



AMERICA'S ESSENTIAL HOSPITALS

May 9, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Ave., SW
Washington, DC 20201

Ref: CMS-1670-P: Medicare Program; Part B Drug Payment Model

Dear Mr. Slavitt:

Thank you for the opportunity to provide comments on the above-captioned proposed rule. America's Essential Hospitals welcomes the opportunity to join the conversation on rising drug costs and their impact on patient access and health outcomes. Rising drug costs are unsustainable for patients, hospitals, and taxpayers and underscore the urgent need to address the underlying factors driving the cost increases. As the Centers for Medicare & Medicaid Services (CMS) works toward its goal of tying Medicare fee-for-service payments to value, we encourage the agency to implement well-researched policies that are proved to enhance patient care. Instead of expanding access and improving quality of care, the agency's proposed model would undermine physician judgment and reduce reimbursement to hospital outpatient departments at the expense of the needs of clinically complex and vulnerable patients.

Essential hospitals are committed to expanding access to affordable, high-quality care for their patients. As CMS focuses on the issue of costly prescription drugs, we encourage the agency to consider that vulnerable patients with chronic conditions and complex illnesses turn to essential hospitals for their care. These same essential hospitals will be disproportionately affected by the payment model because of their patient populations. Until CMS has conclusive evidence to demonstrate that the proposed payment model will actually improve quality of care and patient outcomes, it should not make policy changes that might have the opposite effect. Any policies that aim to slow rising drug costs should enable essential hospitals to fulfill their

missions to treat vulnerable patients in underserved communities and not imperil the ability of vulnerable patients to receive lifesaving drugs.

America's Essential Hospitals is the leading association and champion for hospitals and health systems dedicated to high-quality care for all, including the most vulnerable. Our nearly 275 member hospitals provide access to high-quality health care for their patients, predominantly serving patients covered by public programs and the uninsured.¹ Of the outpatient services our members provide, 21 percent are to Medicare beneficiaries, 27 percent are to Medicaid recipients, and 24 percent are to uninsured patients. Our members provide this care while operating on margins substantially lower than the rest of the hospital field—an aggregate operating margin of *negative* 3.2 percent, compared with positive 5.7 percent for all hospitals nationwide.²

Essential hospitals serve as cornerstones of care in their communities, providing essential community services, such as graduate medical education, and the continuum of primary through quaternary care, including trauma care and public health services. In particular, essential hospitals play a vital role in providing ambulatory care to their communities. The average member operates a network of more than 20 ambulatory care sites. And in 2013, the average member saw nearly four times as many nonemergency outpatient visits as other acute care hospitals nationwide. Our members provide comprehensive ambulatory care through networks of hospital-based clinics that include onsite features—radiology, laboratory, and pharmacy services, for example—that freestanding physician offices typically do not offer. They deliver ambulatory care services to communities and housing developments through mobile units that efficiently bring health care to patients where they need it. Our members' ambulatory networks also offer behavioral health services, interpreters, and patient advocates who can access support programs for patients with complex medical and social needs.

To ensure essential hospitals have sufficient resources to continue to provide this coordinated, high-quality care and are not unfairly disadvantaged for serving the most vulnerable among us, it is imperative that CMS understand the effect of its proposals on essential hospitals. To this end, we urge the agency to consider the following comments before making the above-mentioned proposed rule final.

1. CMS should thoroughly research the effect that its proposed payment model will have in a changing payment landscape and ensure the model will improve patient access and health outcomes.

The mandatory payment model, to be implemented through the Center for Medicare & Medicaid Innovation, is divided into two phases, the first of which is scheduled to begin in the fall of this year. All participating providers will be divided into four test arms, with each arm being subject to a different combination of phase

¹Reid K, Roberson B, Landry, C, Laycox S, Linson M. *Essential Hospitals Vital Data: Results of America's Essential Hospitals Annual Characteristics Survey, FY 2013*. America's Essential Hospitals. March 2015. <http://essentialhospitals.org/wp-content/uploads/2015/03/Essential-Hospitals-Vital-Data-2015.pdf>. Accessed May 2, 2016.

²Ibid.

I and/or phase II, and one test arm being a control group. The model will include the vast majority of Medicare Part B drugs, which are those usually administered in physician offices or hospital outpatient departments incident to a physician service, as well as those administered using durable medical equipment. CMS has explained its methodology for using primary care service areas (PCSAs) as the unit of analysis and assigning PCSAs to one of the four test arms using random statistical assignment. CMS has not yet released these assignments, and providers are therefore unable to evaluate the specific impact the proposal will have on their operations. However, while information is not yet available on which providers will be subject to each of the four test arms, it is clear that hospital outpatient departments affected by phase I will see a disproportionate negative effect due to their patients' higher acuity.

In proposing the Part B drug payment model, CMS states that its goal is to reduce Medicare program expenditures while enhancing quality of care. The agency also places the Part B model within the administration's broader goal of aligning Medicare payments with quality or value through alternative payment models (APMs). The administration recently announced that it is ahead of schedule in meeting its goal of linking 30 percent of Medicare payments to APMs by the end of calendar year (CY) 2016.³ That goal increases to 50 percent by the end of CY 2018. **We commend the administration's progress in prioritizing quality and value. However, we are concerned that moving too quickly with a proposal based on an economic model and not on the best interests of the patient has the potential to undermine quality, access, and safety initiatives.**

Additionally, CMS should remain cognizant of the effect of many other concurrent and pending payment changes, both legislative and regulatory, to provider reimbursement. For example, Section 603 of the recently enacted Bipartisan Budget Act (BBA) of 2015 mandates that CMS pay newly created off-campus hospital outpatient departments under an applicable payment system other than the Outpatient Prospective Payment System. The cuts in outpatient Medicare payments under the BBA will reduce payments for many services by about 50 percent and, in some cases, by close to 90 percent. Essential hospitals expand their ambulatory care networks into their patients' communities not for financial gain but because their patients face challenges in accessing care that are driven by the social determinants of health. And because such patients often are uninsured, there are no other providers in their communities willing and able to provide the comprehensive care that essential hospitals can provide. Also, securing transportation to a clinic outside of their neighborhood may be a challenge. Thus, these patients benefit greatly from having a hospital-based clinic in their neighborhood.

Hospitals planning on expanding access into these very communities will face the added challenge of reduced reimbursement under Section 603, coupled with potentially disruptive policies in the Part B drug payment model. The added

³U.S. Department of Health and Human Services. Press release. HHS reaches goal of tying 30 percent of Medicare payments to quality ahead of schedule. March 3, 2016. <http://www.hhs.gov/about/news/2016/03/03/hhs-reaches-goal-tying-30-percent-medicare-payments-quality-ahead-schedule.html>. Accessed May 2, 2016.

uncertainty about the future of payment to certain outpatient departments will make it more difficult for essential hospitals to continue to expand access, which will be detrimental to the vulnerable populations most in need of care.

In addition to Section 603 of the BBA, pending omnibus guidance from the Health Resources and Services Administration (HRSA) would impinge on the ability of essential hospitals to operate their ambulatory care networks in low-income communities. HRSA, which oversees the 340B Drug Pricing Program, issued far-reaching subregulatory guidance in August 2015 that would constitute an unprecedented narrowing of the scope of the 340B Program. The 340B Program enables hospitals to purchase discounted drugs and realize savings they can then pass on to vulnerable patients in the form of no-cost or heavily discounted drugs and expanded access to other services. If implemented, the proposed reductions in the scope of patient eligibility and the drugs for which such discounts apply will restrict patients' access to critical drugs and undermine quality of care. Against the backdrop of these pending policy changes to providers, finalizing the Part B drug payment model would add barriers to patient access and uncertainty for hospital outpatient departments.

2. CMS should withdraw its phase I proposal to change the average sales price (ASP) plus 6 percent reimbursement methodology.

Phase I would test the use of a different reimbursement rate for Part B drugs, instead of the current 106 percent of ASP. Using the new methodology, CMS will pay providers 102.5 percent of ASP plus a flat fee add-on of \$16.80 for each drug per day administered. The 6 percent add-on is intended to account for acquisition and pharmacy overhead and related expenses. Reducing the add-on amount paid to providers will cut into their ability to cover these costs.

The revised payment methodology will result in payments lower than current rates for Part B drugs with an ASP of more than \$480, while drugs with an ASP under this threshold will receive higher payments compared with current levels. Drugs that fall on the higher end of the price spectrum tend to be more costly because they are used to treat patients with chronic conditions and more-severe illnesses—cancer drugs, for example. Less costly drugs, on the other hand, generally are those used for less complex conditions, such as in the primary care setting. **CMS should withdraw its phase I proposal because it will disproportionately affect providers treating patients with chronic conditions and complex illnesses.**

The proposed rule essentially will redistribute Part B payments from certain specialties and hospital outpatient departments to primary care providers. CMS notes in the preamble to the proposed rule that the revised payment methodology would have the net effect of redistributing payments away from “physician specialties that heavily utilize drug therapy” in favor of specialties like primary care.⁴ The impact table in the proposed rule projects that hospitals will lose more than 2 percent in Part B drug reimbursement, while many physician specialties will receive up to 44 percent higher reimbursement. One independent study estimates that 60

⁴Part B Drug Payment Model Proposed Rule, 48 Fed. Reg. 13230, 13241 (March 11, 2016).

percent of reductions in Part B drug reimbursement will be borne by hospital outpatient departments.⁵ Such drastic reductions in payments to hospitals will impede their ability to provide the most effective treatment to their patients.

Hospital outpatient departments are equipped to treat the highest-acuity patients with chronic conditions and multiple comorbidities, and they treat more of these patients than physicians in freestanding offices. Therefore, the clinical needs of these patients necessitate the use of more-costly drugs than, for example, a patient seeking care at a primary care practice. The study cited above also illustrates that a small subset of drugs, such as cancer drugs and ophthalmic drugs, will receive the largest cut in reimbursement. Many of these drugs do not have lower-cost alternatives. Physicians choose which drugs to prescribe based on the specific clinical needs of their patients, and there is little evidence to suggest that physicians' decisions are dictated by financial considerations. On the contrary, indirectly penalizing providers who treat the most complex patients has the opposite effect—it will hinder quality improvement initiatives and patient access to lifesaving drugs. It is for these reasons that we believe phase I must be withdrawn.

3. CMS should ensure that any value-based purchasing tools in Phase II of the model are proved to improve patient outcomes without undermining physician judgment.

In phase II of the model, CMS proposes various value-based purchasing (VBP) tools that will tie the payment for Part B drugs to the effectiveness of the drugs and clinical outcomes. CMS says that it will begin phase II no earlier than 2017 and it will provide the opportunity for public comment as it determines which VBP tools to apply to which drugs. CMS does not yet propose specific phase II tools but provides multiple examples of the types of tools that it might consider proposing.

Some of the tools CMS is expecting to employ are reference pricing, indications-based pricing, outcomes-based risk sharing arrangements, and beneficiary copayment reductions. Reference pricing sets a uniform benchmark price for a group of therapeutically similar drugs. The benchmark price can be based on the lowest-price drug in the group or an average of the price of the drugs. CMS would pay a provider the benchmark rate any time a provider administers a drug in the therapeutically similar group.

While CMS has yet to determine the exact methodology of a reference pricing tool, the model raises many questions. For example, how would CMS determine which drugs are “therapeutically similar” and would therefore be grouped together and paid at the benchmark rate? Because drug effectiveness might vary significantly from patient to patient, a physician’s decision to treat a patient with a drug is guided by how that particular patient will respond to the drug. Reference pricing attempts to drive providers toward prescribing lower-cost drugs in the group, but those drugs

⁵Avalere Health. Proposed Medicare Part B Rule Would Reduce Payments to Hospitals and Some Specialists, While Increasing Payments to Primary Care Providers. April 7, 2016. <http://avalere.com/expertise/managed-care/insights/proposed-medicare-part-b-rule-would-reduce-payments-to-hospitals-and-some-s>. Accessed May 2, 2016.

will not always be the optimal choice for a particular patient. In this way, reference pricing will undermine clinical judgment as well as patient choice, potentially resulting in patients losing access to lifesaving drugs. If CMS were to proceed with a reference pricing approach, it would have to ensure that physicians are able to prescribe the higher-cost drug in a group when the patient's specific needs dictate such a decision.

An indications-based pricing approach would vary prices for specific drugs when used for different indications, based on the drugs' differing clinical effectiveness for these indications. If a specific drug generally treats one condition more effectively, then the drug would be reimbursed at a higher rate when used to treat that condition. As with reference pricing, we look forward to receiving more information on the specifics of how CMS would implement such an approach. In the meantime, we urge CMS to consider multiple questions, such as the difficulty of conclusively establishing which drugs are effective for which patients and which indications. **Before CMS proceeds with any VBP tools in phase II, it should ensure that these tools are not interfering with the physician's ability to provide the most effective drug for each particular patient.** Clinical decision making is a nuanced process that requires the evaluation of patient-specific factors that often are not accounted for in sweeping policy changes. We look forward to evaluating how CMS will protect the autonomy of the physician and patient when it releases more information on the VBP tools in phase II for public comment.

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America's Essential Hospitals appreciates the opportunity to submit these comments. If you have questions, please contact Director of Policy Erin O'Malley at eomalley@essentialhospitals.org or 202-585-0127.

Sincerely,

/s/

Bruce Siegel, MD, MPH
President and CEO