AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Kevin Brady
Chairman
Committee on Ways and Means
1102 Longworth House Office Building
Washington, DC 20515

The Honorable Richard Neal
Ranking Member
Committee on Ways and Means
1102 Longworth House Office Building
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The Honorable Peter J. Roskam
Chairman
Subcommittee on Health
Committee on Ways and Means
1102 Longworth House Office Building
Washington, DC 20515

The Honorable Sander Levin
Ranking Member
Subcommittee on Health
Committee on Ways and Means
1102 Longworth House Office Building
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Dear Chairman Brady, Ranking Member Neal, Chairman Roskam, and Ranking Member Levin:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing in response to your letter dated February 27, 2018, seeking feedback from stakeholders to inform the development of future legislation by the Committee on Ways and Means (the Committee) to respond to the opioid crisis. 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 a commitment by physicians and all health care professionals 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 15 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 more than 136 million in 2016. Less positively, 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. And, as you point out in your letter, the epidemic is increasingly impacting the Medicare population. With one-third of Part D beneficiaries receiving an opioid prescription in 2016, it is particularly important that we are vigilant about potentially at risk beneficiaries while appropriately addressing chronic and acute pain in this vulnerable population.

Generally, the issues you raise for patients with Medicare also apply to patients with Medicaid, including those with Medicare Advantage (MA) and Medicaid managed care plans, as well as those who purchase health insurance policies in the commercial market. This is not to suggest that the issues you raise

regarding Medicare patients do not have unique characteristics, but the AMA wants to emphasize that many aspects of this epidemic carry across all patient populations. To the extent that there are Medicare-specific issues, we raise them below.

Overprescribing/Data Tracking

1. Perverse Incentives in Medicare

As a threshold issue, the AMA strongly supports efforts to help ensure that patients have access to and coverage of comprehensive, multidisciplinary pain care, including the use of non-opioid alternatives when appropriate. One perverse incentive, although not unique to Medicare, is the frequent lack of insurance coverage for non-pharmacologic therapy and non-opioid pharmacologic therapy. We have long said that physicians should avoid initiating opioids for new patients with chronic non-cancer pain unless the expected benefits are anticipated to outweigh the risks. Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred. And if opioids are indicated, then we advocate for physicians to limit the amount of opioids prescribed for post-operative care and acutely-injured patients. Physicians should prescribe the lowest effective dose for the shortest possible duration for pain severe enough to require opioids, being careful not to prescribe merely for the possible convenience of prescriber or patient. Physician professional judgment and discretion as well as consultation with the beneficiary are important in this determination.

We note that the number of opioid prescriptions and opioid prescription dose strength continue to significantly decrease. Between 2013 and 2016, opioid prescriptions decreased in every state—a 14.6 decrease nationally, and preliminary data presented by the U.S. Substance Abuse and Mental Health Services Administration shows that morphine milligram equivalents of those prescriptions have dropped by even greater proportions.[1] The AMA is pleased that the nation's opioid supply that could potentially be diverted is decreasing, and we note that the decreases have generally occurred before new policies were implemented by states and others to restrict opioid prescriptions. Physicians have made progress in making more judicious prescribing decisions, but it is less clear whether the reduction in prescribing has led to improved pain care outcomes. Rather, we urge further support for research that specifically identifies best practices in settings ranging from surgical[2] to the emergency department.

One program that might be of interest to the Committee is a 10-hospital pilot led by Colorado's emergency medicine community to improve pain care and reduce the state's opioid supply available for diversion, which recently reported a 36 percent decrease in opioid prescribing during the 6-month pilot

[1] Presentation by Christopher M. Jones, PharmD, MPH, Director, National Mental Health and Substance Use Policy Laboratory, Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services. March 2018.

[2] For example, a recent study in the *Journal of the American Medical Association* found that optimal opioid prescribing rates differed by type of general surgery procedure, ranging from a median of four days for general surgery procedures, four days for women's health procedures, and six days for musculoskeletal procedures. The study also found that prescription lengths associated with lowest requirement for refill were nine days for general surgery, 13 days for women's health, and 15 days for musculoskeletal procedures . Scully, Rebecca, et al. "Defining Optimal Length of Opioid Pain Medication Prescription After Common Surgical Procedures." January 2018. Available at https://jamanetwork.com/journals/jamasurgery/article-abstract/2654949.

study. The study relied heavily on guidelines developed by the Colorado chapter of the American College of Emergency Physicians (COACEP).

The COACEP Guidelines are a comprehensive approach to pain management and harm reduction strategies, including multiple sections with practice recommendations, use of non-opioid medications as well as policy recommendations. The guidelines were developed by a multidisciplinary panel of emergency physicians, addiction and harm reduction specialists, pharmacists, paramedics, emergency department nurses, and medical students. According to COACEP, "These guidelines are not meant to replace clinical judgment, but rather inform and augment it. Although we acknowledge the value of opioids in certain clinical situations, including the treatment of cancer pain or hospice patients, we advocate extreme caution in all cases."

While the Colorado pilot study may not be replicable in all states, it is the type of tangible, physician-led, team-based effort to improve pain care that the AMA recommends be at the heart of all efforts to reduce opioid-related harms. This is why the AMA strongly supports efforts to remove barriers to multidisciplinary pain care and non-opioid options. We note that this view is shared by the nation's attorneys general, who have urged[3] the nation's health insurance plans to remove barriers to non-opioid pain care.

The AMA urges MA and Part D plans to 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 growth in the number of Medicare patients with OUD.

In addition, the prompt review requirements imposed on the plans for prior authorization (PA) 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; PA 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. We know, for example, that Medicare uses DUM for ophthalmology drugs, especially for glaucoma, and for some allergy drugs. Humana, for example, requires PA for various pain management procedures, such as epidural injections, facet injections, spinal surgery, and pain infusion pump. The Centers for Medicare & Medicaid Services (CMS) should prohibit the use of these DUM requirements, especially for OUD treatment, and the Ways and Means Committee should urge CMS to do so.

We support recent actions taken by CMS to impose oversight of Part D plans' PA practices. In the 2019 Draft Call Letter from CMS, CMS states:

[3] Letter from the National Association of Attorneys General to Marilyn Tavenner, President and CEO, America's Health Insurance Plans. September 18, 2017. Available at https://ag.ny.gov/sites/default/files/final_naag_opioid_letter_to_ahip.pdf .

> "While CMS continues to work closely with Part D sponsors and other stakeholders to help combat inappropriate opioid utilization, it is imperative to also ensure that Medicare beneficiaries have appropriate access to medication-assisted treatment (MAT). As noted in previous Call Letter guidance, CMS will closely scrutinize formulary and benefit submissions with respect to formulary inclusion, utilization management criteria, and cost-sharing of Part D drugs indicated for MAT. Benefit designs that would substantially discourage enrollment by beneficiaries who need these therapies will not be approved. We continue to expect Part D sponsors to include products in preferred formulary tiers, and to avoid placing generic drugs indicated for MAT in brand tiers. As noted in previous Call Letter guidance, PA criteria that duplicate those requirements already set forth in the FDA Risk Evaluation and Mitigation Strategies and Drug Addiction Treatment Act of 2000 for applicable MAT products will not be approved.
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> On September 20, 2017, FDA announced that they recently had strengthened labeling requirements for buprenorphine MAT products to emphasize that treatment may be required indefinitely, as long as the use contributes to the intended treatment goals (https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm576752.htm). Consistent with FDA's position, CMS will not approve PA criteria that require a beneficiary to need an authorization any more frequently than once during a plan year. Further, when a sponsor has authorized MAT for a beneficiary in the prior plan year, we expect that the sponsor would carry that authorization through to the next plan year."

While we support these actions, we believe that CMS should go further and prohibit the use of these DUM requirements, especially for OUD treatment, and the Ways and Means Committee should urge CMS to do so.

It is also important to ensure that quality measurement in the context of pain treatment does not lead to treating pain inappropriately. 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.

2. Second fill limits

The AMA does not have specific policy regarding "second fill limits." We do, however, support partial fill policies—such as included in the Comprehensive Addiction and Recovery Act—which can help reduce the supply of Schedule II controlled substances that can be misused and diverted. This will help reduce prescription opioid-related overdose and death. Partial fill also encourages physicians and other health care professionals to have meaningful discussions with patients about the expected duration of pain, and the risks and benefits of prescription opioids. Partial fill also empowers patients to be able to request a lesser amount of a Schedule II controlled substance, which can help ensure that unwanted medications are not able to be diverted. As such, partial fill legislation can be an important component of a state's strategy to end the opioid epidemic.[4] The AMA continues to work with states to implement this important strategy. In addition, we note that it if were easier to electronically prescribe controlled substances, it would be easier to write shorter term prescriptions and to do partial fills (see further discussion under next question). Moreover, if the goal is to limit the quantity of medication prescribed initially, prescribers must be able to order second fills when necessary.

3. Tools to Prevent Opioid Abuse in the Medicare Program

An important tool that could be used to curb opioid abuse and dependence is the use of electronic prescribing of controlled substances (EPCS). Currently, however, 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.

In addition, as described in more detail under number 6 below, PDMPs are another important tool but are in need of improvements in terms of functionality and interoperability.

4. Medication therapy management (MTM)

The AMA strongly supports efforts to provide beneficiaries with services that improve patient care coordination and enhance communication among a patient's physician(s) and other health care providers. To that end, the AMA supports MTM programs where pharmacists communicate with the prescriber (as well as the supervising or collaborating physician if the prescriber is not a physician).

[4] See, for example, American Medical Association support for California Assembly Bill 1048, an act in support of partially filling Schedule II opioid prescriptions. June 22, 2017. Available at https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2FAMA-Letter-to-Joaquin-Arambula-MD.pdf

Physician training focuses on assessing, diagnosing, and managing the full range of patients' medication and other health and medical needs. Pharmacist training focuses on assessing, monitoring, and helping manage patients' medication therapies using an evidence-based approach to care. When physicians and pharmacists decide to work together for purposes of MTM, they do so in order to complement one another's unique roles. For example, the well-known Asheville Project has demonstrated the positive effects of physician-pharmacist collaborative relationships on improving patients' diabetes outcomes. Multiple studies, furthermore, demonstrate the benefits of pharmacists in improving patients' pharmacotherapy outcomes in the hospital, outpatient, and other settings. Pharmacists' pharmacotherapy training combined with the extensive diagnostic and management training of physicians can lead to effective collaborative pharmacotherapy decision-making that improves patients' medication-related outcomes.

Effective and appropriate MTM arrangements allow physicians and pharmacists to make the most of their respective education and training for patients' best interests—the primary concern of the AMA. That said, physicians remain responsible for overseeing the care of their patients, and must see to it that they receive the highest quality of care from ancillary providers. To provide comprehensive MTM, the pharmacist must coordinate with physicians who prescribe medications for the patient, especially if the pharmacist recommends changes to the patient's medication therapies. Failure to do so may result in danger to the patient, piecemeal care, and further fragmentation of health care. Other issues that should be addressed include the potential for conflict of interest when a pharmacist both initiates and dispenses a pharmaceutical product, and patient privacy issues with regard to obtaining histories and sensitive medical information in a public/community retail setting.

5. Electronic Prior Authorization (ePA)

With mounting concerns regarding the administrative burdens, costs and inefficiencies associated with PA, the health care industry has begun to explore a variety of approaches to reduce PA burdens. The AMA supports an automated PA process that utilizes standard electronic transactions to increase uniformity across health plans and streamline practice workflows. For medications, the automation of PA is sometimes referred to as electronic prior authorization (ePA). The National Council for Prescription Drug Programs (NCPDP) has created standard transactions for ePA. The ePA transactions are part of NCPDP's SCRIPT e-prescribing standard and intended to facilitate integration of the pharmacy PA process into physicians' prescribing workflow. Health plans and vendors are in various stages of implementing the NCPDP ePA transactions, and physicians can ask payers and vendors about the availability of this technology. Although the NCPDP ePA transactions standardize the overall PA process, they do not mandate uniform PA question sets. Health plans and other payers can still use proprietary PA questions with the NCPDP ePA transactions.

Benefits of ePA for prescription drugs including the following:

- Where available, integrated into the EHR and e-prescribing (eRx) workflow.
- Alerts the prescriber to PA requirement before issuing the prescription, allowing PA to be completed before prescription is sent to pharmacy and reducing chances of patient medication nonadherence.
- PA questions are presented onscreen for prescriber or staff.
- Conditional logic ensures that physician only answers relevant questions.
- Average approval time can be dramatically reduced.
- PAs can be electronically appealed and cancelled.
- Pharmacy ePA solutions integrated into EHR workflow are not yet widely available; some state mandates require availability in early 2016.
- PA requirement is not always known at the point of prescribing due to inaccuracy/ incompleteness of EHR drug formulary data.
- Response may not be in real time due to manual health plan processing and review.

6. Prescription Drug Monitoring Programs

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.

Access to data in PDMPs has been an area of intense state-based activity, but it remains unclear how these databases have affected patient outcomes. There is no question that the technology supporting PDMPs has improved in many states, including the development of more readable interfaces, more relevant information being provided on screen, increased speed of accessing the PDMP itself, and data sharing that now exists between at least 44 state PDMPs. While these improvements may not reflect every practice setting or physician's experience, the trend is generally positive in terms of increased physician use of PDMPs. It remains inconclusive, however, whether or how the new mandates and increased use have reduced opioid related mortality or improved pain care on a broad scale.

Addressing the merits of greater access by CMS or others raises multiple issues. As noted above, increased use of PDMPs is generally viewed as a positive trend in terms of physicians seeking more information on which to make more informed prescribing decisions. Yet, those increases have occurred in "mandate" and "non-mandate" states as well as states where law enforcement, Medicaid and other entities have access and where access to the patients' personal health information is more closely protected. The AMA would welcome the opportunity to learn more about the reasons CMS has for wanting access to this information.

Communication and Education

1. Beneficiary Notification

The AMA generally supports public education efforts regarding the health and well-being of the nation. There needs to be a careful balance, however, when considering how to effectively help patients understand the appropriate role of different forms of pain care, whether acute, chronic, cancer-related, or care at the end-of-life. While the data show that some initial users of prescription opioids following an acute care episode or surgery become persistent, chronic opioid users, there also are important distinctions between long-term care that results from complicated medical conditions post-surgery, care that is appropriately and carefully monitored by a physician to prevent opioid-related overdose and other side effects, and issues that arise when individuals misuse opioids that they may have obtained from a friend, family member or illicit source. We continue to hear reports from chronic pain patients who have been stable on opioid therapy regimens, but the current opioid phobic environment has caused their pharmacy, health insurance company, or physician to no longer provide care to the patient out of fear of being targeted by the DEA or another entity. This was the topic of several individuals and organizations at the U.S. Food & Drug Administration's (FDA), January 30, 2018 Opioid Policy Steering Committee-Prescribing Intervention—Exploring a Strategy for Implementation.[5] It is critical to avoid stigma, "i.e., blaming the patient," with respect to education and communication for the patient being treated for pain conditions and for OUD.

The AMA also supports discussions of a full range of treatment options for pain, but as noted above, this requires access to those treatment modalities. The AMA is concerned by reports that health insurance companies use PA and other utilization management procedures to restrict access to non-opioid pain care. More details are discussed in section 3 under Treatment. The AMA welcomes efforts by the Committee to reduce the burdens and obstacles our patients face on a regular basis.

2. Prescriber Notification and Education

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 took 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

[5] Full session presentations from the meeting are available at https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm583543.htm

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.

With respect to provider notification, the AMA notes that several states have undertaken efforts to provide physicians with benchmark data comparing them to their peers, highlighting the "top 50" prescribers in a state, and other efforts to provide physicians with actionable data. To date, the AMA is not aware that these efforts have been studied to determine whether they have resulted in improved pain care, and we would support studies that evaluate the impact of such efforts.

On the other hand, the AMA is aware of multiple efforts taking place throughout the nation that are resulting in improved pain care. Consistently, these efforts typically begin with an institution or physician practice reviewing its own prescribing and other data. Then, the data are reviewed by department heads alongside clinical pharmacists and practicing physicians within the department to better understand practice patterns, potential best practices, and whether "outlier" data truly is outside the norm. After this review, groups including the Permanente Medical Group, Kaiser Permanente, Geisinger Health System, Intermountain Healthcare, the University of Chicago Pain Stewardship Program, and others have implemented systems-wide protocols to support comprehensive, multidisciplinary pain care that includes appropriate use of opioid analgesics as well as non-opioid pain care. These efforts are occurring in many other settings, and they are the types of comprehensive efforts indicative of physicians' commitment to end the nation's opioid epidemic by improving pain care.

Treatment

1. Opioid Treatment Programs and Medication Assisted Treatment

The AMA strongly supports efforts to increase 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 MA 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 Ways and Means Committee urge CMS to take this action.

In addition, Medicare should allow 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.

2. Reimbursement

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. In addition to extending Medicare coverage for methadone treatment and eliminating payment barriers for Medicare Advantage and Part D plans such as PA and DUM, 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.

3. Alternate Options for the Treatment of Pain

As previously mentioned, lack of insurance coverage and insurance administrative hassles present barriers to accessing alternative options for the treatment of pain. For example, Medicare currently does not cover massage and acupuncture, and limits coverage for behavioral counseling. These non-pharmacologic therapies can be effective for individuals depending on the diagnosis. Among the types of barriers that physicians have reported to the AMA are the following:

- Limits on non-opioid pain care. This includes hard limits and prior authorization by payers on modalities such as physical therapy, non-opioid medications (e.g., Lidoderm patches, Voltaren gel, buprenorphine, tapentadol, Cymbalta and Lyrica).
- PA and denials of non-opioid pain care. This includes medical devices and interventional procedures such as mechanical braces and spinal cord stimulators and Transcutaneous Electrical Nerve Stimulation (TENS) devices.
- Discrepancies between hospital-administered care and outpatient therapy. For example, some non-opioid therapies (e.g., pain creams) that can be directly applied to amputee patients in the hospital setting have been denied when the patient seeks to fill a prescription in the outpatient setting.
- Multiple co-pays for multimodal care in the same setting. For example, if a patient has appointments with a physical therapist, occupational therapist, psychologist, and other specialists, the patient often is required to pay multiple co-pays, which often limits patient participation in the modalities.

Several physician organizations have also been working to develop alternative payment models that would support multimodal approaches to the management of pain, especially back pain, including the American Academy of Physical Medicine and Rehabilitation. Among the best examples of programs that support multimodal approaches are those that have been developed by the Department of Defense, which recognized a number of years ago the detrimental impact of long-term opioid use on wounded warriors' functioning and quality of life. Barriers to accessing appropriate access to non-opioid treatments for pain, such as those mentioned above, must be addressed if we are going to encourage multimodal treatment of pain.

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

Sincerely,

James L. Madara, MD