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February 9, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: Electronic Clinical Quality Measure (eCQM) Development and Maintenance for Eligible Professionals (EP eCQM) Potential Opioid Overuse-Contract Number HHSM-500-2013-13011I/HHSM-500-T0001

Dear Administrator Verma:

The American Medical Association (AMA) is writing in response to the Centers for Medicare & Medicaid Services (CMS) request for comment on a new electronic quality measure (eCQM) focused on the degree of potential opioid overuse. CMS has contracted with Mathematica Policy Research on the following measure: *potential opioid overuse, percentage of patients aged 18 years or older who receive opioid therapy for 90 days or longer and who are prescribed a 90 milligram or greater morphine milligram equivalent (MME) daily dose*. The AMA is actively working to reverse the opioid epidemic, particularly through the activities of the AMA Opioid Task Force, which was formed in 2014 and includes 26 national medical specialty and state medical associations, the American Osteopathic Association, and the American Dental Association. Performance measurement may be one avenue by which we can track progress and make improvements to reduce the opioid epidemic. The AMA supports every effort underway to meet this need.

The AMA does not agree with the fundamental premise of this measure that daily dose and duration of therapy involving prescription opioid analgesics can serve on its own as a measure of quality patient care. Instead, quality measurement needs to focus on how well patients' pain is controlled, whether functional improvement goals are met, and what therapies are being used to manage pain. If pain can be well-controlled and function improved without the need of high doses of opioids over a long period of time, that is an indication of good patient care; but a reduction in opioid dose alone is not an appropriate goal. In fact, since the Centers for Disease Control & Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain was issued, there have been many reports of patients who have been successfully managed on opioid analgesics for long periods of time but forced to abruptly reduce or discontinue their medication regimens with sometimes extremely adverse outcomes, including depression, loss of function, and even suicide.

Identifying those patients for whom opioid prescriptions exceed \Rightarrow 90 morphine milligram equivalents (MME)/day may serve as an indicator of whether a patient is at risk of overdose and should be co-prescribed naloxone, but the AMA believes that significant revisions and testing are required prior to implementing this measure in any federal program. The measure as constructed implies that patients who do not receive \Rightarrow 90 MME/day over a 90-day period receive higher quality care. We do not believe that the measure, with its broad denominator population and limited exclusions, adequately captures the recommendations from the CDC.¹ The recommendations allow for physicians to document a clinical rationale or justification when 90 MME/day is exceeded; yet, the measure does not capture if a justification exists nor does it provide a well-defined and targeted denominator.

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

Clinical decision making should be based on a relationship between the clinician and patient, and an understanding of the patient's clinical situation, functioning, and life context. The recommendations in the guideline are voluntary, rather than prescriptive standards. They are based on emerging evidence, including observational studies or randomized clinical trials with notable limitations. Clinicians should consider the circumstances and unique needs of each patient when providing care.

In addition, the unintended consequences of this measure must be clearly analyzed prior to moving forward. Specifically, if the measure does not adequately define the patients for whom higher doses of opioids may be appropriate, the measure may provide invalid representations of physician performance. There is also a risk that physicians reduce opioid prescriptions in order to score well on this measure and leave patients without access to appropriate therapy.

Information on how the measure performed when tested must be released publicly in order for physicians and others to adequately evaluate this measure. For example, it is critical that the measure have been tested in different patient populations and medical specialties to understand whether differences in performance scores are due to the complexity of patient population treated across various specialties. This testing would then allow CMS to identify what additional refinements are needed to reflect evidence-based care, whether the measure is appropriate for all patients receiving opioids for 90-days or longer, and if it should be applied to all medical specialties. The results may also confirm that the measure as defined is not appropriate for quality improvement and/or accountability purposes.

¹ Centers for Disease Control & Prevention. Guideline for Prescribing Opioids for Chronic Pain. 2016. Available at: <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>. Accessed January 23, 2018.

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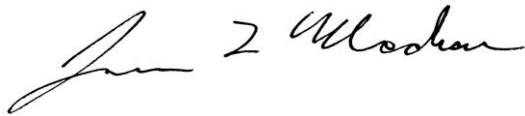
Alternative measures or ones that provide complementary information on the quality of care should also be explored, such as the proportion of patients with acute or chronic pain whose pain was well controlled and/or functioning improved without needing > 90 MME opioids for > 90 days.

We are also concerned with the feasibility of directly calculating the measure from the electronic health record (EHR). The eCQM is reliant on a function that is not consistently supported by EHR vendors, and participation with the measure would require additional costs or vendor fees placed on the physician. It is our understanding that the EHR does not uniformly capture MMEs and this calculation would be necessary to populate the measure's numerator. There are also Internet, iOS and Android-based apps that perform this functionality, but in order to implement, the physician would need to manually enter patient information and calculate the MME. This would introduce the possibility for human error. In addition, terminology and code mappings play a big role in how well an EHR-based calculator works, but due to the lack of consistency and standardized code mappings the results produced are not very reliable.

In addition, it is not clear that a large number of physicians are: (1) able to electronically prescribe controlled substances (EPCS) and; (2) have seamless integration between their EPCS systems and their EHR systems. This could present additional problems in capturing the needed eCQM information.

We request that CMS significantly revise the measure, and we welcome the opportunity to work with CMS on the revisions to the measure. Thank you for the opportunity to comment. If you have any questions regarding this letter, please contact Koryn Rubin, Assistant Director, Federal Affairs, at koryn.rubin@ama-assn.org or 202-789-7408.

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