AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: Request for Information for the Development of a CMS Action Plan to Prevent Opioid Addiction and Enhance Access to Medication-Assisted Treatment

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to respond to the Request for Information from the Centers for Medicare & Medicaid Services (CMS) to inform the development of an action plan to prevent opioid addiction and enhance access to medication-assisted treatment (MAT). Improving comprehensive and multimodal pain management and ending the epidemic of opioid-related overdose deaths are high priorities for the AMA. The AMA strongly supports the final report and recommendations of the Pain Management Best Practices Interagency Task Force and urges CMS to implement them. Please see our responses to the questions in the Request for Information below.

Questions on Acute and Chronic Pain

1. What actions can CMS take to enhance access to appropriate care for acute and/or chronic pain in Medicare and Medicaid, including:

    a. For special populations (for example, individuals with sickle cell anemia or individuals living in health professional shortage areas) and/or
    b. Through remote patient monitoring, telehealth, and other telecommunications technologies?

    Pain care needs should be determined between patients and their physicians. It is not just "special populations" who may have complex or special pain care needs. Pain is the number one reason a patient goes to a physician. Some patients may require interventional, behavioral or restorative therapies. Some may require pharmacologic therapies, whether opioid or non-opioid. The focus should not be on limiting evidence-based pain care to "special populations," but on ensuring that patients have access to a wide range of multidisciplinary, multimodal pain care options.

    This is a major reason that the recent report of the Pain Management Best Practices Interagency Task Force emphasized the need for patients to be treated *as individuals*. As the Centers for Disease Control and Prevention has recently acknowledged, guidelines, and policies that impose one-size-fits-

all standards, such as the number of days or dosage of opioid analgesics, are harmful to patients. CMS payment policies should support:

- complete diagnostic work-ups, including assessment of patients' pain;
- development of comprehensive multimodal treatment plans to manage pain;
- screening for substance use disorders and risk factors for them;
- coordination in the provision of medical, social, behavioral, and primary care services;
- patient education about their condition, how best to manage it at home, and when they should contact their physician between visits to address symptoms or exacerbations that occur;
- follow-up to reconsider and adjust treatment plans if pain is not adequately controlled; and
- measurement of key patient health outcomes like functional status and quality of life.

CMS should also help to eliminate the stigma associated with pain care and addiction treatment, as stigma is a major barrier to accessing appropriate treatment.

It is also important to recognize that CMS efforts to exclude special populations, such as those with sickle cell anemia or cancer, from pain care policies that apply to other patient populations, while well-intentioned, may not be effective in practice. Although policies aimed at limiting initial opioid prescriptions may have been written to exclude cancer patients and those who have been on long-term therapy with opioid analgesics, for example, there have been many reports of patients with advanced cancer being denied their prescribed medications, even to the point of being admitted to the hospital for uncontrolled pain. CMS policies need to be carefully crafted to avoid these types of unintended consequences.

The AMA urges CMS to help ensure the unique needs of pregnant, postpartum and parenting women and children are met. Opioid use disorder (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 the U.S. Department of Health and Human Services 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. The AMA urges support for and communication of policies that encourage pregnant, postpartum, and parenting women to obtain vital perinatal care and treatment. Research has found that non-punitive public health approaches to treatment result in better outcomes for both moms and babies. The AMA would be pleased to work with CMS to support patient and public education as well as outreach to policymakers to ensure evidence-based care guidelines and treatment options are the preferred course for improved maternal and child health.

With regard to telehealth and remote monitoring, these types of remote services may help in some situations to provide insight and feedback on a patient's treatment regimen, and in some cases assist with diagnosis and management, but they are not a substitute for the patient-physician relationship or network adequacy requirements under state or federal law. The AMA agrees with the Pain Management Task Force recommendation that payers cover pain management services in a manner that facilitates access in underserved locations through telehealth or other technology-assisted delivery methods.

2. What, if any, payment and coverage policies under Medicare and/or Medicaid for the treatment of acute and/or chronic pain, do you believe, may have contributed to the use of opioids? If answering this question, please provide information on how these policies have contributed.

   Reliance on patient satisfaction measures that tie payment rates to reported satisfaction with the amount of pain medicine prescribed to patients has led to more opioid prescribing. Coverage limitations on non-opioid pain medications and non-pharmaceutical methods of managing pain, especially use of prior authorization requirements, have also increased use of opioids. For example, a 2018 paper published in *JAMA*, "Prescription Drug Coverage for Treatment of Low Back Pain Among US Medicaid, Medicare Advantage, and Commercial Insurers," found that Medicare Advantage plans applied prior authorization requirements more frequently to non-opioid analgesics than to opioid analgesics.

   The AMA supports patients receiving the right care at the right time in the right care setting. For too long, opioid analgesic therapy has been the lowest-cost and most preferred option by payers. Where state Medicaid plans have taken action to increase access to non-opioid pain care alternatives, there has been increased utilization of those services, decreases in opioid analgesic utilization and, also increased savings from reduced hospitalization, for example. Focusing on only one aspect of care (e.g., are opioids good/bad) has led to an inappropriate focus on restricting access to opioid therapy while far less attention has been spent on broadening access to comprehensive pain care.

3. What, if any, payment and coverage policies in Medicare and/or Medicaid have enhanced or impeded access to non-opioid treatment of acute and/or chronic pain?

   There are generally two classes of non-opioid treatments for pain: non-opioid pharmaceuticals and non-pharmaceutical therapies. For non-opioid pharmaceuticals, prior authorization requirements, placement on a higher tier in the formulary than opioids or exclusion from the formulary, and step therapy and quantity limits can all impede access. Access to non-pharmaceutical treatments for pain, such as physical therapy, is also impeded by prior authorization and coverage limits and exclusions, and some patients lack access to in-network health professionals who provide these services. Prohibitions on patients receiving multiple services on the same day in the same encounter (e.g., physical therapy and cognitive/behavioral health services) also impede access.

4. What evidence-based treatments, Food and Drug Administration (FDA)-approved evidence-based medical devices, applications, and/or services and items for the following conditions are not covered, or have limited coverage for Medicare beneficiaries with:

   a. Acute and/or chronic pain;
   b. Pain and behavioral health needs requiring integrated care across pain management and substance use disorder (SUDs), with consideration of high-risk patients (i.e., multiple medications, suicide risk)?

   One of the Interagency Task Force recommendations is to make greater use of buprenorphine to treat pain, which could be especially beneficial for patients at risk of OUD. The Task Force also states that primary use of buprenorphine should be encouraged, not just use after failure of other analgesics. The AMA agrees with this recommendation. In addition, the Task Force recommends that evidence-informed interventional procedures be covered early in the course of treatment when clinically

appropriate. It notes that these procedures can be paired with medication and other therapies to improve function, quality of life, and activities of daily living. The AMA agrees.

5. What payment and service delivery models, such as those that utilize multimodal and multi-disciplinary approaches to effectively manage acute and chronic pain and minimize the risk of opioid misuse and OUD, could be tested by the Center for Medicare and Medicaid Innovation or through other federal demonstration projects?

    a. What existing models, treatments or strategies identify and effectively manage the population of individuals misusing prescription opioids or using illicit opioids who then develop new or exacerbating pain?

    Comprehensive care models put forward by pain stewardship programs at integrated health systems such as Kaiser Permanente, Intermountain Health Care, Geisinger Health System, and the University of Chicago offer several examples. Although these are not the only systems that are focusing on pain stewardship, they illustrate how models can focus on improving patient care for acute and chronic pain as well as minimizing OUD risk.

    Alternative payment models could be an extremely effective means to improve pain care. The traditional fee-for-service approach does not adequately support the complex diagnostic process, including history taking, screening for substance use, lab tests, querying prescription drug monitoring programs, and development of a multidisciplinary and/or multimodal treatment plan that many patients need. It also does not support team leaders, innovative approaches such as "pre-habilitation" (improving patient health status before surgery using preoperative physical therapy, behavioral health and other services), or Enhanced Recovery After Surgery. Patients may also need support from care coordinators and patient educators to help them adhere to their treatment plan and get the most benefit from it, and to understand self-management of their condition. Well-designed alternative payment models can help support these types of services.

6. What can CMS do to better ensure appropriate care management for Medicare beneficiaries with pain who transition across settings, and/or between pain therapies?

    Better information sharing would be very helpful. If CMS could inform patients' community physicians when they are admitted and discharged from a facility, such as a hospital, medical practices could better assist with care transitions. Physicians who may be managing patients' treatment for substance use should be consulted by the perioperative team about postoperative pain control. Also, as described above, CMS payment systems need to support additional staff such as care coordinators and patient educators to help patients successfully manage transitions in their care, adhere to their treatment plan, and understand how best to manage their condition at home, including what types of symptoms should prompt a call to their physician's office so that treatment plans can be adjusted before serious complications develop.

    CMS should also work with other federal agencies, including the Drug Enforcement Administration (DEA), to reduce physician fear about appropriately treating patients' pain, including prescribing opioid analgesics when indicated. Physicians need to be able to have confidence that law enforcement action is appropriately targeted only at intentional criminal behavior that clearly violates the law.

7. How can Medicare and Medicaid data collection for acute and chronic pain better support coverage, payment, treatment, access policies, and ongoing monitoring?

   Medicare data collection policies have been too focused on measuring the number of days and dosage of opioid analgesics instead of on how well patients' pain is controlled, whether their functional improvement goals are met, and whether they are screened and, if appropriate, treated for substance use disorders. Social risk factors play a role in supporting better health outcomes from pain care as well. CMS should look at patients' barriers to care, such as lack of transportation to physical therapy appointments.

8. What other issues should CMS consider to improve coverage and payment policies in Medicare and Medicaid to enhance access to and effective management of beneficiaries with acute and/or chronic pain?

   Ensuring adequate Medicaid reimbursement rates is a necessary element to any plan to improve access to care. Despite the mandate requiring states to ensure that Medicaid payments are consistent with efficiency, economy, and quality of care and sufficient to enlist enough providers of covered services, Medicaid payment rates lag behind private insurance and Medicare. Because of inadequate payment rates, participating physicians remain sparse in many areas of the country, and access to health care services remains unequal. Lack of access to participating physicians puts all patients, including those with acute and/or chronic pain, at risk of harm or even death.

   In July, CMS published the Proposed Rule with Comment Period, Methods for Assuring Access to Covered Medicaid Services, that would rescind regulations that provide federal oversight of state Medicaid payment policies. As the AMA wrote in comments to the Proposed Rule, we do not support rescission of the regulations. The regulations proposed for rescission establish the only standardized, evidence-based methodology to prospectively review and retrospectively monitor potentially injurious payment policies, an essential oversight process because history has demonstrated that states are unable to comply with access standards on their own. In order to enhance access and effective management of beneficiaries with acute and/or chronic pain, it is imperative that CMS maintain robust oversight of state Medicaid payment policies that have direct impact on beneficiaries' ability to access treatment.

Questions on Substance Use Disorders, including Opioid Use Disorders:

1. What, if any, payment and coverage policies under Medicare and/or Medicaid for the treatment of SUDs, including MAT, do you believe, may help address the Nation's opioid crisis? If answering this question, please provide information on how these policies may help.

   Remove prior authorization for all forms of MAT. Ensure that patients with a substance use disorder also have access to necessary behavioral and mental health services. Remove restrictions on receiving multiple services on the same day. A patient with a substance use disorder may require physician services for the medical care as well as physician or allied health services for mental and behavioral health needs. The patient would benefit most if provision of those services could be coordinated at the same practice, if available, rather than require the patient to schedule appointments across multiple days.

2. What, if any, payment and coverage policies in Medicare and/or Medicaid have enhanced or impeded the identification of, and access to the treatment by, beneficiaries with SUDs, including OUD?

   While Medicare and Medicaid allow for provision of methadone to patients, states do not always make that option available. It may not be the actual policy inasmuch as it is the lack of oversight of those policies. Similarly, prior authorization requirements for MAT options often serve to delay or deny care to patients, and they take up significant amounts of physicians' time to resolve a prior authorization request. Removing these administrative burdens would help more patients obtain evidence-based care and allow more physicians time to treat a greater number of patients.

3. What evidence-based treatments, FDA-approved evidence-based medical devices, applications, and/or services that treat or monitor SUD, including OUD, monitor substance use withdrawal and/or prevent opioid misuse and opioid overdose are not covered, or have limited coverage, in Medicare?

   The AMA supports providing patients with access to all forms of MAT without prior authorization, as well as keeping medications that treat OUD on the lowest formulary tiers so that high cost-sharing is not a barrier.

4. What payment and service delivery models that identify and treat people with pain who are at risk of, or have a past history of, OUD, could be tested by the Center for Medicare and Medicaid Innovation, or through other federal demonstration projects?

   The AMA and the American Society of Addiction Medicine have previously provided the Centers for Medicare & Medicaid Services Innovation Center with a concept paper describing P-COAT, the Patient-Centered Opioid Addiction Treatment model. P-COAT provides separate payments for the initial induction phase of OUD treatment and the maintenance phase, with risk-stratified payments to reflect that some patients need more resource-intensive services than others. P-COAT also supports patient access to both addiction medicine specialists and primary care practices that treat patients with OUD, and allows for different ways of organizing the delivery of services as some practices have addiction specialists, behavioral health counselors, and other team members on site, for example, and others need to coordinate patients' care with multiple organizations that provide different aspects of care.

5. What actions could CMS take to improve access to evidence-based, FDA-approved MAT or other therapies in Medicare and Medicaid, including for special populations (for example individuals living in health professional shortage areas)?

   There are many counties throughout the United States in which residents have no access to office-based treatment for OUD. This scarcity is not confined to health professional shortage areas. A major step to improve access to MAT would be the elimination of the federal requirement that DEA-registered clinicians who wish to prescribe buprenorphine must take special training, obtain a special waiver, adhere to burdensome recordkeeping and reporting requirements, be subjected to audits from the DEA, and adhere to special limits on the number of patients that they can manage with MAT including buprenorphine. The AMA supports elimination of these requirements so that any DEA-registered clinician who can prescribe other controlled substances can also prescribe buprenorphine.

6. What can CMS do to expand program access to the treatment of SUDs, including OUD, in Medicare and Medicaid through remote patient monitoring, telehealth, telecommunications and other technologies?

   The Medicare physician payment schedule proposed rule for 2020 includes new bundled episode payments for office-based treatment of OUD and coverage of corresponding telehealth services, which the AMA supports.

7. What recommendations do you have for data collection in Medicare and/or Medicaid?

   a. On the treatment of SUDs, including OUD, to better support coverage, payment, treatment, access policies, and ongoing monitoring, and/or
   b. To facilitate research, policy development, and inform coverage and payment policies to prevent OUD?

   CMS should analyze data on patients receiving MAT and those who have an OUD diagnosis but are not receiving MAT to determine where there are gaps in care, unmet needs, and/or problems with care coordination. For example, if patients with OUD are making emergency department visits or being admitted to the hospital for OUD-related reasons, there may be opportunities to improve their care or reduce fragmentation in their care. It is also important to review how long someone receiving MAT continues in treatment and consider how to promote long-term adherence.

8. What recommendations do you have to lower prices of drugs used to reverse opioid overdoses (e.g., naloxone) for consumers?

   CMS should ensure that all forms of naloxone are available to patients with no out-of-pocket costs.

The AMA appreciates the opportunity to provide input and thanks you for considering our views. If you have any questions, please feel free to contact Margaret Garikes, Vice President, Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,

James L. Madara, MD