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Marilyn B. Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2014 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies, and 2014 Call Letter

Dear Acting Administrator Tavenner:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments on the *Advance Notice of Methodological Changes for Calendar Year 2014 for MA Capitation Rates, Part C and Part D Payment Policies and 2014 Call Letter*. The AMA continues to generally support CMS efforts to refine the policies governing Medicare Advantage (MA) and Medicare prescription drug plan (Part D) sponsors; however, we are concerned about the short window of opportunity for public comments on the wide range of policies discussed in the annual Call Letter. We applaud a number of provisions that would strengthen beneficiary protections, but we also outline several concerns with the draft Call Letter guidance and urge CMS to reconsider and modify it consistent with our recommendations.

As a threshold matter, the AMA strongly supports the necessary refinements that CMS has proposed to the risk adjustment methodology. It is appropriate for the agency to improve the accuracy with which the agency pays plan sponsors based on the patient population served.

Expansion of Part D Policy on Utilization Review Controls

Last year, the AMA provided comments on CMS' initial proposal to require plan sponsors to expand use of utilization review controls to all drugs. We urged CMS to instead tailor its guidance to the concerns raised in the cited September 2011 Government Accountability Office (GAO) report that the authors identified as instances of questionable access to drugs as a result of patterns that suggested doctor shopping. The report noted that 80 percent of the instances of potential doctor shopping involved hydrocodone and oxycodone. As a result, the final CMS guidance requires plan sponsors to tailor the utilization review controls to address these two highly diverted and abused drugs. We generally concurred with this approach as it is supported by widespread reports, studies, and statistical reviews that document a national epidemic of opioid prescription drug diversion and abuse.

CMS' current proposal to expand the utilization review controls beyond hydrocodone and oxycodone renews the many concerns we raised about last year's draft Call Letter.

We were gratified that CMS accepted our previous comments on limiting utilization review controls to prescription opioids, as well as our subsequent comments on the methodology for conducting the utilization review. In the current draft Call Letter, CMS has not provided adequate information or notice to justify the expansion of this tool to other drugs or classes of drugs. **We strongly oppose the inclusion of any additional drugs or classes of drugs to mandated utilization review controls. At a minimum, before such expansion is considered, CMS needs to identify each drug or class of drugs, the evidence documenting concerns that outweigh obstacles to access this would create for vulnerable beneficiaries, and the methods and targets for identifying overutilization that would be applied.** After the foregoing steps, we urge CMS to then solicit feedback and comment from a broad cross-section of stakeholders, including those who represent patients, physicians, and other health care providers. As we have stressed, barriers to treatment disproportionately burden the elderly and those who are medically fragile. Furthermore, we oppose regulatory and insurance practices that undermine the clinical judgment of treating physicians who understand the risks and benefits of a course of treatment to their patient, as well as their patient's preferences, better than can be surmised by third party, often a non-physician based on population-level averages and conclusions that do not account for individual patient needs.

Medication Therapy Management (MTM)

The AMA strongly supports efforts to provide beneficiaries with services that improve patient care coordination and enhance communication among a patient's physician(s) and other health care providers. To that end, the AMA supports MTM programs where pharmacists communicate with the prescriber (as well as the supervising or collaborating physician if the prescriber is not a physician).

Physician training focuses on assessing, diagnosing, and managing the full range of patients' medication and other health and medical needs. Pharmacist training focuses on assessing, monitoring, and helping manage patients' medication therapies using an evidence-based approach to care. When physicians and pharmacists decide to work together for purposes of MTM, they do so in order to complement one another's unique roles. For example, the well-known Asheville Project has demonstrated the positive effects of physician-pharmacist collaborative relationships on improving patients' diabetes outcomes. Multiple studies, furthermore, demonstrate the benefits of pharmacists in improving patients' pharmacotherapy outcomes in the hospital, outpatient, and other settings. Pharmacists' pharmacotherapy training combined with the extensive diagnostic and management training of physicians can lead to effective collaborative pharmacotherapy decision-making that improves patients' medication-related outcomes. Effective and appropriate MTM arrangements allow physicians and pharmacists to make the most of their respective education and training for patients' best interests—the primary concern of the AMA. That said, physicians remain responsible for overseeing the care of their patients, and must see to it that they receive the highest quality of care from ancillary providers. To provide comprehensive MTM, the pharmacist must coordinate with physicians who prescribe medications for the patient, especially if the pharmacist recommends changes to the patient's medication therapies. Failure to do so may result in danger to the patient, piecemeal care and further fragmentation of health care.

We are concerned that CMS has indicated that plan sponsors are simply urged to encourage beneficiaries to provide the MTM standardized medication action plan and personal medication list from their comprehensive medication review (CMR) to any medical encounter that they have with a physician or other health care provider. We urge CMS to require that this information be transmitted to the prescribers of the medication (as well as the supervising or collaborating physician if the prescriber is not a physician). A patient's physician should serve as an essential part of the health care team and failing to ensure that a patient's physician receives and has access to this medical information is inconsistent with the overriding purpose of the MTM program to improve care coordination and patient outcomes for all the reasons discussed above.

Similarly, we strongly urge CMS to require plan sponsors and their MTM providers to communicate with a patient's treating physician when the beneficiary is in a long-term care (LTC) setting. We would fully expect significant overlap between the monthly drug regimen reviews (DRR) required in LTC and Part D MTM reviews. We strongly urge CMS to mandate that plan sponsors ensure MTM providers confer with a patient's treating physician(s) when undertaking the CMR and development of the standardized medication action plan. We agree that plans should avoid conflicting recommendations and urge CMS to mandate that the MTM provider must coordinate the recommendations for drug therapy changes as a result of a MTM encounter with the beneficiaries' health care team.

Other issues that should be addressed include the potential for conflict of interest when a pharmacist both initiates and dispenses a pharmaceutical product, and patient privacy issues with regard to obtaining histories and sensitive medical information in a public/community retail setting.

Formulary and Beers Criteria

The Beers Criteria is a useful resource for physicians in making prescribing decisions. However, **it is not appropriate to use the Beers Criteria in a prescription drug plan coverage decision, nor is it appropriate to make formulary changes that involve restriction of certain medications based on the Beers Criteria**. The Beers Criteria may serve as an important tool in a physician's clinical practice and serves as an educational tool for physicians and other clinicians to inform their prescribing practices and help monitor prescription drug use in older patients. However, it is imperative that these types of lists and/or criteria not be used by insurers, benefit managers, and other payors to make coverage determinations or penalize physicians that prescribe outside the criteria when appropriate. These types of coverage and reimbursement restrictions are contrary to the goals of the American Geriatrics Society (AGS) Panel that recently revised the Beers Criteria. The AGS Panel clearly states that "the list is not meant to supersede clinical judgment or an individual patient's values and needs." Just as the criteria should not dictate prescribing, they should not be the sole basis for formulary decisions, nor should they be used in any punitive manner.

Physicians who care for aging patients will agree that there are times when a drug on the Beers Criteria is the only reasonable option for a patient. A commonly cited example of appropriate deviation from the Beers Criteria is when a patient is being provided end-of-life or palliative care, and the benefits of providing an identified drug to an older patient may outweigh the risks associated with prescribing it. In such a situation, the drug should be made available to the patient and the physician should not be penalized or inappropriately burdened for prescribing it.

As the practice of medicine and the provision of health care services rely more and more on the use of clinical guidelines, we encourage physicians to use every tool and resource available to them to make informed and clinically sound recommendations to patients. However, as AMA policy conveys, even evidence-based guidelines, such as the Beers Criteria, can never substitute for the individual physician's clinical judgment. Therefore, the guidance provided by CMS should ensure that physicians retain the discretion to prescribe drugs on the list when a physician believes it is appropriate.

Language Requirements

The AMA has received complaints from the Medical Society of the State of New York regarding an MA plan that limits its network to only physicians who can fluently speak Chinese, Korean, or Spanish in addition to English. We are concerned that this stringent limitation is placing undue restrictions on choice and access to care for patients enrolled in the plan. Physicians can accommodate the needs of patients with limited English proficiency through a variety of language access services, such as interpreters. Limiting a plan's physician network to only those who are fluent in one of three second languages may deny patients ready access to a number of specialists and subspecialists that are already in scarce supply, with even more severe limitations on the number that fluently speak a language besides English. The AMA encourages CMS to give serious consideration to the concerns that have been raised about these network limitations.

Grievances & Appeals

We continue to have concerns that all MA and Part D plan sponsors have not established accessible and reasonable means for patients and physicians (who often serve as a patient's advocate) to challenge denials and decisions that are adverse to patient health outcomes. There is an uneven playing field with regard to information between plan sponsors and beneficiaries/physicians in the grievance and appeals process. This leaves beneficiaries and physicians at a disadvantage and undermines their ability to effectively advocate for appropriate and medically necessary care. If plans are able to force beneficiaries and physicians through a lengthy appeals and/or grievance process where the latter have limited access to essential information, beneficiaries may acquiesce to the plan's decision and/or suffer adverse health consequences and/or incur significant costs in order to secure appropriate care. In light of the foregoing, we support the agency's efforts to facilitate beneficiary access to their personal health information by requiring plans to implement the Blue Button Initiative.

More significant reforms of the appeals and grievance process are needed as these decisions are typically directly contrary to a treating physician's determination of appropriateness and medical necessity. The consequences of these denials will typically have an immediate or long-lasting adverse impact on patient health outcomes. We urge CMS to require plan sponsors to:

- Add the Blue Button icon and functionality to existing or new plan portals or websites, thereby providing beneficiaries with one-click secure access to download and/or print their health information.

- Provide access on their marketing and other publicly branded websites to information on the plan's grievance and appeals process, contacts (including phone number and email contacts), and a method to submit online appeals and grievances.

- Require and provide information on initiating an appeal or grievance by mail, by electronic mail, by facsimile, by a web portal interface, or by telephone.

- Notify beneficiaries upon denial of requested treatment, placement, or service that the beneficiary may utilize the grievance or appeal process and/or contact a state ombudsman and/or the relevant regional CMS office contact providing oversight to the MA plan sponsor.

- Provide beneficiaries with an interactive secure online portal or phone query system to submit complaints and documentation as well as to track the status of their grievance and/or appeal.

Finally, we support CMS' requirement that Part D plan sponsors must have real-time access to critical systems and the decision that CMS may issue a serious compliance action against the Part D plan sponsors if they do not have real-time access to information involving appeals and grievances. We urge CMS to include similar provisions in the guidance materials for MA plan sponsors. Furthermore, we urge CMS to undertake an assessment of the grievance and appeals process offered by plans including assessing why beneficiaries withdraw or decline to continue participating in the appeals or grievance process.

Prior Authorization

The AMA strongly supports CMS' decision to reinforce the obligation that plans have to comply with existing CMS guidance on acceptable uses of prior authorization. As we have noted above, barriers to accessing medically necessary care are often insurmountable to overcome for medically fragile beneficiaries and their often overtaxed caregivers. Beneficiaries may face financial, physical, and cognitive barriers that impact their ability to obtain appropriate and medically necessary care and we urge CMS to continue to exercise concerted oversight of plan practices that adversely impact on patient outcomes. We strongly support the following reminders to plans that CMS prohibits:

- Requirements that are more restrictive than CMS-approved prior authorization criteria.

- Limited Access or Step Therapy restrictions not consistent with the CMS-approved formulary.

- Quantity Limits (QL) that are inconsistent with maximum doses from Food and Drug Administration approved labeling or not consistent with the CMS-approved formulary.

- Prior Authorization criteria not submitted for Health Plan Management System (HPMS) approved formulary medications.

- Steering of physicians or beneficiaries to a sponsor's and/or pharmacy benefit manager's (PBM) own mail order pharmacy.

- Steering of physicians or beneficiaries to a sponsor's and/or PBM's own specialty pharmacy for drugs which are not Limited Access eligible.

Drug Class Quantity Limits

We oppose CMS' proposal to reject a valid prescription at point-of-sale (POS) based on QL related to daily morphine equivalent dose (MED) across the opioid class. CMS acknowledges that claims for quantities below the MED-based QL could be rejected at POS depending upon previously dispensed quantities of other opioids. This is very concerning. CMS states that it is not feasible to collect additional quantity limit information based on all of the various possible combinations of opioids. However, we would note that this places the burden directly on beneficiaries to provide the requisite documentation within a compressed period of time and such a rejection is very likely lead to adverse health consequences for obviously medically fragile patients. We have already discussed the costly burdens associated with the appeals and grievance process. These concerns are amplified when the adverse impact is highly probable, and there is little time to remedy an inappropriate rejection without harmful consequences.

CMS has indicated that it is seeking industry comment regarding the cumulative MED level that could be implemented at POS that would be an effective safety measure, but would not inappropriately restrict access to medically necessary drugs. However, CMS has already acknowledged that the above proposal and method of reporting may not be safe for certain patients at certain times. For example, if a patient has been prescribed an immediate-release opioid analgesic for use as a rescue dose to manage acute exacerbations of cancer pain or other persistent pain conditions in patients who are already receiving a long-acting opioid, the combination for flare ups, it could exceed the previously recognized MED of greater than 120 mg used by CMS for a retrospective drug utilization review (DUR) and case management. However, DUR allows for adequate time to obtain the necessary documentation to assess whether this was an appropriate prescription/dose. In contrast, utilizing a MED level of 120 mg to implement at POS in order to reject claims prospectively poses a number of access challenges and risks to some of the most medically fragile patients. In addition to rescue doses, other common situations where the MED level of 120 mg (or any other threshold established within that ballpark) could be exceeded—when another opioid analgesic drug is prescribed (substituted) in the class because of adverse reaction to another previously prescribed drug or alternatively because of increased tolerance or diminishing clinical response and corresponding need for opioid rotation.

We urge CMS to provide greater explanation as to why the current DUR is not adequate to address concerns in this area. In light of the foregoing, we do not support this method and urge greater stakeholder engagement consistent with prior recommendations.

Risk Adjustment Methodology and Data Validation Audits

The AMA continues to receive regular communications from physicians who are experiencing burdensome document requests from MA sponsors conducting plan-initiated Risk Adjustment Data Validation (RADV) audits. The AMA would like to underscore that there remains a pressing need to standardize the methods utilized by MA plans to conduct plan-initiated RADV audits and establish basic parameters with regard to appropriate notification to physicians of the legal basis of the audit requests, limits on document requests, compensation for record retrieval and reproduction, and limits on the number of times a physician or practice is subject to such audits. Currently, MA sponsors fail to adequately communicate that these plan-initiated audits are not CMS mandated RADV audits. As a result, physicians are led to believe that CMS has initiated labor intensive and costly audits, when

the audit has been initiated by the plan to improve its risk-adjustment. We continue to receive reports from physicians who receive requests covering a large number of their patients/beneficiaries and voluminous record requests. Physicians are often not compensated for staff time or record reproduction costs. The foregoing imposes uncompensated costs on physician practices and detracts from the delivery of direct patient care.

Incremental Fills of Schedule II Controlled Substances Prescriptions

The AMA strongly urges CMS to proceed with caution when assessing plan sponsor compliance with guidance in the context of Part D payment for refills of Schedule II controlled substances prescriptions in light of the limitations in the current HIPAA billing standards. As noted by CMS, the existing billing standards have created the perception that a partial fill is an illegal refill. It is evident that the new regulation, 42 C.F.R. §423.154, requiring dispensing in no greater than 14-day increments to Part D enrollees in LTC facilities will exacerbate this problem. Therefore, it would be inappropriate and contrary to the obligation of plan sponsors to honor requests for partial fills for covered drugs when appropriate and medically necessary to compel the plan sponsor to reject such requests. CMS should ensure that plans have a clear obligation to verify that a request is for a partial fill before rejecting the request as an illegal re-fill. Enforcement of this requirement without ensuring or requiring that plan sponsors verify that an appropriate partial fill has been requested will further hamstring the ability of LTC health care teams to provide essential medical care. It will also place some of the most vulnerable patients in need of pain management at-risk of adverse outcomes. LTC health care teams are already facing significant regulatory challenges and barriers to securing prescriptions for Schedule II controlled substances for their medically vulnerable population as a result of regulatory requirements mandated by the Drug Enforcement Agency (DEA) and enforcement actions taken by the DEA against LTC pharmacies.

Shifting Drug Coverage from Part B to Part D

We continue to have concerns that merely reminding MA plan sponsors that they are not allowed to compel beneficiaries to utilize the beneficiary's Part D benefit to obtain otherwise covered Part B drugs is not sufficient. The AMA has significant concerns with the practice of indirect, unsupervised acquisition, handling, preparation, and disposal of pharmaceuticals administered by physician practices as this presents significant safety risks to patients. We urge CMS to discourage this practice and require plans to demonstrate that patient outcomes are not harmed when patients elect to obtain the otherwise covered by Part B drug is obtained under the Part D benefit. We urge the agency to provide heightened oversight over patterns that suggest that a MA plan sponsor exhibits a pattern and practice based on beneficiary claims data that indicates MA plan sponsors are engaged in this practice.

Total Beneficiary Cost (TBC)

The AMA also strongly supports the proposal to reduce the TBC and supports the agency's stated intention to continue to monitor changes from one year to the next in order to limit excessive increases in the TBC. We agree that it is essential that CMS is able to ensure that beneficiaries who continue enrollment in the same plan are not exposed to significant cost increases. We are aware of one significant example where plan sponsors eliminated coverage of the plan cost sharing for chemotherapy drugs without sufficient notice to beneficiaries who were unaware of the significant

out-of-pocket liability they faced. These changes have a significant potential for a direct and significant impact on patient access and outcomes. We applaud the agency's careful and ongoing evaluation of these plan changes.

We appreciate the opportunity to provide comments on the proposed Payment Policies and Call Letter. We welcome the opportunity to convene a group of interested stakeholders representing physicians and beneficiaries to address the items we have noted that warrant greater input and consideration from a broad and diverse spectrum of stakeholders. The AMA remains committed to promoting improved patient outcomes and addressing the many regulatory and paperwork burdens that serve as barriers to beneficiaries and detract from the provisions of clinical care to patients.

Sincerely,

James L. Madara, MD