



STATEMENT

of the

American Medical Association

to the

**U.S. House of Representatives
Committee on Oversight and Reform**

**Re: Medical Experts: Inadequate Federal Approach to
Opioid Treatment and the Need to Expand Care**

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June 19, 2019

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The American Medical Association (AMA) appreciates the opportunity to provide testimony to the U.S. House of Representatives Committee on Oversight and Reform as part of the hearing entitled, “Medical Experts: Inadequate Federal Approach to Opioid Treatment and the Need to Expand Care.” As the largest professional association for physicians and the umbrella organization for state and national specialty medical societies, the AMA has been, and continues to be, deeply committed to confronting and ending the epidemic of opioid use disorder (OUD) and related overdose deaths which are having a devastating effect across our nation. We commend the Committee for holding this important hearing to examine current challenges to funding OUD treatment and the need for new policies and infrastructure to remove barriers to evidence-based care treatment and improve access to care.

Background

The nation’s epidemic of opioid-related overdoses and deaths continues to worsen. More than two million people in the United States have OUD, putting them at a greatly increased risk of early death from overdose, infectious diseases, trauma, and suicide (NASEM Consensus Study Report, Medications for Opioid Use Disorder Save Lives, March 2019). Of the 70,237 drug overdose deaths in 2017, 68 percent (47,600) were from opioid-related causes, according to the Centers for Disease Control and Prevention (CDC-KFF). This means that every day in 2017, more than 130 people in the United States died from an opioid-related cause (National Institute on Drug Abuse), and one person died of an opioid-related cause every 11.4 minutes (The National Institute for Health Care Management NIHCM Foundation).

For the past several years, the dynamics of the opioid epidemic have changed from one driven by prescription opioids to one that is driven by heroin and illicitly manufactured fentanyl and fentanyl analogs. Deaths due to prescription opioid and heroin-related causes appear to have plateaued but remain at historic highs. In 2017:

- 28,466 died from illicit fentanyl-related overdose (19,413 in 2016);
- 15,482 died from heroin-related overdose (15,469 in 2016);
- 14,495 died from prescription opioid-related overdose (14,487 in 2016). (More than 60 percent of people who misuse prescription opioids steal them or obtain them from a family member or friend); and

- 3,194 died from methadone-related causes—the lowest number since 2003. The data does not distinguish whether methadone was used for pain or for the treatment of OUD (SAMHSA).

Significantly, mortality rates for prescription opioids, fentanyl, and heroin vary state by state. For example, the data shows that some states are seeing progress in terms of reducing prescription opioid-related mortality. Twenty-eight states saw decreases in mortality related to prescription opioids from 2016-17 with four states seeing a second consecutive-year decrease (AR, MO, OR, RI) and three seeing a third consecutive-year decrease (NM, UT, WV). Between 2015-2016, only 16 states saw a decrease. Yet, prescription opioid-related mortality was the leading cause of opioid-related mortality in 20 states in 2017; it was also the leading cause of opioid-related mortality for 21 states in 2016.

With respect to illicit opioid-related mortality, heroin-related overdose mortality decreases were seen in 20 states, with four states seeing a second consecutive-year decrease (MA, NH, RI, VT). Fourteen states saw both a decrease in prescription opioid and heroin-related mortality (CT, HI, ID, KS, KY, MD, MA, MO, NH, NM, NC, PA, RI, UT). Only two states saw a decrease in illicit fentanyl-related death—NM and ND. NM is the only state that saw decreases in all three categories.

The good news is that we know that there are policy and clinical interventions that work and have a direct impact on saving lives and improving care. There are also lessons to be learned from policies that have harmed patients, such as opioid restriction policies based on arbitrary thresholds and mandated, non-consensual tapering policies, which have not had their intended consequences of reversing opioid overdoses and deaths.

The bad news is there is a huge gap in access to treatment. It is estimated that less than 35 percent of adults with OUD had received treatment for it in 2018 (Jones and McCance-Katz, 2019, cited in NASEM, Consensus Study Report). There are numerous barriers that prevent broader access to evidence-based treatment, including payer practices that delay or deny care, reluctance among some providers and individuals to use medication-assisted treatment (MAT), stigma, and lack of sufficient treatment facilities and addiction medicine specialists. However, there are policy interventions that can address these barriers, which are discussed in more detail below.

Physician progress to end the epidemic

The AMA continues its aggressive advocacy efforts in support of patients with pain and those with a substance use disorder. In 2014, the AMA convened more than 25 (there are now 28 participating organizations) national, state, specialty and other health care associations to form the AMA Opioid Task Force to coordinate efforts within organized medicine to help end the nation's opioid epidemic. For the past three years, the AMA has measured several aspects where physicians have taken action to end the epidemic. The AMA has issued a report each year highlighting these areas. The [2019 report](#) was issued recently and shows that physicians and other health professionals are taking significant actions in the face of the epidemic, and some reports suggest that prescription opioid-related mortality may be leveling off. Key findings from the report include:

- **Opioid prescriptions decrease.** Opioid prescriptions decreased 33 percent (more than 80 million prescriptions) between 2013-2018, including more than 12 percent (more than 20 million prescriptions) between 2017-2018 alone.
- **PDMP use increases.** Nearly 2 million physicians and other health care professionals are registered to use state-based PDMPs, a 290 percent increase from 2014. Use of PDMPs increased to more than 450 million queries in 2018, a 56 percent increase from 2017 and a 651 percent increase from 2014.

- **Education increases.** In 2018, more than 700,000 physicians and other health care professionals completed medical education trainings and accessed other educational resources provided by the AMA, and state and specialty medical societies. These materials included opioid prescribing, pain management, screening for substance use disorders, and related areas in 2018, up from 118,500 in 2015-16.
- **More physicians certified to treat opioid use disorder.** More than 66,000 physicians (and a growing number of nurse practitioners and physician assistants) are certified to provide in-office buprenorphine, up from 37,000 in 2016.
- **Naloxone co-prescribing increases.** Access to naloxone has saved tens of thousands of lives. In 2018, the number of naloxone prescriptions reached a record high in the U.S. to more than 598,000 prescriptions, a 107 percent increase from 2017 and a 338 percent increase from 2016.

This progress, however, has not led to an overall reduction in mortality or a measurable increase in positive patient outcomes. Death from heroin and illicitly manufactured fentanyl and fentanyl analogs are at historic levels. In issuing the report, AMA President, Patrice A. Harris, MD, MA, who chairs the AMA Opioid Task Force, stated, “The opioid epidemic is at a crossroads. While physicians must continue to demonstrate leadership by taking action, it is clear that these significant reductions in opioid prescribing, increases in prescription drug monitoring program (PDMP) use and taking more education—by themselves—will not stop people from dying.” Dr. Harris also noted, “Progress has been made, but much more work remains. It is time for states to end prior authorization and other barriers to medication-assisted treatment for opioid use disorder; and time for payers, pharmacy benefit management companies (PBMs), and pharmacy chains to re-evaluate all policies restricting access evidence-based care for pain and substance use disorders. If it weren’t for naloxone, it is likely that tens of thousands more Americans would be dead. The report shows that to save many more lives, policymakers, payers, PBMs and pharmacy chains must remove all barriers to evidence-based care.”

AMA Recommendations to Improve Access to Care for OUD

1. Remove Barriers Imposed by Payers

As noted by both the AMA Opioid Task Force and the National Academies of Sciences, Engineering, and Medicine’s March 2019 Consensus Study Report, “Medications for Opioid Use Disorder Save Lives,” existing tools to counter the opioid epidemic—i.e., evidence-based medications to treat OUD—save lives and yet are not being used to their maximum effect. There is clear evidence in support of MAT as a proven medical model to support recovery, save lives, reduce crime, and improve quality of life. Methadone, buprenorphine, and extended-release naltrexone are approved medications to treat OUD, but, as noted earlier, most individuals with OUD in the U.S. receive no treatment at all, and only a small portion of those who do receive MAT.

In its latest report, the AMA Opioid Task Force forcefully calls on all payers—commercial insurers, self-insured plans, Medicare, and Medicaid—as well as PBMs to end prior authorization and other unnecessary utilization management protocols for the treatment of OUD. Payers, PBMs, and pharmacy chains need to re-evaluate all policies restricting access to evidence-based care for pain and substance use disorders. This also includes ensuring that MAT is available on the lowest cost-sharing tier to promote affordability as well as prompt availability. It is time for all payers to support increased access to MAT.

Maryland was the first state to remove prior authorization for MAT in 2017, five years after the epidemic began. Stories from physicians indicate that they have seen immediate results in their practices from prior authorization being removed. One physician wrote to the AMA that “No longer does she have to spend hours a week answering panicked phone calls from patients at the pharmacy, and then making calls to the

insurer and pharmacists to try and straighten it out. But the biggest change was removing the fear of ‘will I be able to fill my prescription?’ for her patients.”

Before 2019, in addition to Maryland, only three states—Illinois, Arizona, and Pennsylvania—had legislation or other initiatives that removed prior authorization for MAT. So far in 2019, AMA model legislation and policy efforts have supported new laws and policies to remove prior authorization for MAT in the commercial and/or Medicaid markets in Arkansas, Arizona, Colorado, DC, Iowa, Maine, Missouri, New Jersey, New York, Pennsylvania, Washington, and Vermont; the AMA is also working with other states to introduce legislation. Legislation failed, however, due to health insurance company opposition in California, Kentucky, and Montana.

On the federal side, we are pleased that language we recommended on prior authorization was included in the “Comprehensive Addiction Resources Emergency (CARE) Act,” S. 1365/H.R. 2569. The provision would require the Secretary of the U.S. Department of Health and Human Services (HHS) to give grant funding preference to states that have prohibited prior authorization and step therapy for MAT. The AMA believes this language will help to incentivize those states that have not yet removed prior authorization to do so.

Most recently, at the AMA’s Annual Meeting last week, our policymaking body, the House of Delegates, adopted several new policies that further barriers imposed by payers:

- That our AMA support amendments to opioid restriction policies to allow for exceptions that enable physicians, when medically necessary in the physician’s judgment, to exceed statutory, regulatory or other thresholds for post-operative care and other medical procedures or conditions.
- That our AMA oppose health insurance company and PBM utilization management policies, including prior authorization, that restrict access to post-operative pain care, including opioid analgesics, if those policies are not based upon sound clinical evidence, data and emerging research.
- That our AMA support balanced opioid-sparing policies that are not based on hard thresholds, but on patient individuality, and help ensure safe prescribing practices, minimize workflow disruption, and ensure patients have access to their medications in a timely manner, without additional, cumbersome documentation requirements.
- That our AMA oppose the use of “high prescriber” lists used by national pharmacy chains, pharmacy benefit management companies or health insurance companies when those lists do not provide due process and are used to blacklist physicians from writing prescriptions for controlled substances and preventing patients from having the prescription filled at their pharmacy of choice.

Greater Enforcement of Mental Health and Substance Use Disorder Parity

The AMA notes that very high rates of mental disorders co-exist among patients with opioid use disorders as well as among patients with chronic pain conditions leading to increased risk for suicide. The 2017 National Survey on Drug Use and Health found, however, that 92 percent, or 19.7 million people, with a substance use disorder (SUD) receive no treatment, and 57 percent, or 46.6 million people, with a mental illness receive no treatment. The Mental Health Parity and Addiction Equity Act was signed into law by President George W. Bush on October 3, 2008. On the tenth anniversary of the passage of the law, the AMA called on state and federal policymakers to enforce the law’s provisions to help end the opioid epidemic, specifically noting that insurers need to be held accountable for complying with their legal

obligations under the law. This means that health insurance companies must have addiction medicine and psychiatric physicians not only in the network but accepting new patients, as well as mental health and SUD coverage that is on par with medical and surgical benefits. The AMA also strongly supports assessment, referral, and treatment for co-occurring mental health disorders.

Legal and Regulatory Barriers that are not Evidence-Based

There is a growing trend in reports of patients being denied access to opioid therapy. These stories are not new, as the AMA has received them since certain pharmacy chains instituted proprietary opioid analgesic restriction policies dating to 2012-2013. However, these reports increased following publication of the CDC Guideline for Prescribing Opioids for Chronic Pain in 2016, and further escalated following health insurance company, pharmacy chain and PBM actions to further restrict opioid prescribing. States have also incorporated the CDC guidelines into state laws and/or regulations. While the stated laudable intent of those policies was to limit the initial opioid prescription for acute pain (typically following minor surgery), the practical effect was that the guidelines were misapplied and resulted in payers, pharmacies, and PBMs reducing or denying opioid therapy to patients, including many with chronic pain, cancer, in hospice or who were receiving palliative care. There also have been growing reports of patients being tapered—consensually or non-consensually—from current opioid doses. In addition to ongoing AMA advocacy emphasizing the need for individualized patient care and opposing the misapplication of the CDC Guideline, more than 300 physicians [sent a letter to CDC](#) highlighting reports of patient harm, including suicides.

In response to these increasing reports of patient harm from the opioid restriction policies and nonconsensual tapering, the U.S. Food and Drug Administration (FDA) and CDC have recently made significant statements to mitigate patient harms. On February 28, 2019, the CDC [sent a letter](#) to the National Comprehensive Cancer Network, American Society of Clinical Oncology and American Society of Hematology noting that “The [CDC opioid prescribing] Guideline is not intended to deny any patients who suffer with chronic pain from opioid therapy as an option for pain management,” and that “CDC encourages physicians to continue to use their clinical judgment and based treatment on what they know about their patients, including the use of opioids if determined to be the best course of treatment.” The FDA on April 9, 2019 [issued a statement](#) emphasizing that it is “requiring changes to the prescribing information for these medicines that are intended for use in the outpatient setting. These changes will provide expanded guidance to health care professionals on how to safely decrease the dose in patients who are physically dependent on opioid pain medicines when the dose is to be decreased or the medicine is to be discontinued.”

Then on April 24, 2019, the *New England Journal of Medicine* published a CDC “[Perspective](#)” in which the authors of the 2016 CDC Guideline said that while “Efforts to implement prescribing recommendations to reduce opioid-related harms are laudable. Unfortunately, some policies and practices purportedly derived from the guideline have in fact been inconsistent with, and often go beyond, its recommendations.” The authors went on to note multiple ways in which the guidelines have been misinterpreted as inflexible standards, including support for individualized patient care: “Policies should allow clinicians to account for each patient’s unique circumstances in making clinical decisions.”

The AMA [welcomed](#) the CDC’s revised view of the guidelines, emphasizing that while the AMA continues to encourage judicious prescribing decisions, “the guidelines have been misapplied so widely that it will be a challenge to undo the damage.” The AMA adopted new policy at its recently-held Annual Meeting to advocate that clinical practice guidelines specific to cancer treatment, palliative care, and end of life be utilized in lieu of the CDC’s Guideline for Prescribing Opioids for Chronic Pain as per the CDC’s clarifying recommendation. Moreover, the AMA recognizes that some patients with acute or chronic pain can benefit from taking prescription opioid analgesics at doses that may be greater than

guidelines or thresholds put forward by federal agencies, health insurance companies, pharmacy chains, pharmacy benefit management companies and other advisory or regulatory bodies. The AMA continues to urge physicians to make judicious and informed prescribing decisions to reduce the risk of opioid-related harms, but acknowledges that for some patients, opioid therapy, including when prescribed at doses greater than recommended by such entities, may be medically necessary and appropriate.

Stigma

Stigma continues to be a major barrier for individuals seeking and staying in treatment and toward medications used to treat OUD. Patients in pain and patients with a substance use disorder need comprehensive treatment, not judgment, but judgment is often what they receive, from friends and family, the community, law enforcement, and some medical professionals. Some providers may be reluctant to prescribe MAT out of concerns over misuse or diversion. Removing stigma is essential to ending the opioid epidemic.

We also need to distinguish medical accuracy from popular myth. Just as we would never call a diabetic who relies on insulin an insulin addict; or we would never call someone with heart disease a beta-blocker addict; or we would never call someone with anxiety and depression a serotonin addict, so too must we move beyond medically inaccurate terminology for medication that saves lives. Someone with an opioid use disorder can lead a healthy, fulfilling life by taking MAT drugs. Stigmatizing language only serves to prolong the epidemic.

Maternal and Child Health/Incarceration

The AMA strongly supports a special focus of resources and policy proposals on maternal and child health in the context of the opioid crisis, and we supported the many provisions in CARA and the SUPPORT Act that addressed programs for OUD treatment for pregnant women and post-partum women. Consistent with this, the AMA and the AMA Opioid Task Force believes it is essential to specifically highlight the important roles of physicians and policymakers in ensuring the unique needs of pregnant, postpartum, and parenting women and children are met. OUD among women of reproductive age and pregnant, postpartum, and parenting women has increased over recent years, mirroring the epidemic seen in the general population. According to HHS's Office of Women's Health, the number of women dying from overdose of prescription drugs rose 471 percent between 1999 and 2015, compared to 218 percent for men, and heroin deaths among women increased at more than twice the rate of men.

MAT is the recommended evidence-based treatment for pregnant and breastfeeding women with OUD. Threats of incarceration, immediate loss of child custody, and other potential punishments drive pregnant, postpartum, and parenting women away from vital prenatal care and treatment. Research has found that non-punitive public health approaches to treatment result in better outcomes for both moms and babies. We believe that additional efforts are needed for patient and public education as well as outreach to policymakers to ensure evidence-based care guides treatment options for maternal and child health.

Civil and Criminal Justice Reforms

The AMA and the Opioid Task Force believe that all persons entering jails or prisons (both for men's and women's facilities), while incarcerated, and upon release, will benefit from enhanced OUD screening protocols to identify those persons arrested if they are currently on MAT, or would like to begin treatment. We also support the use of evidence-based protocols for maintaining continuity of care for persons released from jail or prison, including—as necessary—enrollment in Medicaid, coordination with peer counseling or other similar services to ensure the person has linkages to treatment providers in the community, and other such services so as to maintain access to and a continuum of care to sustain and

promote recovery. This recommendation also applies to drug courts and other diversion services to support evidence-driven care for persons with OUD.

Funding (CARE Act)

Even if all the barriers discussed above were eliminated, there still would not be enough treatment due to lack of funding. The AMA has been calling for increased federal funding for several years to address the opioid epidemic and was pleased that the 2018 and 2019 appropriations bills included over \$10 billion to combat the epidemic. However, given the unprecedented nature of the current epidemic, much more funding will be needed to reverse and end this epidemic. We believe the CARE Act, through policy and funding, is a major step forward in addressing the opioid epidemic. It would authorize \$100 billion over 10 years, a substantial increase and in keeping with the enormity of the epidemic. The CARE Act is intended to fill the current funding gap and sets up a framework to do so.

AMA Recommendations for Removal of Barriers to Evidence-Based Pain Care

Access to evidence-based pain care is the opposite side of the coin to access to evidence-based treatment for OUD. The AMA (Opioid Task Force) supports patients having access to the right treatment at the right time without administrative barriers or delay from health insurance carriers or other payers and pharmacy benefit or behavioral health management companies. There is no question that the nation's physicians have reduced opioid analgesic supply—both in volume and dose strength—but there has not been a concomitant increase in access to or affordability of evidence-based non-opioid alternatives. The AMA supports the removal of barriers, including prior authorization, to non-opioid pain care.

This mirrors a new recommendation from the AMA Opioid Task Force: as part of current and future efforts to reverse the nation's opioid epidemic, the Task Force supports increased research and access to evidence-based treatment, including:

- Medication, including non-opioid pain relievers, anticonvulsants, antidepressants, musculoskeletal agents, anxiolytics as well as opioid analgesics when appropriate. The Task Force notes that physicians and patients now face a multiplicity of new laws, guidelines and policies from payers, PBMs and national organizations, which are often contradictory.
- Restorative therapies, which include physical therapy, occupational therapy, physiotherapy, therapeutic exercise, osteopathic manipulative therapy (OMT), and other modalities such as massage and therapeutic ultrasound.
- Interventional procedures, such as neuromodulation, radio frequency ablation, peripheral nerve stimulation, central and peripheral nerve ablation, spine surgery and steroid injections, and other emerging interventional therapies as part of the multimodal pain care plan.

This recommendation further calls for more detailed regulatory review of formulary and benefit design by payers and PBMs to ensure that patients have affordable, timely access to evidence-based non-opioid alternatives, pharmacologic and non-pharmacologic. In conducting such reviews, the Task Force urges policymakers to work closely with physicians to ensure appropriate clinical input. The AMA is doing this with state regulators in Pennsylvania and Colorado to ensure non-opioid pain care options are available and affordable.

Conclusion

Unless and until policy makers focus on removing barriers to high-quality, evidence-based care for SUD—and removing barriers to comprehensive, multidisciplinary, multimodal pain care—this epidemic will not end. We need help from policymakers to ensure more people have access to treatment ... we

cannot enforce parity laws or eliminate administrative barriers without the help of state and federal authorities, and that's what is limiting treatment now.