

March 5, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8013
Baltimore, MD 21244-8013

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter

Dear Administrator Verma:

On behalf of more than 37,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to comment on the CY 2019 Advanced Notice and draft Call Letter for the Medicare Advantage program and the Part D Prescription Drug Benefit Program.

As CMS proposes methodological changes for these programs for CY 2019, we offer the following comments.

Drug Utilization Review Controls in Medicare Part D

ACEP appreciates the urgency of addressing our nation's growing opioid crisis, as our members see its impact every day as they work in emergency departments on the front lines of this epidemic all across the country. We support the effort to institute policies that align with evidence-based guidelines, which will provide flexibility to allow for appropriate clinical judgement and to account for the unique nature of care that is provided in emergency departments.

Cumulative Morphine Milligram Equivalent Daily Dose (MME) Safety Edits for High, Chronic Prescription Opioid Users

CMS is proposing to require plan sponsors to implement hard formulary-level cumulative opioid safety edits at the point-of-sale at the pharmacy (which can only be overridden by the sponsor) at a dosage level of 90 Cumulative Morphine Milligram Equivalent Daily Dose (MME) per day, with a 7-day supply allowance. CMS states that edits "are not intended as a means to implement a prescribing limit or apply additional clinical criteria for the use of opioids, but instead to give physicians important additional information about their patients' opioid use." CMS also outlines

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an expedited coverage determination process which relies on an attestation from the prescribing physician that a higher MME is medically necessary.

While ACEP appreciates that the edits are not intended to place a prescribing limit for physicians and that patients and prescribers have an opportunity to request an expedited coverage determination, the unique nature of care in the emergency department can make these edits a major barrier and burden for some patients to receive pain medication that is prescribed by an emergency physician. Emergency physicians operate in shifts, and therefore it may be logistically challenging for a patient or pharmacist to immediately reach out to the physician who treated the patient. We therefore recommend that CMS consider creating a more flexible policy for opioids prescribed by emergency physicians in emergency departments in order to account for situations when a pharmacy or sponsor is unable to reach the emergency physician who ordered the prescription. We understand that it might be difficult for a pharmacy to know where the prescription originated from based on the claim, and we would like to work with CMS to help operationalize this type of policy.

ACEP also seeks clarification on whether this hard edit applies to opioid prescriptions that treat both chronic and acute pain. CMS states that the 90 MME threshold “aligns with the CDC Guideline, which recommends to generally avoid increasing the daily dosage of opioids to 90 MME.” However, the CDC recommendation related to the 90 MME threshold in the Guideline¹ is in reference to chronic pain only. The Guideline contains a separate recommendation (#6) for prescribing opioids for acute pain, which only discusses a day supply limit and does not address a particular dosage threshold. Since CMS has a separate proposal related to the treatment of acute pain (discussed below), it is unclear whether this hard edit must be used only for patients with chronic pain or for patients with acute pain as well.

Days Supply Limits for Opioid Naïve Patients

CMS expects plan sponsors to implement a hard safety edit for initial opioid prescription fills that exceed 7 days for the treatment of acute pain. CMS does not want to compromise appropriate pain management or add any burden on clinicians and their patients. CMS is seeking comment on the 7-day supply limit and whether an alternative would be more appropriate (such as 3 days or 5 days). CMS also requests comments on both inclusions and exceptions for specific clinical situations.

As stated previously, ACEP believes that hard safety edits impose a burden and potential access barrier on patients who receive prescriptions from emergency physicians in the emergency department. We would like to work with CMS on a more flexible policy that helps balance the need to monitor new opioid prescriptions while at the same time not compromising the ability for emergency physicians to provide appropriate pain management treatment to their patients. Evidence shows that emergency physicians are responsible for only a small portion of opioid prescriptions, and were declining even before national attention began to increase on the opioid epidemic. A recent study² showed that between 1996 and 2012, the share of prescription opioids originating from emergency departments declined from 7 percent to 4

¹ Dowell D, Haegerich TM, Chou R. “CDC Guideline for Prescribing Opioids for Chronic Pain” United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: <http://dx.doi.org/10.15585/mmwr.rr6501e1>

² “Emergency Department Contribution to the Prescription Opioid Epidemic.” Axeen, Sarah et al. *Annals of Emergency Medicine*; Available at [http://www.annemergmed.com/article/S0196-0644\(17\)31969-8/fulltext](http://www.annemergmed.com/article/S0196-0644(17)31969-8/fulltext)

percent. Similarly, another study found that between 2007 and 2012, the greatest percentage drop in opioid-prescribing rates across specialties occurred in emergency medicine (−8.9%).³

We also strongly believe that CMS should not finalize a supply limit that is less than 7 days. There are many cases where a prescription is ordered by an emergency physician on a Friday before a holiday weekend, and the patient is unable to obtain follow-up care with an appropriate specialist until the following week. For example, if a patient is seen in the Emergency Department for a limb fracture at the beginning of a holiday weekend, it could easily be up to five days until the patient is able to get in to see an orthopedist who can stabilize and fully set the fracture, and, if needed and appropriate, provide a prescription for additional opioids. While 7 days is generally an acceptable limit, we also note that in some extreme situations, such as natural disasters, a 7-day supply may be insufficient. ACEP recommends that CMS consider allowing a longer supply limit in certain exceptional circumstances.

Access to Medication-Assisted Treatment

ACEP strongly supports CMS' proposal to work with plan sponsors to ensure that Medicare beneficiaries have appropriate access to medication-assisted treatment (MAT). CMS should continue to encourage plans to establish benefit designs that would allow beneficiaries to have full access to these therapies.

Voluntary and Mandatory Maximum out-of-pocket (MOOP) Amounts for Emergency Care/Post Stabilization Care

CMS is proposing to increase the Emergency Care/Post Stabilization Care limit in CY 2019 to “better align cost sharing with actual costs and as an incentive to use primary and specialty care services for routine care and avoid using the emergency room for non-emergent routine services.” The voluntary Maximum out-of-pocket (MOOP) amount would increase from \$100 to \$120, while the mandatory MOOP amount would increase from \$80 to \$90. CMS also increased both the voluntary and mandatory MOOP amounts for Emergency Care/Post Stabilization Care in 2018 (these amounts were both \$75 in 2017). Thus, over a two-year period, CMS would be increasing the voluntary and mandatory MOOP amounts by 60 percent and 20 percent respectively. ACEP believes that CMS is unfairly penalizing Medicare beneficiaries who receive emergency services. Recent studies have shown that only a small percentage of emergency department visits are avoidable.⁴ In many cases, Medicare beneficiaries cannot tell whether their pain is life threatening or not. Regardless of the final diagnosis, if they believe that they are having a medical emergency, they are entitled to go to the emergency department and be treated. Continuing to increase co-payments may have the undesirable outcome of deterring some beneficiaries from going to the emergency department even when they truly need immediate care. Thus, ACEP strongly urges CMS not to finalize the increase in the MOOP amounts and to maintain the 2018 Emergency Care/Post Stabilization Care limits.

Enforcement Actions for Provider Directories

CMS is imposing civil monetary penalties and other enforcement actions on Medicare Advantage Organizations (MAOs) that do not comply with provider directory requirements. A 2017 survey from CMS

³ “Trends in Opioid Analgesic–Prescribing Rates by Specialty, U.S., 2007–2012.” Levy, Benjamin et al. *American Journal of Preventive Medicine*, Volume 49, Issue 3, 409-413; Available at [http://www.ajpmonline.org/article/S0749-3797\(15\)00089-6/ppt](http://www.ajpmonline.org/article/S0749-3797(15)00089-6/ppt)

⁴ “Avoidable Emergency Department Visits: A Starting Point.” *International Journal for Quality in Health Care*, Volume 29, Issue 5, 1 October 2017, Pages 642–645; Available at <https://doi.org/10.1093/intqhc/mzx081>

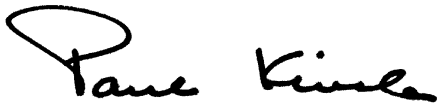
showed that over 45 percent of provider directory locations listed in MAO online directories were inaccurate. ACEP agrees with CMS that inaccurate provider directories can bring into question the adequacy and validity of an MAO network. When individuals enroll in Medicare Advantage plans, they have every right to expect that network adequacy criteria and standards for clinical and institutional providers will be monitored and enforced. Maintaining adequate networks is essential to ensuring that patients have access to the care they need. Therefore, we support CMS' continued effort to improve the accuracy of the provider directories, as well as other initiatives that enforce strong network adequacy requirements.

Medicare Advantage and Part D Prescription Drug Plan Quality Rating System

In the CY 2019 Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program proposed rule, CMS sought comment on whether the agency should include survey measures of physician experiences in setting Star Ratings, noting that physicians also interact with health and drug plans on a daily basis on behalf of their patients. In ACEP's formal comments on the rule⁵, ACEP expressed support for CMS developing a survey tool for collecting standardized information on physicians' experiences with health and drug plans and their services. We note that CMS did not propose in the draft Call Letter to potentially incorporate survey measures related to physician experience into the Star Ratings for 2020 or later, and encourage CMS to continue exploring the development of these measures.

We appreciate the opportunity to share our comments and look forward to continuing working with you and your staff. If you have any questions, please contact Jeffrey Davis, ACEP's Director of Regulatory Affairs at jdavis@acep.org.

Sincerely,



Paul D. Kivela, MD, MBA, FACEP
ACEP President

⁵ ACEP Response to 2019 Medicare Advantage and Part D Proposed Rule; Available at <https://www.acep.org/Legislation-and-Advocacy/Regulatory/ACEP-Response-to-2019-Medicare-Advantage-and-Part-D-Proposed-Rule/>