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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: Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 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 the Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 Draft Call Letter. The AMA provides detailed comments below on the following issues:

- CMS should continue to make improvements to the MA Star Rating program, including allowing for more general exclusions for patients with specific conditions, comorbidities or allergies from measures, and refining Star Ratings to better measure the quality of the MA plan itself, and things over which the plan has control and the data to support.
- The AMA supports CMS' plan to establish a Technical Expert Panel in 2018 comprised of representatives across various stakeholder groups to obtain feedback on the Star Ratings framework, topic areas, methodology, and operational measures.
- The AMA urges CMS to continue to evaluate the impact of monitoring and compliance activities on physician burden.
- The AMA supports the MA Value-Based Insurance Design model test, and the idea that plan sponsors could offer greater flexibilities to target enhanced benefit design to certain patients.
- The AMA strongly supports CMS' clarification that while MA plans must cover Medicare Diabetes Prevention Program (MDPP) services, they may also offer additional MDPP-like services as supplemental benefits.
- The AMA continues to urge CMS to strengthen network adequacy standards for MA plans.
- While the AMA has been a strong supporter of the Overutilization Management System (OMS), the AMA does not support CMS' proposal to add a concurrent opioid-gabapentin/pregabalin flag to CMS at this time.

- The AMA strongly opposes CMS' proposal that all sponsors should implement hard formulary-level cumulative opioid safety edits at point of sale at the pharmacy dosage level of 90 morphine milligram equivalent per day, with a seven day supply allowance.
- The AMA opposes CMS' proposal to establish a day supply limitation policy for opioid naïve patients.
- The AMA has concerns regarding CMS' proposal to require all Part D plan sponsors to implement a soft point of sale edit for duplicative long-acting opioid therapy for 2019, with or without a multiple prescriber criterion, which can be overridden by a pharmacist.
- The AMA strongly opposes the use of drug utilization management (DUM) for medication-assisted treatment, and urges CMS to eliminate the use of prior authorization, step-therapy, and other DUM requirements for medication-assisted treatment.

Medicare Advantage Issues

MA Star Ratings Program

Allow for Additional Exclusions

We remain concerned that CMS' Star Ratings program is impeding clinical care and leading to increased administrative burden on physicians. In order for plans to comply and earn incentives from CMS, they must often set unrealistic targets on physicians within their physician contracts; they must also do this to score well in the Star Ratings program. In many cases, physician compliance with a measure must be at 100 percent, regardless of whether it would constitute appropriate and medically necessary care in all cases. There may be instances when compliance with a measure is contrary to appropriate care, but plans do not incorporate exceptions or exclusions related to the measures due to CMS' Star Ratings compliance requirements. CMS should allow for more general exclusions for patients with specific conditions, comorbidities, or allergies from measures to ensure patient and clinical differences are accounted for and do not interfere with clinical decision making, and denominators of quality measures should be appropriately defined to ensure patients for whom the treatment may not be appropriate are excluded from the measure.

Measure Quality of MA Plans

A large percentage of the measures within the MA Star Ratings program are based completely on physician action and compliance. For example, as part of their clinical data submission requirements, plans are requiring practices to submit data on all patient lab results and tests in order to increase their Healthcare Effectiveness Data and Information Set (HEDIS) scores and earn greater incentives from CMS. The plans state that they impose these requirements due to the Star Ratings HEIDS requirements. Many of the measures, particularly the HEDIS *Effectiveness of Care* measures, have more to do with physician quality than assessment of a health plan. The *Effectiveness of Care* measures are really targeting clinical quality, which is a physician or facility issue—i.e., physicians and facilities have the data. Without a better focus, the MA ratings program is just one more burden on physicians and does not provide beneficiaries with the information they need to determine the most appropriate MA or drug plan. CMS should refine Star Ratings to better measure the quality of the MA plan itself and measures over which the plan has control and the data to support.

Administrative Burden

While the Star Ratings program has expanded and plays a larger financial role on health plans' bottom lines, the administrative demand has simultaneously increased on physicians. Given the Administrator's Patients Over Paperwork Initiative, the AMA believes that this is an excellent time for CMS to reduce the administrative burden that the MA Star Ratings program places on physicians. Specifically, as the HEDIS standards continue to evolve, laboratory data are playing an increasingly critical role in increasing HEDIS scores. Often the plans require this information to be submitted within 30 days and state it is due to the Star Ratings HEDIS requirements.

Some of the measures that are leading to this tedious and time consuming demand on physicians are the following:

- NCQA 0575: Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) Control (<8.0 percentage).
- NCQA 0057: Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) Testing.
- NCQA 0062: Comprehensive Diabetes Care: Medical Attention for Nephropathy NCQA.
- NCQA 0018: Controlling High Blood Pressure.

Plans have also expressed an intention to expand these requests to additional types of clinical data to support other HEDIS measures, including those addressing blood pressure control and BMI assessment. Practice burdens will continue to grow as plans ask for more types of clinical data to support increased Star Ratings.

We urge CMS to require health plans to: allow practices to respond *at-will (i.e.*, at a time of their choosing and with a minimum of at least 90 days to respond); support the use of electronic methods of data submission; and adequately compensate physicians for the time and burden. We also urge CMS to refocus Star Ratings on metrics over which health plans have direct control, as continued inclusion of clinical quality measures in the program will invariably burden physicians with data requests from health plans.

Technical Expert Panel (TEP)

The AMA supports CMS' plan to establish a TEP in 2018 comprised of representatives across various stakeholder groups to obtain feedback on the Star Ratings framework, topic areas, methodology, and operational measures. We commend CMS for taking the first steps to make needed changes to the Star Ratings program. We also urge CMS to ensure that there is significant physician participation and input into the TEP and its recommendations and welcome the opportunity to participate in activities related to improving the Star Ratings program.

Forecasting to 2019 and Beyond

CMS has proposed changes to existing measures and potential new measures. The AMA offers the following feedback on specific measures:

Telehealth and Remote Access Technologies: The AMA supports including telehealth and/or remote access technology encounters as "eligible encounters" in various Part C quality measures to the extent the

telehealth services are allowed under the current statutory definition of Medicare covered telehealth services and/or as a provided by the MA sponsor as a MA supplemental benefit. Telehealth and remote access technology, while very limited under Medicare currently and still quite limited under MA, increasingly provide access to services that currently are equivalent to in-person care and services.
Cross-Cutting Exclusions for Advanced Illness: The AMA supports excluding individuals with advanced illness from selected Part C measures. The health status of these individuals often makes compliance with the measure difficult and/or inappropriate. We also recommend that CMS allow for more general exclusions for patients with specific conditions, comorbidities or allergies from Part C measures to ensure patient and clinical differences are accounted for and do not interfere with clinical decision making, and for denominators of quality measures to be appropriately defined to ensure patients for whom the treatment may not be appropriate are excluded. As mentioned above, many of the measures within the Star Ratings program are heavily reliant on physician action and data, and there are instances where strict adherence to a measure interferes with patient preferences and/or is clinically inappropriate. For example, the *Medical Attention to Nephropathy measure,* which is part of the Comprehensive Diabetes Care composite, requires a physician to prescribe an ACE inhibitor or ARB. We have heard of instances where a physician must deviate from the measure due to patient allergies. However, the measure does not account for this type of exclusion, and the plan and physician are penalized. Broadening exclusions may also assist with dealing with the cut point issue because not all care can be completed at a hundred-percent level and allow for encounters that warrant physician non-conformance with measure specifications.

CMS Monitoring and Compliance Activities

Encounter Data

As CMS implements increased monitoring and compliance activity in this area, 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. As CMS hosts additional listening forums on the submission of encounter data in 2018, the agency should ensure that physicians, as well as MA plans, are adequately represented.

Medical Record Requests

As the AMA has previously stated in our letters on regulatory relief, MA plans routinely demand medical records from physician practices as a means of identifying information plans use to support increases in payments from CMS that are tied to the health status of plan enrollees. Only a small fraction of these requests are linked to CMS audits of MA risk adjustment data and plans generally provide no compensation for staff time required to pull records and make copies. Furthermore, we frequently hear from physicians that charts are demanded for large numbers of patients and that the same practices are repeatedly subject to these demands, often for the same patients. MA plans frequently subcontract the chart audits to third parties so the medical practice has no idea which plan is making these demands, and misleading statements are made that the audits are required by CMS when they are not.

In order to reduce documentation and regulatory burden for physicians, CMS should instead accept physician attestations to support MA beneficiaries' diagnosis instead of requiring documentation from

medical records. In addition, once beneficiaries have been diagnosed with a permanent condition (e.g., multiple sclerosis, quadriplegia, arthritis) the diagnosis should follow them from year-to-year and not have to be re-designated each year. Finally, CMS should eliminate ambiguity as to the authority, regulation, policy, and MA plan contract that is the basis for medical record requests by requiring all MA plans to use a standard letter.

Medicare Advantage Value-Based Insurance Design Model Test (MA-VBID)

The AMA supports the MA-VBID model test, and the idea that plan sponsors could offer greater flexibilities to target enhanced benefit design to certain patients, particularly those with chronic conditions. We also support the development of MA Alternative Payment Models (APMs) that physicians could participate in to help achieve thresholds to be considered a qualified participant, and thus be excluded from the Merit-Based Incentive Payment System (MIPS) program. Center for Medicare and Medicaid Innovation's VBID model allows MA plans to offer supplemental benefits or reduced cost sharing to enrollees with CMS-specified chronic conditions. The model aims to test whether this can improve health outcomes and lower expenditures for MA enrollees. Given that the VBID model began January 1, 2017 and will run for five years, we urge CMS to analyze and make adjustments to its proposal based on what it learns from the VBID demonstration in future years.

Medicare Diabetes Prevention Program (DPP) Services Clarification

Addressing pre-diabetes is one of the AMA's strategic focus areas, and we have strongly supported CMS moving forward with the Medicare DPP. We also strongly support CMS' clarification that while MA plans must cover MDPP services in accordance with MDPP regulations, they may also offer additional MDPP-like services as a supplemental benefit. We particularly appreciate the example CMS provides, noting that although MDPP services cannot be provided in a 100 percent virtual format under current regulations, such as a basic benefit under Part B, a MA plan may offer similar services in a virtual format as a supplemental benefit through the Remote Access Technology supplemental benefit. The AMA has supported CMS pursuing further testing on a virtual DPP model in the future for Medicare and MA beneficiaries.

Network Adequacy

The AMA continues to urge CMS to strengthen network adequacy standards for MA plans. A recent survey released by the AMA and LexisNexis® found that more than half of physicians in the U.S. say they encounter patients every month with health insurance coverage issues due to inaccurate directories of in-network physicians. The survey findings illustrate a continued need to eliminate potential barriers to care when patients rely on outdated, inaccurate, or incomplete directory data to locate an in-network physician. In addition, the survey underscores that network directories are a critical tool for patients when making decisions about their health care.

Medicare Part D Issues

Enhancing the OMS by Flagging Opioid Potentiator Drugs

The AMA has been a strong supporter of the OMS, which has been very successful in reducing high risk opioid overutilization in the Part D program by 61 percent from 2011 through 2016. CMS now proposes

to enhance the OMS by adding additional flags for high risk beneficiaries who use "potentiator" drugs, such as gabapentin and pregabalin, in combination with prescription opioids. CMS notes that it already flags concurrent benzodiazepine use and that higher gabapentin use has been observed among opioid users. In addition, the Office of the Inspector General has identified gabapentin as an independent risk factor for opioid-related deaths.

While we share CMS' concern that the increase in gabapentin and pregabalin use and higher doses among opioid users may place beneficiaries at a higher risk for adverse events, the AMA believes that it is premature to label these drugs as "potentiators" and to have Part D sponsors raising red flags about them because there is insufficient information about them. The U.S. Food and Drug Administration (FDA) is tracking the use and misuse of gabapentinoids, and trying to study the use patterns of these drugs. An increase in non-opioid prescriptions was advocated by the Centers for Disease Control and Prevention (CDC) guidelines and was to be expected. We believe that physicians certainly should pay attention to abuse of these drugs by patients with a substance use disorder, but do not support CMS' proposal to add a concurrent opioid-gabapentin/pregabalin flag to CMS at this time.

Hard Safety Edit of 90 MME at Point-of-Sale, with 7-Day Supply

The AMA is actively working to reverse the opioid epidemic, particularly through the activities of the AMA Opioid Task Force, which was formed in 2014 and includes 26 national medical specialty and state medical associations, the American Osteopathic Association, and the American Dental Association. The AMA supports every effort underway to reduce the opioid epidemic. However, the AMA strongly opposes CMS' proposal that all sponsors should implement hard formulary-level cumulative opioid safety edits at point-of-sale (POS) at the pharmacy at a dosage level of 90 morphine milligram equivalent (MME) per day, with a seven day supply allowance. We believe this proposal will result in patient harm.

The AMA does not agree with the fundamental premise of this proposal that daily dose and duration of therapy involving prescription opioid analgesics can serve on its own as a measure of quality patient care. Instead, quality measurement needs to 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 an indication of good patient care; but a reduction in opioid dose alone is not an appropriate goal. In fact, since the CDC 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. Imposing a hard edit at the pharmacy could lead patients to switch to street drugs (e.g., heroin and/or fentanyl), which are even more likely to lead to overdose deaths.

The CDC Guideline was not intended to be used as a one-size-fits-all limit. For example, the Guideline states:

> Clinical decision making should be based on a relationship between the clinician and patient, and an understanding of the patient's clinical situation, functioning, and life context. The recommendations in the guideline are voluntary, rather than prescriptive standards. They are based on emerging evidence, including observational studies or randomized clinical trials with

notable limitations. Clinicians should consider the circumstances and unique needs of each patient when providing care.

Originally developed as a guide to switching or rotating various opioid medications, MMEs are estimated equianalgesic doses of other opioid analgesics compared to morphine, where the potency of other members of the class are typically compared to a 10-mg parental dose of morphine. Various equianalgesic conversion tables or calculators exist; calculated MMEs may vary between tools for certain opioids, depending on the algorithm used. Comparative values should be considered approximations only and do not account for genetic factors, tolerance (and incomplete tolerance between various opioids), and the type of pain (i.e., acute vs. chronic) and duration of treatment. Patient-specific factors affecting drug disposition (i.e., hepatic function, renal function, age) are very important as well, because individual differences in pharmacokinetics can be substantial. As a result, there is great potential for patients to not receive the care that is needed, particularly for those with chronic pain.

To summarize, the AMA is very concerned that CMS' proposal could leave patients with chronic pain without access to appropriate therapy, and we urge CMS to withdraw this proposal.

Implementing a Day Supply Limit for Initial Fills for Treatment of Acute Pain

For the same reasons set forth above, we oppose CMS' proposal to establish a day supply limitation policy for opioid naïve patients. Specifically, CMS expects all Part D sponsors to implement a hard safety edit for initial opioid prescription fills that exceed seven days for the treatment of acute pain with or without a daily dose maximum. While seven days may be sufficient for most patients, we believe that imposing a specific day limit with a hard edit at POS is arbitrary. CMS itself acknowledges that implementing such restrictions may create important challenges. We believe this proposal could leave patients without adequate treatment and create a great deal of confusion and anxiety at pharmacies across the country when patients go to fill their prescriptions.

Expecting Part D Sponsors to Implement Soft POS Safety Edits based on Duplicative Therapy

Based on its concern that the use of long-acting (LA) opioids and the number of opioid prescriptions are associated with a higher risk of mortality, CMS expects all Part D plan sponsors to implement a soft place of service edit for duplicative LA opioid therapy for 2019, with or without a multiple prescriber criterion, which can be overridden by a pharmacist. We have concerns about this proposal. Some patients need multiple drugs. 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. That is why CMS has the OMS. The AMA does not believe that this policy is necessary on top of OMS. Pharmacists are not managing patients' pain and cannot be expected to override the edits. This could result in delays in filling needed prescriptions and adversely affect patient health and well-being.

Access to Medication-Assisted Treatment (MAT)

We agree with CMS that it is important to ensure that Medicare beneficiaries have appropriate access to evidence-based medication-assisted treatment MAT. However, we disagree that prior authorization (PA) should be allowed at all for MAT. Plans have placed too many drug utilization management requirements, including PA and step therapy, on medical practices and hurdles in front of patients' rapid

access to their medications. The prescribing clinician's judgment that the medication is needed for the patient should be accepted at the time that the prescription is initially written. The best time to get a patient into treatment is during the patient's appointment at the physician's office; PA and step therapy requirements impose unnecessary administrative burdens on prescribers and unjustified access delays on patients. CMS should prohibit the use of these drug utilization management requirements.

In addition, CMS could help to improve access to MAT by creating a seventh protected class of drugs under Part D for MAT. 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 (FDA for **opioid use disorder [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.

Improving Access to Part D Vaccines

The AMA agrees that MA plans should take steps to improve immunization rates, and we support CMS' plan to encourage Part D sponsors to offer either a $0 vaccine tier, or to place vaccines on a formulary tier with low cost-sharing.

We thank you for the opportunity to provide input on this final rule 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