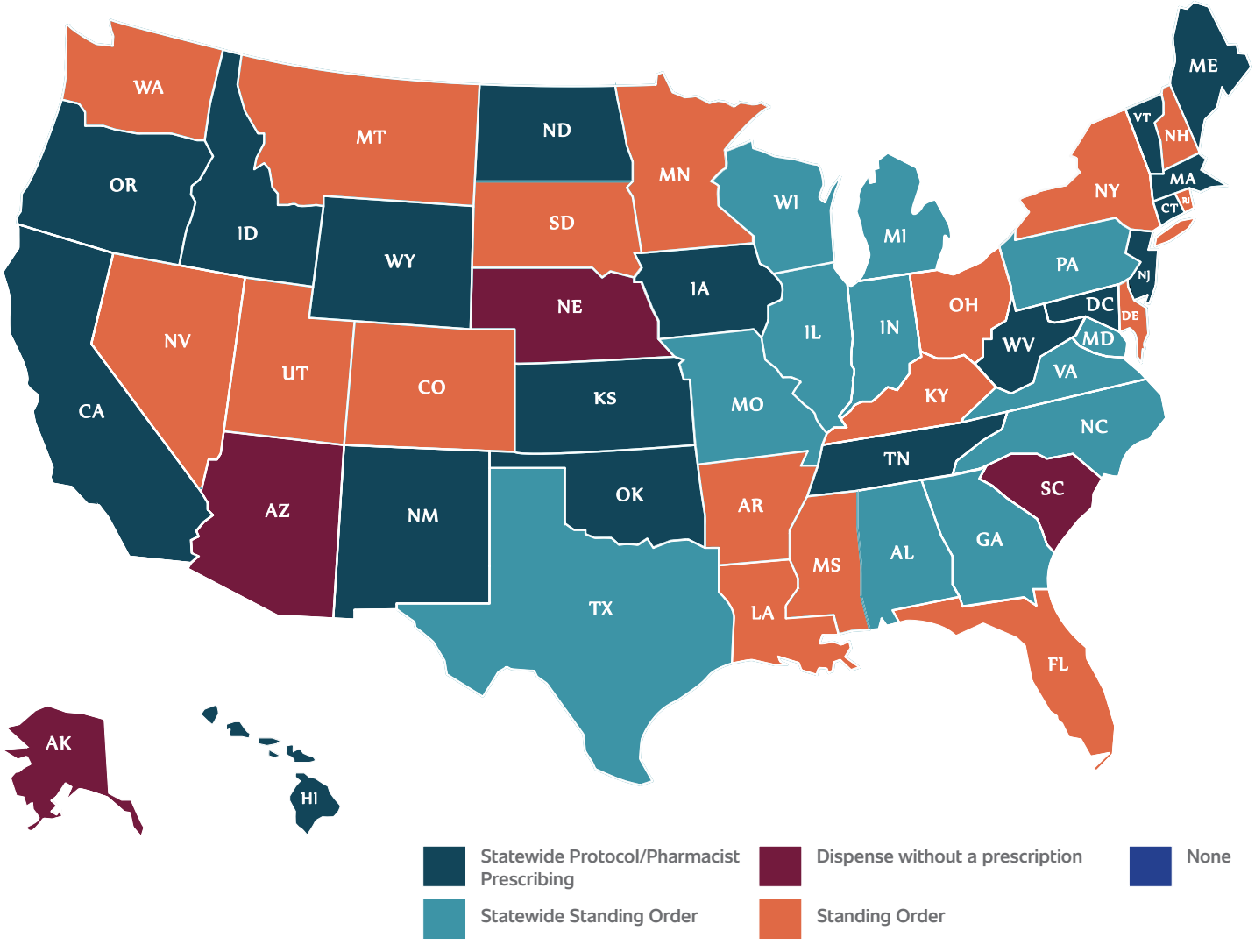
Source: World Health Organization

Naloxone

Naloxone is a life-saving medication that can be used to reverse opioid overdose until EMT personnel arrives. It is a pure opioid antagonist that works by competitively blocking opioids from attaching to receptors in the brain, restoring breathing. Through various distribution programs, non-medical personnel are able to access this antidote. While this has prompted concerns that making naloxone widely available may encourage an increase in opioid use, there is no evidence indicating the correlation.

Another objection to naloxone distribution is that the medication should be administered by health professionals, since opioid overdose is a serious medical condition. However, several studies have shown that laypeople are capable of administering the medication with basic training.[20] Between 1996 and 2014, naloxone was used to reverse over 26,000 opioid overdoses. Many law enforcement agencies have begun supplying officers with this life-saving antidote.[21] In 2018, 48 states and Washington, D.C. allow pharmacists to dispense naloxone without a prescription.[22]

Naloxone Access in Community Pharmacies



Prescription Drug Monitoring Programs (PDMPs)

PDMPs are state-run electronic databases that collect information on the prescribing and dispensing of controlled drugs (drugs being monitored vary from state to state). The purpose of the databases is to allow pharmacists, practitioners, regulatory boards, and law enforcement to monitor for abuse and diversion. PDMPs are also instrumental in helping healthcare providers identify patients at risk for drug abuse and misuse, intervene early, and therefore reduce opioid-related deaths.

Death rates related to opioid- overdose have been shown to be lower in states where PDMP data is updated more frequently.[23]

While monitoring programs do result in lower rates of prescription drug abuse, prescriber utilization of PDMPs remains low. Approximately half of the states have mandated prescribers to check the PDMP before prescribing controlled medications. However, such mandates are met with opposition by prescribers who claim that the requirement places undue burden on their practice. Objections include difficulty in obtaining logins, failure of the mandate to address situations where systems are down, lack of PDMP data integration into clinical workflow, incomplete data, and minimal guidance regarding how to appropriately interpret query results.[24]

EnlivenHealth™ Solutions: Prevention, Monitoring, and Management

A Better Way with EnlivenHealth™

Patient education and early intervention are paramount to solving the opioid epidemic. Medication management for controlled substance use is important in both acute and non-acute care settings, and requires care coordination by healthcare providers, particularly during care transitions.

EnlivenHealth™ Patient Engagement

The EnlivenHealth™ Patient Engagement platform offers multiple solutions for comprehensive care management, including opioid mitigation.

EnlivenHealth™ Opioid Mitigation employs a predictive algorithm to identify patients at highest risk for prescription opioid abuse and misuse.

Tasks appear in the pharmacy workflow, prompting interventions to enable the pharmacy to intervene to improve therapy. Guided by decision tree logic, the pharmacist is able to initiate a sensitive, stigma-free conversation to provide education and capture feedback to assist in reducing opioid-related morbidity, mortality, and costs.

Summary

The abuse/misuse of opioids and other controlled medications impacts patients and healthcare providers every day in every healthcare setting, interfering with patient care and adversely impacting health outcomes. The EnlivenHealth™ Patient Engagement platform with Opioid Mitigation enables pharmacists in community and outpatient settings to provide better care through technology- assisted targeting of high-risk patients. It also prompts the right interventions to prevent, monitor, and manage opioid abuse and misuse.

REFERENCES

1. National Institute on Drug Abuse website. Opioid Overdose Crisis. https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose- crisis. January 2019. Accessed 12/31/19.
2. American Society of Addiction Medicine. Opioid Addiction 2016 Facts & Figures. https://www.asam.org/docs/default-source/advocacy/opioid- addiction-disease-facts-figures.pdf. Accessed 12/31/19.
3. Centers for Disease Control and Prevention website. Opioid Overdose. http://www.cdc.gov/drugoverdose/data/prescribing.html. Accessed 12/31/19.
4. Centers for Disease Control and Prevention. Number and age-adjusted rates of drug-poisoning deaths involving opioid analgesics and heroin: United States, 2000-2014. http://www.cdc.gov/nchs/data/health_ policy/AADR_drug_poisoning_involving_OA_Heroin_US_2000-2014. pdf. Accessed 12/31/19.
5. National Safety Council website. Nearly half of opioid painkiller users unaware they are taking drugs as additive as heroin. June 23, 2015. https://www.nsc.org/in-the-newsroom/nearly-half-of-opioid-painkiller- users-unaware-they-are-taking-drugs-as-addictive-as-heroin. Accessed 12/31/19.
6. CNBC. The true cost of opioid epidemic tops $500 billion, White House says. November 20, 2017. https://www.cnbc.com/2017/11/20/the-true- cost-of-opioid-epidemic-tops-500-billion-white-house-says.html. Accessed 12/31/19.
7. Birnbaum HG, White AG, et al. Societal costs of prescription opioid abuse, dependence, and misuse in the United States. Pain Medicine. 2011;12:657-667.
8. Centers for Disease Control and Prevention website. Prescription Painkiller Overdoses: A Growing Epidemic, Especially Among Women. http://www.cdc.gov/vitalsigns/prescriptionpainkilleroverdoses/index.html. Accessed 12/31/19.
9. Haight SC, Ko JY, Tong VT, Bohm MK, Callaghan WM. Opioid Use Disorder Documented at Delivery Hospitalization — United States, 1999–2014. Centers for Disease Control and Prevention website: Morbidity and Mortality Weekly Report. August 10, 2018;67:845-849. https://www.cdc.gov/mmwr/volumes/67/wr/mm6731a1.htm?s_cid=mm6731a1_w. Accessed 12/31/19.
10. American Academy of Pediatrics infographic: America's Opioid Crisis: The Unseen Impact on Children. 2018. https://www.aap.org/ en-us/advocacy-and-policy/federal-advocacy/Documents/Opioid- StateFactsheets/opioid_fs_united_states.pdf. Accessed 12/31/19.
11. Dean O. Prescription Drug Abuse Among Older Adults. AARP Public Policy Institute. 2017:1-8. https://www.aarp.org/content/dam/aarp/ ppi/2017/07/prescription-drug-abuse-among-older-adults.pdf. Accessed 12/31/19.
12. Moreno MA, Furtner F, Rivara FP. Adolescent opioid abuse. Archives of Pediatrics & Adolescent Medicine. 2012;166(9):880.
13. Jacobs H. The states prescribing the most painkillers aren't the ones you think. Business Insider. March 23, 2016. https://www. businessinsider.com/these-are-the-states-prescribing-the-most- opioid-painkillers-2016-3.%20. Accessed 12/31/19.
14. Brady, KT, McCauley JL and Back SE. Prescription opioid misuse, abuse, and treatment in the United States: an update. American Journal of Psychiatry. 2016;173(1):18-26.
15. Sehgal N, Manchikanti L, Smith H. Prescription opioid abuse in chronic pain: a review of opioid abuse predictors and strategies to curb opioid abuse. Pain Physician. 2012;15:ES67-ES92.
16. Dowell D, Haegerich RM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016. Centers for Disease Control and Prevention website: Morbidity and Mortality Weekly Report. http:// www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm. Accessed 12/31/19.
17. Centers for Disease Control and Prevention website. Opioid Painkiller Prescribing. https://www.cdc.gov/vitalsigns/opioid-prescribing/index.html. Accessed 12/31/19.
18. U.S. Department of Health and Human Services website. Report: Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing. 2017. https://oig.hhs.gov/oei/reports/oei-02- 17-00250.asp. Accessed 12/31/19.
19. Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 4, 2016. https://www.cms.gov/ Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/ Announcement2017.pdf. Accessed 12/31/19.
20. Bazazi AR, Zaller ND, Fu JJ, et al. Preventing opiate overdose deaths: examining objections to take-home naloxone. Journal of Health Care for the Poor and Underserved. 2010;21(4):1108-1113.
21. American Medical Association. Help Save Lives: Co-Prescribe Naloxone to Patients at Risk of Overdose. August 2017. https://www.aafp.org/ dam/AAFP/documents/patient_care/pain_management/co-branded- naloxone.pdf. Accessed 12/31/19.
22. Gorman A. Pharmacists slow to dispense lifesaving overdose drug. January 3, 2018. The Washington Post. https://www.washingtonpost. com/national/health-science/pharmacists-slow-to-dispense- lifesaving-overdose-drug/2018/01/03/0628c8e2-f06f-11e7-95e3- eff284e71c8d_story.html?utm_term=.8d9ecb65088d. Accessed 12/31/19. Map: https://naspa.us/resource/naloxone-access-community- pharmacies/.
23. National Institute on Drug Abuse website. Prescription Drug Monitoring Programs Linked to Reductions in Opioid Overdose Deaths. June 22, 2016. https://www.drugabuse.gov/news-events/news- releases/2016/06/prescription-drug-monitoring-programs-linked-to- reductions-in-opioid-overdose-deaths. Accessed 12/31/19.
24. Haffajee R, Jena AB, Weiner SG. Mandatory use of prescription drug monitoring programs. Journal of American Medical Association. 2015;313(9):891-892.

EnlivenHealth™
an Omnicell Innovation

About EnlivenHealth™

EnlivenHealth™ provides the most proven and advanced technology solutions for intelligent patient engagement and communications. Trusted by a national network of leading pharmacies, the EnlivenHealth™ Patient Engagement Platform empowers pharmacies and health plans to significantly improve medication management, adherence, and safety for their patient populations. Our mission is to help you ensure lifelong optimal health for your patients and members, measurably improve quality scores, and strengthen business results. EnlivenHealth™ is a division of Omnicell, Inc. (NASDAQ: OMCL), a leading provider of medication management solutions and adherence tools for healthcare systems and pharmacies.