

December 27, 2018

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

**Re: CMS-5528-ANPRM**

**Re: Medicare Program; International Price Index Model for Medicare Part B Drugs**

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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 an Advance Notice of Proposed Rulemaking (ANPRM) that discusses a potential new mandatory payment model out of the Center for Medicare & Medicaid Innovation (CMMI) called the “International Pricing Index” (IPI) payment model. In addition to providing our feedback on the potential model, we would like to briefly address how high drug prices are affecting the patients we serve.

**High Drug Prices**

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. Therefore, ACEP strongly supports the Trump Administration’s objective to reduce drug prices and offers our assistance in helping to achieve our shared goal of making life-saving medicines more affordable for 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 emergency department (ED) with a 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

of how medication costs adversely affect patients. Many of these cases unfortunately result in costly inpatient admissions.

As well, when patients come to the ED, it is difficult for emergency physicians to know the specific costs to the patient of various medications that they could prescribe. Without real-time formulary information, emergency physicians have to 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 pharmacy calls about the prescriptions. The end result is a delay in patients receiving needed therapy and added administrative burden for the physician, pharmacy, and sometimes even the insurer.

### ***The IPI Payment Model***

Payment for drugs under both Medicare Part B and Part D does not directly affect reimbursement for emergency physicians, as drugs administered by us in the ED are bundled into the facility level of service. Therefore, we do not have any specific comments on the payment changes discussed in the ANPRM and how they could potentially affect the provision of certain Part B drugs in the ED. However, there are a few other aspects of the IPI payment model that could have a direct impact on emergency physicians and our patients, were it to be implemented.

### ***Drug Shortages***

ACEP supports excluding drugs from the IPI payment model that are identified by the Food and Drug Administration (FDA) to be in short supply. We believe that CMS should avoid making any payment changes that could potentially exacerbate the drug shortage problem we are facing in this country. In fact, the shortage of life-saving medicines is one of the greatest problems that emergency physicians deal with on a day-to-day basis. A report from the Government Accountability Office (GAO) from 2014 found that both new shortages and ongoing shortages have increased each year since 2007.<sup>1</sup> The GAO also conducted interviews for the report with providers, who stated that the shortages led to “delays in or rationing of care, difficulties finding alternative drugs, risk associated with medication errors, higher costs, reduced time for patient care, and hoarding or stockpiling of drugs in shortage. During a shortage, providers may have to cancel or delay procedures, which can have detrimental health effects on patients. Providers may also have to ration care by prioritizing the patients who have a greater need for the drug.”<sup>2</sup> The GAO concluded that the main cause of drug shortages were manufacturer production issues.<sup>3</sup>

With respect to emergency medicine, the shortage crisis affects drugs across all classes of medications. As of June 2017, there are 69 preparations of 28 emergency care medications that are in shortage, including most forms of adenosine, atropine, bicarbonate, calcium, dextrose, dopamine, epinephrine, fentanyl, furosemide, labetalol, magnesium, lorazepam, and paralytic agents.<sup>4</sup> In May, a major supplier of medications to emergency providers reported there are 156 emergency medication preparations and 50 intravenous fluid preparations that are not available. This will have a significant impact on emergency patient care.

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<sup>1</sup> United States Government Accountability Office, “Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability,” February 2014, <https://www.gao.gov/products/GAO-14-194>

<sup>2</sup> Ibid

<sup>3</sup> Ibid

<sup>4</sup> ACEP Now, “Emergency Departments Need Plan to Deal with Drug Shortages,” Augustine, James J., 2017, August 15, <https://www.acepnow.com/article/emergency-departments-need-plan-deal-drug-shortages/?singlepage=1&theme=print-friendly>

ACEP is extremely pleased that the FDA has convened a new Drug Shortages Task Force that is looking for holistic solutions to addressing the underlying causes of drug shortages. ACEP has been actively participating in the Task Force's public listening sessions and looks forward to continued engagement on this issue.

### *Beneficiary Cost-Sharing*

Under the IPI payment model, model participants would continue to collect beneficiary cost-sharing. However, to reduce the impact on Medicare beneficiaries, CMS is considering an administrative approach that deducts the cost-sharing amounts from Medicare payments made for other services to the model participants. As CMS considers the best approach for collecting beneficiary cost-sharing in the model, ACEP urges CMS to mitigate any potential unintended increases in provider burden. The ED is often responsible for collecting cost-sharing from beneficiaries once they have been stabilized, and it is unclear how the changes CMS is envisioning would affect the responsibilities of providers. Furthermore, it is also not clear operationally how cost-sharing would actually be deducted from Medicare payments made for other services. This lack of clarity causes us to be concerned that the approach could wind up putting providers at financial risk for not collecting the full drug cost-sharing amount from the beneficiary or the supplemental insurer.

### *Mandatory Model*

CMS is proposing that providers in selected geographic regions would be required to participate in the IPI payment model. While ACEP understands that mandatory models may in some cases reduce selection bias and increase the potential for cost savings, ACEP does not believe that providers should be forced to participate in models, especially when they are being exposed to financial risk for the first time. We therefore strongly urge CMS to continue to test voluntary models. Many emergency physicians are ready to take on downside risk and participate in alternative payment models (APMs). However, there are currently no APMs that are specifically geared towards emergency physicians. ACEP developed a physician-focused payment model (PFPM) called the Acute Unscheduled Care Model (AUCM), which the Physician-Focused Payment Model Technical Advisory Committee (PTAC) recently recommended to the HHS Secretary for full implementation. Since emergency physicians have few, if any, opportunities to fully participate in APMs, ACEP conceived of the AUCM as a voluntary model that would be flexible enough allow the full spectrum of emergency physicians to participate -- from those with dedicated infrastructure and experience with reporting and meeting quality metrics and taking downside risk, to smaller groups of physicians who do not have as much experience in these areas.

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](mailto:jdavis@acep.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Vidor E. Friedman". The signature is fluid and cursive, with a large, sweeping flourish at the end.

Vidor E. Friedman, MD, FACEP  
ACEP President