American College of Emergency Physicians®
ADVANCING EMERGENCY CARE

February 28, 2019

Re: CMS-2018-0154

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 Draft Call Letter

Dear Administrator Verma:

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On behalf of nearly 38,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to comment on the CY 2020 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, we offer the following comments.

Part 1 of the Advance Notice

Medicare Advantage Risk Adjustment Model

In Part 1 of the Advance Notice, CMS implements changes to the Medicare Advantage (MA) CMS-HCC risk adjustment model based on the requirement included in the 21st Century Cures Act that the model take into account the number of conditions an individual beneficiary may have. ACEP appreciates CMS' effort to update the MA risk adjustment model in a manner that best accounts for medical complexity. In the notice, CMS proposes an alternative Payment Condition Count (PCC) model that has additional hierarchical condition categories (HCCs) for dementia and pressure ulcers. With respect to pressure ulcers, despite best practices, these continue to be a complicating factor in many emergency department (ED) visits, and unfortunately, some studies suggest that the incidence of pressure ulcers developing in the ED has increased.[1] ACEP believes that it would be appropriate to particularly recognize this problem in the calculation of patient risk scores as proposed in the CMS alternative.

[1] "The Incidence of Pressure Ulcers in the Emergency Department: A Metaanalysis." Wounds. 2017 Jan;29(1):14-19. Epub 2016 Oct 24.

Part 2 of the Advance Notice and Call Letter

Follow-up after Emergency Department Visit for Patients with Multiple Chronic Conditions (Part C)

ACEP supports CMS' proposal to add a new Healthcare Effectiveness Data and Information Set (HEDIS) measure to the 2020 display page on CMS.gov that assesses follow-up care provided after an emergency department visit for patients with multiple chronic conditions. We agree with CMS that patients with multiple chronic conditions are more likely to have complex care needs and that follow-up after an acute event, like an ED visit, can help prevent the development of more severe complications. We believe that this measure will push health plans and outpatient providers to improve access to care for these beneficiaries after an ED discharge.

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

CMS is proposing to maintain the Emergency Care/Post Stabilization Care out-of-pocket limits in 2020 after increasing them in both 2018 and 2019. The voluntary maximum out-of-pocket (MOOP) amount is $120, and the mandatory MOOP amount is $90. Over a two-year period, CMS had increased the voluntary and mandatory MOOP amounts by 60 percent and 20 percent respectively. ACEP had opposed these increases in the past since we believed that CMS was unfairly penalizing Medicare beneficiaries who receive emergency services. Recent studies have shown that only a small percentage of emergency department visits are avoidable.[2] In many cases, Medicare beneficiaries cannot tell whether their condition is life-threatening or not. Regardless of the final diagnosis, if they believe that they have a medical emergency, they are entitled to go to the emergency department and be treated. Increasing co-payments may have the undesirable outcome of deterring some beneficiaries from going to the emergency department even when they truly need immediate care. Although we still believe that both the voluntary and mandatory MOOPs have increased too much over the last few years, we are happy that CMS is at least maintaining them and urge the agency to not increase them above their current levels in the future.

Non-Opioid Pain Management Supplemental Benefits

CMS is encouraging Medicare Advantage organizations (MAOs) to consider Part C benefit designs for supplemental benefits that address medically-approved non-opioid pain management and complementary and integrative treatments. ACEP fully supports the use of non-opioid related pain treatments in the ED. As emergency physicians, we see the devastating effects of the opioid crisis every day. In fact, according to the Centers for Disease Control and Prevention (CDC), there was a 30 percent increase in opioid overdoses presenting in the ED for treatment from July 2016 through September 2017.[3] Emergency physicians are taking steps right now to address the opioid crisis by implementing innovative alternative treatments to opioids (ALTO) programs. ALTO uses evidence-based protocols like nitrous oxide, nerve blocks, trigger point injections, and other non-opioid pain management tools to treat a patient's pain in the ED. Successful ALTO

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[2] "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

[3] The Centers for Disease Control and Prevention, "Opioid Overdoses Treated in Emergency Departments. https://www.cdc.gov/vitalsigns/opioid-overdoses/index.html.

programs in New Jersey and Colorado have dramatically and quickly reduced opioid prescriptions in the ED. In New Jersey, the ALTO program at St. Joseph's Hospital saw opioid prescriptions drop by 82 percent over two years. These results were replicated at ten hospitals in Colorado, where hospital systems noted a 36 percent drop in opioid prescriptions in just the first six months of the program. The recently enacted Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act authorize grants to expand the ALTO program in EDs across the country. CMS can point to the ALTO program as an example of how non-opioid related treatment can be effectively utilized.

Special Supplemental Benefits for the Chronically Ill (SSBCI)

ACEP is extremely supportive of the flexibility provided in the Bipartisan Budget Act of 2018 to expand supplemental benefits that may be offered by MA plans to chronically ill patients. We believe that granting MA plans the ability to offer "non-primarily health related" items or services (such as transportation for non-medical needs or home-delivered meals) to chronically ill enrollees can truly benefit our most vulnerable patients. Providing these beneficiaries with social support services will in many cases help prevent their underlying chronic conditions from becoming exacerbated and allow them to avoid a trip to the ED or admission or readmission to the hospital. We hope that MA plans will take advantage of this additional opportunity to improve the overall health of the chronically ill.

Provider Directories

ACEP is extremely concerned that CMS has concluded, after a three-year review of online provider directories, that there has not been any improvement in the accuracy of these directories. Inaccurate provider directories can bring into question the adequacy and validity of an MAO network. When individuals enroll in MA 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. While CMS states that the agency will continue "its focus on and work with stakeholders to improve provider directory accuracy," the agency does not list any concrete steps it plans to take to address this important issue. ACEP fully supports imposing civil monetary penalties or taking other enforcement actions on MAOs that do not comply with provider directory requirements. In the final notice, CMS should include a list of these enforcement actions as well as provide an overall strategy of how the agency plans on addressing this problem.

Naloxone Co-Prescribing

In line with the recent CDC recommendations and Department of Health and Human Services (HHS) guidance, CMS is encouraging the co-prescribing of naloxone with opioid prescriptions to beneficiaries who are at an increased risk for opioid overdose. ACEP agrees that the co-prescribing of naloxone can truly benefit patients, and in general, we believe that access to naloxone must be increased. Naloxone is a life-saving drug that when used properly can reverse opioid overdoses and save lives. While we strongly support the wide utilization of naloxone, we want to emphasize ACEP's positions on a number of important issues: 1) guidelines for prescribing naloxone; 2) education and training; and 3) cost.

Guidelines for Prescribing Naloxone

ACEP believes that an effective naloxone program requires appropriate prescribing guidelines. We support the recommendations established by the Substance Abuse and Mental Health Services Administration (SAMHSA)[4], which encourage physicians to prescribe naloxone to at-risk patients in the following circumstances:

- Discharged from the ED following opioid intoxication or poisoning;
- Taking high doses of opioids or undergoing chronic pain management;
- Receiving rotating opioid medication regimens;
- Having a legitimate need for analgesia combined with a history of substance abuse;
- Using extended-release/long-acting opioid preparations;
- Completing mandatory opioid detoxification or abstinence programs; and/or
- A recent release from incarceration and past misuser of opioids.

Education and Training

Health care providers that administer naloxone treatment must undergo proper training. They should complete an educational program regarding the signs and symptoms of opioid overdose, naloxone effects and side effects, and indications for naloxone administration. ACEP believes Good Samaritan laws should be implemented in every state in order to shield health care personnel and lay persons from liability when administering naloxone to individuals suspected of opioid overdose. The administration of naloxone is part of core education for emergency physicians who are board certified by the American Board of Emergency Medicine (ABEM) or by the American Osteopathic Board of Emergency Medicine (AOBEM). Emergency physicians must take a comprehensive exam every ten years as well as an annual exam that focuses on recent changes to clinical protocols. Therefore, ACEP would suggest that additional educational requirements should not be added to physicians who participate in the Maintenance of Certification by ABEM and AOBEM.

We believe that pharmacists should be allowed, but not required, to dispense naloxone over the counter (OTC). As with prescribing health care professionals, appropriate related indemnification should be extended to involved pharmacists. If a pharmacist chooses to distribute/dispense OTC naloxone, they should provide the patient with information regarding the signs and symptoms of opioid overdose, the importance of promptly accessing emergency medical services via 911, naloxone effects and side effects, indications for naloxone administration, and at minimum, chest compressions for suspected cardiopulmonary arrest. As the OTC dispersal of naloxone becomes more common, it may also be worthwhile to provide support for research into the full implications and downstream consequences of this growing trend.

Laypersons should also be allowed to administer this medication for cases of suspected opioid overdose. Seconds matter in overdose cases, and it may be necessary for a bystander who could be a stranger (or who could be a friend, family member, or an off-duty EMT, nurse, or physician) to provide the treatment to save a patient's life. A study conducted by the CDC found that at least 26,500 opioid overdoses in the United States

[4] Substance Abuse and Mental Health Services Administration. SAMHSA Opioid Overdose Prevention Toolkit. HHS Publication No. (SMA) 14-4742. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014.

were reversed by laypersons using naloxone from 1996 to 2014.[5] While naloxone is relatively safe, it is nevertheless important that any regulatory or legislative efforts to expand naloxone to the public be accompanied by robust public education programs to improve the chances of correct patient selection and proper naloxone administration.

Educating the public can also help address the stigma that often goes along with overdoses. It is a common misperception that a patient rescued from an opioid overdose who wakes up agitated is "angry" and that someone has "ruined" his/her "high." That is an extremely rare viewpoint of the patient. The truth is that naloxone when administered to an opioid-dependent patient usually results in a medical condition known as naloxone precipitated withdrawal (NPW), which can last an hour, or sometimes several hours (depending on the dose of naloxone administered). This withdrawal state can be very distressing to the individual and produces several symptoms, including agitation, anxiety, and restlessness (as well as potentially abdominal pain, vomiting and diarrhea). However, this is certainly an acceptable "adverse" or "side" effect of the drug, if the alternative is death or an anoxic brain injury. Therefore, public education may be helpful so that laypersons understand what to expect when administering the drug and are not led to believe that they have injured the recipient of naloxone.

Cost

While there has been a movement to increase prompt access to naloxone for opioid overdose victims over the last several years, the price of naloxone in nearly all forms of packaging has been steadily climbing in this country. These rising prices have affected the ability of EMS providers to obtain enough naloxone to treat all the overdose cases they see. In addition, the cost of naloxone products that laypersons can obtain may in some cases be the highest of all, limiting their ability to provide immediate treatment to members of their communities. ACEP urges the Administration and Congress to do everything in their power to ensure that naloxone is available for community use at an affordable price.

Beyond the principles we lay out above, going forward, we recommend scientific research to study the consequences of naloxone distribution. Widespread use of a therapeutic agent should be embraced based on sound scientific evidence of its efficacy to patients. We also recommend societal resources to offer treatment for opioid addiction, including making inpatient and outpatient treatment available to all patients who need treatment, regardless of gender, age, income, education level, or ability to pay.

Access to Medication-Assisted Treatment

ACEP agrees with CMS that it is essential that Medicare beneficiaries have appropriate access to medication-assisted treatment (MAT). Emergency physicians have seen great results with initiating treatment (e.g., buprenorphine) in the ED and starting patients on the path to recovery. By implementing this treatment regimen, we can address a substance abuse disorder (SUD) patient's immediate symptoms and cravings, which allows time to coordinate care and provide a "warm handoff" to substance use disorder specialists and other community resources who can appropriately carry out long-term treatment. There are study results showing promise for ED-initiated buprenorphine and its effectiveness in treating opioid use disorder.

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[5] The Centers for Disease Control, Morbidity and Mortality Weekly Report (MMWR), "Prevention Programs Providing Naloxone to Laypersons — United States, 2014," 19 June 2015, available at https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6423a2.htm

Initiating MAT in the ED has shown to be more successful than simple referral – after one month, 78 percent of patients started on MAT in the ED remained in treatment programs, compared to 37 percent who only received a simple referral.[6] Furthermore, studies of patients in California and elsewhere with opioid use disorder have demonstrated an instantaneous reduction in mortality after buprenorphine-assisted detoxification, justifying its use in the ED even when access to long-term maintenance and follow-up is not available.[7] Finally, a study conducted using a retrospective chart review of 158 patients treated at a single ED with buprenorphine for opioid withdrawal found no instances of precipitated opioid withdrawal (a potential medical complication of buprenorphine), and a greater than 50 percent reduction (17 percent versus 8 percent) in return-rate to the same ED for a drug-related visit within one month, compared to the return-visit rate for usual care.[8] In all, research suggests that the sooner we can start patients on the right path and keep them engaged in treatment, the more successful their recovery can be.

Opioid Safety Alerts

CMS is not modifying the policies finalized in 2019 that are aimed at helping Medicare Part D sponsors prevent and combat opioid overuse. Part D sponsors are expected to implement a real-time opioid care coordination safety edit at 90 morphine milligram equivalent (MME) at the time of dispensing. Furthermore, Part D sponsors are required to implement a hard safety edit to limit initial opioid prescription fills for the treatment of acute pain to no more than a 7-day supply.

In ACEP's comments on the CY 2019 Advanced Notice and draft Call Letter, we had asked CMS to take into account the unique nature of care in the ED when finalizing any policies around opioid-related safety edits. 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 had recommended that CMS create a more flexible policy for opioids prescribed by emergency physicians in emergency departments to account for situations when a pharmacy or sponsor is unable to reach the emergency physician who ordered the prescription. While the care coordination safety edits that were finalized are less restrictive than the hard edits that CMS had proposed, they still require the pharmacist to contact the prescriber to override the edit. If the pharmacy cannot reach the prescriber, the beneficiary, a representative of the beneficiary, or the prescriber can request an expedited coverage determination, which must be resolved within 24 hours. However, an expedited determination process still usually involves a supporting statement from the prescriber that the drug is necessary. Thus, this new safety edit could impose a burden on both the beneficiary and the prescriber.

We also continue to believe that the supply limit for initial opioid prescription fills should be no less than the current requirement of seven 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 ED for a limb fracture at the beginning of a holiday weekend, it could easily be up to five days until the patient can 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 seven days is generally an acceptable limit, we also note that in some extreme

[6] D'Onofrio G, O'Connor PG, Pantalon MV, et al. Emergency department-initiated buprenorphine/naloxone treatment for opioid dependence: a randomized clinical trial. JAMA. 2015;313(16):1636-1644.
[7] Elizabeth Evans et al., "Mortality Among Individuals Accessing Pharmacological Treatment for Opioid Dependence in California, 2006-10," Addiction 110, no. 6 (June 2015): 996-1005.
[8] Berg ML, Idrees U, Ding R, Nesbit SA, Liang HK, McCarthy ML. Evaluation of the use of buprenorphine for opioid withdrawal in an Emergency Department. Drug Alcohol Depend. 2007;86:239-244.

situations, such as natural disasters, a 7-day supply may be insufficient. Going forward, ACEP recommends that CMS consider allowing a longer supply limit in certain exceptional circumstances.

We appreciate the opportunity to share our comments. If you have any questions, please contact Jeffrey Davis, ACEP's Director of Regulatory Affairs at jdavis@acep.org.

Sincerely,

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