AMA
AMERICAN MEDICAL ASSOCIATION

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January 16, 2018

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: Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs and the PACE Program

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 Medicare Program Contract Year 2019 Policy and Technical Changes to the Medicare Advantage (MA), Medicare Cost Plan, Medicare Fee-for-Service, Medicare Prescription Drug Benefit and PACE Program proposed rule.

While the AMA supports many of the policies finalized by CMS for 2019, we also believe there are several proposals that could be improved. We strongly support many of CMS' proposals including:

- CMS' proposal to define opioids as "frequently abused drugs" for plan year 2019;
- CMS' proposal to exempt from the at-risk designation beneficiaries who have elected to receive hospice care, are residents of long-term care facilities, or have a cancer diagnosis;
- CMS' proposals to codify the current Part D Opioid drug utilization review (DUR) policy and overutilization monitoring system (OMS) policy, and agree with CMS' proposed requirements that a Part D plan sponsor must meet to operate a drug management problem;
- CMS' proposed limits and requirements for default enrollments into MA plans, and CMS' proposed new, simplified election process that would allow beneficiaries to "opt-in" to a health plan;

- CMS' effort to gather further stakeholder input on MA Star Ratings issues and provide comments on several issues, including the establishment of cut points, the inclusion of physician experience survey measures, and improvements to the policies on plan consolidation;
- CMS' proposal to revise its policies on how Part D plans handle exceptions to formulary tiering;
- CMS' proposal to eliminate the current regulations that require prescribers to enroll in or opt out of Medicare for a pharmacy claim for a Part D drug prescribed by a physician to be covered;
- CMS' proposal to eliminate the requirement that compliance training be provided to first-tier, downstream, and related entities; and
- CMS' proposal to treat follow-on biological products as generics for non-low income subsidy (LIS) catastrophic and LIS cost sharing.

There are also several policies which the AMA believes could be improved, including:

- The documentation burden for physicians that arises from MA organization medical record documentation requests;
- CMS' proposal to reduce from three months to one month the required availability of a transition supply of medications for patients in long-term care facilities; and
- CMS' proposal to lengthen the adjudication timeframes for Part D payment redeterminations and Independent Review Entity (IRE) considerations.

In this comment letter, the AMA also recommends additional strategies for use by Medicare Advantage and Part D plans to address the opioid epidemic.

I. Implementation of the CARA Provisions

The Comprehensive Addiction and Recovery Act (CARA) includes new authority for the establishment of drug management programs in Medicare Part D. This proposed rule would implement the CARA Part D drug management program provisions by integrating them with the current Part D Opioid DUR Policy and OMS. 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. Given OMS' track record, we believe that CMS has taken the right approach by integrating the CARA Part D drug management program provisions with the existing OMS program. Our comments below focus on the areas of the proposed rule that we support and where we have concerns.

Frequently Abused Drug

The AMA supports CMS' proposal to define opioids as "frequently abused drugs" for plan year 2019. This is consistent with current policy, and we urge CMS to finalize this proposal. We agree with CMS that non-opioid medications, including benzodiazepine, should not be included in the definition. We also agree with the proposal that future designations of frequently abused drugs by the Secretary should primarily be included in the annual Parts C&D Call Letter or in similar guidance, which would be subject to public comment.

Exempted Enrollees

The AMA appreciates that CMS has proposed to exempt from the at-risk designation beneficiaries who have elected to receive hospice care, are residents of long-term care facilities, or have a cancer diagnosis. We urge CMS to finalize these provisions. While the AMA had previously commented on including additional categories of patients, such as patients receiving palliative care, those with a terminal condition who may not have elected hospice care, and patients receiving medication-assisted treatment (MAT) for substance use disorders (see, e.g., AMA letter to Chad Buskirk on "Implementation of Certain Medicare Part D Provisions in CARA," dated November 30, 2016), we believe that CMS has put sufficient safeguards in place to protect such patients with its proposed provisions on communications through case management with prescribing physicians, requiring prescribers to agree with a drug management plan for a patient, and exempting buprenorphine for MAT from being designated as "frequently abused drugs."

Proposed Requirements of Drug Management Programs

CMS proposes to codify the current Part D Opioid DUR policy and OMS policy. In brief, Part D plan sponsors will continue to engage in case management with prescribers when an enrollee is found to be taking a very high dose of opioids and obtaining them from multiple prescribers and multiple pharmacies. CMS proposes several requirements that a Part D plan sponsor must meet to operate a drug management problem. We agree with the proposed requirements relating to written policies and procedures, and we support the case management/clinical contact/prescriber verification requirements, whereby the plan sponsor's clinical staff must conduct case management for each potential at-risk beneficiary for the purpose of engaging in clinical contact with the prescribers of frequently abused drugs and verifying whether a potential at-risk beneficiary is an at-risk beneficiary. Through this process, the plan sponsors will: send written information to the beneficiary's prescribers that the beneficiary meets the clinical guidelines and is a potential at-risk beneficiary; elicit information from the prescribers, including whether prescribed medications are appropriate for the beneficiary's medical conditions or the beneficiary is an exempted beneficiary; and, when the prescribers have not responded, make reasonable attempts to communicate via phone with the prescribers within a reasonable period after sending the written information. We urge CMS to finalize these requirements in the final rule.

CMS proposes that before a Part D plan sponsor could limit the access of an at-risk beneficiary to coverage for frequently abused drugs, the sponsor must first conduct the case management

discussed above, including prescriber verification, and first obtain the agreement of the prescribers of such drugs with the limitation (unless the prescribers were not responsive to outreach by the plan sponsors). We strongly support the proposal to require prescriber agreement with limiting access of an at-risk beneficiary to frequently abused drugs. As CMS notes in the preamble, while a prescriber may verify that a patient is at-risk, the prescribing physician may not agree that limiting access to a particular opioid is appropriate for the patient. The patient's physician (or physicians) is best able to provide the plan sponsor with the medical background of the patient and additional considerations that may justify not limiting access to a particular drug. Conversely, the patient's physician, after obtaining additional information from the plan sponsor during case management, including the patient's utilization of a frequently abused drug, may decide that adjusting the dosage or changing the prescription, and counseling the patient about the risks of over-utilizing a particular drug, may be all that is needed to safely manage the patient's use of an opioid, thereby obviating the need to limit access through, for example, pharmacy lock-in. For these reasons, we urge CMS to retain this requirement in the final rule.

We strongly agree with CMS that prescriber lock-in should be a tool of last resort to manage at-risk beneficiaries' access to opioids, after other approaches have been tried and been unsuccessful. As CMS notes in the preamble, "Limiting an at-risk beneficiary's access to coverage for frequently abused drugs from only selected prescribers impacts the beneficiary's relationship with his or her health care providers and may impose burden upon prescribers in terms of prescribing frequently abused drugs." Accordingly, we support CMS' proposal that a Part D sponsor must not limit an at-risk patient's access to coverage for frequently abused drugs through prescriber lock-in unless at least six months have passed from the date that the patient was first identified as a potential at-risk beneficiary and the patient meets the clinical guidelines to be designated an at-risk beneficiary. This will allow time for alternative interventions or limitations to be instituted. We also support additional proposed requirements that the sponsor must take any preferences for prescribers and/or pharmacies indicated by a patient into consideration in imposing lock-in on a patient. CMS should finalize these provisions.

The AMA supports the requirements CMS proposes for beneficiary notices. We especially support the proposal that the Part D plan sponsor must make reasonable efforts to provide the beneficiary's prescriber(s) of opioids with a copy of the notice. We also support the requirement that the notice include information about where and how to access resources to address substance use disorder. In addition, we agree with CMS' statement in the preamble that plan sponsors should not send a potential at-risk beneficiary an initial notice until after the sponsor has been in contact with the beneficiary's prescribers. We believe this is critically important, especially in order to avoid unduly alarming the patient who may ultimately be determined not to be an at-risk beneficiary after the sponsor receives clinical information from the prescriber about the patient. This requirement should be added to the regulatory text.

The best way for patients to learn about identified risks associated with their medications is from their physician(s). Physicians should be encouraged by the plan sponsor to discuss a drug

management plan with their patients and the potential risks of their medications, and ideally, this should be done before a patient receives a notice from the plan sponsor. Notices sent by a plan sponsor to patients or patients' caregivers who have not discussed the drug risks with their physicians will interfere with patient-physician relationships, harm trust, and potentially lead patients to abruptly discontinue therapy. Patients with substance use disorders need to be referred for treatment, and their physicians need to coordinate their care and referrals.

There is one issue that we believe needs to be addressed with regard to reasonable access. While the proposal accounts for ensuring access to opioids in the case of emergency services, the proposed rule does not appear to cover situations where a patient who is under a lock-in provision is hospitalized (e.g., for non-emergency surgery) or develops a new medical condition that requires that they see a new physician. For example, as part of a patient's discharge, physicians at the hospital, most likely hospitalists, may write prescriptions for the patient and these physicians will not be part of the authorized lock-in provider. This could also occur if a patient develops a new medical condition and is referred to a different physician than the one they are locked into. It could also occur if a patient is discharged from another type of facility, such as an ambulatory surgery center, or if a patient experiences a dental condition and their dentist prescribes pain medication for them. CMS should consider providing additional flexibility for such unexpected or unplanned situations.

II. Medicare Advantage (MA) Issues

Flexibility in MA Uniformity Requirements

Previously, CMS required MA plans to offer all enrollees access to the same benefits at the same level of cost sharing. In this proposed rule, CMS proposes to allow MA organizations the ability to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees that meet specific medical criteria, provided that similarly situated enrollees are treated the same. For example, an MA plan could identify enrollees diagnosed with specific diseases such as diabetes or chronic heart failure as medically vulnerable and in need of certain services, which could be offered to these enrollees in the form of tailored supplemental benefits.

The AMA appreciates CMS sentiment that would allow plan sponsors greater flexibilities to target enhanced benefit design to certain patients, particularly those with chronic conditions. As CMS notes in the proposed rule, CMS is currently testing elements of these flexibilities through the Center for Medicare and Medicaid Innovation (CMMI) Value Based Insurance Design (VBID) model. CMMI'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.

While the AMA is generally supportive of this proposal, we also urge CMS to provide additional details. How will this proposal relate to the VBID demonstration and what has CMS learned from the VBID demonstration that it can apply to the current proposal? 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.

Coordination of Enrollment and Disenrollment through MA Organizations and Effective Dates of Coverage and Change of Coverage

The AMA strongly supports CMS' proposed limits and requirements for default enrollments into MA plans. Specifically, we support only allowing seamless default conversions upon conversion to Medicare in the following limited circumstances: 1) the individual is enrolled in an affiliated Medicaid managed care plan and is dually eligible for Medicare and Medicaid; 2) the state has approved use of this default enrollment process and provided Medicare eligibility information to the MA organization; 3) the individual does not opt out of the default enrollment; 4) the MA organization provides a notice that meets CMS' requirements to the individual; and 5) CMS has approved the MA organization to use the default enrollment process before any enrollments are processed.

The AMA also strongly supports CMS' proposed new, simplified positive election process that would allow beneficiaries to "opt in" to a health plan. We have repeatedly urged CMS to advance policies that encourage people new to Medicare to make an active and informed choice about the coverage options that are right for them. Making a choice about one's Medicare coverage when initially eligible is critically important and all beneficiaries should be encouraged to actively opt in to the health care plan of their choice.

MA Quality Rating System

We support CMS' effort to gather further stakeholder input on MA Star Ratings issues. The AMA has previously expressed our concerns that the current program often impedes clinical care, leads to increased administrative burdens on physicians, and does not provide much of a beneficiary benefit.

Specifically, we appreciate CMS' request for comments on the establishment of cut points for Star Ratings and whether the relative performance as reflected by the existing cut points accurately reflects plan quality. As the AMA has noted in previous comment letters, many of the measures within the MA Star Ratings program are based completely on physician action and compliance. In order for plans to comply with and earn incentives from CMS, plans must often set unrealistic targets within their physician contracts in order for the plan to score well due to the Star Ratings cut points.

Often physician compliance with a measure must be at 100 percent regardless of whether it would in all cases constitute appropriate and medically necessary care. For example, for the Diabetes Care - Blood Sugar Controlled measure, it is not reasonable to assume that every physician could achieve an A1c less than nine percent in every patient. The American Diabetes Association and other medical societies are moving toward more percent-centered individualized A1c goals, which allow for patients to keep their A1c closer to eight but not exactly eight. Therefore, if a MA plan's physicians treat more elderly or sicker patients, it might be unfairly

penalized if the A1c target is less than nine and the compliance with the measure is set at 100 percent. In addition, there may be instances when compliance with a measure is contrary to appropriate care, but plans do not incorporate exceptions, suitable exclusions or risk-adjustment models related to the measures due to the requirements CMS has set up for Star Rating compliance. All care should not be the same for all patients because no measure is precise enough to account for all the nuances in practice, patient adherence, and other relevant factors that impact patient care and health outcomes. It is not possible to achieve one hundred percent adherence to a measure, and there is a lack of data on what optimal performance should be for every measure. Therefore, we urge CMS to reevaluate the cut points to ensure the Star Ratings accurately reflect plan quality and based on evidence.

In addition, the AMA would support the inclusion of survey measures of physicians' experiences, as long as these surveys are *voluntary*. Currently, CMS only measures beneficiaries' experiences with their health and drug plans. We agree that the development of a survey tool that would collect standardized information on physicians' experiences with health and drug plans and their services could improve the Star Ratings programs. We urge CMS to make these surveys optional for physicians so the surveys do not further increase physicians' administrative burden, but we agree that physicians can provide a valuable perspective on the quality of drug and health plans that should be incorporated into the plans overall quality ratings.

The AMA is also pleased that CMS recognizes that its current policy on consolidation needs to be modified. Under current CMS policy, the star rating of the surviving contract determines the star rating for the consumed contracts for bonus purposes. Discussions by Medicare Payment Advisory Commission (MedPAC) have made it clear that this policy is generating a high degree of gaming of contractual relationships in order to extend higher star ratings bonuses to far more MA organizations than have actually earned them. The CMS proposal is a step in the right direction, but the MedPAC recommendation goes farther. The CMS proposal would change from having the star rating based on the surviving contract to having a weighted average rating based on the number of enrollees in the consumed contract and the surviving contract. Instead of being able to upgrade to quality bonus payments simply by changing the organization's contract, the MedPAC recommendation would preserve the consumed contract's own star rating for its enrollees, and would require quality data to be reported at the local level and have star ratings determined at the local level so a plan could not avoid its lower ratings in particular market areas by consolidating many of its contracts in numerous states into one national contract.

Medical Record Documentation

CMS requests comments from stakeholders on burdensome requests from MA organizations for their patients' medical record documentation. 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, i.e., 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.

III. Medicare Part D Issues

Part D Tiering Exceptions

The AMA agrees with the CMS proposal to revise its policies on how Part D plans handle exceptions to formulary tiering and urges the agency to finalize the proposal. It is certainly true that the current array of five or six tiers leads to much more confusion than the original structure of four or fewer tiers with separate tiers for generic and brand drugs. Under the new proposed policy, plans would not be permitted to exclude a tier containing alternative drugs with more favorable cost-sharing from their tiering exception procedures just because that lower-cost tier is dedicated to generic drugs. Plans will also need to establish specific tiering exceptions policies for biological products.

Changes to the Days' Supply Required by the Part D Transition Process

The AMA is concerned about the proposal to reduce from three months to one month the required availability of a transition supply of medications for patients in long-term care facilities. Medication changes for patients with hypertension, for example, can lead to falls. The transition from the home to a long-term care facility can be extremely stressful for elderly patients, which presents a risk to patient safety. Rushing to change their drug regimens would heighten these concerns. It is conceivable that CMS has not seen evidence of problems for patients transitioning to long-term care precisely because it has had a longer transition fill policy in place.

Preclusion List Part D Provisions

The AMA supports CMS' proposal to eliminate the current regulations that require prescribers to enroll in or opt out of Medicare for a pharmacy claim for a Part D drug prescribed by a physician to be covered. We have strongly advocated for the elimination of this regulation in previous comment letters, and commend the administration for this proposal, which will help reduce the physician administrative burden. CMS proposes instead to require plan sponsors to reject claims for Part D drugs prescribed by providers on the preclusion list. We agree with CMS that this

approach will reduce physician administrative burden while still protecting beneficiaries from prescribers who could present risks.

Compliance Training

The AMA strongly supports the elimination of the requirement that compliance training be provided to first-tier, downstream and related entities. This is an important step in reducing regulatory burden for physicians.

Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes

The AMA has concerns that Part D plan sponsors change formularies and formulary design once beneficiaries are no longer able to change to a different plan. The AMA agrees with MedPAC's observation that the continuity of a plan's formulary is very important to all beneficiaries in order to maintain access to the medications that were offered by the plan at the time the beneficiaries enrolled. The AMA does not support removing important beneficiary protections to provide plans more flexibilities.

Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing

The AMA strongly supports CMS' proposal to treat follow-on biological products as generics for non-LIS catastrophic and LIS cost sharing. This will increase patient access and encourage prescribing where clinically appropriate of relatively less costly treatments.

Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale

The AMA appreciates CMS' request for information regarding the application of manufacturer rebates and pharmacy price concessions to drug prices at the point of sale. This policy would add much needed transparency and ensure that beneficiaries benefit from discounts. It would also protect the Medicare Trust Fund.

Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations

The AMA does not support lengthening the adjudication timeframes for Part D payment redeterminations and IRE reconsiderations. Specifically, we have concerns that beneficiaries will be denied access to potentially clinically necessary care. Physicians and staff and pharmacies will have to spend additional resources while a beneficiary potentially is harmed.

Additional CMS Strategies for Addressing the Opioid Epidemic

As the preamble describes, the CMS OMS has been very effective in reducing the number of Medicare beneficiaries who are at risk for opioid overutilization. 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. Where both the current and the proposed CMS policies fall short, however, is in

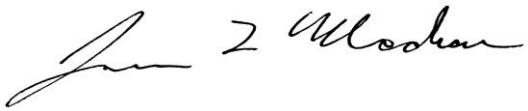
ensuring access to evidence-based medication-assisted treatment (MAT) for Medicare patients with opioid use disorder.

In the same way that CMS currently requires that plan sponsors cover all drugs in the six protected classes (i.e., anticonvulsants, antidepressants, antineoplastic, antipsychotics, antiretrovirals, and immunosuppressants), the AMA urges CMS to require all MA Part D and standalone Part D plans to cover all medications approved by the U.S. Food and Drug Administration (FDA) for the treatment of certain substance use disorders. While not every individual may require an FDA-approved medication, those who do should be able to access whichever medication their physician recommends to treat their substance use disorder, and also not be restricted by coverage or utilization management procedures such as prior authorization or step therapy.

In addition, all MA and Part D plans should 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 rapidly accelerating growth in the number of Medicare patients with opioid use disorder. According to a study by the Agency for Healthcare Research and Quality, the number of inpatient hospital admissions for opioid overuse grew an average of more than 10 percent a year among Medicare patients since 1993. By 2012, there were 211,200 Medicare inpatient stays for opioid overuse, just slightly less than the 226,600 Medicaid inpatient stays due to opioid overuse.

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