Recognizing the Needs of PAIN PATIENTS IN SUBSTANCE USE POLICY
Introduction
The United States is facing twin epidemics of pain and opioid misuse. Both are challenging, multifaceted problems with numerous comorbidities, treatment gaps, stigma, and increased risk of death. The role of prescription opioids in soaring rates of drug overdose and death has drawn considerable policy attention at the federal and state levels. While the focus on limiting the flow of medications is understandable, it may, intentionally or not, hinder access for patients who rely on opioids as a component of managing chronic or end-of-life pain. This issue brief outlines the ways in which some of the key policy responses to the opioid epidemic — prescription drug monitoring programs, heightened DEA enforcement, “lock-in” programs, prescriber restrictions, and even guidelines — could affect patients in pain. Important as these policies may be, very limited attention has been paid to minimizing collateral harm to people living with or dying in pain. Additional oversight and monitoring is crucial to ensure that individuals in pain are not harmed by the unintended consequences of various policy responses.

Background
The U.S. healthcare system faces a two-sided challenge: the crisis of pain, including chronic pain, and that of opioid misuse and overdose.

Pain in America
Chronic pain is the most common cause of long-term disability and is associated with reduced physical, psychological, and social well-being, resulting in increased use of health services. A recent analysis of the 2012 National Health Interview Survey found that an estimated 25.3 million adults – or 11.2% – experience chronic pain, defined as pain every day for the past three months. Chronic, non-cancer pain is a symptom of many diseases (e.g. osteoarthritis, diabetic neuropathy, HIV, sickle-cell disease) and often occurs in the absence of a specific underlying diagnosis.

Chronic pain is associated with an increased rate of mental health comorbidities and suicide. Compared to the general population, those with chronic pain have a significantly higher prevalence of depression, anxiety, and post-traumatic stress disorder. People with chronic pain are twice as likely as those with no pain to commit suicide.

A number of comorbid physical conditions are also associated with chronic pain including obesity, reduced capacity for physical function, and disability – particularly among patients who have little belief in their ability to manage their chronic pain. While chronic pain may precede such physical conditions, it may also follow physical trauma such as injuries sustained in traffic accidents, traumatic brain injury, and stroke. Individuals who already suffer from poorer health may be more likely to develop chronic pain after physical trauma, which suggests that the association between physical conditions and chronic pain is multi-directional.

A recent analysis of the 2012 National Health Interview Survey found that an estimated 25.3 million adults – or 11.2% – experience chronic pain, defined as pain every day for the past three months.
Chronic pain presents an enormous economic burden on the United States; between the cost of medical treatment for chronic pain, the effect of chronic pain making treatment for other ailments more difficult, and lost worker productivity, the US pays upwards of $635 billion annually to deal with chronic pain.16

A high proportion of people also experience pain at the end of life, with a range of studies finding approximately half or more patients experiencing pain in the last month of life. Rates are higher among certain patients, such as those with advanced cancer, including children with terminal cancer.17

In 2011, the National Institutes of Health (NIH) and the Institute of Medicine (IOM) released a report that called for a cultural transformation in pain management and acknowledged the need for a “comprehensive population health-level strategy”18 to address pain, with an emphasis on chronic pain. In response to the report, the Office of the Assistant Secretary for Health at the Department of Health and Human Services (HHS) released the first National Pain Strategy (NPS), which outlines the federal government’s coordinated plan to reduce the burden of chronic pain.19

The NPS includes recommendations and action plans in six areas: population research; prevention and care; disparities; service delivery and payment; professional education and training; and public education and communication.20 Specifically, the strategy calls for: improved public understanding of pain to reduce stigmatization; increased quality measures to monitor and improve the prevention and care of pain; improved access to high-quality pain care; and the development of a system of integrated, biopsychosocial pain management practices that allows patients and providers access to the full range of pain interventions.21

One such intervention in the treatment of pain is opioid therapy. The appropriate role of opioids in the management of chronic pain is still an area of research and debate, though many experts regard opioids as an effective therapy for relieving chronic pain.22,23,24 As the National Pain Strategy notes:

Pharmacy shortages and regulated dispensing policies might result in inadequate treatment for those patients where the benefits of opioids outweigh the risks. While all patients who are on opioid therapy for chronic pain are at risk for opioid use disorder, limited recent studies have shown that most (74-96%) of these patients use their prescriptions without suffering from opioid addiction. All people with pain should receive adequate care. In some clinical contexts, opioids can help manage pain when other pain medicines have not or are not expected to provide enough pain relief.25

Opioid medication is just one component of comprehensive pain management. There is a broad spectrum of pain interventions available to address the biopsychosocial nature of pain including psychological therapies, regional anesthetic interventions, rehabilitative and physical therapy, integrative and complementary medicine, and other medications.16 Unfortunately, many individuals face barriers to receiving the full range of potential interventions, and most Americans who live with chronic pain do not receive appropriate care.26,27 In addition, although primary care physicians play a critical role in treating pain, few medical schools offer adequate training in pain management.28
Opioid Misuse and Overdose

Opioids include prescription pain medications as well as illegal drugs, including heroin. Opioid-related deaths in the U.S. have increased five-fold since 1980, totaling 33,000 deaths in 2015. In 2010, over 60% of drug overdose deaths involved opioids, compared to 30% in 1999. As of 2014, there were approximately 4.3 million people who had engaged in non-medical use of prescription painkillers in the prior month and 435,000 who had used heroin.

The Centers for Disease Control and Prevention (CDC) estimates that in 2014, there were one and a half times as many drug overdose deaths as deaths from motor vehicle accidents. More Americans are now dying from opioid-related overdoses each year than died due to AIDS during the peak of that epidemic. Most strikingly, the overall life expectancy in the U.S. has dropped for the first time since 1993, particularly for those under age 65. The high increase in the cause of death is due to unintentional injuries, including drug overdoses.

The number of opioid prescriptions written in the U.S. annually is now roughly equal to the number of adults in the population. In a 2015 Kaiser Family Foundation study, more than half of people surveyed had a personal connection to opioid abuse. The study found that people were similarly affected across multiple socioeconomic and demographic features and that nearly every geographic area in the county has seen increases in drug overdose deaths involving opioids.

In a 2015 Kaiser Family Foundation study, more than half of people surveyed had a personal connection to opioid abuse.

Opioid policy responses that could hinder access for pain patients

In response to the opioid crisis, policy makers at the state and federal levels have passed a broad range of laws and implemented other public policies to reduce opioid misuse. Many of these policies directly regulate access to prescription opioids. These efforts aim to reduce the risk of misuse among the people for whom prescriptions are written, as well as to reduce the risk of diversion of medication to others.

The goal of this paper is not to weigh the full scope of the potential benefits and drawbacks of these approaches, nor to characterize the evidence base for their effectiveness (due to the recentness of many of these policy changes, effectiveness is often unknown). Rather, we argue here that each of these policies could have the unintended consequence of hindering access to pain medications for chronic or end-of-life pain patients who need them as part of their pain management regime. We believe that each of these policy approaches, whether already in place or under consideration by a federal or state legislature or health agency, should be implemented only with careful monitoring to gauge the effect on access to pain treatment.

Another concern is the potential for reductions in access to opioids to lead people with opioid addiction to switch to heroin use. Abuse of, or dependence on, prescription opioids has been identified by CDC as the most significant risk factor for heroin use; however, studies have not identified a link between efforts to curb opioid prescriptions and increases in heroin initiation. (Vital Signs: Demographic and Substance Use Trends Among Heroin Users — United States, 2002–2013. MMWR July 10, 2015 / 64(26):719-725. Available at https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6426a3.htm). Careful monitoring of effects on heroin use, while beyond the scope of this paper, is crucial as well.
Key policy responses to the opioid crisis include:

**Prescription drug monitoring programs:** Forty-nine states and the District of Columbia have prescription drug monitoring programs (PDMPs). PDMPs are state government-run registries of prescriptions for controlled substances that allow prescribers to identify what other opioid prescriptions a patient has received. PDMPs vary with regard to which scheduled drugs are included; the required frequency of updates; which department in a state runs the PDMP; who is allowed to access the database (e.g. whether law enforcement is allowed access); whether prescribers are required to access the PDMP before prescribing; whether the database generates reports in reaction to a request or whether it proactively looks for patterns; and whether the state shares data with other states.37

A primary purpose of PDMPs is to provide patient prescription information to prescribers and dispensers, in the service of improving the safety and efficacy of opioid prescribing. PDMPs can allow for the identification, prevention and treatment of drug abuse. States have noted declines in opioid prescribing subsequent to the establishment of PDMPs,38 but it is not clear whether these declines include a decrease in prescribing of controlled substances for people with a legitimate medical need. In addition, the ability of law enforcement to access the databases in all states with PDMPs except Nebraska could have an unintended chilling effect on both doctors and patients.39

**Drug Enforcement Agency (DEA) enforcement:** Until the 2000s, the Drug Enforcement Agency’s primary focus was on increasing the law enforcement response against illicit drugs like heroin, crack, cocaine, methamphetamines, and methylenedioxy-methamphetamine (MDMA), a synthetic drug that alters mood and perception. However, over the last decade the DEA has turned its attention to policing the abuse of legally prescribed opioid medications.40 The Department of Justice has charged the DEA with “prosecut[ing]...the leaders of traditional drug trafficking organizations as well as...rogue health care providers, pharmacists, and pharmaceutical employees who contribute to the available supply and overuse of prescription opioid painkillers.”41

Experts have expressed concern that aggressive DEA enforcement has led to an unintended chilling effect in cases where prescription of opioid medication is medically indicated, such as in the field of palliative oncology.42 Undertreatment of pain could form grounds for medical malpractice suits.43
Lock-in programs: Forty-six states and the District of Columbia have established Medicaid “lock-in” programs that limit enrollees with suspect utilization patterns to a limited set of providers (e.g. one prescriber, one pharmacy). These programs vary with respect to: lock-in provisions (Florida restricts beneficiaries to one pharmacy; DC restricts beneficiaries to one pharmacy chosen by the beneficiary from a list of three pharmacies), lock-in duration (Pennsylvania: five years; Tennessee: discontinued after six months if the beneficiary meets certain requirements), enrollment criteria (based on number of prescriptions filled, number of pharmacies visited, and/or number of prescribers accessed within a given period of time), and notifications and appeals processes. There is very little published literature evaluating the effectiveness of state Medicaid lock-in programs, and most of the publicly available internal state evaluations of these programs mainly report economic outcomes in terms of money saved due to reductions in prescriptions of narcotic analgesics. Further research is needed to determine whether these reductions in opioid use are occurring among patients with a medically legitimate need for opioids to relieve pain and whether patients who experience reduced access to opioids are receiving other forms of pain relief.

More rigorous evaluations should be conducted of Medicaid lock-in programs to monitor access to needed medications. In addition, lock-in programs should only be implemented alongside comprehensive reviews of whether the state Medicaid program is covering a broad range of services and supports for people living with pain.

In the 2016 Comprehensive Addiction and Recovery Act (CARA), Congress created a lock-in program within Medicare, giving Medicare prescription drug plan (PDP) sponsors the ability to identify and limit access to “frequently abused drugs” for “at-risk beneficiaries.” Patients may appeal their status and may request a specific prescriber or pharmacy that is most convenient for them, but the preferences may be disregarded at the plan’s discretion. The effect of the Medicare lock-in program on patient access should be monitored closely, especially since the program serves a population – people aged 65 and over and those with permanent disability – who may be particularly challenged by barriers to accessing pain medication.

State lock-in program data can additionally help identify patients accessing opioids outside of the lock-in program. Compared against PDMP data for the same patient, this data can identify patients who obtain prescriptions for controlled substances by paying cash or who otherwise avert the lock-in parameters. A preliminary one-year study in Kansas found that approximately one third of lock-in patients obtained at least one prescription for a controlled substance by paying with cash, suggesting that this area merits further study.

State-level regulation of prescribers and providers: Many states have enacted laws directly regulating prescriptions, providers, and pain clinics. Several have pending or enacted legislation that would restrict the length of an opioid prescription. For example, recent legislation in Kentucky would limit outpatient opioid prescriptions to three days, with some exceptions. Providers would be allowed exemptions for patients with chronic pain, pain associated with cancer, post-surgical symptoms, narcotic treatment, or palliative care. To extend the prescription
past a three-day supply, providers would be required to justify the extension and describe why an alternative would not be appropriate. In 2017, Virginia enacted similar legislation that limits opioid prescriptions to 14 days to treat individuals undergoing surgery or other invasive procedures.52 Other states with similar restrictions include Oregon53 and Washington,54 which places a three-day restriction on dentists for initial prescriptions of opioids.

Pending legislation in Vermont would require new pain clinics to obtain a Certificate of Need by demonstrating, among other things, that “treatment provided at the pain management clinic reduces reliance on opioids and supports public health efforts in Vermont.”55

All of these policies may be reasonable approaches. Documentation of the justification for extended opioid supplies may itself lower instances of inappropriate prescriptions. However, the impact on access to pain medication, and the availability of alternative and complementary modalities for treating pain, should be closely monitored.

**CDC’s prescribing guidelines:** In 2016, the CDC issued prescribing guidelines for opioids. The intent was to “ensure patients have access to safer, more effective chronic pain treatment while reducing the number of people who misuse, abuse, or overdose from these drugs.” 56 The American Medical Association (AMA) submitted comments to the CDC noting a range of concerns about the guidelines when they were in draft form, including a dearth of pain clinicians on the expert panel that developed the guidelines and an overall lack of “a patient-centered view” or “any real acknowledgement or empathy of the problems chronic pain patients may face.”57 The AMA went on to describe specific concerns with the substance of the recommendations, including:

- The guidelines fail to acknowledge gaps in coverage and in clinician availability for other modalities of pain treatment.
- Establishing “improvement in function” as a criterion for continued opioid therapy disregards the needs of some patients for whom functional improvement is not possible.
- The CDC’s recommendations regarding dosage levels are “in direct conflict” with FDA-approved product labeling. Further, there is insufficient evidence as to whether regulation of dosage is effective; in Ohio, a specific prescribing threshold was followed by reduced prescriptions but an ongoing increase in opioid deaths, particularly from heroin.
- The quantity of opioids prescribed for acute pain should be based on the lowest effective dose, but should not be based on an arbitrary limit.58

Despite these issues, the CDC finalized the guidelines with few changes. As these guidelines are disseminated and begin to influence clinical practice, it is crucial that their impact on pain patients be evaluated along with rigorous assessments of their effectiveness in addressing opioid misuse and overdose, including possible diversion to heroin use.

The AMA expressed concerns that the CDC guidelines lacked “a patient-centered view” or “any real acknowledgment or empathy of the problem chronic pain patients face.”
Discussion

These and other policy approaches may be wholly appropriate responses to the opioid epidemic. But ongoing monitoring and evaluation must take place to ensure that the needs of pain patients are not inadvertently dismissed by these efforts.

Highly effective interventions in the opioid epidemic should not put an undue burden on legitimate pain patients. For example, in 2010, Florida regulated pain clinics by banning health care providers from dispensing prescription opioid pain relievers directly from their offices. Requiring that patients collect their medicines from a separate pharmacy makes the availability of opioid pain relievers similar to that of most medications, and thus does not represent a major barrier to access for patients in need. Within two years of this policy change, oxycodone overdose deaths decreased over 50% in Florida; this was lauded by the CDC as “the first documented substantial decline in drug overdose mortality in any state during the previous ten years.”

When opioids are prescribed, states could adjust insurance coverage requirements to ensure that limited prescription periods (such as seven-day limits) do not result in a burden on the patient. For example, a bill introduced in 2017 in New York would prohibit insurance companies from imposing cost sharing on follow-up visits to refill a limited opioid prescription of seven days or less. Other states have made efforts to cover abuse-deterrent opioid formulations under state employee health plans and state Medicaid programs. In addition, to reduce the unnecessary use of leftover medicines, states could allow patients to return prescription drugs and allow those who accept these unused drugs to dispose of them safely.

States could also make greater efforts to cover and promote other pain management approaches in their Medicaid programs. Kaiser Family Foundation data indicates that 17 states cover no physical therapy in their Medicaid programs, and many of those that do cover it place limits on visits, eligible patients, and settings. A 2016 analysis of 41 states by the National Academy for State Health Policy found that only 12 states have implemented policies to encourage or require the use of non-opioid pain treatment modalities. There appears to be a great deal of room for improvement in the way Medicaid meets the needs, pharmaceutical and otherwise, of patients experiencing pain.
Similarly, commercial insurers could be doing more to promote access to comprehensive pain treatment, including non-opioid modalities. A recent study by the Center on Health Insurance Reforms at Georgetown University found that some issuers are taking steps to promote the use of non-opioid pain treatment, but noted that “the steps taken by these issuers fall short of closing barriers to non-opioid treatments that are built into insurance practices, such as limits on physical therapy, difficulties accessing covered mental health services, and burdensome medical management policies.”

For providers to prescribe opioids safely and effectively, it is important that they are familiar with pain management best practices and the risks associated with opioids, as well as with the mental health comorbidities that might make a patient more susceptible to addiction and abuse. Requiring continuing education on addiction and related topics may help ensure consistent quality of care. Because virtually every opioid user is at risk of overdose, this education may be ongoing and include information about opioid antagonists and how to access them.

Better education also serves to increase patients’ self-efficacy. With more information about controlled substances, patients may be better equipped to participate as equals in conversations with their provider and determine pain management treatment plans that reduce their risk of addiction.

Conclusion

The public health responses to both pain and opioid abuse are taking place against an unpredictable federal backdrop. Despite campaign promises to stop the opioid epidemic, recent actions by the current administration may present challenges to patients who rely on such drugs for therapeutic purposes, as well as to efforts to address substance use disorders.

First, efforts by the current administration, along with the Republican-led Congress, to eliminate the Affordable Care Act could result in loss of health coverage for millions of Americans. The latest Congressional Budget Office score of the amended American Healthcare Act (AHCA) which passed in the House of Representatives in May 2017 estimates 14 million people would lose health insurance coverage within the first year of AHCA implementation, and 23 million would lose coverage by 2026. The bill would also undo the ACA requirement that all state Medicaid expansion programs cover basic mental health and substance use disorder services for expansion populations, leaving that decision up to the states. Nearly 1.3 million people receive mental health and substance use disorder coverage under this ACA requirement and many could lose this important coverage. Additionally, nearly 2.8 million people with a substance abuse disorder, including 222,000 with an opioid disorder, are estimated to lose some or all health coverage if the ACA were repealed. Lack of coverage will make it next to impossible for people living with pain to access comprehensive care for their pain or for people with addiction to get effective treatment.

Second, the administration has not shown a clear and consistent interest in basing health policy on evidence. Recent comments from HHS leadership conveyed uncertainty about medication-assisted treatment such as methadone, despite such treatment constituting the standard of care for opioid addiction, as supported since 2005 by SAMSHA guidelines. These comments have created significant concern among addiction specialists. It is unknown what HHS or other administration officials think about the importance of care and treatment for pain overall.

The resulting unpredictable political context makes it all the more important that public health professionals and stakeholders monitor both opioid misuse and pain. With opioids understandably receiving heightened attention across the country, most policy actions are taking place with a focus on reducing access to the medications. Careful monitoring must be established to ensure that pain patients who need opioids as part of a comprehensive biopsychosocial treatment program are not left behind.

NB: This brief was written before the publication of Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use by The National Academies Press, which should be noted and taken into consideration for future discussion and policy review.
References


18) The National Academies, Institute of Medicine (US) Committee on Advancing Pain Research, Care, and Education. Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. 2011.


20) Ibid.

21) Ibid.


26) The National Academies, Institute of Medicine (US) Committee on Advancing Pain Research, Care, and Education. Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. 2011.


45) Megan Olsen, Medicaid Lock-in Programs: What do they look like and do they have an impact?  
49) Ibid.  
50) K-TRACS & Medicaid: Evaluation of lock-in patient data and associated costs. Authors: Morris, C & Twillman, RK. Presented at the Annual Meeting of the National Association of Controlled Substance Authorities, October 2012, Scottsdale, AZ.  
57) Letter from James Madara, MD, Executive Vice President and CEO, American Medical Association, to Thomas Frieden, MD, MPH, Director, Centers for Disease Control and Prevention (Oct. 1, 2015).  
58) Ibid.  
64) Kaiser Family Foundation. Medicaid Benefits: Physical Therapy Services online interactive tool, timeframe 2012. Accessed 5/31/17 from: http://kff.org/medicaid/state-indicator/physical-therapy-services/?currentTimeframe=0&sortModel=%7B%22cOLl%22:%22Location%22%2C%22sort%22:%22asc%22%2C%227D  
The Pain Action Alliance to Implement a National Strategy (PAINS) is a consortium of leaders from professional societies, patient advocacy organizations, policy groups, consumers, third-party payers and the private sector collaborating to achieve a common vision and mission. PAINS is a program of the Center for Practical Bioethics, a private, nonprofit organization that has a broad-based stream of revenues, including institutional memberships, endowments, grants and contributions from individuals, corporations and foundations (both public and private), and fee-for-service. The Center brings a wealth of experience in coordinating national programs. Its staff includes nationally recognized leaders in chronic pain.

Learn more at painsproject.org

This copy is made available to you by:

For additional information about PAINS and resources on the topic of pain, go to painsproject.org.