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January 24, 2019

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

Re: CMS-4180-P

Re: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses

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Dear Administrator Verma:

On behalf of nearly 38,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to respond to the proposed rule that would make changes to the current Medicare Advantage and Medicare Part D Prescription Drug Programs. There are a few proposed policies that have a direct impact on our members and the patients we serve.

Protected Classes

ACEP does not support the proposed changes to the current formulary requirements for protected classes. Under Part D, plans are required to include on their formularies all drugs in six categories or classes: (1) antidepressants; (2) antipsychotics; (3) anticonvulsants; (4) immunosuppressants for treatment of transplant rejection; (5) antiretrovirals; and (6) antineoplastic. The proposed rule would create three exceptions to this policy, allowing plans to: (1) implement broader use of prior authorization (PA) and step therapy (ST) for protected class drugs, including to determine use for protected class indications; (2) exclude a protected class drug from a formulary if the drug represents only a new formulation of an existing single-source drug or biological product, regardless of whether the older formulation remains on the market; and (3) exclude a protected class drug from a formulary if the price of the drug increased beyond a certain threshold over a specified look-back period.

We believe that any modifications to the protected classes requirements could pose significant risks to patients. What works for one patient may not work for another, and there are variations in how each patient responds to chemically similar drugs. We are particularly concerned that current rules do not address what happens when a Part D Medicare beneficiary comes to the emergency department (ED). While emergency physicians rarely prescribe most of the drugs in the six protected categories, particularly in the context of Part D, we do prescribe short courses of antidepressants and administer

anticonvulsants. The Emergency Medical Treatment and Labor Act (EMTALA) requirements preclude emergency physicians from asking patients about their insurance coverage before a medical screening examination is completed, so we do not know which type of plan and formulary the patient may have. The urgency of treatment in the emergency setting requires our members to provide medications that may or may not be on a more restricted future Part D plan formulary.

Without real-time formulary information, emergency physicians also have to constantly play a guessing game of what drugs are on-or-off formulary for that patient's particular insurance type or coverage. If emergency physicians guess incorrectly and prescribe drugs that are off formulary, not only do we have to worry about patients being unable to fill their prescriptions due to high cost, but we will also be faced with fielding multiple pharmacies calls about the prescriptions. The result is a delay in patients receiving needed therapy and added administrative burden for the physician, pharmacy, and sometimes even the insurer.

Therefore, while we oppose the changes overall, we believe that at the bare minimum, **CMS should exempt prescriptions that originate in the ED from these proposed restrictions**. Plans must be required to cover all protected class drugs on their formularies without exception in an emergency situation.

Pharmacy Price Concessions to Drug Prices at the Point of Sale

CMS is considering for a future year, which could be as soon as 2020, to require Part D plans to include performance-based pharmacy price concessions in the price of the drug. Currently, these concessions are not included in the "negotiated price" of the drug since they are contingent upon performance measured over a period that extends beyond the point-of-sale. Including these concessions would lower the cost of the drug for the Medicare beneficiary at the point-of-sale.

In general, ACEP supports policies such as this one that would help make life-saving medicines more affordable to our patients. From our perspective as emergency physicians who treat patients with both acute and chronic conditions, we see every day how the high price of prescription drugs can impact the health and wellbeing of our patients. The issue of high drug prices has become a major public health crisis. It is an all-too-common occurrence for patients to come to the ED with the condition that was in part caused by their inability to take their medications as prescribed by their doctor because they were unable to afford them. We have seen patients taking their daily prescriptions every two days (or cutting their pills in half); patients with allergic reactions who could not afford an EpiPen; patients with asthma who could not afford to refill their albuterol inhalers and came to the ED once their current dose ran out; patients who could not afford their prescribed antibiotics and had to return to the ED with a much more serious infection requiring hospitalization; and patients who could not afford their prescription medicines and decided to take some "leftover" medicine from a family member that was contraindicated for their current condition. There are numerous other examples that emergency physicians routinely see how medication costs adversely affect patients. Many of these cases, unfortunately, result in costly inpatient admissions.

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,

Vidor E. Friedman, MD, FACEP
ACEP President