AMA
AMERICAN MEDICAL ASSOCIATION

JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org
t (312) 464-5000

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The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244-8016

Re: CMS-2482-P; Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third-Party Liability Requirements; Proposed Rule

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I write to respond to the proposed Medicaid policies that would impose a variety of safety edits and limitations on prescription opioid analgesics. The AMA strongly recommends that these proposals not be finalized. The AMA supports the proposal for states to consider ways to expand use, distribution, and access to naloxone when clinically appropriate.

In its preamble to the new proposals, the Centers for Medicare & Medicaid Services (CMS) acknowledges that the 2019 Pain Management Best Practices Inter-agency Task Force Report (PMTF) emphasizes the need for a person-centered approach to pain care that includes the use of individualized, multimodal treatment based on an effective pain treatment plan. **The AMA strongly supports the PMTF recommendations and agrees that physician management of patients' pain must be tailored to the needs of each individual patient.** CMS also notes that the PMTF cited unintended consequences that have resulted from the opioid prescribing guidelines issued in 2016 by the Centers for Disease Control and Prevention (CDC), and quotes the PMTF report's discussion of a "pivotal article in the *New England Journal of Medicine* on April 24, 2019, specifically reiterating that the CDC Guideline has been, in some instances, misinterpreted or misapplied."

The AMA shares with CMS the goal of reducing the burden of harm from controlled substances, including opioid analgesics. The individual and family tragedies and societal costs attributable to opioid-related overdose, emergency department visits, deaths, and untreated substance use disorders are deeply concerning. To make meaningful progress towards ending the epidemic of opioid-related overdose deaths, a broad-based public health approach is required. This approach must balance patients' needs for comprehensive pain management services, including access to non-opioid pain care as well as opioid analgesics when clinically appropriate, with efforts to promote appropriate prescribing, reduce diversion and misuse, promote an understanding that substance use disorders are chronic conditions that respond well to evidence-based treatment, and expand access to such treatment for individuals with substance use disorders.

In the proposed rule, CMS describes data from the CDC that two out of three opioid-involved overdose deaths in 2018 involved synthetic opioids (other than methadone). Most opioid-involved overdose deaths are not due to prescription opioid analgesics, but rather to heroin and illegally manufactured fentanyl and fentanyl analogs, as well as stimulants such as methamphetamine and cocaine. Given these data, it is difficult for us to understand why the current CMS proposals for state Medicaid programs are based on an erroneous view of drug-related mortality as seen through a prescription opioid-myopic lens. **The AMA encourages CMS to take a broader view and to craft policies that will help ensure patients have access to person-centered, evidence-based, comprehensive care for pain and substance use disorders, free from the stigma that patients with these conditions experience on a regular basis, especially those in minoritized and marginalized communities.**

Proposed Minimum Standards for DUR Programs

CMS proposes that state Medicaid programs impose so-called "safety edits" for prescription opioid analgesics relating to: the number of days that the medication is supposed to last; the dose of the prescription as measured by morphine milligram equivalents; early refills; and for patients who are prescribed an opioid analgesic after having been prescribed one or more medications used in the treatment of opioid use disorder (OUD). Despite its acknowledgement that the 2016 CDC guidelines have been misapplied and had unintended consequences, CMS proposes to require that state Medicaid programs impose prescribing and dispensing limits that are derived from these flawed guidelines.

The PMTF has been very clear that patients experiencing pain need to be treated as individuals, not according to one-size-fits-all algorithms and policies that do not take individual patient's needs into account. Instead, CMS is recommending exactly the type of "shortcut" to safer prescribing that the CDC criticized in its *New England Journal of Medicine* article, which cited "inflexible application of recommended dosage and duration thresholds" as well as misapplication for patients with "pain associated with cancer, surgical procedures, or acute sickle cell crises." Meaningful and appropriate treatment of pain is best achieved via shared decision-making. Health disparities in pain management and access to opioid analgesics for pain remain evident, and clinically relevant differences in pain expression and responsiveness based on sex, race, ethnicity, and genetic constitution also exist. Patients suffering from pain increasingly view themselves as collateral damage in efforts to restrict opioid prescribing decisions via policies such as those that CMS currently proposes.

Many health plans have already imposed the types of limits that CMS proposes for Medicaid. These policies have not withstood any meaningful evaluation or data analysis as to whether they have improved pain care or reduced opioid-related harms. There also are no data to suggest that health plans have increased access to non-opioid pain care options. Instead, there is evidence that health plans continue to erect and support barriers to non-opioid pain care. A 2019 survey from the American Board of Pain Medicine found:

- 72 percent of pain medicine specialists said that they—or their patients—have been required to reduce the quantity or dose of medication they have prescribed;
- 92 percent of pain medicine specialists said that they have been required to submit a prior authorization for non-opioid pain care—with the physicians and their staff spending hours per day on such requests; and
- 66 percent of pain medicine specialists said that they have had to hire additional staff to handle the prior authorization requirements.

Instead of adopting additional policies focused on limiting prescription opioids, the AMA recommends that CMS encourage state Medicaid programs to:

1. Remove coverage and formulary limits, prior authorization, step therapy, and other inappropriate administrative burdens or barriers that delay or deny treatment with all medications approved by the Food and Drug Administration for OUD.

2. Support assessment, referral, and treatment for co-occurring mental health disorders as well as enforce meaningful oversight and enforcement of state and federal mental health and substance use disorder parity laws.

3. Remove administrative and other barriers to comprehensive, multimodal, multidisciplinary pain care and rehabilitation programs.

4. Support maternal and child health by increasing access to evidence-based treatment, preserving families, and ensuring that policies are non-punitive.

To improve care coordination for patients being treated with medication for OUD, state Medicaid programs should provide adequate support for all of the care management and counseling services needed in a biopsychosocial model of care. A safety edit for patients who are prescribed an opioid analgesic after having been prescribed medication for OUD will not improve patient care. Within Medicare, in 2020 CMS began offering monthly bundled payments for office-based treatment of OUD and weekly bundled payments for treatment provided by Opioid Treatment Programs. Other examples of the kind of support that is needed are found in the Virginia Medicaid Addiction and Recovery Treatment Services program and the Vermont Blueprint for Health hub and spoke model. The AMA recommends that CMS propose expanded adoption of these and similar models of care in state Medicaid programs instead of safety edits.

Naloxone

CMS proposes that states identify patients insured by Medicaid who could be at high risk of opioid overdose and should be considered for co-prescription or co-dispensing of naloxone. The proposed rule notes that naloxone works quickly to restore normal respiration to a person whose breathing has slowed or stopped as a result of an opioid overdose, including both illicit and prescription opioids. CMS recommends that states consider how to expand use, distribution, and access to naloxone when clinically appropriate. The AMA agrees with this proposal. In addition, the AMA recommends that CMS encourage state Medicaid programs to facilitate the development of and support services within the state that help get patients into treatment for OUD following an overdose and rescue with naloxone, such as the services offered in a number of emergency departments to help patients initiate treatment with buprenorphine.

The AMA appreciates the opportunity to share our views regarding the opioid-related policies which CMS has included in this Medicaid proposed rule and thanks the agency for its consideration. If you have

any questions please contact Margaret Garikes, Vice President of Federal Affairs, at 202-789-7409 or margaret.garikes@ama-assn.org.

Sincerely,

James L. Madara, MD