

February 16, 2018

The Honorable Orrin G. Hatch
Chairman
Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Hatch and Ranking Member Wyden:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing in response to your letter to stakeholders dated February 2, 2018, seeking policy recommendations within the Senate Finance Committee's jurisdiction to address the ongoing opioid epidemic. The AMA has been actively involved over the past several years in efforts to reverse the nation's opioid epidemic. Ending this epidemic requires leadership and commitment from all health care stakeholders, policymakers, law enforcement, the justice system, and local communities. It also requires strong, dedicated physician leadership and commitment by all physicians to reduce prescription opioid-related mortality and increase access to treatment for opioid use disorder (OUD), while, at the same time, ensuring that patients with pain receive appropriate treatment.

The medical profession's collective efforts are having an impact, but much more work remains to end this epidemic. From 2013 to 2016, opioid prescriptions in the United States decreased by 43 million—a nearly 17 percent decrease nationally. There has also been a significant increase of 121 percent in the number of queries by health professionals to state Prescription Drug Monitoring Programs (PDMP), from roughly 60 million queries in 2014 to almost 140 million in 2016. There is still an enormous gap between the number of people who need OUD treatment and those who are receiving it. Opioid-related morbidity, overdoses and deaths continue to occur across the country, in communities large and small, with especially rapid growth in deaths attributed to heroin and illegally imported fentanyl.

Federal payment and delivery system reforms provide opportunities to better support and incentivize clinicians who enhance their education on pain management and safe prescribing, become certified to prescribe buprenorphine, co-prescribe naloxone, utilize PDMP data in clinical practice, and coordinate treatment and support services for patients experiencing pain and/or addiction. We provide some specific examples below of ideas that the Finance Committee might consider to integrate opioid epidemic solutions into Medicare and Medicaid:

- **Create a 7th Protected Class of Drugs under Part D for Medication-Assisted Treatment.** Under Medicare, the Centers for Medicare & Medicaid Services' (CMS) overutilization monitoring system (OMS) has been effective in reducing the number of Medicare beneficiaries who are at risk for opioid overutilization. Providing information to the multiple prescribers who may be writing prescriptions for opioid analgesics to the same patient about the total opioid prescribing for that patient has been shown to be helpful in improving care coordination. Where both the current and the proposed CMS policies fall short, however, is in ensuring access to evidence-based medication-assisted treatment (MAT) for Medicare patients with opioid use disorder. In the same way that CMS currently requires that plan sponsors cover all drugs in six protected classes (i.e., anticonvulsants, antidepressants, antineoplastic, antipsychotics, antiretrovirals, and immunosuppressants), CMS should create a new category of drugs under Part D and require all Medicare Advantage Part D and standalone Part D plans to cover all medications approved by the U.S. Food and Drug Administration (FDA) for OUD treatment. While not every individual may require an FDA-approved medication, those who do should be able to access whichever medication is most appropriate to treat OUD based on their particular circumstance. We believe that CMS has the authority to create a new protected class of drugs under Part D, and recommend that the Finance Committee urge CMS to take this action.
- **Improve Coverage and Eliminate Payment Barriers for MA and Part D Plans.** All Medicare Advantage (MA) and Part D plans should eliminate barriers to multimodal treatment for pain by covering non-opioid analgesics and non-pharmaceutical treatments for pain. Better coverage of these other therapeutic options could help reduce overreliance on opioid analgesics and lessen the rapidly accelerating growth in the number of Medicare patients with OUD. In addition, the prompt review requirements imposed on the plans for prior authorization and step therapy have the perverse effect of producing prompt denials if the physician does not have sufficient time to provide the requested information to the plans. The best time to get a patient into treatment is during the appointment at the physician's office; prior authorization and step therapy requirements impose unnecessary administrative burdens on prescribers and unjustified access delays on patients. Plans have placed too many drug utilization management (DUM) requirements on medical practices and hurdles in front of patients' rapid access to their medications. The prescribing clinician's judgment should be accepted at the time that the prescription is initially written that the medication is needed for the patient. CMS should prohibit the use of these DUM requirements, especially for OUD treatment, and the Finance Committee should urge CMS to do so.
- **Allow Medicare Coverage of Methadone.** While methadone and other MAT are effective, evidence-based treatments for OUD, methadone is covered under Medicare Part D only when prescribed for pain, but not when given as part of an OUD outpatient treatment program. The AMA has long called for expansion of MAT, and we are pleased

that the President's Commission on Combating Drug Addiction and the Opioid Crisis' final recommendations recognize that Medicare's lack of coverage for methadone and other MAT create treatment barriers for the many Medicare patients who need outpatient services. Removing this barrier is particularly important since OUD is a large and growing problem among Medicare beneficiaries. Research by the Agency for Healthcare Research and Quality found that, although Medicaid had the largest proportion of hospital stays involving opioid overuse, Medicare has had the largest annual increases over time. By 2012, Medicaid and Medicare each were billed about one-third of all opioid-related stays. The Medicare Beneficiary Opioid Addiction Treatment Act (H.R. 4097), introduced by Representative Richard Neal (D-MA), would allow Medicare beneficiaries access to critical opioid addiction treatment medication, i.e., methadone, in outpatient and physician settings.

- **Ensure Quality Measurement Does Not Lead to Inappropriately Treating Pain.** Quality measures with an emphasis on opioid use should focus on how well patients' pain is controlled, whether functional improvement goals are met, and what therapies are being used to manage pain. If pain can be well-controlled and function improved without the need of high doses of opioids over a long period of time, that is a good indication of patient care, but focusing on a reduction in opioid dose alone, such as opioid prescriptions that exceed => 90 morphine milligram equivalents (MME)/ day is not an appropriate goal. Focusing on daily dose may serve as an indicator of whether a patient is at risk of overdose and should be co-prescribed naloxone, but does not provide a signal that a physician provides poor quality care. In fact, since the Centers for Disease Control and Prevention Guideline for Prescribing Opioids for Chronic Pain was issued, there have been many reports of patients who have been successfully managed on opioid analgesics for long periods of time, but forced to abruptly reduce or discontinue their medication regimens with sometimes extremely adverse outcomes, including depression, loss of function and even suicide.
- **Support Alternative Payment Models for Opioid Therapy.** The AMA recommends that health programs such as Medicare and Medicaid prioritize innovative approaches to preventing and treating pain and addiction as they design new payment models. The AMA has been working with the American Society of Addiction Medicine (ASAM) on the design of an alternative payment model called Patient-Centered Opioid Addiction Treatment or P-COAT. The epidemic of deaths due to opioid overdoses is widespread, growing rapidly, and has overtaken many other leading causes of death. Substantial medical literature documents the clinical effectiveness of MAT for opioid addiction. Despite this evidence and the worsening epidemic, MAT, particularly using buprenorphine, is significantly underutilized. One reason for its underutilization is that traditional physician payment systems provide little or no support for non-face-to-face services such as phone calls and email consultations with patients, collaboration between addiction specialists and other physicians, as well as between outpatient treatment

programs and other health care providers such as emergency departments, and coordination of the behavioral, social and other support services that patients being treated for opioid use disorder need in addition to their medication. Payer adoption of P-COAT would provide comprehensive payments for induction and treatment services that would support these services in order to help encourage more physicians to manage patients with opioid use disorder. Alternative payment models were one strategy for expanding access to treatment included in a recent Government Accountability Office review of efforts to expand MAT access for OUD.

- **Enhance Education of Physicians and other Providers.** A key part of our commitment to reversing the current opioid epidemic is supporting enhanced education, training and resources for physicians and other health care professionals across the continuum of medical education to ensure that they have the resources they need to make informed prescribing decisions. In 2015 and 2016, more than 118,000 physicians have taken educational courses related to opioid prescribing, pain management, substance use disorders, and related topics offered by national organizations, as well as medical specialty and state medical societies. This has been the direct result of collective efforts by the AMA Opioid Task Force and the nation's medical societies, which recognize the urgency to reduce opioid-related harms, prevent diversion, and provide access to treatment for opioid use disorder, while maintaining a clinical practice environment that enables physicians to manage an individual patient's pain and suffering in the most effective and safe manner. The AMA has collected nearly 300 educational resources addressing these objectives and regularly promotes them to physicians through a new AMA microsite: www.end-opioid-epidemic.org. The AMA strongly supports efforts to enhance education, but believes that it should occur at the state level to avoid creating confusion and unnecessary federal overlap with existing state law. Because current educational mandates have not been shown to correlate with lower morbidity or mortality rates, we believe that a more innovative approach is required. One possible approach to consider is the Prescriber Support Act (H.R. 1375), introduced by Representatives Katherine Clark (D-MA) and Evan Jenkins (R-WV), which would combat the opioid epidemic by authorizing a new public health grant program to establish comprehensive state-based resources for physicians and other prescribers to consult when treating patients with pain and identifying signs of substance misuse and substance use disorders. The grants authorized under this legislation would be used to create a peer-to-peer consultation program that would enable prescribers to receive real-time expert consultation, both in person or remotely, with a pain or addiction specialist when treating patients. In addition, the grant funding would enable prescribers to connect with community-based resources and services, including mental health and substance abuse resources, pain and addiction specialists, primary care resources and support groups. These resources would provide another important tool to help physicians in taking care of their patients and in addressing the broader opioid epidemic.

- **Improve Access to Naloxone.** If it were not for expanded use of naloxone, there would likely be tens of thousands more deaths from opioid-related overdoses. State policies have helped spur widespread access, but the AMA remains concerned that some patients may not be able to access this life-saving opioid antidote medication due to its high cost. Manufacturers and health insurers need to act responsibly in helping to ensure that first responders, community-based organizations, family members and patients can readily access and administer naloxone. The AMA urges the Finance Committee to consider ways to expand access to naloxone in the Medicare and Medicaid programs.

In addition, the AMA offers the following policy recommendations on the issues raised in the Stakeholder Letter to assist the Finance Committee in its deliberations on ways to address this epidemic:

- **Support continued Medicaid coverage for treatment of opioid use disorders and pain management.** Medicaid expansion under the Affordable Care Act (ACA) has been a path to treatment for hundreds of thousands of individuals with opioid use disorders. Such treatment must be sustained in any future health system reform legislation or regulation. In addition, Medicaid also provides insurance coverage that is critical to treatment of acute pain so that it does not become chronic pain, as well as treatment of mental health issues that people with opioid use disorders often have.
- **Increase inpatient treatment capacity under Medicaid and waive or repeal Medicaid's 15-bed IMD limit.** When Medicaid was created, coverage of treatment at Institutions for Mental Diseases (IMD) with more than 15 psychiatric beds was excluded. This well-meaning provision was intended, in part, to discourage the “warehousing” of patients with mental disorders in state hospitals and nursing homes. However, as evidenced-based treatment for addiction has progressed, the provision now serves as an obstacle to access treatment. The AMA strongly supports either waiving or repealing the 15-bed IMD exclusion. Given that only about 10 percent of the nearly two million patients with a substance use disorder can access treatment, it is essential that treatment capacity be increased as expeditiously as possible. Removing the 15-bed IMD exclusion is an important first step to increasing physicians’ ability to care for patients with an opioid use disorder. Two bipartisan pieces of legislation currently before Congress seek to address this barrier. The Medicaid Coverage for Addiction Recovery Expansion Act (or Medicaid CARE Act, H.R. 2687 and S. 1169) would allow for Medicaid coverage in facilities with up to 40 beds. The Senate bill was introduced by Senator Richard Durbin (D-IL) and Rob Portman (R-OH). In addition, in the House, Representative Brian Fitzpatrick (R-PA) has introduced similar legislation. The Road to Recovery Act (H.R. 2938) currently has the support of 37 bipartisan cosponsors, and would repeal the current IMD exclusion.

- **Medicaid Coverage for Incarcerated Individuals.** Federal law currently prohibits the use of Medicaid funds for the cost of any services provided to an “inmate of a public institution,” except when the individual is a patient in a medical institution. This policy, referred to as the Medicaid Inmate Payment Exclusion, has resulted in many states not enrolling their inmates in Medicaid. In addition, some state laws prohibit the submission of Medicaid applications during incarceration; whereas others permit submission, but no earlier than 30 days before release from custody. According to the Kaiser Family Foundation, the majority of states terminate, instead of suspend, Medicaid eligibility upon intake into a correctional system. It is widely acknowledged that the incarcerated population has a higher rate of chronic diseases, mental health conditions, substance use disorders, and contagious diseases than the general population. Moreover, recent research demonstrates that individuals who are released back into the community post-incarceration are approximately eight times more likely to die of an opioid overdose in the first two weeks after being released compared to other times. Providing states with the flexibility to restart Medicaid coverage for eligible incarcerated, addicted individuals up to 30 days prior to their release would help to provide for critically needed health care, care coordination activities, and linkages to care for such individuals. This, in turn, would help establish coverage effective upon release, assist with transition to care in the community and help reduce recidivism. Representative Paul Tonko (D-NY) has introduced an AMA-supported bill to provide such coverage, H.R. 4005, the Medicaid Reentry Act, which we encourage the Finance Committee to consider.
- **Encourage Electronic Prescribing of Controlled Substances (EPCS).** Drug Enforcement Administration (DEA) requirements for biometric devices limit user-friendly consumer electronics already found in physicians’ offices, such as fingerprint readers on laptop computers and mobile phones, from being utilized for two-factor authentication in EPCS. This and other rules contribute to cumbersome workflows and applications which are an impediment to physician EPCS uptake. Encouraging EPCS uptake and interoperability of PDMP databases and electronic health records would improve the integration of controlled substance use data into practice workflows and clinical decision-making. While we recognize that the DEA is not within your specific committee jurisdiction, we recommend that you urge DEA to be responsive to removing their regulatory barriers to EPCS.
- **Support Implementation of the National Pain Strategy (NPS).** The NPS was published in 2016 but little progress has been made on implementing its core elements to improve the state of pain care in the nation. The AMA believes that—along with comprehensive treatment of opioid use disorder—the capability to deliver multidisciplinary treatment of pain is also necessary to reverse the nation’s opioid overdose and death epidemic. The NPS calls for developing a system of patient-centered integrated pain management practices based on a biopsychosocial model of care that enables health professionals and patients to access the full spectrum of pain treatment

options, and it also calls for taking steps to reduce barriers to and improve the quality of pain care for vulnerable, stigmatized and underserved populations. NPS implementation will change the paradigm for treating pain and ensure that physicians can recommend all pain management modalities to patients and know that insurance plans will cover those treatments. When payers use high deductibles, yearly limits on treatments such as physical therapy, and prior authorization to delay or deny care, patients often are left with few non-opioid pain treatments. In addition, employers need to recognize that patients may require time away from work to participate in therapeutic modalities so that opioid analgesics are not the only affordable option.

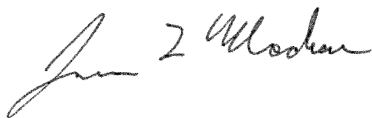
- **Support State-Based Innovations.** In the past 2-3 years, several hundred new policies have been enacted at the state and local levels to address the opioid epidemic. The AMA strongly urges that efforts be undertaken to fully evaluate how these new laws and policies affect access to treatment for opioid use disorder, impact pain care, or might be associated with unintended consequences. As the nation's opioid epidemic is increasingly fueled by heroin and fentanyl and other illicit, synthetic derivatives, the AMA urges the Committee to consider how public policies focusing on opioid supply need to be balanced by policies that offer a measure of hope to those individuals and families already affected by this epidemic.
- **Support and Expand Innovative Medicaid Waivers to Improve Treatment.** Several states are implementing Medicaid waivers to improve substance use disorder treatment. In December 2016, CMS approved a section 1115 demonstration project for Virginia that authorizes the state to strengthen its OUD delivery system to improve the care and health outcomes for Virginia Medicaid beneficiaries. Virginia's new OUD benefit and delivery system, called the Addiction and Recovery Treatment Services (ARTS) Delivery System Transformation, contributes to a comprehensive statewide strategy to combat opioid use disorders by expanding the OUD benefits package to cover the full continuum of care, integrating OUD services into comprehensive managed care and introducing new program, provider and managed care requirements to improve the quality of care consistent with national treatment guidelines established in the ASAM Criteria. In November 2017, Utah received approval from CMS to provide health coverage for about 6,000 poor adults without children. The waiver and accompanying federal funding will enable eligible residents—they must be homeless or in the criminal justice system and earn no more than five percent of the federal poverty level—to receive treatment for opioid use disorder through expanded inpatient treatment capacity. Also in November, West Virginia became the first state to receive a Medicaid waiver to treat Neonatal Abstinence Syndrome. California, Massachusetts, and Maryland also have Medicaid waivers for OUD treatment.

While the following ideas for consideration that are outside the Finance Committee's direct jurisdiction, your support for these efforts would be helpful:

- **Suspend Federal Regulatory and Other Barriers to Providing Buprenorphine.** The AMA supports eliminating the requirement for obtaining a special federal waiver to prescribe buprenorphine for the treatment of OUD. Even though the regulatory approach has eased somewhat since 2016, there still are considerable barriers in place. Removing the federal waiver requirement will give many more patients new access to treatment from physicians and other qualified health care professionals. The safety and effectiveness of MAT is well-established, and we need to do all we can to encourage more qualified clinicians to care for OUD patients. The Finance Committee should consider suspending the waiver requirements for physicians providing buprenorphine under the Medicaid and Medicare programs.
- **Strengthen State-Based PDMPs.** As previously noted, physicians' consultation of these databases has increased from 61 million queries in 2014 to more than 136 million in 2016. PDMPs are now functional in almost every state, and most state PDMPs can share data. To expand the use of these clinical support tools, the AMA urges increased research and funding to help integrate PDMPs into electronic health records and physician workflow in a meaningful, user-friendly manner.
- **Enforce existing substance use disorder parity laws.** More resources need to be provided for enforcing the Mental Health Parity and Addiction Equity Act. This can be done at both the state and federal levels, but America's patients also need your leadership to encourage health insurance companies and pharmacy benefit managers to end the type of prior authorization, step therapy, and fail first protocols that only serve as barriers to MAT and multimodal pain care. While some payers already have taken positive steps to remove some barriers, this epidemic requires all payers to work to ensure access to care.

Thank you for the opportunity to offer our recommendations. We look forward to working with you and your colleagues to confront and reverse the devastating opioid epidemic.

Sincerely,



James L. Madara, MD