AMA
AMERICAN MEDICAL ASSOCIATION

JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

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

April 6, 2020

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

Re: Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (CMS-4190-P)

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 and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly Proposed Rule (Proposed Rule).

Below is a summary of our key recommendations followed by our detailed comments:

- Inclusion of supports and services designed to identify and address chronically ill patients' social determinants of health will increase the effectiveness of healthcare for chronically ill individuals;
- The AMA urges caution in mandating Part D drug management programs as efforts to exclude special populations from drug management plans may not be effective in practice;
- CMS should encourage MA plans to facilitate enrollees' access to medical treatment with buprenorphine or other appropriate medications to manage opioid use disorder;
- In addition to in-home health risk assessments and safe drug disposal information, CMS should require information on safe medication storage;
- Opioid prescribing decisions must be made between the physician and his/her patient;
- CMS policy should focus on the need to improve pain management practices instead of narrowly focusing on the prescribing of opioid analgesics;
- Part D sponsors should be required to increase coverage, availability, and affordability of non-opioid treatment options, including placing non-opioid pharmacologic and non-pharmacologic options on the lowest cost-sharing tiers with minimal co-pays and benefit limitations;
- CMS should delay implementation of the provision from the SUPPORT Act pertaining to EPCS for Part D prescriptions;

- CMS needs to ensure that end stage renal disease patients are properly informed so that they can make good decisions as they consider switching to MA for their health care coverage.
- Any Medicare patients currently stabilized on a specialty drug should be exempt from unfavorable coverage changes resulting from a secondary specialty tier;
- The AMA shares CMS' goal of improving patients' access to useful information regarding drug benefits and costs, however, when considering implementation of real-time benefit technology, we urge CMS to consider the ability of such tools to support patient-physician discussions regarding treatment selection and the utility of the data for the majority of Medicare patients;
- The AMA generally supports CMS' proposal to increase the weight of the patient experience and access measures in MA and Part D Star Ratings programs, but encourages CMS to work with AHRQ to update the Health Plan CAHPS survey;
- Improving the prior authorization process for patients and physicians is a priority for the AMA as such, CMS should consider the inclusion of processing time, approval/denial rates, and denials overturned on appeal in prior authorization metrics in MA plan Star Ratings;
- Given the strain the unprecedented COVID-19 pandemic is placing on the health care system, the AMA urges CMS to suspend weighing the Effectiveness of Care Measures based on 2020 data given the amount of clinical information required of plans to collect from practices, and immediately send out an advisory notice to plans informing them of this suspension, as well as recommend in the guidance that they suspend collecting the information from physicians;
- To improve network adequacy, CMS should require plans to report the percentage of physicians in the network who actually provided services to plan members during the prior year and publish the research supporting the ratio and distance requirements CMS use;
- CMS should improve beneficiary and physician access to accurate network directory information.
- MA plans should be encouraged to cover all visits and other services that are on the Medicare telehealth list when provided through telehealth by patients' physicians; and
- CMS should consider allowing patient conditions and symptoms documented during telehealth visits to be incorporated into MA plan risk scores.

Special Supplemental Benefits for the Chronically Ill (SSBCI)

The AMA is pleased to see the Administration is including supports and services designed to identify and address chronically ill patients' social determinants of health (SDOH). The AMA knows that for individuals with chronic illnesses to effectively manage their conditions and prevent exacerbations and complications, they must have access to resources that include, but are not limited to, community support systems, food, transportation, and pest control. Accordingly, the AMA strongly supports the inclusion of SSBCI that are not primarily health related. The ability to consider social determinants when identifying chronically ill enrollees, whose health could be improved or maintained with SSBCI, will enable healthcare providers to better address social barriers to care and will increase the effectiveness of healthcare for chronically ill individuals within Medicare Advantage (MA) plans.

Physicians need to be able to effectively treat patients; this means that physicians need the flexibility to tailor care to individuals' specific needs. Generally, §422.100(d) and other regulations require all MA plan benefits to be offered uniformly to all enrollees residing in the service area of the plan. However, Section 1852(a)(3)(D)(ii)(II) of the Act would authorize CMS to waive the uniformity requirements generally applicable to benefits covered by MA plans with respect to SSBCI. The AMA supports tailoring treatment to each patient's needs, goals of care, and preferences. This increased flexibility to provide chronic care management will promote effective and efficient communication and care coordination

between patients, physicians, and support teams. Moreover, having the capability to waive uniformity requirements, and create specific treatment plans for patients with chronic diseases, will allow physicians to better serve patients, improve health outcomes, and creates the potential for physicians to further tailor strategies for enrollees with multiple and specific chronic diseases.

Mandatory Drug Management Programs (DMPs)

The AMA generally supports the implementation of Part D, DMPs in that they have sought to focus their use on those who would most benefit. The AMA supports the fact that not all Part D sponsors, or the patients whom they serve, have been required to implement the programs. While DMPs have likely helped many patients, the AMA is not aware of outcomes data that would support mandatory implementation. If CMS has such data, it should publicize the information to establish the evidence for requiring mandatory implementation. This data should include findings that show that mandatory implementation would not adversely affect patients' access to medications, especially since CMS efforts to exclude special populations from drug management plans, such as those with sickle cell disease or cancer, 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 sickle cell disease or advanced cancer being denied their prescribed medications, even to the point of being admitted to the hospital for uncontrolled pain. CMS policies for MA and Part D drug management plans need to avoid these types of unintended consequences.

Beneficiaries with History of Opioid-related Overdose in DMPs

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.

CMS should encourage MA plans to facilitate enrollees' access to medical treatment with buprenorphine or other appropriate medications to manage opioid use disorder (OUD).

In 2020, Original Medicare began making monthly payments for office-based OUD treatment. MA plans should be strongly encouraged to make this type of treatment available and accessible to patients. MA networks should include addiction medicine specialists and other physicians who are certified and willing to provide office-based treatment for OUD.

Moreover, the AMA agrees that those who have a history of opioid-related overdose must continue to have their physician address the risk factors that may have led to the overdose. For some patients, it may be beneficial for the patient to be part of a DMP, but as discussed above, requiring all patients to participate in a DMP may not be warranted. While the presence of overdose in a patient's medical history is a cause for concern, the AMA prefers the focus to be, as CMS suggests, on "Part D plan sponsors and providers to work together to closely assess these beneficiaries' opioid use and determine whether any additional action is warranted." The AMA notes that this language is in relation to appeals of a DMP

determination, but the AMA recommends that it also serve as a first line of inquiry rather than requiring all Part D enrollees to automatically be placed into a DMP.

Information on the Safe Disposal of Prescription Drugs

The AMA supports requiring MA plans to provide in-home health risk assessments as well as verbal and written information on the safe disposal of prescription drugs. We recommend that CMS go further, however, and require verbal and written information on safe storage of prescription drugs and that the information is not just limited to controlled substances, but all prescription and other medication, including over-the-counter medications. This was one of the first recommendations of the AMA Opioid Task Force (Task Force).

Specifically, the Task Force recommended that MA plans talk to their enrollees and educate them about safe use of prescription medications—between 60-70 percent of people using opioid analgesics for nonmedical reasons, for example, get them from family or friends. Opioid analgesics, like all medications, should only be taken as directed since misuse or diversion of these products can be illegal, extremely harmful, and even deadly.

Second, the AMA encourages MA plans to remind patients that medications should be stored out of reach of children, and in a safe place—preferably locked—to prevent other family members and visitors from taking them. The Centers for Disease Control and Prevention (CDC) recommends that prescribers and other health care professionals "discuss risks to household members and other individuals if opioids are intentionally or unintentionally shared with others for whom they are not prescribed, including the possibility that others might experience overdose at the same or at lower dosage than prescribed for the patient."

Third, the AMA supports requirements for MA plans to talk with enrollees and provide them with information about the most appropriate way to dispose of expired, unwanted and unused medications. The preferred option is that unwanted or unused pills, liquids, or other medications should be disposed of in a local "take back" or mail back program or medication drop box at a police station, DEA-authorized collection site or pharmacy, if the pharmacy has a secure drop-box program.

The AMA also recommends that this information be developed and provided in a format, reading level, and using appropriate visuals to ensure understanding by Part D enrollees. Finally, the AMA cautions that this requirement should not result in costs passed on to Part D enrollees.

Beneficiaries' Education on Opioid Risks and Alternative Treatments

The AMA appreciates the multiple options that are offered as part of educating patients about the risks and benefits of treatment that might include opioid analgesics. We have three overarching concerns that apply to each of the suggested options.

First, the decision about whether to prescribe an opioid analgesic must remain one that is determined between the physician and his/her patient. A Part D sponsor should not have arbitrary policies discouraging any particular therapy.

The AMA continues to be very concerned that CMS is narrowly focusing on the prescribing of opioid analgesics instead of the need to improve pain management practices. The AMA strongly supports the final report and recommendations of the Pain Management Best Practices Interagency Task Force and urges CMS to implement them. 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. CMS should focus 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 CDC 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.

Second, patients with pain who benefit from opioid therapy have been subject to considerable stigma, as though they are at fault for being helped by a legitimate medical option. While the AMA strongly urges discussion of the risks and benefits of any course of therapy, singling out opioid therapy may unintentionally increase the stigma already felt by patients with pain.

Third, if Part D sponsors are to be encouraged to increase discussion of opioid alternatives, then they should be required to increase coverage, availability, and affordability of those non-opioid treatment options. This includes requiring Part D sponsors to provide clear information to enrollees about non-opioid pharmacologic and non-pharmacologic options available in a plan's formulary and benefit design. And it further encompasses requiring Part D sponsors to include those non-opioid options on the lowest cost-sharing tiers of the formulary, as well as availability of non-pharmacologic pain care, without strict or limited benefits. CMS guidance to MA and Part D plans should encourage their payment policies to 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.

Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures

The AMA appreciates CMS's attempt to try and define "inappropriate prescribing." We agree that "all of the facts and circumstances of a particular situation" must be considered during the process of understanding the unique situation that each patient presents. As physicians and patients work to reduce opioid-related misuse, millions of Americans still have chronic pain and require help. In 2016, the latest year for which data is available, the CDC estimated that 20.4 percent (50.0 million) of U.S. adults had chronic pain and 8.0 percent of U.S. adults (19.6 million) had high-impact chronic pain. As policymakers and prescribers continue to decrease access to opioid analgesics to treat pain, as explained above, it is vital to expand access to non-opioid pain management strategies, including non-opioid prescription

medications and behavioral, cognitive, restorative, and interventional therapies. Physicians need to be able to tailor pain treatment to patients' needs. Even prior to the nation's extensive policymaking to restrict the prescription of opioid analgesics, physicians and other health care professionals were making more judicious prescribing decisions, leading to a 33 percent decrease in the prescription of opioid analgesics between 2013 and 2018.

State laws and national guidelines, in combination with payer, pharmacy, and pharmacy benefit manager (PBM) restriction policies, have contributed to further reductions. For example, in 2016 the CDC issued guidelines on opioid prescribing that suggested dosage and duration thresholds, as well as limits on, and tapering of drug dosage. While the guidelines were meant to be voluntary and advisory, many policymakers and insurers incorporated them into laws, regulations, and policies. Unfortunately, there is growing evidence that the abrupt termination of a patient's prescription opioid medication, or nonconsensual tapering, can have unintended consequences, including increased pain, use of illicit opioids, or even in some instances, patient suicide. Many of these restriction policies have inappropriately focused on arbitrary quantity and dose thresholds.

As a result of both growing reports of patient harms and ongoing physician advocacy, on April 9, 2019, the FDA issued a special safety announcement emphasizing the potential harm to patients who are receiving opioid therapy for pain and are forced to taper or discontinue that therapy. The CDC followed the next day with a letter clarifying that "[t]he Guideline does not endorse mandated or abrupt dose reduction or discontinuation, as these actions can result in patient harm." Shortly thereafter, the CDC published a much more formal clarification in the *New England Journal of Medicine*. The guidelines have been misapplied so widely, however, that it will be a challenge to undo the damage, which has also included nonconsensual tapering and patients being denied their prescriptions.

There is a pressing need for regulators and policymakers to reevaluate current policies' effects on patients and ensure that formularies and benefit designs support comprehensive, multimodal, multidisciplinary pain care. The AMA is greatly concerned that while the proposed definition—on its face—may call for a comprehensive review—the practice of policymakers has been to focus mainly on dose and quantity without considering the multiple factors that affect patients and physicians, including health insurers who have not provided affordable access to non-opioid pharmacologic and non-pharmacologic options on the lowest cost-sharing tiers with minimal co-pays and benefit limitations. In addition, the AMA urges CMS to review information from the AMA about the types of treatments pain medicine physicians commonly use, but are too often subject to prior authorization, step therapy, and other utilization management barriers. The AMA strongly encourages CMS to require Part D sponsors to increase availability and affordability of non-opioid pain care options so that physicians have the option of offering non-opioid treatments rather than being forced into a Catch-22 of having only generic opioid analgesic options on the lowest cost-sharing tier, while other non-opioid options are unaffordable or not on the formulary.

Electronic Prescribing of Controlled Substances (EPCS)

CMS should delay implementation of the provision from the SUPPORT Act pertaining to EPCS for Part D prescriptions. The Drug Enforcement Administration (DEA) has not yet revised the requirements for multifactor authentication to make adoption of EPCS more feasible for physicians and better integrated into their practice workflows. The volume of controlled substance prescriptions for a subset of physician practices makes compliance with the biometric component of two-factor authentication, particularly as a distinct process from e-prescribing of non-controlled substances, onerous and a significant strain on

practice workflows. On top of the fact that few health information technology vendors support EPCS, and the cost of add-on modules and separate monthly service fees, the methods and processes that vendors utilize for EPCS are often not well-aligned with normal e-prescribing workflows. These problems with EPCS systems and DEA requirements were also noted in the strategy for reducing administrative and regulatory burden issued by the National Coordinator for Health Information Technology. The AMA has provided specific recommendations to the DEA for modifying its EPCS regulations under §1311.116 additional requirements for biometrics. Until the DEA complies with the mandate from SUPPORT that the EPCS requirements for the biometric component of multifactor authentication be updated, the AMA strongly urges CMS not to issue any regulations requiring EPCS for Medicare Part D prescriptions.

Implementation of Certain Provisions of the 21st Century Cures Act

The AMA supports the implementation of the 21st Century Cures Act. However, as patients are given the opportunity to receive care for ESRD under MA plans, the AMA cautions that patients must be properly informed as to how this change may affect their health care. Patients must have the opportunity to understand the benefits, risks, and costs of switching to a Medicare Advantage plan. Moreover, CMS has the primary responsibility to inform patients with ESRD about plan provisions that will affect the availability of ESRD care throughout this transition. As patients consider switching to Medicare Advantage plans, CMS should ensure that patients have access to:

- Clear information about the plan's network, including whether the patient's nephrologist, primary care physician, and other physicians are in the plan's network, as well as any facilities that the patients use regularly, such as dialysis centers, hospitals, or imaging centers;
- For any clinicians or facilities that the patient will need to access that are not in the plan's network, what out-of-pocket costs or other hurdles to access is the patient likely to face;
- Disclose any financial and other factors that could affect the patient's care, such as not having access to Medicare supplemental coverage to help with cost-sharing;
- Coverage for relevant treatment alternatives that may not be covered under the patient's health plan, or may have utilization restrictions such as prior authorization, formularies, or constraints on referrals;
- Plan provisions for obtaining desired care that would otherwise not be provided, such as provisions for off formulary prescribing; and
- How changes could be made, for example, if the patient chooses to return to Original Medicare or switch to a different MA plan.

Overall, CMS must ensure that patients are properly informed so that they can make the best possible decision as they consider switching to MA plans for their future health care coverage.

Permitting a Second "Preferred" Specialty Tier in Part D

The AMA is concerned about the implication of adding a second specialty tier for patients currently receiving specialty therapies. Creation of a second specialty tier may lead to increased patient copays/cost shares for a chronic medication on which the patient is stabilized. In the case of biologic medications, switching to a biosimilar on a lower specialty tier may have negative clinical implications for a patient stabilized on a reference product. The AMA urges CMS to consider any Medicare patients currently stabilized on a specialty drug be exempt from unfavorable coverage changes (e.g., increased patient copays/cost shares) resulting from a secondary specialty tier.

Beneficiary Real Time Benefit Tool (RTBT)

The AMA applauds CMS' efforts to improve the access of Medicare Advantage Prescription Drug Plan (MA-PD) and Part D beneficiaries to useful information about their drug benefits and costs of prescribed medications. Provision of appropriate and meaningful data about medication coverage to beneficiaries has the potential to support and enhance informed conversations about treatment selection between patients and their physicians and facilitate shared decision-making. Addressing coverage restrictions and drug costs in prescribing discussions between physicians and patients also increases the likelihood of medication adherence by preventing surprises (e.g., unmet prior authorization requirements or high co-pays) at the pharmacy counter.

The importance of drug benefit and cost transparency at the point of prescribing has been repeatedly stressed by the AMA and many other health care stakeholders. In 2017, the AMA, in collaboration with 16 other organizations representing physicians, hospitals, pharmacists, medical groups, and patients, released a set of 21 Prior Authorization and Utilization Management Reform Principles. In addition to other key utilization management reforms, these principles call for disclosure of accurate formulary data and cost-sharing information to physicians, plan members, and prospective patients, as indicated in Principle #8: "Utilization review entities should publicly disclose, in a searchable electronic format, patient-specific utilization management requirements, including prior authorization, step therapy, and formulary restrictions with patient cost-sharing information, applied to individual drugs and medical services." Principle #9 specifically highlights the importance of these data being available to physicians at the point of prescribing: "Utilization review entities should provide, and vendors should display, accurate, patient-specific, and up-to-date formularies that include prior authorization and step therapy requirements in electronic health record (EHR) systems for purposes that include e-prescribing."

Similar concepts were supported in the Consensus Statement on Improving the Prior Authorization Process, which was released in 2018 by the AMA and the American Hospital Association, America's Health Insurance Plans, American Pharmacists Association, BlueCross BlueShield Association, and Medical Group Management Association. Of note, the consensus agreement encourages "transparency and easy accessibility of prior authorization requirements, criteria, rationale, and program changes to contracted health care providers and patients/enrollees" and "communication of up-to-date prior authorization and step therapy requirements, coverage criteria and restrictions, drug tiers, relative costs, and covered alternatives (1) to EHR, pharmacy system, and other vendors to promote the accessibility of this information to health care providers at the point-of-care via integration into ordering and dispensing technology interfaces; and (2) via websites easily accessible to contracted health care providers."

Given the AMA's leadership role in the initiatives referenced above, we clearly share CMS' goal of improving Medicare beneficiaries' access to useful information regarding drug benefits and costs. However, we are concerned about some of the specific proposals regarding beneficiary RTBTs. When considering implementation of this technology, we urge CMS to consider two critical factors: (1) the ability of such tools to support patient-physician discussions regarding treatment selection and, more broadly, the patient-physician relationship and (2) how useful the data will be to the majority of Medicare beneficiaries.

Facilitation of Physician/Patient Discussions Regarding Medication Selection

The AMA maintains that information about drug benefits and costs will be most useful and actionable for MA-PD and Part D beneficiaries when it is reviewed and discussed with the patient's physician. As CMS notes in the proposed rule, most Medicare beneficiaries "may not have the clinical background required to accurately discern the clinical appropriateness of the alternatives that would be presented" by RTBTs. Moreover, factors related to medication adherence, such as dosing frequency or pill burden, could be involved in a physician's rationale for choosing a particular treatment regimen for a patient. Thus, there may be unintended consequences of patients reviewing RTBT data without consulting with their physicians, such as interference in the patient-physician relationship, creation of confusion or distrust, or even therapy disruption.

To ensure that physicians are able to fully discuss the range of treatment options with their patients, along with their respective costs, we urge CMS to prioritize the provision of accurate, real-time formulary data, to include coverage restrictions and patient cost, to physicians and other prescribers in EHRs at the point-of-care and clinical decision-making. In addition, it is critical that these data be available across all prescription drug plans, patients, and EHR systems.

Unfortunately, many physicians do not have access to drug formulary and cost data for their patients. For example, in the 2018 AMA Prior Authorization Physician Survey, 69 percent of physicians reported that it is difficult to determine whether a prescription drug or medical service requires prior authorization. In the Medicare Advantage and Part D Drug Pricing Final Rule issued in May 2019, CMS required each Part D plan to adopt one or more RTBTs that are capable of integrating with at least one EHR system by January 1, 2021. While the AMA strongly supports the overall goal of providing formulary and drug cost data in EHRs, we find the current CMS requirements for prescriber-facing RTBTs insufficient to facilitate widespread physician adoption. If Part D plans adopt a single RTBT that integrates with only one EHR system, physicians will be forced to support multiple RTBTs for various plans—a financially infeasible solution for most practices—or face major gaps in the drug formulary data available to them. The current status quo, characterized by proprietary RTBTs that only contain data for certain plans and connect with particular EHRs, limits the utility of this technology for physicians and hinders widespread adoption.

If CMS proceeds as planned and requires MA-PD and Part D plans to offer beneficiary RTBTs by January 1, 2022, physicians will be further challenged and frustrated, as their patients may be able to access formulary and drug cost information that is inaccessible in EHRs. This scenario could strain physician-patient relationships and disrupt practice workflows, as patients may request physicians to prescribe different medications based on data presented in beneficiary RTBTs but absent from EHRs. We are concerned that offering RTBTs to Medicare beneficiaries before a fully viable prescriber-facing RTBT solution is in place will have the unintended consequences of increasing administrative burdens for physicians, lead to tension between physicians and patients, and ultimately confuse rather than empower beneficiaries. To ensure that any beneficiary RTBTs improve rather than detract from shared decision-making regarding medication selection, we urge CMS to:

- Address the deficiencies in the current prescriber-facing RTBTs by mandating adoption of an RTBT standard as soon as possible. In August 2019, the National Council for Prescription Drug Programs (NCPDP) approved a BETA version of an RTBT standard, which is currently being piloted by multiple organizations. NCPDP anticipates that the standard will be finalized and recommended to CMS for adoption by the end of 2020. The AMA strongly supports a mandated RTBT standard over

the current proprietary solutions, as this will ensure that physicians can access formulary and drug cost data across all patients and plans, regardless of their EHR system.

- Harmonize the data presented in prescriber- and beneficiary-facing RTBTs so that physicians and patients view the same data. Discrepant data between physician- and patient-facing RTBTs will lead to practice workflow disruptions and burdens, in addition to confusion and frustration for both physicians and beneficiaries. While there is currently no standard for patient-facing RTBTs, we are aware that both NCPDP and Health Level Seven (HL7) have initiated work in this area and are using the NCPDP prescriber-facing RTBT draft standard as the foundation for their efforts. This consistency between physician- and patient-facing data is critical to ensuring the utility of RTBTs in patient-physician treatment discussions.

- Delay implementation of beneficiary RTBTs until (1) a prescriber RTBT standard has been mandated and implemented; and (2) a patient-facing RTBT standard that aligns with the prescriber standard has been developed. While the AMA fully supports improved transparency of drug formulary and cost data for patients, we are deeply concerned that premature deployment of beneficiary RTBTs could negatively impact bo th physicians and patients. We urge CMS to reconsider the timeframe of beneficiary RTBT implementation and view this effort as a holistic process that begins with physicians first having access to standardized RTBTs in their EHRs and sufficient time to become comfortable using RTBTs with their patients. CMS should delay a mandate on beneficiary RTBTs until such time as a standard is available that will ensure consistency in the data available to prescribers and patients.

Maximizing Utility of Formulary and Drug Cost Data for Patients

The AMA commends CMS for recognizing the need for MA-PD and Part D beneficiaries to have access to up-to-date and accurate information regarding their plan's formulary, benefits, and drug costs. However, we urge CMS to consider the utility of the information being offered to patients when determining requirements for beneficiary RTBTs. It is critical that these tools only present truly useful formulary and benefit information, avoid overwhelming or confusing patients, and encourage patient-physician discussions and collaborative treatment decisions. To ensure that these goals are met, we recommend that CMS:

- Emphasize the importance of patients carefully researching MA-PD and Part D plans during the enrollment process. It is paramount that beneficiaries be fully aware of coverage restrictions and anticipated costs for all their current medications when selecting a prescription drug plan. Because plan selection will ultimately determine patient drug costs throughout the benefit year, CMS should place renewed focus on encouraging beneficiaries to research how selection of a drug plan for the upcoming benefit year would impact their access to prescribed medications as well as their cost share. While we see the potential value of patients having access to real-time pharmacy benefit information, we believe that CMS' first priority should be educating beneficiaries on the importance of fully investigating their plan options before making a selection, as this decision will ultimately have the greatest effect on the patient's cost share during the benefit year. Any treatment choices influenced by beneficiary RTBTs will ultimately be constrained by the patient's MA-PD or Part D plan enrollment.

- Limit the information offered in beneficiary RTBTs to avoid overwhelming or confusing patients. We believe that beneficiary RTBTs will be most useful to patients if they present a concise amount of useful information, such as real-time remaining deductible, utilization management requirements (prior authorization, step therapy, and quantity limits), and accurate cost information for prescribed medications. We caution that information about alternative medications with pricing may ultimately be confusing to patients, most of whom lack the clinical expertise to evaluate the appropriateness of potential therapeutic alternatives. Of particular concern is CMS' suggestion that plans be allowed to select which alternative medications be presented to beneficiaries. Although CMS states an intent to "monitor for improper use of this discretion" and that alternatives should "be excluded based only on clinical appropriateness, not based on cost implications," it is unclear how these patient protections would be enforced.

- Require beneficiary RTBTs to direct patients to their physician(s) before acting on any of the information presented in the tool or discontinuing therapy. It is imperative that any beneficiary RTBT instruct patients to discuss any questions or concerns regarding prescribed medications with their physician(s) and clearly convey that RTBTs do not constitute medical advice. Again, we urge CMS to keep the patient-physician relationship first in mind when developing beneficiary RTBT requirements, as a technology that provides a plan-curated list of potential therapeutic alternatives without consideration of the patient's unique clinical circumstances could negatively impact medication adherence or patient safety.

- Clarify that beneficiary RTBTs are to be used to obtain information about prescribed medications. For patients to receive accurate information about medication coverage and cost from beneficiary RTBTs, they must first have a prescription in hand. Without having a prescription from which to obtain the medication name, dose, and quantity, most patients will be unable to obtain useful or accurate information from RTBTs.

- Ensure that beneficiary RTBTs are developed to price a prescribed medication at a specific pharmacy. While we appreciate CMS' efforts to prevent RTBTs from steering beneficiaries to particular pharmacies, we are puzzled by the statement that these tools cannot "include pharmacy-specific cost sharing information." Plans will be unable to accurately price a prescribed medication unless the RTBT factors in the patient's pharmacy of choice, as patient copays vary based on pharmacy network status. CMS should also consider requiring beneficiary RTBTs to present a medication's cost at alternative pharmacies based on the patient's geographic location.

- Include patient-physician consultations in any reward and incentives (RI) offered by plans for accessing RTBTs. We understand that prescription drug plans may wish to offer RI as a means to encourage use of the RTBTs in which they have invested. However, we are concerned that, as described, RI may entice potentially vulnerable beneficiaries to access RTBTs and consider drug selection only in the context of cost, rather than clinical efficacy and appropriateness. While cost can be an important factor in treatment selection, care quality, value, and appropriateness are also important pieces of the equation and can only be evaluated in consultation with a physician. If CMS allows plans to offer RI for RTBT consultations, a requirement should be added that the patient discuss the information with his/her physician to ensure that such incentives do not interfere with the patient-physician relationship. Physicians should be included in any medication "shopping" experience enabled by beneficiary RTBTs to provide a clinical perspective, as well as to protect

patients from any commercial biases introduced in RTBTs by pharmaceutical manufacturers or drug plans.

Patients, physicians, and prescription drug plans all benefit when it is possible to identify high-quality treatment options that minimize patient financial burden and ensure continuity of care. The AMA urges CMS to prioritize improving the availability of real-time pharmacy benefit data in physicians' EHRs before finalizing any requirements for beneficiary RTBTs to protect patient-physician relationships and shared clinical decision-making. We also recommend that CMS carefully consider the utility of data included in beneficiary RTBTs and focus on how this information can best be used to support conversations between physicians and patients.

Establishing Pharmacy Performance Measure Reporting Requirements and MA and Part D Prescription Drug Plan Quality Rating System

CMS plans to require Part D sponsors to standardize the measures they require pharmacies to report, and in general, the AMA supports the following principles CMS has outlined:

Measures should:

- Improve medication use and outcomes for the beneficiaries served;
- Be specified at the right level of attribution and appropriate level of comparison considering pharmacy type;
- Factor in both pharmacy accountability and drug plan performance goals;
- Have clear specifications and be established prior to the measurement period;
- Be reliable, transparent and fair; and
- Use threshold minimums if appropriate.

However, we recommend CMS refine the principles to better articulate the type of measures CMS is interested in and to avoid duplication of the principles. We suggest tweaking the 4th principle to state "precise" instead of "clear". While it might appear a minor word change, precise indicates that the coding and definition are provided, and sites implement the measures as consistently as possible. Otherwise, there is potential for vagueness when implementing the measures specifications and unreliable comparisons. The 2nd, 4th and 5th bullets are also duplicative and could be combined. Therefore, we recommend that the principles are altered to state the following, measure should:

- Be precisely specified at the appropriate level of attribution and level of comparisons considering pharmacy type.
- Be demonstrated to be reliable and valid and assessed for potential unintended consequences at the appropriate level of attribution.
- Be established prior to the measurement period.

Measure Weights

The AMA supports CMS' proposal to increase the weight of the patient experience and access measures in the Medicare Advantage and Part D Star Ratings programs. The AMA has repeatedly highlighted to CMS the need for the Star Ratings program to focus more on compliance and communication, as opposed to the current focus that relies on physician action. In order for health plans to increase their Healthcare

Effectiveness Data and Information Set (HEDIS) scores and earn greater incentives from CMS, plans are requiring practices, as part of their clinical data submission requirements, to submit data on all patient lab results and tests and the plans state it is due to the Star Ratings HEDIS 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—and therefore physicians and facilities have the data. In addition, the patient experience ratings are heavily based on Health-Plan, Consumer Assessment of Healthcare Providers & Systems (CAHPS) that emphasizes physician communication and behavior. While communication between a physician and patient is important, asking the questions in a de-identified survey does not lead to quality improvement or address potential challenges patients experience when seeking care. Similar questions are also in the hospital and clinician-group CAHPS survey and the more appropriate avenues for addressing provider communication in the context of patient experience. 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 and high-quality MA or drug plan. Therefore, to further improve the information CMS receives about patients experience with their plans, we encourage CMS to work with AHRQ to update the Health Plan CAHPS survey. The last update to the health plan survey was May 2012 and the private insurance market has significantly changed in the last eight years.

Increasingly common in private insurance markets, including MA, is the utilization of narrow networks. Narrow physician networks create challenges for patients seeking care and pose potential patient protection issues. Specifically, a narrow network might have shortages of specific specialties, and plans may purposefully understaff specialties to avoid attracting enrollees with expensive pre-existing conditions, like cancer and mental illness. Generally, such plans offer enrollees a narrow set of physicians and hospitals in a geographic area in exchange for lower premiums. Although the traditional Medicare program allows seniors to visit any physician or hospital that accepts Medicare patients, access for MA beneficiaries is limited to physicians and hospitals within plan networks. More than one in three MA enrollees are in a narrow physician network, which is defined as participation of less than 30 percent of physicians in the corresponding county. Another 43 percent of enrollees are in medium networks, defined as participation of 30 to 69 percent of physicians within the corresponding county. On average, MA networks include less than half of all physicians in a given county.

Out of the 39 questions included in health plan-CAHPS only four ask about access and in a very broad context:

- In the last 6 months, when you needed care right away, how often did you get care as soon as you needed?
    1. Never
    2. Sometimes
    3. Usually
    4. Always

- In the last 6 months, how often did you get an appointment for a check-up or routine care at a doctor's office or clinic as soon as you needed?
    1. Never
    2. Sometimes

3. Usually
4. Always

- In the last 6 months, how often was it easy to get the care, tests, or treatment you needed?
  1. Never
  2. Sometimes
  3. Usually
  4. Always

- In the last 6 months, how often did you get an appointment to see a specialist as soon as you needed?
  1. Never
  2. Sometimes
  3. Usually
  4. Always

The current survey also does not assess the extent to which physicians in the network are willing and able to see new patients or the extent to which patients want to use the physicians in the network. If most plan members are receiving services only from a subset of physicians in the network, that subset may not represent the "true" network that is available to patients. Therefore, we encourage CMS to work with AHRQ and consider expanding the "Your Health Care in the Last 6 Months" and "Getting Health Care from Specialists" sections of the survey. Preferably, this should include questions assessing whether patients are able to find physicians who accept new patients, including specialists within their insurance network, maintain utilization of physicians who have longitudinally provided them treatment, distance needed to travel to obtain care, the average time required to make an appointment when actively seeking care, ability to obtain care at an in-network hospital and at an in-network hospital where the patient's physician has staffing privileges.

Stability of Networks: There is a need to evaluate patients experience with the stability of insurance network plans. There is currently no way to determine if MA plans tend to have the same physicians in-network each year or if their networks change significantly from year-to-year. Patients need to know whether they are likely to need to keep changing physicians if they choose a particular plan.

Accuracy of provider directories: We recommend AHRQ and CMS to consider expanding the content of the survey to include questions around accuracy of provider directories and ease of accessing the information. MA plans are required to maintain accurate provider directories on a real-time basis, but they are currently only required to submit provider directories to CMS when the plan first begins operations in an area, and then once every three years unless CMS requests a review based on significant terminations of contracts or complaints. Since CMS has begun conducting triennial reviews of directories, it has found significant inaccuracies, which impacts a patient's experience with a health plan and obtaining care.

Finding out whether a patient's physicians are in each plan's network requires navigating each health plan's website, finding the directory, and then successfully searching for appropriate physician information. If a patient receives care from multiple physicians, this requires considerable time and effort. Additionally, there is no mechanism in place for a physician to determine whether they are being accurately reported as in-network by contracted plans, and out-of-network by other plans. It is also difficult for patients to determine which plans will have physicians available nearby if new conditions

arise or their existing condition worsens. The inadequate availability of this important information makes it difficult for patients to effectively compare plans based on the relative size and specialty structure of their networks.

Prior Authorization Metrics

In the 2021 MA and Part D Advance Notice, CMS requested feedback on the addition of metrics regarding MA plans' prior authorization programs in Star Ratings. The AMA strongly supports this concept, as prior authorization negatively impacts both patients and physician practices. In the 2018 AMA Prior Authorization Physician Survey, 91 percent of physicians reported that prior authorization leads to an overall negative impact on patient clinical outcomes, and 28 percent indicated that prior authorization has led to a serious adverse event for a patient in their care. Practices report completing an average of 31 prior authorizations per physician per week, a workload that consumes nearly two business days a week of physician and staff time.

CMS should consider inclusion of the following prior authorization metrics in MA plan Star Ratings:

- Processing time: MA plans should be required to report the average elapsed time from the receipt of all necessary supporting documentation until communication of the prior authorization decision. In the AMA survey, 91 percent of physicians reported that prior authorization can delay necessary patient care. These care delays, along with the patient harms cited above, support the need for data reporting regarding MA plans' prior authorization processing times.
- Approval/denial rates: In the AMA's survey, an overwhelming majority (88 percent) of physicians reported that prior authorization burdens have increased over the past five years. Given CMS' strong interest in reducing administrative burdens, we recommend that MA plans required to (1) report approval/denial rates for all services subject to prior authorization and (2) eliminate requirements for any services with high average approval rates (e.g., 90 percent approval threshold). This would reduce burdens for both practices and MA plans, as well as prevent unnecessary care delays.
- Denials overturned on appeal: An Office of the Investigator General report from September 2018 found that MA plans overturned 75 percent of their own prior authorization and claim denials between 2014 and 2016. This high rate of overturned denials is alarming, particularly when one considers that beneficiaries and providers appealed only 1 percent of initial denials. We strongly urge CMS to include overturned prior authorization denials in MA plan Star Ratings, as we believe that this data may uncover problems with MA beneficiaries accessing medically necessary care.

Improving the prior authorization process for patients and physicians is a priority for the AMA. We welcome the opportunity to further discuss other potential prior authorization metrics to include in MA plan Star Ratings.

Impact of COVID-19 on Star Ratings and Data Requests to Support MA Risk Adjustment Scores

Given the strain the unprecedented COVID-19 pandemic is placing on the health care system, we recommend CMS suspend weighing the Effectiveness of Care Measures based on 2020 data given the amount of clinical information required of plans to collect from practices, and immediately send out an advisory notice to plans informing them of this suspension, as well as recommend in the guidance that

they suspend collecting the information from doctors. This reprieve will free up practices time and resources.

In addition, 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. Plans generally provide no compensation for staff time required to pull records and make copies. Physicians frequently complain 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. Although having more complex patients involves more physician work, physicians do not receive any additional compensation from MA plans that have higher risk adjustment scores. Instead, those practices that are able to help plans increase their scores are likely to face repeated demands for risk information in the future, adding to their regulatory burdens.

Network Adequacy and Telehealth

The AMA is pleased to see the Administration seeking comment to strengthen network adequacy rules for MA plans and welcomes this opportunity to provide comment. Our AMA strongly supports the use of telemedicine services for patients, and we agree that telemedicine can be used to meet patients' needs in areas with gaps in provider access. Moreover, we appreciate that the proposed rule acknowledges concerns previously expressed by the AMA and other physician organizations that CMS should not allow MA plans to replace in-person health care delivery with telehealth services. Based on these concerns, CMS emphasizes the importance of MA plans maintaining an in-person network. The AMA agrees and supports CMS in abstaining from proposing any changes to how it currently calculates minimum requirements in each specialty.

Additionally, we believe that lowering the provider counts for MA plans that employ in-network telehealth providers does not assess the extent to which these physicians in an MA network are willing and able to accept new patients, or the extent to which patients want to use the physicians in the network. If most plan members are receiving services only from a subset of physicians in the network, that subset may not represent the "true" network that is available to patients. In addition, current adequacy standards are established separately for each specialty and there is no requirement that physicians who work together must all be included. Accordingly, we suggest that CMS take the following actions to ensure that network adequacy standards provide adequate access for beneficiaries and support coordinated care delivery by:

- Requiring plans to report the percentage of physicians in the network, broken down by specialty and subspecialty, who actually provided services to plan members during the prior year;
- Publishing the research supporting the adequacy of the ratios and distance requirements CMS currently uses to determine network adequacy;
- Conducting a study of the extent to which networks maintain or disrupt teams of physicians and hospitals that work together; and
- Evaluating alternative/additional measures of adequacy.

The rapid deployment of telehealth services by physicians in response to the COVID-19 pandemic is significantly changing the practice of medicine in ways that are likely to last long after the pandemic. Many patients are now having office visits with their regular physicians via telehealth. The AMA strongly encourages MA plans to cover telehealth visits and other services, at a minimum for those on the Medicare telehealth list, with their physicians. The AMA is aware that some plans contract with telehealth providers and encourage their enrollees to use these other services instead of covering telehealth services provided by the patients' regular physicians. Patient advocates have made it very clear that what is most important to patients is for all members of the patient's health care team to be involved in, and adhere to, the patient's treatment plan. This continuity of care will not be possible if patients are directed to separately contracted telehealth providers even when the patients' regular physicians are able to provide the services via telehealth themselves.

As telehealth services become more commonly utilized in patient care, the AMA recommends that CMS consider allowing patient conditions and symptoms documented during telehealth visits to be incorporated into MA plan risk scores. Diagnoses that are recorded when patients may be too sick or infectious to come to the physician's office in-person should not be omitted from the HCC system.

As telehealth services are expanded to aid remote diagnosis, treatment, and monitoring of patients during the COVID-19 pandemic, monitoring devices may be required for physicians to adequately provide these services to their patients. The AMA recommends that MA plans consider covering the provision of validated devices, including self-measured blood pressure devices, particularly as hypertension is an underlying risk factor for exacerbated COVID-19 adverse outcomes.

We thank you for the opportunity to provide input on the proposed 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 202-789-7409 or margaret.garikes@ama-assn.org.

Sincerely,

James L. Madara, MD