



AMERICA'S ESSENTIAL HOSPITALS

September 27, 2019

Seema Verma, MPH
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-1717-P: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals

Dear Administrator Verma:

Thank you for the opportunity to submit comments on the above-captioned proposed rule. America's Essential Hospitals appreciates Centers for Medicare & Medicaid Services (CMS) work to improve the delivery of high-quality, integrated health care across the continuum. We are deeply concerned about several provisions of the proposed rule that exceed the agency's statutory authority and would have a disproportionately negative impact on essential hospitals, which provide stability and choice for people who face barriers to care.

America's Essential Hospitals is the leading champion for hospitals and health systems dedicated to high-quality care for all, including the vulnerable. Filling a vital role in their communities, our more than 300 member hospitals provide a disproportionate share of the nation's uncompensated care and three-quarters of their patients are uninsured or covered by Medicare or Medicaid. Our members provide state-of-the-art, patient-centered care while operating on margins one-fifth that of other hospitals—1.6 percent on average compared with 7.8 percent for all hospitals nationwide.¹ Essential hospitals' commitment to serving all people, regardless of income or insurance status, and their diverse patient mix pose unique challenges. A disproportionate number of their patients face sociodemographic challenges to accessing health

¹ Clark D, Roberson B, Ramiah K. *Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2017 Annual Member Characteristics Survey*. America's Essential Hospitals. April 2019. www.essentialdata.info/. Accessed September 1, 2019.

care, including poverty, homelessness, language barriers, and low health literacy. Ten million people in essential hospital communities have limited access to healthy food, and nearly 24 million live below the poverty line.² Essential hospitals are uniquely situated to address these social determinants of health and are committed to serving these vulnerable patients. These circumstances, however, compound essential hospitals' challenges and strain their resources, necessitating flexibility to ensure they are not unfairly disadvantaged for serving the vulnerable and can continue to provide vital services in their communities.

Essential hospitals offer comprehensive, coordinated care across large ambulatory networks to bring vital services to where patients live and work. Our members provide comprehensive ambulatory care through networks of hospital-based clinics that include onsite features—radiology, laboratory, and pharmacy services, for example—not typically offered by freestanding physician offices. 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.

The high cost of providing complex care to low-income and uninsured patients leaves essential hospitals with limited resources, driving them to find increasingly efficient strategies for providing high-quality care. Improving care coordination and quality while maintaining a mission to serve the vulnerable is a delicate balance. This balance is threatened by aspects of this proposed rule.

We are particularly concerned that the agency's proposals regarding the public posting of charges, in particular the posting of negotiated rates, offer little benefit to the consumer, add substantial burden to hospitals, and pose harm to competition, potentially driving up prices.

CMS' continued payment cut to office visits at excepted off-campus provider-based departments (PBDs) would severely limit the ability of essential hospitals to provide comprehensive, coordinated care to disadvantaged populations. The agency's expansion of its payment policy for drugs purchased by non-excepted PBDs through the 340B Drug Pricing Program is impeding essential hospitals from providing such care. CMS' inequitable policy to reduce Part B drug payments to hospitals with the most vulnerable patients already has severely impacted essential hospitals. It undermines these providers' ability to offer heavily discounted drugs to patients in the face of rapidly increasing drug prices. Essential hospitals, which represent 12 percent of 340B hospitals paid under the Outpatient Prospective Payment System (OPPS), would be disproportionately affected by the Part B drug payment policy, receiving more than 21 percent of the payment cut. Similarly, essential hospitals would receive a disproportionate portion of the cuts to off-campus PBDs in CY 2020. In our detailed comments below, we urge CMS to withdraw its PBD and 340B payment proposals.

² Ibid.

- 1. For CY 2020, CMS should pay hospitals participating in the 340B program the statutory default payment of average sales price (ASP) plus 6 percent. CMS' alternative payment methodology exceeds the agency's statutory authority, undermines the Public Health Service Act (PHSA), and has irreparably harmed low-income patients and the hospitals committed to treating them.**

For hospitals purchasing certain separately payable drugs through the 340B program, CMS proposes to continue its policy initially enacted in the CY 2018 OPPI final rule. Under this policy, CMS reduced Part B reimbursement to 77.5 percent of ASP, compared with current payment at 106 percent of ASP, the statutory default payment methodology for these drugs. This represents a 27 percent reduction in Medicare reimbursement targeted at hospitals participating in the 340B program, while those not participating in the program continue to receive payment at 106 percent of ASP. **America's Essential Hospitals implores CMS to withdraw this policy, which a federal district court already has declared unlawful for CYs 2018 and 2019.**

Congress created the 340B program, codified in section 340B of the PHSA, to allow covered entities to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."³ Under the 340B program, covered entities can purchase certain outpatient drugs at discounted prices, enabling savings critical to the operations of hospitals that fill a safety-net role. Essential hospitals reinvest 340B savings into programs to coordinate care and improve outcomes for disadvantaged populations, including initiatives to reduce readmissions, ensure medication compliance, and identify high-risk patients in need of ancillary services. The 340B program is structured by statute to offer hospitals discounts for covered outpatient drugs provided to patients of a covered entity, regardless of a patient's insurance status. Congress plainly expected that various public and private payers would reimburse hospitals at rates higher than the cost of the discounted drugs they receive from manufacturers, which is how hospitals were expected to stretch resources to expand access to medications and other vital services.

For the third year, we urge the agency to reverse Part B payment cuts to 340B hospitals. As the U.S. District Court for the District of Columbia has unequivocally held, CMS' policy violates the Medicare statute.⁴ The lack of statutory authority is supported by independent stakeholders, including the Government Accountability Office (GAO) and Office of Inspector General (OIG) and conflicts with section 340B of the PHSA, which governs the program.^{5,6} Continuing for an additional year a policy already deemed unlawful is ill-advised and detrimental to hospitals and their patients. In the two years since CMS first proposed this sweeping policy change, the agency has yet to demonstrate that the policy lowers drug prices, financially helps beneficiaries, or improves access to or quality of care for Medicare beneficiaries. On the contrary, as we establish in more detail in the following sections, CMS' drug reimbursement policy already has begun to undermine a key policy lever that has proved effective in combating high drug prices.

³ H.R. Rep. No. 102-384, pt. 2 (1992).

⁴ The American Hospital Association et al., v Alex M. Azar II, United States Secretary of Health and Human Services, et al. Civ. Action No. 18-2084 (RC), December 27, 2018.

⁵ Government Accountability Office. Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals. June 2015. <https://www.gao.gov/assets/680/670676.pdf>. Accessed August 28, 2018.

⁶ Office of Inspector General. Part B Payments for 340B-Purchased Drugs. November 2015. <https://oig.hhs.gov/oei/reports/oei-12-14-00030.pdf>. Accessed August 28, 2018.

- a. CMS' policy continues to violate the plain language of the Social Security Act (SSA) and is impermissible under the Administrative Procedure Act.

CMS should reverse its policy of reducing payments for separately payable drugs purchased through the 340B program because it is inconsistent with the agency's statutory authority under the SSA. CMS should revert to its statutory default methodology, under which it paid all hospitals before the CY 2018 OPPS final rule. As independent advisory and oversight agencies have noted when examining similar policies, changes to Medicare reimbursement for 340B drugs can be made only through legislation and are outside CMS authority.⁷ We agree with these experts that CMS lacks the legal authority to implement a reduced payment rate for 340B drugs. As held by the U.S. District Court for the District of Columbia, CMS "fundamentally altered the statutory scheme established by Congress for determining [specified covered outpatient drug] reimbursement rates, thereby exceeding the Secretary's authority to 'adjust[]' SCOD rates under §(t)(14)(A)(iii)(II)."⁸ More specifically, as we have established in greater depth in previous comments, CMS lacks the authority for the payment cut for these reasons:

- CMS' policy is an unlawful departure from the statutory default payment for separately payable Part B drugs, which requires the agency to pay at ASP plus 6 percent if it does not have acquisition cost data.
- CMS' nearly 30 percent payment cut to a specific subset of hospitals does not constitute an "adjustment" under section 1883(t)(14)(A)(iii)(II) of the SSA. The adjustment is excessive and would have to be applied to all OPPS hospitals, not just one subset of hospitals.
- CMS cannot attempt to pay at acquisition cost when it lacks acquisition cost data and has been paying under the ASP methodology in section 1833(t)(14)(A)(iii)(II).
- CMS' payment methodology conflicts with another statute, the PHSA, and undermines Congress' intent in enacting the 340B program. By redirecting funds intended for 340B hospitals to other hospitals in the Medicare program, CMS' policy violates the intent of the 340B program.

Given that the court already has struck down the policy for CYs 2018 and 2019, implementing it for another year not only will impede hospital operations and patient access but also impose an unnecessary burden on the agency and hospitals when, as we expect consistent with prior decisions, the court also invalidates the 2020 policy. Hospitals will continue to be underpaid for another year, while the agency will have to reverse course and implement a remedy to make hospitals whole after its cuts begin for 2020.

⁷ See, e.g., Government Accountability Office. Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals. June 2015. <https://www.gao.gov/assets/680/670676.pdf>. Accessed September 9, 2019.; Medicare Payment Advisory Commission. Report to the Congress: Medicare Payment Policy. March 2016. <http://www.medpac.gov/docs/default-source/reports/march-2016-report-to-the-congress-medicare-payment-policy.pdf>. Accessed September 9, 2019.; Office of Inspector General. Part B Payments for 340B-Purchased Drugs. November 2015. <https://oig.hhs.gov/oei/reports/oei-12-14-00030.pdf>. Accessed September 9, 2019.

⁸ The American Hospital Association et al., v Alex M. Azar II, United States Secretary of Health and Human Services, et al. Civ. Action No. 18-2084 (RC), December 27, 2018.

- b. CMS has failed to analyze the effect of the policy on hospitals and on beneficiaries' access to care.

Since CMS implemented this policy, which has reduced 340B hospital payments by more than \$3 billion over two years, the agency has not provided evidence that the policy has benefited Medicare beneficiaries or improved access to and the quality of health care. Since the policy's implementation, CMS has not analyzed whether the policy has met its intended goals, how it has affected patient access, whether it has lowered drug prices, or how it has affected hospital operations. It is irresponsible to continue a policy that has an aggregate impact in the billions of dollars without any understanding of how it impacts hospitals or patients.

- c. CMS' 340B drug payment policy harms essential hospitals and their patients while providing minimal benefit to the Medicare program and its beneficiaries.

The 340B program is critical to ensuring low-income and other disadvantaged people can access the types of services best provided by essential hospitals. 340B hospitals already have begun to experience the effects of the more than \$3 billion cut in Medicare payments. Hospitals participating in the 340B program operate on margins significantly narrower than margins of other hospitals, with many operating at a loss. With respect to Medicare outpatient margins, 340B hospitals affected by the policy already operate in the red. Accounting for the reduced OPPS reimbursement resulting from the Part B payment reduction, 340B hospitals' Medicare outpatient margins would drop even further, to negative 19 percent.⁹ At the same time, because of the redistributive nature of the policy, non-340B hospitals will see their Medicare outpatient margins increase. Given the fragile financial position of essential hospitals, policy changes that jeopardize any piece of the patchwork support on which they rely, including the 340B program, can threaten their ability to maintain critical services. CMS' policy to cut payments on Medicare Part B drugs only for 340B hospitals, which already operate on substantially negative Medicare outpatient margins, has begun to severely restrict essential hospitals' ability to serve their communities.

A reduction in Medicare payment rates to 340B hospitals significantly erodes the value of the program. These policies are most damaging to essential hospitals, given their high levels of uncompensated care, narrow margins, and large proportion of patients with Medicare and Medicaid coverage. Some hospitals now are reconsidering programs made possible by 340B savings. Program participation comes with significant administrative costs and compliance-related resources, including hiring the appropriate staff, such as pharmacists and pharmacy technicians, to ensure compliance with very technical and evolving requirements. In addition, 340B hospitals must invest in appropriate billing software and allocate resources to comply with the program and respond to audits. As a result of policies that significantly gut the program's benefit on top of these added expenses, some hospitals might have to pull back on the services they offer to patients.

The OPPS payment policy for 340B hospitals has many negative consequences for patients and providers and does not save the Medicare program money. Because CMS has implemented the policy in a budget-neutral manner, the cut in funding does not go back to the Medicare program

⁹ Data from internal analysis conducted for America's Essential Hospitals by Dobson DaVanzo & Associates. September 2019 (See appendix for a more detailed discussion of the methodology used to calculate Medicare outpatient margins).

or directly to beneficiaries; instead, CMS updates the OPPS conversion factor, providing an increase in OPPS payment rates for ambulatory payment classifications (APCs) unrelated to drugs. The result is a redistribution to non-340B hospitals at the expense of 340B hospitals and their patients. Further, in the aggregate, Medicare would not save any money through this proposed policy.

CMS also justified its policy by claiming that patients would benefit from reduced costs. America's Essential Hospitals recognizes and is concerned with the burden of even limited cost-sharing on low-income patients, but we question whether this policy has benefited individual patients. Because CMS implements this policy in a budget-neutral manner that raises OPPS rates for other APCs, all beneficiaries pay higher copays for other services.

Moreover, most patients do not directly receive the benefit of this copayment reduction, even if reduced payments for 340B drugs lower coinsurance amounts for these drugs. The vast majority of Medicare patients have supplemental sources of insurance coverage that would cover their copayments. The Medicare Payment Advisory Commission (MedPAC) has noted that, in total, 87 percent of Medicare beneficiaries are covered by some source of supplemental coverage, whether Medigap, Medicaid, or employer-sponsored supplemental coverage.¹⁰ These supplemental coverage sources are likely to pay for at least part of beneficiaries' copayments, meaning most beneficiaries hardly benefit from this policy. It is difficult to justify this policy, which reduces the benefit of the 340B program, while threatening the ability of participating hospitals to provide care to the most vulnerable Medicare beneficiaries and other patients.

d. CMS' policy does not affect the root causes of astronomically rising drug prices.

Like CMS, America's Essential Hospitals is concerned about rising drug prices. Essential hospitals, which are on the front lines of treating low-income patients, have firsthand experience with the pressures associated with annual drug price increases. The rising cost of prescription drugs can have serious consequences for patient access and for the health care system at large, especially if patients are unable to afford the very drugs meant to keep them out of the hospital. Report after report confirm this unsustainable trajectory, caused by manufacturers' unfettered discretion to set prices as they see fit. Year after year, drug manufacturers increase drug prices with impunity. Within days of the new year, manufacturers raised prices on more than 250 prescription drugs.¹¹ OIG has highlighted the connection between rising manufacturer list prices and higher costs for patients and government programs. OIG found Medicare Part D reimbursement for brand-name drugs increased by 77 percent between 2011 and 2015, resulting in increased costs for Medicare and doubling the number of Medicare beneficiaries who had to pay more than \$2,000 in annual out-of-pocket costs for prescription drugs.¹² This trend is bound

¹⁰ Medicare Payment Advisory Commission. Data Book: Health Care Spending and The Medicare Program. June 2018. http://www.medpac.gov/docs/default-source/data-book/jun18_databookentirereport_sec.pdf. Accessed September 9, 2019.

¹¹ Erman, Michael. Reuters. Drug companies greet 2019 with U.S. price hikes. January 2, 2019. <https://www.reuters.com/article/us-usa-drugpricing/drug-companies-greet-2019-with-u-s-price-hikes-idUSKCN1OW1GA>. Accessed September 9, 2019.

¹² Department of Health and Human Services Office of Inspector General. *Increases in Reimbursement for Brand-Name Drugs in Part D*. June 4, 2018. <https://oig.hhs.gov/oei/reports/oei-03-15-00080.asp>. Accessed September 9, 2019.

to continue, with prescription drug spending projected to outpace overall health care spending growth through 2026, mainly due to rapid growth in drug prices.¹³ Rising drug prices put pressure on patients' pocketbooks and strain taxpayers and government programs, such as Medicare and Medicaid. Essential hospitals directly bear the consequences of such price increases, which put increasing strain on hospital budgets and operating margins.

While the evidence is clear that drug list prices have risen from year to year, CMS has provided no evidence of how lowering reimbursement to 340B hospitals for separately payable drugs under the OPSS would counter this trend. The 340B program actually saves money for providers, patients, and the federal government. It is a critical tool that insulates patients from rising drug prices and ensures their continued access to needed therapeutics. The 340B program has enabled essential hospitals to reduce emergency department (ED) usage, increase access to coordinated care, reduce readmissions, and increase availability of lifesaving prescription drugs to low-income patients. By preserving the 340B program, CMS will ensure that hospitals can continue to use their limited resources to develop programs to achieve these shared goals.

A 2017 study showed 340B discounts provided by manufacturers only made up 1.3 percent of net U.S. drug spending in 2015, a percentage so negligible it is implausible to argue that the program is responsible for rising drug prices. Further, drug manufacturers provide other rebates and discounts that are much larger in the aggregate than 340B discounts. Discounts through the 340B program represent only 3.6 percent of total drug rebates and discounts. In contrast, rebates manufacturers negotiate with health plan and pharmacy benefit managers accounted for 34 percent of all rebates and discounts.¹⁴ Given the lack of analysis proving CMS' policy has had any effect on drug prices, a policy of slashing payments to 340B hospitals is unsubstantiated and ill-advised.

CMS lacks statutory authority to implement such a substantial reduction in Part B drug payments, and the agency has failed to produce research connecting this policy to lower drug prices. The reduction in payments to 340B hospitals has negative consequences for essential hospitals and their patients; therefore, **we strongly urge the agency to withdraw its policy and revert to paying 340B hospitals at 106 percent of ASP.** We believe that preserving the intent of the 340B program would better serve low-income Medicare beneficiaries and the Medicare program at large.

2. CMS should propose a remedy to repay hospitals at the full statutory default rate of ASP plus 6 percent for the years the policy has been in effect.

CMS seeks potential remedies for the CY 2018 and 2019 payments and for use in CY 2020 payments in the event the agency receives an adverse ruling by the U.S. Court of Appeals.

We believe the remedy should be as follows: Refund payments should be made to each affected 340B hospital and calculated using the JG modifier, which identifies claims for 340B drugs that were reduced under the 2018 and 2019 OPSS rules; others not adversely impacted by the

¹³ Cuckler G, et al. National Health Expenditure Projections, 2017–26: Despite Uncertainty, Fundamentals Primarily Drive Spending Growth. *Health Affairs*. 2018;37(3).
<https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2017.1655>. Accessed September 9, 2019.

¹⁴ Dobson DaVanzo & Associates LLC. Assessing the Financial Impact of the 340B Drug Pricing Program on Drug Manufacturers. July 2017. http://www.340bhealth.org/files/340B_Financial_Impact_7_17.pdf. Accessed September 9, 2019.

reductions should be held harmless. This remedy would not disrupt the Medicare program and is consistent with those for past violations of law. Our detailed comments follow.

a. The proper remedy is straightforward and easily administered.

There is a straightforward remedy that is easy to implement, will not be disruptive, does not require new rulemaking, and is comparable to those the courts and agency have adopted to correct other unlawful Medicare payment reductions. Specifically, the agency can recalculate the payments due to 340B hospitals based on the statutory rate of ASP plus 6 percent, as provided by the 2017 OPPS rule. Hospitals that have already received partial payment should receive a supplemental payment that equals the difference between the amount they received and the amount to which they are entitled, including ASP plus 6 percent plus interest. Claims that have not yet been paid should be paid in the full amount, including ASP plus 6 percent.

While the claims will be for different total amounts, the percentage of the claim that the hospital was underpaid is identical in each case. These calculations should be on a hospital-by-hospital basis. Once the total amount that each hospital was paid is calculated, that amount can be multiplied by a single factor — which will be uniform across hospitals — to determine how much should have been paid and thus how much the reimbursement was reduced. Each hospital can be compensated according to the amount that its reimbursements were reduced plus interest.

b. There is ample precedent for full retroactive adjustments that are not budget neutral.

There is ample authority for the Department of Health and Human Services (HHS) to remedy the underpayments caused by its unlawful rule, including: *Cape Cod Hospital v. Sebelius*, (D.C. Cir. 2011) (HHS corrected errors for the future and past claims for which hospitals had been underpaid); *H. Lee Moffitt Cancer Ctr. & Res. Inst. Hosp., Inc. v. Azar*, (D.D.C. 2018), (HHS may make a retroactive adjustment without applying the budget-neutrality requirement to cancer hospitals that received a statutorily mandated adjustment a year later than the law required); and *Shands Jacksonville Medical Center v. Burwell*, (D.D.C. 2015), (HHS compensated hospitals for three years of across-the-board cuts with a one-time, prospective increase of 0.6 percent).

The remedy need not be budget neutral. The authority the agency cites is not applicable because such expenditures would be required by a court decision in service of fixing a prior unlawful underpayment. Moreover, the agency does not consistently apply budget neutrality to fix its missteps and in other relevant instances. For example, HHS allows for retroactive correction of the wage index without any budget-neutrality adjustment when it made the error and it was not something a hospital could have known or corrected. In addition, budget neutrality does not apply to changes in enrollment or utilization for drugs when the average sales price increases.

c. There is no basis for paying hospitals less than the statutory ASP plus 6 percent.

The OPPS mandates HHS reimburse hospitals for covered outpatient drugs at ASP plus 6 percent. This was the methodology used from 2013 to 2017. HHS has now requested comment on adjusting the payment for 2018, 2019, and 2020 from ASP plus 6 percent to ASP plus 3 percent. Although the agency has some authority to deviate from this law, the agency is attempting to use a policy rationale that is inconsistent with the law itself and, therefore, it would be unlawful to reduce ASP to 3 percent.

d. New patient copayments are not required.

Medicare reimburses hospitals 80 percent for covered outpatient services and the remaining 20 percent is collected from the patients or their insurance. Because HHS deviated from the lawful payment rate for 2018 and 2019 with a 30 percent reduction, in theory hospitals could collect from patients or their insurance companies the difference between 20 percent of the lawful payment rate and the 20 percent copay that was actually collected. HHS has requested comment on the “most appropriate treatment of Medicare beneficiary cost-sharing responsibilities.”

Although the agency has raised the specter that a remedy would require patient copays to be adjusted retroactively, we do not believe that there is any law that would require hospitals to collect payments altered by the agency’s illegal act. Neither the False Claims nor anti-kickback statutes would apply since patients would not have been induced to seek services. Patients who reasonably believe that they have fully paid for hospital care provided months, or in some cases years, ago should not have to make these payments if hospitals are willing to forego them. We urge HHS to state this clearly in the final rule.

3. CMS should not reduce payments for separately payable drugs purchased through the 340B program and administered at non-excepted PBDs, which exceeds its statutory authority under the SSA.

CMS proposes to continue its extension of its unlawful payment policy for 340B drugs to non-excepted PBDs, as it did for the first time in CY 2019. Specifically, the agency plans to pay at 77.5 percent of ASP for 340B drugs administered in non-excepted off-campus PBDs under section 603 of the Bipartisan Budget Act of 2015 (BBA). These PBDs are not paid for outpatient services at the full OPPS rate but instead under the Medicare Physician Fee Schedule (PFS), as adjusted. As we argue above, the policy to reimburse for 340B drugs at 77.5 percent of ASP under the OPPS is unlawful under the SSA. Extending this policy to non-excepted PBDs is equally untethered from the statute, which also precludes payment at a rate other than 106 percent of ASP for these clinics.

CMS’ rationale for reducing drug payments for non-excepted PBDs is the “significant incongruity” between payment for drugs at excepted and non-excepted PBDs, as well as the “perverse incentives and resulting distortions” that might result from the difference in payment across these settings.¹⁵ Had CMS not instituted its unlawful and ill-advised payment policy for 340B drugs in the first place, there would be no incongruity between drug payment at different types of PBDs. The default payment rate for most separately payable, non-pass through drugs under both the OPPS and PFS is 106 percent of ASP, and this only changed in CY 2018 when CMS decided to create a new payment rate for 340B drugs under the OPPS. If CMS were to revert to its original methodology for paying drugs under the OPPS, there would be no difference between drug payments at excepted and non-excepted PBDs. CMS lacks the legal authority to set the payment rate at 77.5 percent of ASP for non-excepted PBDs, as we establish below.

¹⁵ 83 Fed. Reg. 37046, 37146 (July 31, 2018).

- a. The Medicare PFS is the applicable payment system for non-excepted PBDs, and it requires payment for drugs at 106 percent of ASP.

Congress, in section 603 of the BBA, directed CMS to pay non-excepted PBDs under an “applicable payment system under this part” (referencing Part B of Title XVIII, which governs Medicare Part B payments to physicians and hospital outpatient departments). In the CY 2017 OPSS final rule, CMS determined the applicable payment system to be the PFS and since has established the rates for non-excepted PBDs in the annual PFS rule.¹⁶ Therefore, the payment methodology for Part B drugs administered in these non-excepted PBDs should be the methodology used under the PFS, which is outlined in section 1842(o)(1)(C) of the SSA. This section describes the payment rates for different categories of drugs in the physician office setting and for the separately payable drugs and biologicals in question; it states that the payment rate is to be based on the amount in section 1847A. Section 1847A sets a payment rate of 106 percent of ASP, and CMS pays physician offices this rate for separately payable drugs and biologicals. Because the methodology for drug payments under the PFS is covered by section 1842(o)(1)(C), this is the “applicable payment system” for Part B drugs in non-excepted PBDs.

Previous CMS rulemaking on section 603 confirms that non-excepted PBDs should be paid 106 percent of ASP for Part B drugs. In the CY 2017 OPSS final rule, CMS adopted an interim payment rate for non-excepted PBDs under the PFS. The agency excluded separately payable drugs and biologicals from the analysis used to arrive at the interim payment rate “because those drugs or biologicals are paid the same rate whether they are furnished in the physician office setting or the hospital setting, and because we are not adopting a percentage reduction to separately payable drugs and biologicals.”¹⁷ CMS confirmed that the payment rate for these drugs should be set as if they were provided at a physician’s office, noting that separately payable drugs “will be paid in accordance with section 1847A of the Act (that is, typically ASP + 6 percent), *consistent with payment rules in the physician office setting*” (emphasis added).¹⁸ Payment for Part B drugs in the physician office setting is governed by section 1842(o)(1)(C), so CMS is required to pay 106 percent of ASP under section 1847A.

- b. CMS does not have the authority under the SSA to adjust payment rates for separately payable drugs provided in conjunction with services paid under the PFS to 77.5 percent of ASP.

CMS does not have the statutory authority to make adjustments under the applicable payment system for non-excepted PBDs. Section 1842(o)(1)(C), the applicable payment system for drugs administered at non-excepted PBDs, does not contain an adjustment mechanism like that CMS relies on (erroneously) to justify its drastic payment reduction for 340B drugs under the OPSS. The OPSS language, at section 1833(t)(14)(iii)(II), requires payments at the rate “established under 1842(o) ... adjusted by the [HHS] Secretary as necessary.” The OPSS adjustment is applied after the rate is established under section 1842(o), which itself contains no parallel adjustment authority.

¹⁶ 81 Fed. Reg. 79562, 79570 (November 14, 2016).

¹⁷ 81 Fed. Reg. 79562, 79723 (November 14, 2016).

¹⁸ 81 Fed. Reg. 79562, 79725 (November 14, 2016).

Section 1833(t)(14)(iii)(II) falls under the section of the SSA that dictates OPSS payment and therefore is not applicable to payments for non-excepted PBDs, which are no longer paid under the OPSS. The text of the BBA is clear that non-excepted PBDs are not to be paid under the OPSS but instead should be paid under another “applicable payment system under this part (other than under this subsection).”¹⁹ Because non-excepted PBDs no longer are paid under the OPSS, CMS cannot use the adjustment authority under section 1833(t)(14) to pay at a rate other than 106 percent of ASP.

In last year’s rulemaking, CMS attempted to circumvent this limitation on its adjustment authority by claiming that drugs provided in non-excepted PBDs are exempt from the 106 percent of ASP rate otherwise mandated under section 1842(o). The agency referenced an exemption from the provision’s requirements for a “drug or biological [that] is not paid on a cost or prospective payment basis as otherwise provided in this part.” CMS claimed that because items and services provided by non-excepted PBDs are paid at a rate that is 40 percent of OPSS rates, they are effectively paid on a prospective payment basis and, thus, not subject to the 106 percent payment rate for Part B drugs. CMS is incorrect on several counts.

First, CMS determined in the CY 2017 OPSS final rule that non-excepted PBDs will be paid under the PFS, which is a fee schedule and not a prospective payment system. The interim payment rate of 40 percent, based on a relativity adjuster, is a mechanism used to determine payment rates for non-excepted PBDs; it allows hospitals to continue to bill on an institutional claim form while receiving payment under the PFS. The fact that payment rates are based on OPSS rates does not make the payment system a prospective payment system. CMS finalizes a payment rate for these non-excepted PBDs in the annual PFS regulation, which governs payment for physician offices and is a fee schedule, not a prospective payment system.

Second, section 1842(o) notes that drugs are to be paid under 1847A unless they are “paid on a cost or prospective payment basis as otherwise provided in this part.” The prospective payment system referenced in 1842(o) is under Part B of the SSA, which includes payment systems such as the OPSS and the Federally Qualified Health Center Prospective Payment System. However, it does not include any other systems, including what CMS claims is a prospective payment system for non-excepted PBDs—there is no separate prospective payment system for non-excepted PBDs beyond the PFS.

Last, from a policy standpoint, CMS’ and Congress’ rationale for reducing payment to off-campus PBDs is to equalize payment with physician offices. If that is the desired goal, CMS should be paying hospital off-campus PBDs at 106 percent of ASP, which is what it pays physician offices. Instead, CMS wants to pay these off-campus PBDs even less than physician offices, which does not withstand scrutiny given the rationale behind its site-neutral payment policy.

4. CMS should withdraw its proposal to further reduce payments for clinic visits at excepted off-campus PBDs, which exceeds its authority under the SSA.

As mandated by section 603 of the BBA, CMS discontinued paying certain off-campus PBDs under the OPSS on January 1, 2017; the statute instructs CMS instead to pay these PBDs under another Part B “applicable payment system.” In CY 2017 OPSS rulemaking, CMS decided that

¹⁹ SSA 1833(t)(21)(C).

non-excepted PBDs would be paid under the Medicare PFS. The BBA clearly defines which PBDs would be affected by the law and specifically exempts other types of PBDs from changes in reimbursement. These excepted PBDs, which are clearly outside the reach of the reduced payment amount under section 603, are the excepted PBDs for which CMS now proposes to continue to phase-in its cut—to 40 percent of the OPPS rate in CY 2020—for outpatient clinic visits. These visits, assigned Healthcare Common Procedure Coding System (HCPCS) code G0463, are the most frequently performed service in the outpatient setting and encompass visits from the most basic patients to those with multiple chronic conditions seeking care from specialists. Outpatient clinic visits are necessary to coordinate care, reduce readmissions, and keep patients out of the ED.

CMS' proposal to continue the phase-in of its 2019 policy to reduce payment for outpatient clinic visits at excepted PBDs to 40 percent of the OPPS rate is contrary to the SSA and violates the payment structure of the OPPS. Since the issuance of the proposed rule, a federal judge has confirmed the payment reduction's unlawfulness, decisively ruling against CMS and vacating the 2019 rule that first instituted the policy. In the ruling, the court said the agency's cut is "impermissible and violates its obligations under the statute" and that CMS' interpretation of the SSA would give it "unilateral authority to pick and choose what to pay for [OPPS] services, which clearly was not Congress' intention."²⁰ **CMS should withdraw this unprecedented proposal, for which it lacks authority and which clearly contradicts congressional intent in passing section 603 of the BBA, and revert to paying excepted PBDs the full OPPS rate for clinic visits.**

- a. CMS should comply with the federal court's order by withdrawing its site-neutral payment policy for excepted PBDs.

The district court's opinion provides clear instructions to CMS: Vacate the 2019 rule and expeditiously develop a remedy to compensate hospitals for the loss of Medicare reimbursement thus far in 2019. CMS should immediately comply with this judicial mandate by withdrawing its proposal to continue the cuts in 2020—instead, paying excepted PBDs at the full OPPS rate—and simultaneously working to develop a remedy to compensate hospitals for reduced 2019 payments. By doubling down on its policy in 2020, CMS not only would be in clear contravention of the court's order, but it would further disrupt the OPPS by introducing unnecessary administrative complexity. CMS will have to reverse cuts it continues into 2020, placing burden on the agency and disrupting hospital operations. **We urge CMS to avoid this by reverting to the full payment rate for hospitals and complying with the court order.**

- b. CMS' extension of payment cuts to excepted PBDs violates the SSA, as amended by the BBA.

In drafting section 603 of the BBA, Congress was explicit in creating a distinction between new and existing off-campus PBDs. Congress deliberately chose to apply its policy only to new off-campus clinics—that is, non-excepted PBDs that were not providing OPPS services before November 2, 2015. Section 603 excluded new off-campus PBDs from the OPPS while grandfathering existing clinics into the OPPS. By singlehandedly deciding to use rulemaking to extend what Congress has limited through legislation, CMS upends this language and substitutes

²⁰ *American Hospital Association, et al. v. Alex M. Azar II*. Civil Action No. 18-241 (RMC). Memorandum Opinion. September 17, 2019.

its own judgment for Congress'. In so doing, CMS usurps congressional authority. In disregarding Congress' judgment, CMS appropriates legislative authority for the executive branch in a clear violation of the separation of powers principle in the U.S. Constitution.

The policy effectively eliminates the distinction created by Congress between excepted and non-excepted off-campus PBDs. Section 603 of the BBA, codified at 1833(t)(21), clearly contains an exception for PBDs that were already in existence at the time of enactment:

EXCEPTION.— For purposes of paragraph (1)(B)(v) and this paragraph, the term ‘off-campus outpatient department of a provider’ shall not include a department of a provider (as so defined) that was billing under this subsection with respect to covered [outpatient department] services furnished prior to the date of the enactment of this paragraph.

The addition of this exception to section 603 shows that Congress unambiguously intended to exempt existing PBDs from the payment cut—they were to continue being paid at the higher OPPS rate. Only new clinics (considered “non-excepted” by CMS) were to be paid at the lower rate under another applicable payment system. The text of the statute is clear: Congress did not intend for CMS to adjust payments to excepted PBDs. CMS contravened congressional intent on the need to exclude these departments by cutting payments for excepted departments at the same rate as if they were non-excepted. In so doing, CMS has effectively rendered the statutory language at 1833(t)(21)(B)(ii) (creating an exception for existing off-campus outpatient departments) meaningless—a clear breach of its statutory authority.

- c. CMS’ application of the volume-control methodology violates the SSA because payment changes can only be made through a conversion factor update and after services exceed an established target.

To implement such an unprecedented payment reduction without a specific congressional directive, CMS invokes a provision of the SSA that the agency has never used before. To achieve its policy of reducing payments for all off-campus outpatient departments to equal payments for services in physician offices, CMS says it is implementing a volume-control mechanism under section 1833(t)(2)(F) of the SSA, which states that “the [HHS] Secretary shall develop a method for controlling unnecessary increases in the volume of covered [outpatient department] services.”

CMS’ proposed implementation of the volume-control methodology is contrary to what is required by statute. In fact, the volume-control method under section 1833(t)(2)(F) is not meant to be achieved through a payment adjustment but through the establishment of target rates or other methodologies. As the district court noted, the volume-control method “is not a price-setting tool, and the government’s effort to wield it in such a manner is manifestly inconsistent with the statute.”²¹ Only if the volume-control targets set under this subparagraph are exceeded does HHS then have the authority to make a payment adjustment through (9)(C), which allows an adjustment only in the form of an annual conversion-factor update in a subsequent year. It is clear from the statutory text that CMS is first required to develop a method (“The Secretary shall develop a method...”) before it can apply any payment changes through a conversion-factor

²¹ *American Hospital Association, et al. v. Alex M. Azar II*. Civil Action No. 18-241 (RMC). Memorandum Opinion. September 17, 2019.

update. Once CMS determines “under methodologies described in paragraph (2)(F) that the volume of services ... increased beyond *amounts established through those methodologies*,” (emphasis added) CMS can control these increases through an “update to the conversion factor otherwise applicable in a subsequent year.” This is the only scenario in which CMS can make a nonbudget neutral adjustment—through a conversion factor update applicable to all OPSS services. CMS has never established target amounts for outpatient services. Rather, CMS has arbitrarily decided that outpatient service volume has been increasing too rapidly, without comparing it with any threshold or target that it has previously developed through a methodology under paragraph (2)(F).

Previous rulemaking on this issue is instructive in determining how the agency had considered using the volume-control methodology. In the 1998 proposed rule setting forth provisions for implementing the new OPSS, the Health Care Financing Administration (HCFA) noted that it planned on developing an “appropriate method for determining expenditure targets,” something CMS has not done up to this point. HCFA then would evaluate whether those expenditures exceeded the target amounts and adjust the conversion-factor update in the following year.²² HCFA also suggested that packaging policies could be adopted and could take the place of expenditure targets and conversion-factor updates, but the OPSS did not package many services initially. Ten years later, in the 2008 OPSS final rule, CMS considered packaging payments in the OPSS to be “clearly preferable to the establishment of [a sustainable growth rate] or other methodology that seeks to control spending by addressing significant growth in volume and program spending with lower payment.”²³ Since the OPSS was implemented, CMS has packaged most services in the OPSS, including through the development of 65 comprehensive APCs (C-APCs), which negates the need for any additional volume-control measures through payment adjustments.

While CMS might have the authority to develop a volume-control methodology through packaging or a conversion-factor adjustment, it certainly does not have the authority to make a 60 percent downward payment adjustment for one type of service in one type of setting. There is no support to be found for this method either in the statute or in any regulations in which CMS has considered using a volume-control methodology. Therefore, CMS’ policy is unlawful, and CMS should withdraw it.

- d. CMS’ reduction of the clinic visit payment rate violates the SSA because adjustments under the OPSS must be budget neutral.

Outside the authority to update the conversion factor once a volume control methodology has been established, CMS can only revise payments for specific OPSS services if these revisions are budget neutral. CMS targets the payment reduction to excepted clinics for a specific type of service (one HCPCS code). This targeted reduction falls outside the normal scope of APC weight adjustments CMS is permitted to make under the OPSS. Under the OPSS, CMS does not have the authority to selectively choose services and cut payment for those services outside the regular rate setting process, which allows for the establishment of APCs and an annual reconfiguration of APC weights in a budget-neutral manner.²⁴ As the district court emphasized, the annual rate-

²² 63 Fed. Reg. 47552, 47586.

²³ 72 Fed. Reg. 66580, 66613 (November 27, 2007).

²⁴ *See, e.g.*, Social Security Act 1833(t)(9)(B), stating that, “If the Secretary makes adjustments under subparagraph (A), then the adjustments for a year may not cause the estimated amount of expenditures

setting “process would be totally ignored and circumvented if CMS could unilaterally set [OPPS] service-specific rates without regard to their relative position or budget neutrality.”²⁵

CMS maintains it does not have to implement this change in a budget-neutral manner. However, as noted above, the only non-budget neutral recourse CMS has is through a conversion factor update. Any other changes to OPPS payment for specific services must be done in a budget-neutral manner. Subparagraph 1833(t)(2)(F) governing the volume control methodology falls under subsection 1833(t)(2), which outlines the overall requirements for the OPPS, including that changes to the OPPS are budget neutral. Under section 1833(t)(9)(B) of the SSA, any adjustments referenced in subparagraph 1883(t)(9)(A) (which in turn references (1883(t)(2))) must be budget neutral. CMS contends that the budget neutrality requirement does not apply to the volume-control methodology, because the SSA does not include the word “adjust” in subparagraph 1833(t)(2)(F). This interpretation is completely inconsistent with the rest of the OPPS statute. The full text of subparagraph (t)(9)(A) makes clear Congress expected CMS to review the OPPS system annually and adjust, to ensure its accuracy and appropriateness, it to account for relevant developments in the overall health care system. CMS’ proposed cut purports to be reacting to just such developments in the overall system, and therefore cannot be outside the budget neutrality requirement.

Moreover, where Congress intended for provisions of the OPPS to be non-budget neutral or not to be considered an adjustment, it clearly indicated this in the text of the SSA. In subparagraph 1833(t)(7)(I) of the SSA, the statute clearly indicates that any additional payments made under the paragraph “shall not be implemented in a budget neutral manner” and “shall not be considered an adjustment.” Congress clearly expressed its intent for provisions not to be budget neutral in other contexts, as well, including subparagraphs 1833(t)(18)(C), (19)(A), and (20). Congress would have similarly indicated in statutory text if it did not want to apply the volume-control methodology in a budget-neutral manner.

- e. CMS’ proposal would severely limit patient access to vital services provided in hospital PBDs and run counter to CMS’ goal of providing efficient care in the lowest-cost setting.

CMS has not analyzed the impact of outpatient payment cuts on health care costs, access to care, or quality of care. Further, the agency has not provided any empirical evidence of the reasons for growth under the OPPS, other than speculating that payment incentives are driving the shift in care to the hospital outpatient setting. CMS’ policy proposal is based on flawed assumptions, including that patients at physician offices and hospital PBDs are identical and that the only reason for treating patients in the outpatient setting is to receive a higher payment rate. These assumptions could not be further from the truth, as hospital PBDs treat more complex patients and provide more specialized services than physician offices.

CMS’ policy has and will continue to undermine the ability of essential hospitals to serve vulnerable populations in underserved areas. Many essential hospitals have off-campus clinics in federally designated areas with shortages of providers, including health professional shortage areas (HPSAs) and medically underserved areas (MUAs). Furthermore, these clinics are more likely to serve dual-eligible patients, as well as uninsured patients and those on Medicaid, when

under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made.”

²⁵ *American Hospital Association, et al. v. Alex M. Azar II*. Civil Action No. 18-241 (RMC). Memorandum Opinion. September 17, 2019.

compared with freestanding physician offices. These clinics face severe cuts due to CMS' policy, and their closure would restrict access to care for communities in which access to health care providers is already limited and cannot be provided by freestanding physician offices.

5. CMS should implement section 603 of the BBA consistent with the legislative text to minimize the adverse effect on patient access.

In drafting the BBA, Congress left some specifics of section 603 implementation for CMS to clarify through the rulemaking process. However, in its interpretation, the agency has unnecessarily expanded the law's scope beyond Congress' original intent; this will further harm essential hospitals and the vulnerable patients they serve. **CMS should use its statutory authority to offer flexibility and reduce burden on providers, particularly regarding relocation and change of ownership.**

- a. CMS should allow PBDs to retain their excepted status notwithstanding relocation.

CMS should allow PBDs to retain their excepted status, even if they relocate, if they continue to meet the provider-based requirements. In the CY 2017 OPPS final rule, CMS creates a limited extraordinary circumstances exception that allows a PBD to temporarily or permanently relocate without forfeiting excepted status. However, the exceptions process only covers a few scenarios and does not envision the many reasons for which a PBD might need to relocate. The BBA neither contemplated nor required that PBDs would lose their excepted status if they relocated.

There are many external forces that could compel a hospital to relocate a clinic. For example, when a provider's lease for a PBD expires, it might find the renewal terms unsustainable. As landlords realize that CMS policy effectively makes a PBD a captive audience, they are likely to raise the rent. While any reasonable business facing such unfavorable economic conditions would consider relocation as a response, a PBD might simply close, given the lack of a financially viable alternative under the proposed relocation policy. Other reasons for relocation beyond a provider's control could include a building being closed for reconstruction or demolition, local zoning changes or ordinances, or other state and local laws. CMS' limitation on relocation is guided by the agency's belief that hospitals are motivated only by financial considerations. As these examples show, there are many reasons a provider might have to relocate that fall outside the agency's narrow exception.

There is precedent for allowing the relocation of provider-based facilities, such as in the context of critical access hospitals (CAHs) and their associated off-campus PBDs that were grandfathered as "necessary providers," a designation that allows a CAH to circumvent certain geographical requirements. While the Medicare Modernization Act of 2003 eliminated this designation, CAHs with necessary provider designation were grandfathered if they existed before January 1, 2006. CMS indicated in rulemaking that grandfathered CAHs and their PBDs with necessary provider designation may relocate without losing their status. As noted in the preamble to the CY 2008 OPPS final rule, in response to a question on relocation of PBDs of grandfathered CAHs, CMS "believe[s] it would be reasonable for a CAH to be able to move its facility." Thus, CMS would be consistent in also allowing PBDs of acute-care hospitals to relocate and maintain their excepted status under section 603. **For these reasons, CMS should lift the burdensome limitation on relocation and clarify that a hospital can relocate a PBD that is excepted if it continues to meet the provider-based requirements.**

- b. CMS should permit non-excepted PBDs to retain their excepted status if they change ownership.

In the CY 2017 OPSS final rule, CMS finalized a policy that allows a PBD to maintain excepted status only if the main provider that owns the PBD changes ownership and the new main provider accepts the existing Medicare provider agreement. In scenarios in which the main provider does not change ownership but an individual PBD does, CMS states that the PBD would lose its excepted status. **We recommend that CMS extend the policy on changes of ownership to circumstances in which an individual PBD changes ownership.** It is not uncommon for provider-based facilities to change hands over time for various reasons. For example, a hospital that finds it unsustainable to continue operating an off-campus PBD for financial or other reasons might decide to sell that particular PBD. But if the loss of excepted status makes the PBD unattractive to potential buyers, the hospital might close it. In such a case, patients in the community would lose access to essential outpatient services. Because excepted PBDs that change ownership operated before the date of enactment and would not be newly created, they should remain excepted.

6. Communities served by essential hospitals face unique health and social challenges; CMS should account for these challenges and preserve adequate reimbursement rates for essential hospitals' excepted and non-excepted PBDs.

We urge the agency to reverse course on the expansion of site-neutral payment policies, which disproportionately affect essential hospitals and the patients they serve. If CMS does not revert to the full payment rate for PBDs, the agency must revise its policy in a way that protects essential hospitals and their patients, rather than causing further harm. Essential hospital PBDs are disproportionately impacted by site-neutral payment policies. For hospitals operating on narrow (often negative) margins, these substantially lower payments are unsustainable and will affect patient access in areas with the greatest need for these services. Essential hospitals operate on a negative 23.1 percent Medicare outpatient margin, or 9 percentage points lower than all OPSS hospitals nationally. **We strongly urge CMS to pay non-excepted PBDs of essential hospitals at a rate no lower than 75 percent of the OPSS rate; we have provided further comment in our separate letter on the CY 2020 PFS proposed rule.**

Given essential hospitals' expansive networks of ambulatory care in otherwise underserved communities, site-neutral payments will continue to have a profound negative effect on their patients. In most communities, essential hospitals are the only providers willing to take on the financial risk of providing comprehensive care to low-income patients, including the uninsured and dual-eligible beneficiaries. PBDs enable hospitals to expand access for disadvantaged patients in communities with no other options for both basic and complex health care needs. Essential hospital PBDs often are the only clinics in low-income communities that provide the full range of primary and specialty services.

The patients treated at essential hospitals' off-campus PBDs typically are low-income and racial and ethnic minorities. Compared with patients at other hospitals, a significantly higher proportion of patients treated at essential hospital PBDs are dually eligible for Medicare and Medicaid, which is a key indicator of patient complexity. More than 37 percent of beneficiaries treated at essential hospital PBDs are dual eligibles, compared with 28 percent at other hospitals. Dual-eligible beneficiaries tend to be in poorer health status, more likely to be disabled, and

costlier to treat compared with other Medicare beneficiaries.²⁶ In fact, CMS uses a hospital's proportion of dual-eligible beneficiaries as a proxy for adjusting the hospital readmission measures to recognize differences in sociodemographic factors. Excessively burdensome and restrictive policies on essential hospitals' PBDs undoubtedly will have downstream effects, including limiting patient access.

Essential hospital clinics often fill a void by providing the only source of primary and specialty care in their communities. Because of their integrated health systems, essential hospitals can help drive down overall health care costs, including for the Medicare program, by efficiently providing coordinated care through ambulatory networks. Providing care in the outpatient setting allows hospitals to avoid unnecessary ED visits, manage patients with chronic conditions, provide follow-up care to patients to avoid readmissions, and, in the process, reduce costs for the health care system at large. These are goals CMS should promote—not stifle—through policies that protect patient access to vital clinic visits in essential hospital PBDs.

7. CMS should ensure efforts to improve price transparency are limited to the types of information important and useful to consumers, within the legal authority of the agency, mitigate the risk of harm to competition and consumers, and do not add administrative burden to providers.

America's Essential Hospitals supports CMS efforts to improve transparency and ensure patients have access to vital information to make informed decisions about their care. However, **we oppose policies for the public posting of payer-specific negotiated rates.** The agency's approach to price transparency would confuse—not help—patients in understanding their potential out-of-pocket cost obligations, severely disrupt contract negotiations between providers and health plans, and exceed the administration's legal authority. **We urge CMS to abandon this proposal and instead convene providers, health plans, patients, and other stakeholders on approaches to meeting patient needs.**

Further, information made publicly available must explain how and why the cost of patient care varies among hospitals. Essential hospitals that take on the provision of services vital to the community, such as trauma or behavioral health care, are likely to have higher costs. These hospitals provide services not typically provided to the same extent by other hospitals, including, but not limited to, community clinics; neonatal services; wraparound services, such as social services and interpretation; and coordination of access to food and shelter for patients who otherwise would not have these necessities. Much of this care is provided to disadvantaged populations, who often are uninsured. This leaves essential hospitals to shoulder the costs of the uncompensated care provided to these patients. In addition, essential hospitals are committed to teaching and training the next generation of physicians, further increasing the cost of care. Information provided to patients should include the unique cost challenges essential hospital face in their mission of caring for vulnerable people. We urge CMS to consider the unique role essential hospitals play in serving patients who face social, linguistic, and economic obstacles, as well as the high costs associated with tackling these challenges, when discussing price transparency initiatives or policies.

²⁶ Medicare Payment Advisory Commission. Data Book: Health Care Spending and The Medicare Program. June 2018. http://www.medpac.gov/docs/default-source/data-book/jun18_databookentirereport_sec.pdf. Accessed September 9, 2019.

- a. CMS should ensure information shared publicly on cost is meaningful and accurate, avoids consumer confusion, and reflects vulnerable patients' socioeconomic and demographic circumstances.

America's Essential Hospitals supports patient empowerment to foster shared decision-making and engage beneficiaries in their health care choices. Each patient's out-of-pocket costs must be communicated to the patient individually. Providers must partner with insurers to communicate to patients about their financial responsibilities. This individualized communication should be done in a timely manner, in the language the patient prefers, and in a format the patient can understand.

It also is important to ensure information provided to patients is relevant as they navigate their care decisions and does not create additional uncertainty. Hospitals are required by law to maintain uniform charges for all patients, regardless of their economic or insurance status—the rate represented on their charge description master (CDM). The price in the hospital CDM rarely reflects the amount for which a patient, or their insurer, is responsible. Further, hospital CDMs are complicated documents, filled with technical terms and codes that most consumers would find difficult to interpret without having specialized knowledge. America's Essential Hospitals previously expressed concern over CMS' proposal to require that hospitals post a list of their standard charges online in a machine-readable format. This requirement was finalized and effective January 1, 2019. Essential hospitals worked diligently to ensure compliance with the requirement to post CDMs; however, it is unknown whether consumers are accessing this information and using it to inform their care choices. We continue to believe the posting of gross charges will have the effect of creating more confusion for patients and generate administrative costs and burden on hospitals.

Prices listed in the CDM are no more useful for patients without insurance, as those patients often are eligible for hospital charity care policies or other significant discounts. No single list at an institution can capture this information. Patients should receive adequate and clear information and support regarding financial assistance for the cost of their care so that the fear of responsibility for all or part of a health care bill does not cause a patient to forgo necessary care. While essential hospitals strive to connect eligible individuals to coverage, they acknowledge some individuals will be ineligible or slip through coverage cracks.

Essential hospitals are proud of their mission to provide access to quality care for all. They recognize that interacting with the health care system can be daunting to some individuals, and they strive to implement not only robust charity care policies but also financial navigation assistance to patients who need it. Their patients receive the most timely and accurate information regarding the cost of their care, including through hospitals' charity care programs. For example, an essential hospital in Missouri employs more than 30 financial counselors to help patients navigate the billing process and understand cost assistance for which they qualify. They guide patients who are eligible for their charity program and even post the application for the program online to provide easier access. The hospital provides a steep discount for patients who do not qualify for the charity program and works with patients to ensure they can access care without an excessive financial burden.

Hospital pricing is complex. The final amount a patient pays often depends on insurance benefit design, including deductibles, coinsurance, copayments, out-of-pocket maximum amounts, and how the payer has negotiated a contract with the provider. CMS proposes to expand the scope of

standard charges hospitals would be required to post publicly, beyond gross charges, to include payer-specific negotiated charges. Payer-specific negotiated charges would be defined as the charges the hospital has negotiated with a third party for items or services furnished by physicians and nonphysician practitioners employed by the hospital. CMS also proposes that this definition would include not only individual items and services but also “service packages” for which a hospital has established a charge. Hospital services can be provided and priced based on the service’s individual component parts or as a more inclusive packaged service. For example, a diagnosis related group (DRG) system might be used to define a hospital product based on the characteristics of patients receiving similar sets of itemized services. In its proposed definition, CMS does not limit service packages to DRGs; the agency proposes to include all other service packages provided by the hospital—for example, service packages the hospital provides in an outpatient setting for which a hospital might have established a standard charge.

Given the large number of plans and variation in reimbursement rates set by insurance companies, CMS’ proposal to require the public posting of negotiated charges only will add to the volume of complex and disparate information consumers might neither access nor find useful. The agency itself acknowledges that a fundamental challenge of making health care prices transparent is that, “the ‘standard charge’ for an item or service (including service packages) varies depending on the circumstances particular to the consumer.” This challenge also is expressed in a 2011 GAO study on transparency in health care markets. The GAO report noted several health care and legal factors that might make it difficult for consumers to obtain accurate price information for health care services before selecting medical care, including: (1) difficulty of predicting necessary health care services in advance; (2) billing from multiple providers in and out of network; (3) variety of insurance benefit structures; and (4) contractual obligations that prevent insurers and providers from publicly disclosing their negotiated rates.²⁷ Almost a decade later, these challenges persist and apply directly to CMS’ proposals for the posting of negotiated rates.

Further, CMS indicates its proposals for the public display of standard charges (both gross and payer-specific negotiated rates) “could be of most use to health care consumers indirectly; that is, such data could be used by the public in price transparency tools or integrated into electronic health records (EHRs) for purposes of clinical decision-making and referrals.” It is unclear why the agency’s proposals are so broad in scope and impact, including potential harm to competition, when the direct benefit to consumers is tenuous at best. If a desired benefit from disclosure of prices is improved point-of-care decision-making by clinicians, **we urge CMS to take a more conservative approach to disclosure: one that focuses on the kinds of information that are most useful to consumers and clinicians.**

An essential hospital in Indiana has been at the forefront of providing price information to their patients in a timely manner. This essential hospital invested time and resources to offer a cost estimation tool with which patients can fill out a web-based form that asks about insurance coverage and their specific procedure. A dedicated team of hospital staff then uses the information to create a personalized estimate of the patient’s out-of-pocket costs. When appropriate, the team produces multiple estimates based on various foreseeable circumstances.

²⁷ U.S. Government Accountability Office, GAO-11-791, Health Care Price Transparency: Meaningful Price Information is Difficult for Consumers to Obtain Prior to Receiving Care (2011). Available at: <https://www.gao.gov/assets/590/585400.pdf>. Accessed September 5, 2019.

Accuracy of estimates is a critical component of transparency, and this essential hospital uses internal audits to ensure credibility in their tool.

Another essential hospital, in the Boston area, created a price quote telephone line within its Financial Assistance Department that it promotes externally, via its website, and internally, as a resource for patients to request a price quote for services provided at the hospital. The hospital's customer service staff manage the request internally, utilizing a standardized price quote request form to expedite the process. Coding staff then perform the necessary research and evaluation and convey this information back to the customer service staff. The patient is called with the information and sent a confirmation letter (by mail or email, based on patient preference) once the request is completed. The standard letter format includes both the pricing for the requested services and a link to the website of the payer for the patient to access information related to the required allowed amount by their insurance company. Sharing patient-specific information on their own out-of-pocket costs is a more accurate and potentially less burdensome use of hospital resources and will lead to less confusion among patients, especially essential hospitals' patients, who often have complex needs and low health literacy or limited English proficiency (LEP.) **We urge CMS to support innovation at essential hospitals that allows for the creation of tailored solutions to increase transparency in a meaningful way rather than government regulated policies.**

- b. CMS lacks the legal authority to require that hospitals publicly disclose payer-specific negotiated charges.

CMS proposes that hospitals publicly disclose standard charges, including all payer-specific negotiated charges, in a single digital file in a machine-readable format. The agency also proposes to require that hospitals display, in an easy-to-understand format, negotiated charges and certain other information for 300 "shoppable" items and services. As proposed, payer-specific negotiated charges would be defined as all charges the hospital has negotiated with third-party payers for an item or service. Each list of payer-specific charges must be clearly associated with the name of the third-party payer.

Section 2718(e) of the PHSA does not give CMS authority to establish these requirements. CMS' proposal is contrary to the plain language of the statute, as negotiated charges are not "standard charges." By definition, a "standard charge" is not privately negotiated and does not contemplate different charges for different payers. "Standard charges" has long been understood to be a technical term that means a hospital's usual or customary CDM charge.

CMS' proposed definition also violates the Administrative Procedure Act (APA) because it is unreasonable. In general usage, "standard" means "usual, common or customary."²⁸ Payer-specific negotiated charges are not usual, common, or customary. They vary year to year, payer by payer, and even health plan by health plan. Indeed, CMS has defined "charges" to mean "the regular rates established by the provider for services rendered to both [Medicare] beneficiaries and to other paying patients. Charges should be . . . *uniformly applied to all patients* . . ."²⁹ And the agency's rationale for seeking to require that payer-specific negotiated charges be made

²⁸ See, e.g., <https://www.dictionary.com/browse/standard>.

²⁹ Provider Reimbursement Manual, No 15-1, ch. 22, § 2202.4. (Emphasis added.)

public undercuts the notion that those charges are standard: CMS wants payer-specific charges to be public precisely because those charges are not standard.³⁰

The agency's proposal also would violate the First Amendment by compelling the public disclosure of individual charges privately negotiated between hospitals and health plans. Government regulation of non-misleading commercial speech is unlawful unless it "directly advances" a "substantial" governmental interest and is no "more extensive than is necessary to serve that interest."³¹

CMS' proposal also is much more extensive than necessary to serve the professed interest.

Because hospitals rely heavily on the confidentiality of health plan-negotiated charges to permit them to negotiate arm's-length charges with other health plans, disclosure of prices negotiated with individual health plans would unduly burden hospitals' ability to enter into competitive contracts; it goes well beyond the level of regulation necessary to promote the stated government interest. The charges negotiated between hospitals and health plans are confidential trade secrets.³² As such, requiring their public disclosure would infringe upon intellectual property rights recognized by Congress and individual states.³³

Mandating the public disclosure of trade secrets protected under both federal and state law would result in extreme harm to hospitals and health plans alike. The agency has failed to demonstrate that the proposed regulation is narrowly tailored or that its interests "cannot be protected adequately by more limited regulation of . . . commercial expression."³⁴

- c. CMS' proposed posting of payer-specific negotiated rates would harm consumers and competition.

CMS acknowledges that "the impact from the release of negotiated rates is largely unknown." **In light of this, we urge the agency not to finalize its proposals for the posting of payer-specific negotiated charges.**

Apart from its legal shortcomings, the proposed disclosure threatens competition and the movement toward value-based care. The Federal Trade Commission (FTC) has warned numerous times against disclosure of competitively sensitive information, such as payer-negotiated prices, in the health care marketplace. Such disclosure, the FTC has said, can "facilitate collusion, raise prices and harm...patients...."³⁵ That warning extends explicitly to contract terms with health plans.³⁶ The FTC has urged that transparency be limited to "predicted

³⁰ See, e.g., 84 Fed. Reg. 39,175, 39,577 (Aug. 9, 2019).

³¹ *Central Hudson Gas & Electric Corp. v. Public Service Comm'n of New York*, 447 U.S. 557, 566 (1980). The agency has failed to identify a sufficient predicate to justify the application of *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626 (1985) to the facts presented here. But the regulation fails under either test. Even under *Zauderer*, a disclosure requirement cannot be "unjustified or unduly burdensome." *Id.* at 651.

³² See *West Penn Allegheny Health Sys., Inc. v. UPMC*, 2013 WL 121441532 (W.D. Pa. Sept. 16, 2013) ("[i]nformation regarding pricing and rates constitutes trade secret information").

³³ 18 U.S.C. § 1836.

³⁴ *Central Hudson Gas & Electric Corp. v. Public Service Comm'n of New York*, 447 U.S. 557, 570 (1980).

³⁵ FTC Letter to the Hon. Nellie Pou, April 17, 2001.

³⁶ FTC Letter to Hons Joe Hoppe and Melissa Hortman, June 29, 2015.

out-of-pocket expenses, co-pays, and quality and performance comparisons of plans or providers.”³⁷

The public posting of fees, including discounts and other pricing terms that are typically negotiated between health care providers and plans, in confidence, could undermine the effectiveness of selective contracting—a mechanism used by health plans to lower costs and improve overall value in health care delivery.³⁸ At least one commercial health insurer warned that disclosure of payer-specific negotiated charges would “impair the movement to value-based care” and allow “[d]ominant health plans to seek and use that information to deter and punish hospitals that lower rates or enter into value-based arrangements with the dominant plan’s competitors.”³⁹

We urge CMS to strongly consider the unintended consequences that could come from disclosure of negotiated rates and seek alternatives that better serve the needs of the consumer.

- d. Transparency requirements should not increase administrative or regulatory burden and recognize that essential hospitals already comply with multiple transparency requirements on the state and federal levels.

America’s Essential Hospitals commends the administration for its attempts to reduce regulatory and administrative burden through initiatives such as Patients over Paperwork, with its aim of increasing efficiency in the delivery system by allowing providers to focus their time and resources on patient care. However, a variety of hospital regulatory requirements exist that increase the demand on resources to deliver care, and ultimately the cost of care, without necessarily improving quality or lowering costs. **We urge CMS to consider the administrative burden its transparency policies would impose on essential hospitals.**

The implementation of new transparency requirements, including the posting of payer-negotiated charges, likely would require significant investment of time and resources from essential hospitals—time and resources that otherwise could be spent caring for patients. Contracts with payers are not all structured in the same way, and with individual payers often offering multiple insurance products. Some contracts include percent-of-charge reimbursement methodologies, in which payments are based on a percentage of the CDM. Further, the shift away from fee-for-service payments and toward value-based payments and population health management also is seen in payer contracting. Value-based contracts are just one type of variation that conveys complexity in the posting of negotiated rates and the usability to consumers. The immense volume of rates, rate structures, payers, and services could potentially translate to thousands of line items and iterations of reimbursement. The posting and updating of this information likely would require a substantial investment of staff time with no clear tie to usability by consumers or providers. In the proposed rule, CMS recognizes that “requiring release of all payer-specific negotiated charges for all hospital items and services (both individual items and services as well as service packages) would mean releasing a large amount of data.” The agency’s estimate for total annual burden for hospitals to review and post their standard

³⁷ Ibid.

³⁸ Ibid.

³⁹ UnitedHealth Group Comments on Re: RIN 0955-AAOI, 21st Century Cures Act, Proposed Rule, June 3, 2019.

charges is 12 hours per hospital. **We believe CMS has grossly underestimated the burden to hospitals, particularly given the complexity of information to be provided and resources required to ensure meaningfulness to consumers.**

In addition to federal regulations, hospitals face transparency requirements from their state and local governments. More than half of states have passed legislation establishing price transparency websites or mandating that health plans, hospitals, or physicians make price information available to patients.⁴⁰ Any new reporting requirements should not duplicate other efforts to increase transparency. **Before implementing new price transparency guidelines, CMS should consider the full scope of reporting requirements with which hospitals already comply.**

CMS references New Hampshire—one of the most comprehensive and oldest hospital price transparency laws in the United States⁴¹—as an example of state-level efforts to provide price information to consumers. In 2003, the state created one of the nation’s first all-payer claims databases to collect health care price information and in 2007 New Hampshire’s Insurance Department began publishing health care prices online for the public. On the state-run website, NH HealthCost, consumers can search for approximately 120 medical services and compare prices by hospital and health insurance company in the state.⁴² New Hampshire has struggled with which prices to feature on the website, given health care bills for one procedure can include prices for numerous services, such as care from medical specialists, imaging, and lab tests. The state’s website now includes information on the price of a bundle of services related to one procedure. Even so, only 8 percent of residents use prices on NH HealthCost to make health care decisions.⁴³ Information reported by hospitals and other stakeholders should be limited to content that has been proved meaningful to consumers and providers and will lead to increased quality of care for all. **We urge CMS to examine the usefulness to the consumer of data already reported before implementing additional reporting requirements that only add administrative burden for hospitals and complexity for consumers.**

Additionally, CMS proposes to require a consumer-friendly public display of payer-specific negotiated charges for select services that are “shoppable.” These “shoppable services” are defined as a service package that can be scheduled by a health care consumer in advance. As further described by the agency, these services are “routinely provided in non-urgent situations that do not require immediate action or attention to the patient.” Hospitals would be required to provide payer-specific negotiated charges for a minimum of 300 shoppable services, including as many of the 70 identified CMS-specified services as possible. Specifically, a hospital would make public the payer-specific negotiated charge for each shoppable service in a manner that groups the charge for the primary shoppable service along with charges for associated ancillary services. These ancillary items and services could include laboratory, radiology, drugs, therapy services (physical, speech, occupational), hospital fees, room and board charges, and charges for employed professional services. CMS believes the expansion of hospital charge display

⁴⁰ Kullgren JT, Ducey KA, Werner RM. A census of state health care price transparency websites. *JAMA*. 2013;309(23):2437-2438.

⁴¹ N.H. Code s. 420-G:11, G:11-a (2006).

⁴² HealthCost. Health Costs. NH New Hampshire Insurance Department and University of New Hampshire Mobile Development. N.d. <https://nhhealthcost.nh.gov/costs/select>. Accessed September 4, 2019.

⁴³ Brown, Zach. Equilibrium Effects of Health Care Price Information. July 16, 2018. The MIT Press Journals. https://www.mitpressjournals.org/doi/abs/10.1162/rest_a_00765. Accessed September 5, 2019.

requirements to include information on shoppable items will meaningfully inform patients' decision-making and allow consumers to compare prices across hospitals. However, there is a great deal of variation and complexity in benefit structures. To inform a patient about the estimated price of a health care service in advance, a provider also would have to know the status of consumers' cost sharing under their specific health benefit plan, such as how much consumers have spent in out-of-pocket costs or toward their deductible at any given time. Without this information, hospitals might have difficulty providing accurate out-of-pocket estimates for insured consumers.⁴⁴

While CMS does not propose a specific format for making shoppable services data public online in a consumer-friendly manner, the agency does acknowledge that some hospitals "may not have any experience in displaying charges for shoppable services." It is likely hospitals would have to purchase new systems, such as price estimating systems, to comply with these new requirements. One essential hospital in Florida has rolled out its transparency tool purposefully, taking its time to minimize errors. The process began with requests for proposals for outside developers to create a price and quality transparency tool. After selecting an outside contractor to develop the tool, the hospital relied on an interdisciplinary team as well as a patient and family advisory committee to determine what patients and their families would consider the most useful information as they make important care decisions. The hospital's goal is transparency plus certainty. **We encourage CMS to facilitate the development and voluntary adoption of patient cost-estimator tools and resources by convening stakeholders to identify best practices, recommending standards for common features of cost-estimator tools, and developing solutions to common technical barriers.**

8. CMS should promote the sharing of best practices for providers having individualized cost-of-care conversations rather than imposing requirements for quality measurement in price transparency.

America's Essential Hospitals appreciates the opportunity to respond to CMS' request for information (RFI) about quality measurement related to price transparency. Essentials hospitals are pioneering work to promote communication about health care costs with all patients, including vulnerable patients facing social, linguistic, and economic obstacles.

The cost of health care services greatly influences clinical decision-making and subsequent outcomes, particularly when high costs prevent patients from following recommended treatment. To ensure the best possible care that meets patients' needs, providers, health organizations, and patients must be able to share and receive information about health care costs and related financial constraints. This issue is especially relevant for essential hospitals, which care for vulnerable patient populations, many of whom are underinsured or uninsured and face other financial hardships.

Based on the populations they serve, essential hospitals are likely to need more resources for providing meaningful education related to prices, costs, and quality of care. For example, beneficiary communication about such complex subjects will require resources to overcome language barriers and low health literacy. This requires staff time dedicated to oral explanation

⁴⁴ U.S. Government Accountability Office, GAO-11-791, Health Care Price Transparency: Meaningful Price Information is Difficult for Consumers to Obtain Prior to Receiving Care (2011). Available at: <https://www.gao.gov/assets/590/585400.pdf>. Accessed September 5, 2019.

and the use of interpreters, as needed. It is important that transparency policies fully capture these factors, minimize their effect, and provide additional support to essential hospitals, which already operate with limited resources.

The growing number of patients with LEP experience significant communication barriers when they enter the health care system.⁴⁵ Communication to beneficiaries about prices and costs must be developed and administered in a manner that ensures comprehension by all beneficiaries and, in particular, those with LEP. Further, essential hospitals treat a population that often has a combination of low educational completion and a language barrier, which places many LEP patients at double the risk of not understanding critical information. It is important that communications—both in text and oral explanations—be carried out in a language understood by the patient or the patient’s representative. Further, terminology used should be crafted in a way that enhances comprehension by all patients.

An essential hospital in Illinois provides a plain-language summary of its financial assistance program to patients at several stages of their care, including through the intake process of the ED. This summary, printed in both English and Spanish, also is posted to the hospital’s website. The hospital employs bilingual financial counselors, who assist patients in either accessing coverage or applying for financial assistance. In addition, hospital staff communicate information on copayments and high deductibles to patients.

When implementing cost of care conversations into workflows, the use of a team-based approach along with evidence-driven tools has been shown to be effective. In some cases, nursing staff asks several brief questions to screen patients and communicates concerns to a clinician, who can discuss costs within the context of clinical decision-making. In other instances, social workers or trained office staff can connect patients to financial assistance. There is also a range of assistance that might be provided in response to these conversations, depending on the specific needs of the patient.⁴⁶ **It is in the best interest of the patient to allow for flexibility in how a care team approaches what can be a highly sensitive and individual conversation.**

CMS seeks comment on various ways to assess how well hospitals and other providers communicate and discuss the cost of care with patients, including how to potentially display cost information alongside quality metrics for each hospital in a way that is meaningful to consumers. America’s Essential Hospitals supports quality improvement initiatives and the display of information to help guide patient choice. But we caution that many disparate quality reporting standards serve only to increase administrative burden without necessarily meeting their goals.

The agency also seeks comment on the development of questions for the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey that would assess how well providers convey costs to their patients. In a recent paper, based on interviews with hospital patient experience leaders, America’s Essential Hospitals and other national hospital associations explored how to update patient experience surveying to best improve patient care.

⁴⁵ Hasnain-Wynia R, Yonek J, Pierce D, et al. Hospital language services for patients with limited English proficiency: Results from a national survey. Health Research & Educational Trust and National Health Law Program; 2006.

⁴⁶ Bradham D, Fiscella K, Fox K, et al. How to Integrate Cost-of-Care Conversations into Workflow: Practice Brief #5; 2018. <https://essentialhospitals.org/wp-content/uploads/2018/11/CostofCarePracticeBrief5.pdf>.

Among the findings was the need to revise the HCAHPS survey in light of today's shift to value-based care, changes in health care delivery, improvements in technology, and evolving patient priorities.⁴⁷ More work is needed to ensure all hospitals ask the right questions in a culturally competent, easily understood way and without burdening patients or providers. **CMS must explore what is truly meaningful for patients, in terms of cost and quality, before designing and introducing a new framework for reporting.**

9. CMS should withdraw its proposal to require prior authorization for Medicare services for which, it states, there are unnecessary increases in utilization.

CMS proposes to require prior authorization for five categories of cosmetic services: blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation. This would be the first time that CMS has required prior authorization for OPSS services. CMS cites section 1833(t)(2)(F) of the SSA as its authority for implementing prior authorization, which is the same authority the agency has cited for implementing its payment cut to office visits at excepted off-campus PBDs. **We urge the agency to withdraw this proposal because it is an unlawful exercise of its statutory authority, it would hinder patient access to timely care, and it would impose excessive administrative burden on the agency and hospitals.**

- a. CMS' proposal is a violation of its statutory authority to control for increases in the volume of outpatient services.

CMS intends to use the provision of the SSA that allows it to “develop a method for controlling unnecessary increases in the volume” of OPSS services. This is the same provision that CMS cited in effectuating its payment cut to excepted off-campus PBDs. As we established above in our comments on that policy, the volume control methodology CMS invokes does not provide it with unlimited authority to target specific services for payment cuts or utilization control methods.

CMS has to first demonstrate that certain services have experienced *unnecessary* increases in volume before it can use this authority. In this instance, CMS has not shown that the five categories of services it intends to subject to prior authorization have had unnecessary increases in utilization. CMS looks at data from 2007 to 2017 and points to “higher than expected” increases in volume but fails to consider any of the underlying reasons that could be driving the volume increases. For example, CMS notes that it is “unaware of other factors that might contribute to clinically valid increases in volume.” However, there are many reasons for increase in utilization of outpatient services, including developments in clinical research that demonstrate the benefits of these services for multiple clinical indications, including to treat neurologic disorders and to alleviate pain. In the case of botulinum toxin injections, there has been a marked increase in approved clinical uses, including for migraine headaches, neuralgia, spasticity, excessive perspiration, and urinary incontinence.⁴⁸ CMS failed to take into account

⁴⁷ Modernizing the HCAHPS Survey: Recommendations from Patient Experience Leaders. July 25, 2019.

⁴⁸ Cleveland Clinic. Seven Surprising Uses for Botulinum Toxin. November 15, 2013.

<https://health.clevelandclinic.org/7-surprising-uses-for-botulinum-toxin/>. Accessed September 17, 2019.; see, e.g., Lew MF. Review of the FDA-approved uses of botulinum toxins, including data suggesting efficacy in pain reduction. *Clinical Journal of Pain*. November 2002.

<https://www.ncbi.nlm.nih.gov/pubmed/12569961>. Accessed September 17, 2019.; Fonfria E, et al. The Expanded Therapeutic Utility of Botulinum Neurotoxins. *Toxins*. May 2018.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5983264/>. Accessed September 17, 2019.

these and other clinical uses for botulinum toxin and the other categories of services it has included on the prior authorization list that would account for the increase in utilization.

This would be CMS' first foray into prior authorization for OPSS services in the fee-for-service context. As CMS notes in the rule, it does require prior authorization for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). However, it is granted explicit statutory authority for prior authorization under the DMEPOS fee schedule, which it does not have under the OPSS statute. Section 1834(a)(15) of the SSA clearly gives CMS the ability to require authorization for certain DMEPOS items by developing and updating a list of services to be subject to prior authorization. The volume control methodology CMS cites under the OPSS does not confer the same authority to the agency to use prior authorization. Even if it were to use prior authorization, CMS would have to demonstrate that the increase in utilization was unnecessary, which it has not done in the rule.

b. Prior authorization requirements will impede patient access to medically necessary care.

CMS' proposed prior authorization process will result in delays in patients accessing timely care, including in cases of genuine medical necessity. For a hospital to receive Medicare reimbursement for one of the services on CMS' list, it first would submit a prior authorization request to CMS or its contractors, which will have ten business days to review before responding with a decision. If the service is approved, the provider will receive a provisional affirmation. However, payment for the service may still be denied once the hospital submits a claim for the service. In cases where a hospital requests an expedited review due to risks to the beneficiary's life, health, or ability to regain maximum function, CMS or the contractor would have two business days to respond with a decision. This timeline would seriously jeopardize beneficiary access to care, even in cases of expedited review. For example, in a case where a beneficiary presents to a hospital outpatient department with a condition that requires immediate treatment on a Friday afternoon, CMS would have until Tuesday—four calendar days later—to respond with a decision. This scenario does not account for any additional time the provider will need to gather the necessary documentation and submit the required prior authorization paperwork. Additionally, there is no appeals process through which a provider could contest an adverse decision from CMS once a denial is issued. **CMS should withdraw the prior authorization proposal because it creates unnecessary obstacles to Medicare beneficiaries receiving timely care deemed necessary by experienced clinicians.**

c. CMS' prior authorization proposal would be administratively burdensome for hospitals, their staff, and for the agency.

CMS' proposal would be administratively burdensome for providers and for the agency. This administration has emphasized the importance of reducing provider burden and emphasizing patient care, as exemplified in its "Patients Over Paperwork" initiative.⁴⁹ CMS' proposal is operationally complex, is bound to increase regulatory burden, and will strain hospital systems and staff resources. Before a service is provided to a beneficiary, the provider must submit a detailed prior authorization request with documentation demonstrating that the service meets Medicare coverage, coding, and payment rules. Hospital staff will require extensive training on the list of services subject to prior authorization, as well as the procedures for submitting these

⁴⁹ Seema Verma. Remarks delivered at the Health Care Payment Learning and Action Network Fall Summit. October 30, 2017. <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-10-30.html>. Accessed September 19, 2019.

requests. Providers will also need to spend time explaining to patients the need for prior authorization and will need to develop educational materials for patients on these new requirements. The proposal will also strain CMS and its contractors' resources at a time when they are already facing a backlog in case reviews. **For these reasons, CMS should not finalize its prior authorization proposals.**

10. CMS should continue to refine the Hospital Outpatient Quality Reporting (OQR) Program measure set so it contains only reliable and valid measures that accurately represent care quality in the outpatient setting, account for social risk factors, and do not add administrative burden.

CMS should continue to tailor the Hospital OQR Program measure set to include measures that are useful to hospitals as they work to improve the quality of their care and that benefit the public by accurately reflecting the care hospitals provide. America's Essential Hospitals supports the creation and use of measures that lead to quality improvement. We encourage CMS to verify the measures would not lead to unintended consequences before including them in the OQR Program.

CMS is not proposing additions to the CY 2020 OQR Program measure set. For CY 2022 payment determination, CMS proposes to remove one measure. We ask CMS to consider the following comments as it continues to refine the OQR Program to ensure measures are reliable, valid, and useful in improving the quality of hospital care and the transparency of public reporting.

- a. We encourage CMS to continue its work through the Meaningful Measures Initiative to refine the OQR Program measure set.

Essential hospitals have long supported quality measurement and pay-for-performance initiatives as vitally important tools for improving value. However, continued work to reduce the number of measures and reporting requirements is needed. Although some measures provide useful information, they are limited in their overall effectiveness in improving health system performance by a lack of focus, consistency, and organization. Further, a lack of consistency often leads to inaccurate comparisons of providers and confusion for patients and consumers.

CMS' Meaningful Measures Initiative aims to identify high-priority areas for quality measurement and improvement. We applaud CMS' efforts, through its Meaningful Measures Initiative and Patients over Paperwork, to increase measure alignment across programs and reduce provider reporting burden. This is a step in the right direction for quality measurement—to come to a consensus on a set of meaningful measures across providers, patients, and payers—but more work is needed. **We encourage the agency to continue this work, with input from all stakeholders, to promote improved outcomes while minimizing costs.**

- b. CMS should account for sociodemographic factors, including socioeconomic status, by risk adjusting the measures used in the Hospital OQR Program.

While the health of the U.S. population overall has improved, socioeconomically disadvantaged populations continue to experience a disproportionate share of many diseases and adverse health conditions. Essential hospitals fulfill the complex clinical and social needs of all patients who come through their doors. Our members treat a high proportion of patients with social risk

factors—factors outside the control of the hospital, such as a lack of transportation or limited access to nutritious food—that can affect health outcomes.

America’s Essential Hospitals supports the creation and implementation of measures that lead to quality improvement. We encourage CMS to continue to examine how to account for social risk factors—such as socioeconomic status, employment, community resources, and social support—in quality reporting in the outpatient setting. Before including measures in the OQR Program, CMS must verify they are properly constructed and would not lead to unintended consequences. As quality reporting programs move toward outcome-based measures and away from process measures, CMS must ensure measures chosen for these programs accurately reflect quality of care and account for factors beyond the control of a hospital. The agency should ensure the measure set includes metrics that are valid and reliable, aligned with existing measures, and risk adjusted for sociodemographic factors. **CMS should not include outcomes measures in outpatient quality performance standards until those measures have been appropriately risk adjusted for sociodemographic factors, including socioeconomic status.**

In previous comments on the Hospital Inpatient Quality Reporting Program, we urged CMS to consider the sociodemographic factors—preferred language and existing level of post-discharge support, for example—that might affect patients’ outcomes and include such factors in the risk-adjustment methodology. We made these comments out of a preponderance of evidence that patients’ sociodemographic status affects outcomes of care.⁵⁰

Essential hospitals support quality and accountability. What they want, and what their patients and communities deserve, is an equal footing with other hospitals for quality evaluation. When calculating quality measures, Medicare programs should account for the socioeconomic and sociodemographic complexities of disadvantaged populations to ensure hospitals are assessed on the care they provide, rather than on the patients they serve. Differences in patients’ backgrounds might affect complication rates and other outcome measures; ignoring these differences would skew quality scores against hospitals that provide essential care to the most complex patients, including those with sociodemographic challenges and the uninsured. Further, failing to appropriately risk adjust can mislead and confuse patients, payers, and policymakers by not accounting for the effect of community factors that contribute to worse outcomes.

CMS should develop analytic methods for integrating patient data with information about contextual factors that influence health outcomes at the community or population level.

Identifying which social risk factors might drive outcomes and how best to measure and incorporate those factors into payment systems is a complex task, but doing so is necessary to ensure better outcomes, healthier populations, and lower costs. We look forward to working with CMS to account for social risk factors and reduce health disparities across Medicare programs, including the OQR Program.

⁵⁰ See, e.g., America's Essential Hospitals. Sociodemographic Factors Affect Health Outcomes. October 21, 2015. <http://essentialhospitals.org/institute/sociodemographic-factors-and-socioeconomic-status-ses-affect-health-outcomes/>. Accessed September 1, 2019.

- c. CMS should finalize the removal of OP-33: External Beam Radiotherapy (EBRT) for Bone Metastases measure from the OQR Program to ensure quality of care and patient safety and to reduce administrative burden.

CMS proposes to remove from the OQR Program one quality measure, OP-33: EBRT for Bone Metastases, beginning with the CY 2022 payment determination. This measure assesses the percentage of patients with painful bone metastases and no history of previous radiation who receive EBRT with an acceptable dosing schedule. The measure was adopted to address EBRT treatment variation, ensure appropriate use of EBRT, and prevent the overuse of radiation therapy.

CMS has determined that the costs associated with this measure outweigh the benefit of its continued use in the program. Specifically, numerous questions received by CMS about how to report the EBRT measure and feedback on data collection received by the measure steward have indicated that manual review of patient records by practice staff is required to properly report on this measure. This administrative burden, in addition to complicated measure exclusions and sampling concerns, has caused difficulty in tracking and reporting data for this measure. Further, the measure steward is no longer maintaining this measure and, therefore, CMS can no longer ensure the measure aligns with clinical standards and guidelines. **We support CMS' proposed removal of OP-33 to avoid further reporting and its associated burden on essential hospitals.**

11. CMS should mitigate concerns about the effect of removing total hip arthroplasty (THA) procedures from the inpatient only (IPO) list on Medicare payment models.

CMS maintains a list of procedures that usually are performed only in the inpatient setting and are reimbursed at inpatient rates and not paid for under the OPFS. Each year, the agency reviews this inpatient only (IPO) list for procedures that should be removed because they can be provided in the outpatient setting.

Effective January 1, 2018, total knee arthroplasty (TKA) was removed from the IPO. We previously expressed concerns over the removal of TKA and we believe similar concerns apply to CMS' proposed removal of THA from the IPO list for CY 2020: namely, the effect the proposed removal of THA would have on Medicare payment models and differences in patient populations undergoing the procedure in the outpatient setting.

As with TKA, THA procedure is included in two episode-based payment models—Comprehensive Care for Joint Replacement (CJR) and Bundled Payment for Care Initiative (BPCI). In these models, services are paid on a fee-for-service basis with retrospective reconciliation against target prices based on historical costs associated with the procedure, for a defined period. Being that the THA procedure has been on the IPO list, CMS does not have claims history for beneficiaries receiving THA on an outpatient basis. If CMS were to remove THA from the IPO list, some patients who previously would have received a THA procedure in an inpatient setting could receive the procedure on an outpatient basis. Therefore, establishing an accurate target price based on historical data becomes more complicated within the CJR and BPCI models. Further, the historical episode spending data might no longer be an accurate predictor of episode spending for beneficiaries receiving inpatient THA procedures.

Also, there are differences in patient population for which the THA procedure is performed on an outpatient basis—i.e., they are younger, more active, have fewer complications, and have more support at home than most Medicare beneficiaries. Many Medicare patients have comorbidities and would require intensive rehabilitation after a THA procedure, making it best performed in an inpatient setting. As such, THA procedures performed on an outpatient basis might only be appropriate for a small number of Medicare beneficiaries. CMS would need to identify a methodology for payment model participants that appropriately adjusts target prices for inpatient procedures to reflect the shift of less complex procedures to the outpatient setting. Before removing this procedure from the IPO list, **we urge CMS to account for differences in performing it in both settings to ensure fairness among participants in episode-based payment models.**

12. CMS should provide a three-year exemption from the two-midnight rule for procedures removed from the IPO list.

We appreciate CMS' recognition of the need to exempt procedures recently removed from the IPO list from medical review under the two-midnight rule. **However, we urge the agency to increase the transition period for procedures removed from the IPO list to three years.** Specifically, CMS proposes that procedures that it removes from the IPO list would not be subject to referrals to Recovery Audit Contractors (RACs) and would not be subject to patient status reviews by RACs for one calendar year after their removal from the IPO list. Furthermore, CMS would not deny claims for patient status for procedures within the first year of their removal from the IPO list—that is, it would not deny inpatient payment for a procedure removed from the IPO list that did not meet the two-midnight rule. Beneficiary and family-centered care quality improvement organizations (BFCC-QIOs), which are the first entities to review claims for compliance with the two-midnight policy, would only review claims for educational purposes during this one-year grace period.

The two-midnight rule states that Medicare will only consider an inpatient admission appropriate for Part A reimbursement when the admitting practitioner expects that a patient will require a stay in the hospital exceeding two midnights. If the clinician does not believe the patient needs care expected to exceed two midnights, the practitioner should not admit the patient, unless there is an exception documented in the medical record that demonstrates the need for inpatient care. America's Essential Hospitals has previously noted its objections to the two-midnight policy and emphasized the need to allow physicians to base decisions on genuine medical need and not on arbitrary, time-based presumptions. The two-midnight policy also had caused confusion and added additional administrative burden for hospital staff. CMS made changes to the two-midnight rule in past years that are positive steps toward preserving clinician judgment and addressing these concerns.

Because procedures on the IPO list can only be performed in the inpatient setting, they are an exception to the two-midnight rule. However, once they are removed from the IPO list, they can be provided in the outpatient setting and would be reviewed under the two-midnight rule, except for during CMS' proposed first-year grace period. CMS should increase the transition period to three years to allow hospitals and practitioners sufficient time to adjust their billing and clinical systems, as well as their processes used to determine the appropriate setting of care. Because providers have no experience assessing procedures on the IPO list against the two-midnight benchmark (since they previously could only be performed in the inpatient setting), they will

require time to update their procedures to make appropriate decisions about whether to admit patients for procedures recently removed from the IPO list.

13. CMS should ensure its C-APC policy does not disproportionately impact hospitals treating more diverse and clinically complex patients.

CMS proposes to add two new C-APCs for CY 2020, bringing the total number of C-APCs to 67. Under the C-APC payment policy, CMS packages payment for the primary procedure with other associated services that appear on the claim. CMS pays for these adjunctive services and the primary procedure using a single C-APC payment, instead of paying hospitals separately for the primary procedure and related services and supplies. Adjunctive services include diagnostic procedures, laboratory tests, imaging services, and visits and evaluations provided in conjunction with the primary service. Payments that typically are not made under the OPSS but under a separate fee schedule, including payment for durable medical equipment, also are paid under the OPSS as part of C-APC payment.

We urge CMS to revise its complexity adjustment methodology to account for the higher costs essential hospitals incur when performing complex procedures and treating sicker patients. To calculate the relative payment weight for the C-APC, CMS uses the geometric mean of the estimated costs on all claims for the primary procedures and all adjunctive services. Thus, a hospital receives a single global payment based on average costs across all hospitals, regardless of the cost of the primary procedure at the particular hospital, the intensity of the services provided, how sick and medically complicated the patient is, or the number and cost of adjunctive services actually provided in conjunction with the primary procedure.

This methodology adversely affects essential hospitals. Certain types of tests or diagnostic procedures might be performed more often at essential hospitals, most of which are academic medical centers providing high-acuity care and treating sicker patients. The C-APC policy puts essential hospitals at a disadvantage due to the greater resources needed to provide high-acuity care to clinically complex patients.

CMS uses a complexity adjustment under the C-APC policy that only accounts for identified instances of high-cost combinations of primary procedures. It does not account for patient characteristics. For example, to account for complex cases in which more than one primary procedure with a J1 status indicator appears on a claim, CMS applies a complexity adjustment and pays the hospital the next-highest C-APC amount in the clinical family. The J1 status indicator identifies a primary service that triggers a C-APC payment and results in other services on the claim being packaged into the C-APC payment. While this type of complexity adjustment would account for certain higher-cost cases, it does not consider patient characteristics, such as comorbidities and sociodemographic factors, that require more resources for treatment.

Given essential hospitals' low margins, they must find innovative and efficient ways to provide high-quality care. But essential hospitals' diverse mix of patients, in terms of clinical complexity and sociodemographic factors, complicates care and requires intense resources. **Therefore, CMS should account for these factors outside the hospital's control by adjusting for patient complexity in the C-APC methodology.**

In addition to adjusting for patient complexity, CMS should revise its complexity adjustment methodology to more accurately reimburse hospitals for performing certain costly procedures.

First, CMS should identify additional procedure combinations that could qualify for a complexity adjustment, including procedures with status indicators S or T that are performed in conjunction with a primary procedure. Procedures with S or T status indicators are major procedures, such as costly surgical procedures, that normally are paid separately. However, under the C-APC methodology, payment for these services is packaged into the C-APC when they appear on a claim with a J1 primary procedure. CMS evaluates claims with combinations of J1 or J2 procedures or add-on codes with status indicator N to determine if the combination of procedures is substantially costlier than the other services in the C-APC. Status indicator N denotes services that are packaged and therefore do not have a separate APC payment amount. **We urge the agency to begin evaluating other types of procedures for complexity adjustments to avoid potentially underpaying hospitals for the cost of performing resource-intensive procedures in conjunction with the primary procedure on the claim.**

CMS also should advance a C-APC by two levels within the clinical family when there is a violation of the two-times rule in the receiving C-APC. Under current policy, when a combination of services on a claim meets the criteria for a complexity adjustment, it is paid at the rate for the next-highest C-APC (the “receiving C-APC”) in the clinical family. A procedure violates the two-times rule when its cost is more than twice that of the lowest-cost procedure in the C-APC. **We urge CMS to move the C-APC two levels higher when there is a violation of the two-times rule in the receiving C-APC.** Because the costs of the procedure combination are significantly higher than other procedures in the C-APC, CMS should move the C-APC two levels higher to ensure adequate reimbursement for the cost of furnishing all the services in question. By adopting these recommendations, CMS would ensure that hospitals have sufficient resources to continue providing cutting-edge services to complex conditions.

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

Sincerely,

Bruce Siegel, MD, MPH
President & CEO

APPENDIX
Dobson DaVanzo & Associates, LLC
OPPS Analysis Methodology