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
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Re: Part I and II of the Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates and Part D Payment Policies and 2020 Draft Call Letter

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to offer our comments to the Centers for Medicare & Medicaid Services (CMS) on Part I and Part II of the Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates and Part D Payment Policies and 2020 Draft Call Letter.

Many of the comments detailed below relate to our shared goal of ending the epidemic of opioid-related overdose and death. The AMA strongly supports the policies outlined in the Draft Call Letter that aim to improve patient access to evidence-based treatment for opioid use disorder, non-opioid therapies for pain, and naloxone. The AMA is concerned, however, that the proposed quality measures focus on reducing utilization of opioid analgesics instead of on whether patients' pain and/or substance use issues are appropriately managed. We encourage CMS to align its policies for Medicare Advantage and Part D with the recommendations of the HHS Pain Management Best Practices Inter-Agency Task Force.

2020 ADVANCE NOTICE

<u>CMS Monitoring and Compliance Activities</u>

Encounter Data

As CMS implements increased monitoring and compliance activities, the agency is strongly urged to consider that physicians bear a significant administrative burden because plan sponsors focus on optimizing payment through risk scores. We urge CMS to evaluate the impact of these activities on the additional documentation and record production and other administrative activities physicians will be asked to shoulder by plan sponsors, as this will detract from time and opportunity to render patient care.

2020 DRAFT CALL LETTER

Star Ratings

Changes to Existing 2020 Display Measures Focused on Opioid Overuse

The AMA strongly disagrees with the proposal to implement an updated methodology for the 2020 display page measures (based on 2018 data) that calculate total days supply. We do not agree that patients' total supply of prescription opioid analgesics can serve on its own as a measure of quality patient care. Instead, quality measurement should focus on how well a patient's pain is controlled, whether functional improvement goals are met, and what therapies are being used to manage pain. A reduction in total days supply, in the absence of other findings, is not an appropriate goal and it is not consistent with the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain, a voluntary guideline which recommends that physicians document a clinical rationale or justification for the clinical use of dosages exceeding a daily threshold of 90 morphine milligram equivalents (MME). CDC has consistently emphasized that its guideline should not be used as a hard threshold in the clinical, legislative or regulatory arenas.

CMS should explore more appropriate methods to assess a patient's chronic pain such as the Pain Assessment Screening Tool and Outcomes Registry (PASTOR) and use this patient-reported data as the basis for performance measures. This tool utilizes the Patient Reported Outcomes Measurement Information System (PROMIS) and through the use of Computer Adaptive Testing, key domains such as sleep disturbance and physical function can be assessed in a targeted and patient-directed way. In addition, the excellent draft report of the HHS Pain Management Best Practices Inter-Agency Task Force provides many recommendations for improving the quality of pain care that the AMA strongly supports.

Star Ratings Enhancements

We applaud CMS' proposal to adjust the 2020 Star Ratings to take into account the effects of extreme and uncontrollable circumstances that occurred during the performance period using a similar methodology to the one adopted for the 2019 Star Ratings in the CY 2019 Call Letter. To promote transparency around the disaster adjustments, in future data releases CMS also plans to provide additional information on which contracts were eligible for disaster adjustments.

We also support CMS in its effort to remove three measures from the 2022 Star Ratings (Adult BMI Assessment-Part C; Appeals Auto-Forward-Part D; and Appeals Upheld-Part D) and temporarily remove the Controlling High Blood Pressure (Part C) measure. The AMA applauds CMS' efforts to reduce reporting burden by removing and de-duplicating certain quality measures.

Changes for CY 2020 Formulary Submission

Improving Access to Opioid Reversal Agents

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. The AMA applauds CMS' efforts to encourage Part D sponsors to, at a minimum, place naloxone products on their plan's generic tier(s). We also support CMS efforts to

encourage the placement of these products on the Select Care Tier (i.e., a tier that provides for $0 or low cost-sharing) for those plans that utilize such a tier model.

Co-Prescribing Naloxone: CMS has requested comments from stakeholders on the feasibility of co-prescribing naloxone with concurrent opioid prescriptions when clinically appropriate as defined by the CDC Guidelines and HHS guidance. We support these efforts. In August 2017, the AMA Opioid Task Force released guidance encouraging physicians to consider co-prescribing naloxone when it is clinically appropriate to do so. The AMA believes this is a decision to be made primarily between the patient and physician. As detailed in our guidance to physicians, the AMA believes that although co-prescribing naloxone is not a guarantee for an overdose reversal, it does provide a tangible option for care that otherwise may not be available in a timely manner. In addition:

- Co-prescribing naloxone has been found to reduce emergency department visits, and may help patients become more aware of the potential hazards of opioid misuse.
- Patients often find the offer of a naloxone prescription acceptable.
- Primary care physicians have found co-prescribing naloxone to be acceptable.
- Co-prescribing naloxone does not increase liability risk.

Access to Medication-Assisted Treatment (MAT)

We agree with CMS that it is important to ensure that Medicare patients have appropriate access to evidence-based MAT. The AMA strongly supports the CMS plans to closely scrutinize formulary and benefit submissions for the drugs used in MAT, to disapprove benefit designs that would discourage enrollment by patients with a substance use disorder, and to disapprove prior authorization criteria for MAT drugs that duplicates existing federal requirements. The AMA encourages CMS to further require that plans eliminate any prior authorization requirements for MAT. Additionally, we urge Part D sponsors to ensure that patients have access to MAT options in all drug classes at the lowest cost-sharing tier as was done in Pennsylvania.[1] The best time to get a patient with a substance use disorder into treatment is during the patient's appointment; prior authorization for MAT delays care, and increases the risk of untreated opioid use disorder and of more opioid overdose deaths. We also note that MAT access should include access to mental and behavioral health care to ensure that patients with co-occurring mental illness receive comprehensive care.

Improving Drug Utilization Review Controls in Medicare Part D

The draft report of the HHS Inter-Agency Pain Management Best Practices Inter-Agency Task Force outlines serious adverse effects on patients with pain of certain policies intended to address the opioid epidemic. The 2020 Call Letter describes policies adopted in 2019, such as opioid safety alerts, that have the potential to further exacerbate these problems, and we urge CMS to evaluate them carefully. We understand that the intent of the safety alerts, similar to the older elements of the Overutilization Monitoring System, is to promote good information about all the opioid analgesics that patients may be receiving from multiple prescribers and/or pharmacies, to foster care coordination, and to ensure that the prescribed opioids are medically appropriate. Nonetheless, it is possible that they will have unintended consequences and lead to undertreatment of pain.

[1] https://www.ama-assn.org/press-center/press-releases/pennsylvania-removes-prior-authorization-opioid-treatment

The final Call Letter should also clarify that buprenorphine used in MAT should be excluded from calculations of morphine milligram equivalents. The draft Call Letter says that opioid policies "should not impact" patients' access to MAT, but this needs to be clearer. We note that the CDC has said buprenorphine "should not guide dosing of medication-assisted treatment for opioid use disorder."[2]

The AMA strongly supports providing improved access to non-opioid treatments for pain. CMS lists peer support services, cognitive behavioral therapy, acupuncture, and therapeutic massage, for example, as services that MA plans should consider offering as supplemental benefits. The AMA also recommends that MA plans be encouraged to eliminate barriers that impede access to non-opioid treatments for pain that are part of the standard MA or MAPD benefit. For example, a study of insurance plan policies on coverage of non-opioid pharmaceuticals for pain found that MA plans were the only insurers that had more prior authorization requirements for non-opioid analgesics than for opioid analgesics. MA plans should also examine their coverage and utilization management policies for physical therapy and other non-pharmaceutical methods for managing pain to ensure that they are not promoting over-reliance on opioids for pain management instead of supporting comprehensive, multimodal pain care.

Provider Directories

The AMA appreciates the comments in the Draft Call Letter regarding continued CMS concern about the accuracy of MA provider directories. CMS notes that "there has been a lack of improvement in the accuracy of provider directories over the past three years." The AMA does not agree that the problem is the lack of a centralized repository for provider directory data that can service as a source of truth. MA plans could reduce the administrative burden on themselves and on physicians if they would use a common system for updating provider directory information, such as the AMA/Lexis-Nexis VerifyHCP system.[3]

Prior Authorization (PA)

We urge CMS to provide guidance to MA plans on prior authorization processes and limit the use of PA by stand-alone Part D plans through its 2020 Call Letter. CMS' guidance should direct plans to target PA requirements where they are needed most. Specifically, CMS should require MA plans to selectively apply PA requirements and provide examples of criteria to be used for such programs, including, for example, ordering/prescribing patterns that align with evidence-based guidelines and historically high PA approval rates. At a time when CMS has prioritized regulatory burden reduction in the patient-provider relationship through its Patients Over Paperwork initiative, we believe such guidance will help promote safe, timely, and affordable access to care for patients; enhance efficiency; and reduce administrative burden on physician practices.

A Consensus Statement on Improving the Prior Authorization Process, issued by the AMA, American Hospital Association, America's Health Insurance Plans, American Pharmacists Association, Blue Cross Blue Shield Association, and Medical Group Management Association in January 2018, identified opportunities to improve the prior authorization process, with the goals of promoting safe, timely, and affordable access to evidence-based care for patients, enhancing efficiency, and reducing administrative

[2] https://www.asam.org/docs/default-source/advocacy/letters-and-comments/2018-1-4-letter-on-buprenorphine-and-cdcs-guideline-(002).pdf?sfvrsn=7fa840c2_2

[3] VerifyHCP FAQs https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/verify-health-care-portal-faq-physician.pdf

burdens.[4] It notes that the PA process can be burdensome for all involved—health care providers, health plans, and patients—and that plans should target PA requirements where they are needed most. Providers and health plans agree that making policy changes that eliminate PA on services for which there is low variation in care, promote greater transparency regarding which services are subject to PA, and protect patients to ensure PA does not impact continuity of ongoing care are essential. We also urge CMS to require MA plans to follow the important concepts outlined in the Consensus Statement to improve MA patients' access to timely, medically necessary care.

We thank you for the opportunity to provide input on the 2020 advance notice and draft call letter and look forward to continuing to work with CMS to improve the MA and Medicare Part D programs. If you have any questions regarding this letter, please contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,

James L. Madara, MD

[4] Consensus Statement available at https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf.