

March 4, 2016

Sean Cavanaugh
Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Advance Notice of 2017 Methodological Changes for Medicare Advantage Capitation Rates, Part C and D Payment Policies and 2017 Draft Call Letter

Dear Deputy Administrator Cavanaugh:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to offer comments to the Centers for Medicare & Medicaid Services (CMS) on the 2017 draft Call Letter. Our comments focus on the Part D prescription drug benefit program.

Removal of Measures from Star Ratings: High Risk Medication

The AMA strongly supports and urges CMS to finalize its proposal to remove the high risk medication measure for Part D plans. High risk medication calculations are based on recommendations developed by the American Geriatrics Society known as the Beers Criteria. The 2017 draft Call Letter notes correctly that placement of a medication on the high risk list is not a contraindication to its use, but rather an encouragement for prescribing decisions to consider risks and benefits for the senior population based on individual patient characteristics.

Physicians that care for aging patients 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 a drug to an older patient outweigh the risks associated with prescribing it. In such a situation, the drug should be made available to the patient and neither the physician nor the Part D plan should 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 provides, even evidence-based guidelines such as the Beers Criteria cannot substitute for physicians' clinical judgment.

Improving Clinical Decision-Making for Certain Part D Coverage Determinations

The AMA appreciates the concerns outlined in the draft Call Letter that patients' access to drugs may be delayed due to difficulties obtaining information from prescribing physicians regarding drugs subject to

prior authorization or step therapy requirements. These delays can in turn lead to a denial of coverage because of the plan's inability to satisfy the drug utilization management (DUM) requirements within the window of time set by regulation. The answer, however, is not to extend the timeframe for adjudication of the coverage determination, but rather to accept the prescribing clinician's judgment at the time that the prescription is initially written that the medication is needed for the patient.

Prior authorization and step therapy requirements do nothing to improve the quality of patient care; they only impose unnecessary administrative burdens on prescribers and unjustified access delays on patients. If Part D plans are not able to obtain the information they require to approve coverage before the adjudication timeframe expires, then they should take that as a signal that they are overburdening medical practices with too many DUM requirements and should make an effort to lessen the number of drugs subject to these DUM requirements. Patients are enrolled in an enormous number of different Part D plans, each with their own formularies and DUM requirements. Physicians receive no compensation for the many hours of frustrating administrative time they spend trying to overcome the hurdles that plans have placed in front of their patients' rapid access to their medications. At a minimum, plans should be directed to provide patients' physicians with the benefit of the doubt and issue a partial fill for the medication until they are able to receive the information they say they need for a coverage determination.

Opioids

The draft Call Letter outlines results from the Opioid Overutilization Monitoring System (OMS) showing that the number of Part D beneficiaries identified as potential opioid overutilizers has fallen by nearly half over the past four years. The program is clearly having beneficial results. The AMA appreciates CMS allowing us to provide input into the OMS and for its continued reliance on discussions with patients' prescribing physicians to guide determinations of medical necessity and plan actions to address identified problems.

Some concern is expressed in the draft Call Letter regarding the high rate of responses to potential opioid overutilization indicating that the beneficiary did not meet the sponsor's internal criteria. CMS proposes to address this issue by shortening the measurement period from 12 to 6 months and relying on average morphine equivalent dose (MED) instead of cumulative daily dose. The AMA supports this change.

The AMA also supports the changes being contemplated in the way prescribers are counted in the opioid overutilization criteria in order to avoid false positives. Methods that may have counted prescribers who have multiple offices as being two different prescribers, for example, would be problematic.

Instead of sticking with its current successful approach, for 2017 CMS proposes to have Part D plans implement soft and hard point-of-sale edits tied to daily MED of opioid analgesics. As we have stated in previous comment letters, the AMA strongly opposes this new approach. Although patients with cancer and those who have elected hospice care would be excluded, there are other conditions that can cause severe pain for which patients may be prescribed a rescue dose for flare ups that would cause them to exceed the MED limits. An additional drug in the opioid class also may be prescribed because of an adverse reaction to a previously prescribed drug, or due to increased tolerance and corresponding need for opioid rotation. In addition, any MED calculation would require the use of a conversion calculator among different products. These calculators are based on very limited science in largely opioid naive individuals, and are even less reliable when a patient is opioid tolerant, when switching between different opioid medications, or going from intravenous to oral routes of administration.

A conversation with the patient's prescriber would allow the plan to learn whether or not the dose was appropriate for the patient. In the absence of an accepted standard, point-of-sale edits tied to MED would essentially be arbitrary and could leave medically fragile patients without access to critically important medications. The AMA has worked closely with the National Association of Boards of Pharmacy and other key stakeholders to examine scenarios involving the prescribing and dispensing of controlled substances that indicate a need for greater communication between physicians and pharmacists. Prescription drug plan edits are more likely to hurt than help physician-pharmacist collaboration.

Finally, the AMA is concerned that CMS is requesting comments from plan sponsors on its proposed parameters for formulary-level edits based on MED, including "alternative thresholds, criteria to reduce false positives, and methods to assure prompt access to prescribed opioids when determined medically necessary," and yet the agency proposes to have the plans implement the edits on January 1, 2017. **It is entirely premature to implement such edits in 2017 without clear information on how prompt access to medically necessary pain relief can be assured.**

With respect to concomitant opioid and buprenorphine (for addiction use), there is some literature on pain management in individuals who are receiving office-based treatment with buprenorphine, which suggests this would usually occur in the context of an acute pain episode or hospitalization.

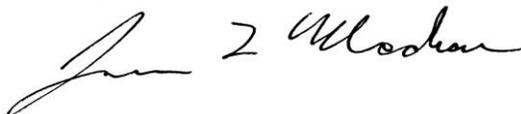
Access to Medication-Assisted Treatment

The AMA has been working in partnership with the Administration to address the nation's opioid epidemic and reduce overdose deaths. A critical component of this effort is increasing access and reducing barriers to comprehensive treatment for opioid use disorder, including medication-assisted treatment. The AMA strongly supports the draft Call Letter's statement that Part D plans should not impose prior authorization requirements or other DUM that could create unnecessary hurdles for patients who need these services.

Methadone is an important component of a comprehensive treatment plan for many patients, particularly in earlier stages of a treatment program. The lack of Part D coverage for outpatient treatment with methadone is a barrier to treatment. Other health insurance coverage does not have this particular barrier, and it should be eliminated in the Medicare program.

We appreciate this opportunity to share the views of the AMA regarding the Part D program and thank you for considering our comments. If you have any questions concerning these comments, please feel free to contact Sandy Marks, Assistant Director for Federal Affairs at sandy.marks@ama-assn.org or 202-789-4585.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, with a large initial "J" and "M".

James L. Madara, MD