AMERICA'S ESSENTIAL HOSPITALS

September 11, 2017

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-1678-P: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

Dear Ms. Verma:

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

America's Essential Hospitals is the leading association and champion for hospitals and health systems dedicated to providing high-quality care to all people. Filling a vital role in their communities, our more than 300 member hospitals provide a disproportionate share of the nation's uncompensated care and devote nearly three quarters of their inpatient and outpatient care to Medicare, Medicaid, and uninsured patients. Our members provide state-of-the-art, patient-centered care while operating on margins less than half that of other hospitals: 3.2 percent in aggregate compared with 7.4 percent for all hospitals nationwide.[1] Individual essential hospitals often operate on negative margins and key sources of savings, such as the 340B Drug Pricing Program, are critical to their viability. Essential hospitals treat more patients who are dually eligible for Medicare and Medicaid than the average hospital. Through their integrated health systems, members of America's Essential Hospitals offer a full range of primary through quaternary care, including organ transplant services, trauma care, outpatient care in

[1]Roberson B, Ramiah K. Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2015 Annual Member Characteristics Survey. America's Essential Hospitals. June 2017. www.essentialdata.info/. Accessed August 12, 2017.

AMERICA'S ESSENTIAL HOSPITALS
401 Ninth St NW Ste 900
Washington DC 20004
t: 202 585 0100
f: 202 585 0101
e: info@essentialhospitals.org

their ambulatory clinics, public health services, mental health services, substance abuse services, and wraparound services critical to disadvantaged patients.

Essential hospitals offer comprehensive, coordinated care across large ambulatory networks to bring services to where patients live and work. The average member operates a network of more than 30 ambulatory care sites and saw nearly three times more non-emergency outpatient visits in 2015 than other acute-care hospitals nationwide. Our members provide comprehensive ambulatory care through networks of hospital-based clinics that include onsite features—radiology, laboratory, and pharmacy services, for example—that freestanding physician offices typically do not offer. 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 to their patients. But improving care coordination and quality while maintaining a mission to serve the vulnerable is a delicate balance. This balance is threatened by aspects of the proposed rule.

We are particularly concerned that CMS' proposed payment reduction for separately payable drugs provided by hospitals participating in the 340B program would drastically limit the ability of essential hospitals to provide coordinated care to disadvantaged populations. The proposal also would inhibit our members' ability to provide heavily discounted drugs to patients in the face of rapidly increasing drug prices. In our detailed comments below, we urge CMS to withdraw this proposal. We also provide recommendations on:

- CMS' implementation of Section 603 of the Bipartisan Budget Act of 2015 (BBA);
- the Outpatient Quality Reporting (OQR) Program;
- the proposed removal of the total knee arthroplasty (TKA) procedure from the inpatient only (IPO) list;
- refining CMS' comprehensive ambulatory payment classification (C-APC) policy; and
- differential payment for services performed in the inpatient and outpatient settings.

To ensure essential hospitals have sufficient resources to provide access and are not unfairly disadvantaged for serving vulnerable populations, CMS should adopt the following recommendations when finalizing the above-mentioned proposed rule.

1. **CMS should withdraw its proposal to reduce Part B drug payment for hospitals participating in the 340B program. This proposal exceeds the agency's legislative authority, undermines the Public Health Service Act (PHSA), and would devastate low-income patients and the hospitals committed to treating them.**

For hospitals purchasing certain separately payable drugs through the 340B program, CMS proposes to cut Part B reimbursement to 77.5 percent of average sales price (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 would continue to receive payment at 106 percent of ASP. **America's Essential Hospitals strongly urges CMS to withdraw the proposal to reduce payments for 340B drugs and to instead continue to pay all hospitals at the statutory default of 106 percent of ASP.**

The 340B program, codified in section 340B of the PHSA, was created by Congress to allow covered entities to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[2] Under the 340B program, covered entities can purchase certain outpatient drugs at discounted prices, enabling savings that are critical to the operations of these hospitals that fill a safety-net role. The 340B program is structured by statute to provide hospitals discounts for covered outpatient drugs provided to patients of the entity, regardless of the patient's insurance status. Congress expected that various public and private payers would reimburse hospitals at higher rates than the discounts they received from drug manufacturers, which is how hospitals were expected to stretch resources to expand access to medications and other vital services.

Essential hospitals reinvest 340B savings into programs to coordinate care and improve outcomes for vulnerable populations, including initiatives aimed at reducing readmissions, ensuring medication compliance, and identifying high-risk patients in need of ancillary services. CMS' ill-advised proposal to enact a targeted cut is essentially a redistribution of Medicare funds from those hospitals Congress intended to benefit from the 340B program to non-340B hospitals. The policy would take money from the safety net and redirect it to hospitals that do not fill a safety-net role, including for-profit hospitals that are excluded by law from participating in the 340B program.

We urge the agency to withdraw its proposal; in doing so, CMS would act on the recommendations of its own Advisory Panel on Hospital Outpatient Payment. CMS' proposal is inconsistent with Medicare statute—a conclusion supported by reports from Government Accountability Office (GAO) and the Office of Inspector General (OIG)—and conflicts with section 340B of the PHSA, which governs the program.[3,4] CMS has

[2]H.R. Rep. No. 102-384, pt. 2 (1992).
[3]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 29, 2017.
[4]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 29, 2017.

not demonstrated that its proposal would lower drug prices, help beneficiaries financially, or improve access to or quality of care provided to Medicare beneficiaries. On the contrary, as we establish in more detail in the following sections, CMS' proposal would undermine a key policy lever that already has proved effective in combating high drug prices and improving medication adherence.

a. CMS' proposal is inconsistent with the plain language of the Social Security Act (SSA) and is impermissible under the Administrative Procedure Act.

CMS should withdraw its proposal to reduce payment for separately-payable drugs purchased through the 340B program, because it is inconsistent with the agency's statutory authority under the SSA. In the proposed rule, CMS cites reports from advisory and oversight agencies as justification for its policy to reduce Part B payment for 340B drugs. But in discussing Part B drug payment, these same reports specifically note that any changes to Medicare reimbursement for 340B drugs can only be made through legislation and are outside of the authority of CMS. For example, GAO noted that CMS is unable to change Part B reimbursement for 340B discounted drugs "because they do not have the statutory authority to do so."[5] The Medicare Payment Advisory Commission (MedPAC) specifically directed to Congress its recommendations on Medicare payment for Part B drugs purchased through the 340B program.[6] OIG echoed these concerns about CMS' statutory authority, noting that sharing 340B discounts "is not possible under the current design of the 340B Program and Part B payment rules."[7] We agree with these experts that CMS does not have legal authority to implement its proposal.

First, the proposal significantly diverts from the statutory default payment of 106 percent of ASP. CMS pays hospitals for separately payable Part B drugs under section 1833(t)(14)(A)(iii)(II) of the SSA. Under this section, referred to as the statutory default methodology, if CMS cannot implement a payment methodology based on acquisition cost under section (iii)(I), then Congress directs CMS to pay for Part B drugs based on average price. This paragraph specifically references sections 1842(o), 1847A, and 1847B of the SSA as the source of definitions for average price. Under section 1847A, which governs most of the drugs at issue, CMS is to pay at "106 percent of ASP." The level of 106 percent of ASP is not a regulatory choice; it is specified in statute. By reducing the payment for these drugs by 27 percent—from 106 percent to 77.5 percent of ASP—CMS is exceeding the discretion Congress granted it in section 1833(t)(14)(A)(iii)(II), which specifically references payment at 106 percent of ASP.

Nor can CMS rely on the authority provided in section 1833(t)(14)(A)(iii)(II) to calculate and adjust the average price, to make such a significant cut. The adjustments

[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 29, 2017.
[6]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 August 29, 2017.
[7]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 29, 2017.

allowed by the statute under subparagraph (II) are meant to allow the agency to adjust for overhead costs in the form of an add-on percentage, as CMS itself noted in the calendar year (CY) 2013 Outpatient Prospective Payment System (OPPS) final rule.[8] Absent a specific directive from Congress allowing these types of adjustments, CMS' proposed reduction of Part B payments to 77.5 percent of ASP is inconsistent with its statutory authority.

Second, CMS inappropriately proposes to adjust rates by incorporating considerations of acquisition cost into a statutory methodology based on average price. In the preamble to the proposed rule, CMS offers the justification that the proposed payment change would more appropriately reflect the resources and acquisition costs of 340B hospitals. However, section 1833(t)(14)(A)(iii)(II) does not provide CMS the authority to base payments on cost considerations; CMS would have to use the average acquisition cost methodology under section 1833(t)(14)(A)(iii)(I) to do so. Congress provided explicit discretion for CMS to adjust rates based on acquisition costs under subparagraph (I). The notable absence of the same explicit discretion in subparagraph (II) means Congress did not intend to provide this authority when CMS relies upon the average price methodology.

CMS previously determined that it cannot appropriately make payments under subparagraph (I), because the agency does not have acquisition cost data on which to base payment to hospitals. After attempting to pay hospitals at acquisition cost and realizing the operational difficulties of doing so, CMS in CY 2013 instead began paying hospitals under the separate authority that bases payment on ASP (i.e., section 1833(t)(14)(A)(iii)(II)). Cost considerations no longer are a factor under this section. The agency determined that this statutory default methodology was the preferred approach that "requires no further adjustment" and "yields increased predictability in payment for separately payable drugs and biologicals under the OPPS."[9] Since CY 2013, CMS has determined that this is the most appropriate methodology for paying for separately payable drugs and has continued paying at this statutory default.

CMS incorrectly conflates the two sections of the statute by trying to account for acquisition cost when using a section that mandates payment based on average price. GAO in its June 2015 report also weighed in on this issue, emphasizing that "Medicare uses a statutorily defined formula to pay hospitals at set rates for drugs, regardless of their costs for acquiring them, which CMS cannot alter based on hospitals' acquisition costs… ."[10]

Third, Congress already has determined that ASP as defined in statute (specifically under section 1847A of the SSA) should not reflect that certain drugs are purchased at 340B discounts. ASP, as defined under section 1847A, excludes prices paid for 340B

[8]77 Fed. Reg. 68210, 68386 (November 15, 2012).
[9]77 Fed. Reg. 68210, 68386 (November 15, 2012).
[10]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 29, 2017.

discounted drugs.[11] Because CMS does not have the authority to consider 340B drugs in calculating ASP plus 6 percent, it is unreasonable to conclude that CMS would have the authority to make an adjustment to the statutory default based on 340B discounts.

Even if CMS were permitted to adjust the ASP-based payment for acquisition cost under its statutory authority, its reliance on 340B pricing as the sole factor affecting acquisition cost is arbitrary and capricious. CMS notes in the proposed rule that drug acquisition costs "may vary among hospitals depending on a number of factors such as size, patient volume, labor market and case-mix."[12] Yet, CMS does not consider any of these factors in determining acquisition cost. Instead, CMS focuses solely on one factor—participation in the 340B program, which affects only a subset of hospitals—while not attempting to adjust for acquisition costs for other factors or non-340B hospitals. Moreover, CMS' proposed estimate for acquisition cost (77.5 percent of ASP) at 340B hospital relies on scant data and faulty analyses and fails to account for the complexities of drug purchases by 340B hospitals. For example, CMS failed to consider that not all separately-payable drugs purchased at 340B hospitals are purchased at the 340B discounted rate. Indeed, due to complexities of inventory management and 340B program rules, a substantial portion of hospitals' affected drugs are purchased at wholesale acquisition cost. It is arbitrary and capricious for CMS to propose an across-the-board payment reduction for one subset of hospitals based on such incomplete and factually inaccurate analyses.

b. <u>CMS' proposal conflicts with another statute, the PHSA, and undermines Congress' intent in enacting the 340B program.</u>

By substantially altering Medicare reimbursement for 340B hospitals, CMS is undermining the intent of section 340B of the PHSA. While the 340B program is not under CMS' purview, the Health and Human Services secretary has an obligation under principles of statutory interpretation to implement the Medicare statute in a way that does not conflict with or undermine another program and its statutory intent, to the extent possible.[13] CMS' existing OPPS policy aligns with this premise, demonstrating that it is possible to implement a reasonable interpretation of Medicare rate-setting authority that also is consistent with 340B program intent. Despite CMS' assertions, the proposed policy is inconsistent with and undermines the purposes of 340B.

In enacting the 340B program, Congress stated that it is "the intent of the 340B program to allow covered entities, including eligible hospitals, to stretch scarce resources while continuing to provide access to care."[14] Congress specifically designated the entities that should benefit from the program, defining eligible DSH hospitals as those serving a disproportionately greater percentage of low-income (Medicaid and Medicare Supplemental Security Income) patients. These hospitals are intended to be the recipients of discounted drugs and are expected to stretch the resources they receive,

[11]Specifically, the ASP definition excludes sales that are exempt from calculation of best price at Section 1927(c)(1)(C)(i)(I), an exemption that explicitly includes 340B discounted drugs.
[12]82 Fed. Reg. 33558, 33635 (July 20, 2017).
[13]See, e.g., Statutory Interpretation: General Principles and Recent Trends (December 19, 2011) at page 29.
[14] H.R. Rep. No. 102-384, pt. 2 (1992).

including Medicare reimbursement, to continue caring for low-income patients—among them, vulnerable Medicare patients.

By redirecting funds intended for 340B hospitals to other hospitals in the Medicare program, CMS' proposed policy violates the intent of the 340B program. Not only would CMS' proposal cut into the scarce resources of hospitals specified in statute, but CMS' budget neutrality adjustment would redistribute these funds to hospitals not participating in the 340B program. As CMS notes in the proposed rule, the $900 million in cuts to 340B hospitals would be reflected in increased payment to all OPPS hospitals for ambulatory payment classifications (APCs) not related to drugs. In essence, CMS is redirecting savings for 340B drugs to hospitals that do not participate in the program, for other OPPS services. Hospitals treating fewer low-income patients would benefit at the expense of essential hospitals. This is clearly not what Congress had intended when it envisioned the 340B program as allowing providers that fill a safety-net role to stretch scarce federal resources as far as possible to reach more eligible patients.

c. CMS has failed to analyze the impact of the proposal on hospitals and is not transparent in its methodology for calculating the aggregate Part B payment reduction.

Before proposing a policy of such magnitude, CMS should ensure that it has calculated the proposal's impact on hospitals and provided the necessary information to stakeholders to verify the accuracy of the agency's analysis. In the proposed rule, CMS includes very limited discussion of the impact of the 340B proposal on hospitals. CMS provides hospital-specific estimates of the impact of its proposed OPPS policies, as well as estimates of impact by hospital groups. Notably absent from these estimates is any consideration of the Part B payment reduction for 340B hospitals.[15] J**ust as CMS does for other policies in the OPPS, CMS should include an analysis of the effect its Part B drug payment reduction would have on hospitals, as well as specific groups of hospitals, such as DSH hospitals and 340B hospitals.**

CMS estimates the total payment Part B drug payment cut across all 340B hospitals to be $900 million, and says that it will re-distribute the $900 million payment cut to 340B hospitals in the form of a 1.4 percent conversion factor increase applied to non-drug APC payments. In its discussion, CMS repeatedly points to the lack of appropriate data to make an accurate estimate of the payment cut or the conversion factor increase. The agency stresses that "it is not possible to more accurately estimate the amount of the aggregate payment reduction and the offsetting" budget neutrality adjustment, and that it will need to re-assess the conversion factor using newly available data in the future.[16] In our attempt to replicate CMS' estimate of the payment cut, we arrived at a significantly larger payment decrease for Part B drugs of $1.52 billion—over $600

[15]See 82 Fed. Reg. 33558, 33712 (July 20, 2017) ("We note that the proposed payment rates and estimated impacts included in this proposed rule do not reflect the effects of this proposal.").
[16]Ibid.

million larger than CMS' estimate of the payment decrease in the rule.[17] Given the lack of transparency in CMS' methodology, it is impossible to determine whether this substantial discrepancy is due to an error on the agency's part or the inclusion of assumptions in its analysis that are not discussed in the preamble to the rule. **It would be ill-advised for CMS to proceed with a proposal that would cut payments to 340B hospitals by up to $1.5 billion without the requisite understanding of how the proposal would affect individual hospitals' Medicare payments and their ability to operate.**

d. If finalized, CMS' proposal would be detrimental to essential hospitals and their patients, while providing minimal benefit to the Medicare program and its beneficiaries.

The 340B program has been critical to ensuring that low-income and other disadvantaged people have access to the types of services best provided by essential hospitals. Hospitals participating in the 340B program operate on margins significantly narrower than margins of other hospitals, with many operating at a loss. Looking specifically at Medicare outpatient margins, 340B hospitals operate on an aggregate negative 15 percent margin, compared to negative 10 percent at non-340B hospitals. Accounting for the reduced OPPS reimbursement resulting from the proposal, 340B hospitals' Medicare outpatient margins would drop even further, to negative 20 percent.[18] At the same time, as a result of the re-distributive nature of the policy, non-340B hospitals would likely 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 a hospital's ability to maintain critical services. CMS' proposal to cut payments on Medicare Part B drugs only for 340B hospitals, which already operate on substantially negative Medicare outpatient margins, would severely restrict essential hospitals' ability to serve their communities.

Essential hospitals provide lifesaving drugs and services through programs made possible by their 340B savings. To cite a few specific examples, essential hospitals have used 340B savings to:

- continue to provide care and medications to all patients, regardless of their insurance status or financial ability;
- provide lifesaving cancer and transplant drugs at no cost or with steep discounts to homeless patients and patients without insurance to ensure they are protected from drug price increases;
- establish clinical pharmacy programs, in which pharmacists interact with patients at bedside and in the emergency department, ensuring patients

[17]Data from internal analysis conducted for America's Essential Hospitals by Dobson DaVanzo & Associates. August 2017. (see appendix for a more detailed discussion of the methodology used to replicate CMS' proposal).

[18]Data from internal analysis conducted for America's Essential Hospitals by Dobson DaVanzo & Associates. August 2017. (See appendix for a more detailed discussion of the methodology used to calculate Medicare outpatient margins).

understand and adhere to their medication regimen. Through these programs, essential hospitals have reduced excess readmissions;
- provide meaningful access to patients, including low-income Medicare beneficiaries, through clinic location, hours of operation, transportation availability, interpretation services, and patient education that is not otherwise available in many places;
- support free clinics in their communities;
- reduce ED use through a medical home program providing primary care to uninsured, low-income patients; and
- provide mental health and substance abuse treatment.

The proposed Part B drug payment reduction would jeopardize these critical programs and undermine the financial stability of essential hospitals. Not only does the proposed rule threaten these innovative developments, but it also would raise overall health care costs by increasing avoidable admissions. As CMS endeavors to improve care, this is not the time to weaken core Medicare providers.

A reduction in Medicare payment rates to 340B hospitals would significantly erode the value of the 340B program. These proposals would be 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 would be forced to reconsider programs made possible by 340B savings, and others might consider leaving the 340B program entirely. For essential hospitals in particular, there are significant administrative costs and compliance-related resources involved with 340B program participation, including the cost of hiring the appropriate staff, such as pharmacists and pharmacy technicians, to ensure compliance with the program's 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. If CMS implements proposals that significantly gut the program's benefit on top of these added expenses, some hospitals might not be able to afford to participate moving forward. By leaving the program, they could purchase outpatient covered drugs through group purchasing organizations (something they are prohibited from doing as 340B participants)—much less of a benefit than 340B discounts, but also much less of a burden. The decision to drop out of the program would be a loss for patients and would undermine efforts to decrease Medicare costs.

If finalized, the proposed rule would have many negative consequences for patients, the Medicare program, and providers, while not saving the Medicare program any money. CMS would implement the proposal in a budget-neutral manner, cutting reimbursement to 340B hospitals by an estimated $900 million. The cut funding would not go back to the Medicare program or directly to beneficiaries; instead, CMS intends to update the OPPS conversion factor, resulting in an estimated 1.4 percent increase in OPPS payment rates for APCs unrelated to drugs. Therefore, in the aggregate, Medicare would not save any money through this proposed policy.

CMS also justifies its proposal 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

proposal would benefit individual patients. CMS proposes to implement this policy in a budget-neutral manner that would raise OPPS rates for other APCs, meaning that all beneficiaries would pay higher co-pays for other services. Moreover, most patients would not directly receive the benefit of this copayment reduction even if reduced payments for 340B drugs lower coinsurance amounts for these drugs.

Our analysis shows that nearly 30 percent of the approximately 11.5 million fee-for-service beneficiaries at 340B hospitals are dually eligible for Medicare and Medicaid.[19] This means Medicaid would cover copayments for more than 3 million beneficiaries who would not directly see the financial impact of this proposal. Further, an estimated 25 percent of beneficiaries at 340B hospitals have Medigap coverage for copayments, and thus would similarly not receive much direct benefit from the proposal.[20] In total, MedPAC has noted that 86 percent of Medicare beneficiaries are covered by some source of supplemental coverage, whether Medigap, Medicaid, or employer-sponsored supplemental coverage.[21,22] These supplemental coverage sources are likely to pay for at least part of beneficiaries' copayments, meaning most beneficiaries would hardly benefit from this proposal.

CMS estimates the proposed rule would save approximately $900 million savings, of which 20 percent, or $180 million, would be from reduced patient copays. But, as noted above, 86 percent of Medicare beneficiaries are estimated to have another source of coverage for copays. Therefore, only about 14 percent, or $25 million, of the total $180 million of the savings from lower copays would accrue to beneficiaries with no supplemental insurance coverage. In reality, roughly 1.6 million of the total estimated 57 million Medicare beneficiaries would realize annual savings of $15.56 each, with the remainder accruing to insurance companies and other payers that cover copayments. It is difficult to justify proposing changes to the 340B program to realize minimal savings for individual Medicare beneficiaries, while threatening the ability of 340B hospitals to provide care to the most vulnerable Medicare beneficiaries and other patients.

e. CMS' proposal would do little to alleviate the root causes of astronomically rising drug prices.

CMS cites rising drug costs as a reason for its proposal. 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 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 that are meant to keep them out of the hospital. To cite one recent

[19]Data from internal analysis conducted for America's Essential Hospitals by The Moran Company. January 2016.
[20]Ibid.
[21]Medicare Payment Advisory Commission. A Data Book: Health Care Spending and the Medicare Program. June 2017. http://medpac.gov/docs/default-source/data-book/jun17_databookentirereport_sec.pdf. Accessed August 16, 2017.
[22]Medicare Payment Advisory Commission. Report to the Congress: Medicare and the Health Care Delivery System. June 2015. http://www.medpac.gov/docs/default-source/reports/june-2015-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf. Accessed August 16, 2017.

example, the price of two lifesaving heart drugs increased exponentially over a matter of just a few years. One of these drugs, which is used to treat high blood pressure, increased in price by 3,000 percent from 2012 to 2015.[23] Essential hospitals directly bear the consequences of such price increases, which put increasing strain on hospital budgets and operating margins.

When the federal government is the primary payer for these drugs through Medicare or Medicaid, these price increases result in increased federal spending. In 2016, the Medicaid program had to pay $3.2 billion more for brand-name drugs because of price increases on common drugs, such as Aleve.[24] The Medicare program continues to experience increased expenditures due to uncontrolled price increases by drug manufacturers, as detailed in an OIG report on Part D spending. The report found that Medicare paid $33 billion in catastrophic coverage payments under Part D in 2015, a threefold increase since 2010. This spending increase was driven by high-price drugs, with 10 drugs accounting for more than a third of Part D catastrophic coverage spending.[25]

While the evidence is clear that drug prices have risen from year to year, the agency has provided no evidence of how lowering reimbursement to 340B hospitals for separately-payable drugs under the OPPS 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.

A recent study showed that 340B discounts provided by manufacturers only make up 1.3 percent of net drug spending, a percentage so negligible that it is implausible to argue that the program is responsible for rising drug prices. Further, drug manufacturers provide other rebates and discounts, which 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.[26]

The sources CMS uses to link 340B and drug spending have serious methodological flaws. In fact, the Department of Health and Human Services (HHS) previously argued against some of these very conclusions. The GAO report on Part B spending at 340B

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[23]Tribble S J. 47 Hospitals Slashed Their Use Of 2 Key Heart Drugs After Huge Price Hikes. NPR "Shots." August 9, 2017. http://www.npr.org/sections/health-shots/2017/08/09/542485307/47-hospitals-slashed-their-use-of-two-key-heart-drugs-after-huge-price-hikes. Accessed August 29, 2017.
[24]Lupkin S. Climbing Cost Of Decades-Old Drugs Threatens To Break Medicaid Bank. *Kaiser Health News*. August 14, 2017. http://khn.org/news/climbing-cost-of-decades-old-drugs-threatens-to-break-medicaid-bank/. Accessed August 29, 2017.
[25]Office of Inspector General. High-Price Drugs are Increasing Federal Payments for Medicare Part D Catastrophic Coverage. January 2017. https://oig.hhs.gov/oei/reports/oei-02-16-00270.pdf. Accessed August 29, 2017.
[26]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 August 29, 2017.

hospitals fails to appropriately examine the connection between patient health status and spending at 340B hospitals. The report notes that average risk scores of beneficiaries at 340B hospitals were higher than risk scores at non-340B hospitals, but it failed to consider this distinction further, instead concluding that these differences "were likely not explained by the health status of the patients served."[27] In its response to the report, HHS stated that patient status could be causing differences in spending and concluded that further examination of differences in patient risk scores was required. GAO's analysis of patient status also excluded certain characteristics that influence the cost of care and patient outcomes, including sociodemographic factors, such as race and homelessness. Most important, HHS took issue with GAO's conclusions that Part B spending at 340B hospitals was "excess" and "potentially inappropriate," and said these claims are "not supported by the study methodology."[28] Given the lack of analysis proving CMS' proposal would lower drug prices, a proposal to slash payments to 340B hospitals is unsubstantiated and ill-advised.

f. CMS has not considered the practical difficulties and excess administrative burden associated with implementing the proposed 340B policy.

CMS fails to account for many of the complexities of the 340B program and the obstacles the agency and hospitals inevitably would face in implementing this proposal. CMS proposes to reduce OPPS payment to 77.5 percent of ASP for all nonvaccine drugs without pass-through status. However, hospitals do not purchase all Part B drugs in this category at 340B prices. Hospitals participating in the 340B program purchase a considerable percentage of their Part B drugs at list price, or wholesale acquisition cost. CMS' proposal could reduce reimbursement for these drugs as well, even though they were not purchased at the 340B price.

To identify 340B drugs, CMS proposes using a modifier that would be required beginning January 1, 2018. CMS provides no additional related details, so it is not possible for stakeholders to provide comprehensive comments on the feasibility of implementing such a modifier in their billing systems. One significant complexity of CMS' proposal is that it would require the modifier to indicate that drugs were *not* purchased at a 340B discount. Such a process would be the opposite of how Medicaid identifies 340B discounted drugs to avoid claiming a rebate and subjecting a drug to a duplicate discount. Medicaid currently identifies drugs that *were* purchased at a 340B discounts by either appending a modifier to 340B drug claims or using an exclusion file to identify and remove 340B pharmacy claims associated with entities providing 340B drugs to Medicaid patients, depending on the state. This difference between these processes likely would cause confusion for hospital billing staff. Furthermore, CMS' and states' experience with implementation in Medicaid should indicate the potentially immense complexity of the proposal. Given the lack of any details on the modifier, it is unrealistic for hospitals to be expected to update their billing systems and comply with the modifier in a matter of months.

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[27]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 29, 2017.
[28]Ibid.

CMS lacks legislative authority to implement such a substantial reduction in Part B drug payments, and the agency has failed to produce research connecting its proposal to lower drug prices. The proposed rule would have negative consequences for essential hospitals and their patients; therefore, **we strongly urge the agency to withdraw its proposal to reduce Part B drug payments to 340B hospitals.** 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 implement Section 603 of the BBA consistent with the legislative text to minimize the adverse effect its policies would have on patient access.

As mandated by Section 603 of the BBA, CMS discontinued paying certain off-campus, provider-based departments (PBDs) under OPPS on January 1, 2017. The BBA instructs CMS to pay these PBDs under another Part B "applicable payment system" instead of the OPPS. In last year's OPPS rulemaking, CMS decided that non-excepted PBDs would be paid under the Medicare Physician Fee Schedule (PFS). The BBA defines which PBDs would be affected by the law and specifically exempts other types of PBDs from changes in reimbursement. Thus far, CMS has adopted an overly restrictive interpretation of Section 603 that goes beyond what Congress has intended in passing the BBA. **CMS should use its statutory authority to offer flexibility and reduce burden on providers, particularly regarding relocation, change of ownership, and expansion of services.**

The BBA's drastic cuts to Medicare payments for new, off-campus PBDs have begun to impede the ability of essential hospitals to provide outpatient services and expand access into underserved communities. CMS' interpretation of the BBA in the CY 2017 OPPS final rule unnecessarily restricted the law's scope. In the CY 2018 PFS proposed rule, CMS would reduce payment rates to non-excepted PBDs by an additional 50 percent. For hospitals operating on narrow (often negative) margins, these cuts are unsustainable. Paying hospital PBDs at 25 percent of what is normally paid under the OPPS inevitably would affect patient access in areas where there is most need for these services. **We strongly oppose this arbitrary payment reduction and provide further comment in our separate letter on the CY 2018 PFS proposed rule.**

Given essential hospitals' expansive networks of ambulatory care in otherwise underserved communities, the BBA will continue to have a pronounced negative effect on patients of essential hospitals. 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 dually eligible beneficiaries. Such clinics 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 seeking care at off-campus PBDs of essential hospitals tend to be lower income and racial and ethnic minorities, and they are more likely to be uninsured. Excessively burdensome and restrictive policies on PBDs of essential hospitals undoubtedly will have downstream effects, including on patient access.

In drafting the BBA, Congress left many specifics of Section 603 implementation for CMS to clarify through the rulemaking process. But in its interpretation in previous rulemaking, the agency unnecessarily expanded the law's scope, compounding the harm to essential hospitals and the disadvantaged patients they serve. **We urge CMS to exercise its statutory authority to implement the BBA in way that mitigates negative consequences to patient access by adopting the following recommendations.**

a. CMS should continue to allow excepted off-campus PBDs to retain their excepted status, even if they expand services.

In the proposed rule, CMS states that it will not cap service-line expansion in excepted PBDs based on volume or types of services provided. We are pleased that CMS will continue this policy, which will allow essential hospitals to adapt and respond to the changing needs of their communities by adding or changing the types of services they provide.

CMS notes that it will continue to monitor service-line expansion using the claims-based modifiers for services provided in off-campus PBDs to determine if it should address the issue of expansion in future rulemaking. While the need to monitor service line growth is understandable, CMS should apply policies that are consistent with the statutory text of Section 603. Section 603, titled "Treatment of Off-Campus Outpatient Departments of a Provider," clearly states that "the term 'off-campus outpatient department of a provider' shall not include a department of a provider (as so defined) that was billing" for outpatient department services furnished pre-enactment.[29] In other words, a PBD that was billing for services before the date of enactment is completely carved out of the definition of "off-campus outpatient department of a provider." Section 603 only reduces reimbursement to applicable items and services provided at "off-campus outpatient departments of a provider," and by carving out existing PBDs from the definition, the BBA is clear that these PBDs and the services they provide are unaffected by its provisions. Additionally, there is no language in the BBA that suggests these PBDs are excepted for only those services provided before enactment. Even the provider-based rules do not limit the scope of services that can be provided by a PBD. In fact, in rulemaking on the provider-based requirements, CMS previously noted that "the provider-based rules do not apply to specific services; rather, these rules apply to facilities as a whole."[30] **Therefore, we urge CMS to act consistently with the statutory text by continuing to allow excepted PBDs to expand services to meet the changing needs of their communities.**

b. 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

[29]Section 603 of Bipartisan Budget Act of 2015. Pub. L. 114-74, codified as Social Security Act §1833(t)(21)(B)(ii).
[30]67 Fed. Reg. 49982, 50088 (August 1, 2002).

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 instance, 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.**

c. <u>CMS should permit non-excepted PBDs to retain their excepted status if they change ownership.</u>

In the CY 2017 OPPS 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 these excepted PBDs that

change ownership already operated before the date of enactment and would not be newly created, they should remain excepted.

3. CMS should continue to refine the 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 OQR Program measure set to include measures that are useful to hospitals as they work to improve the quality of their care and beneficial to the public as an accurate reflection of 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 any additions to the CYs 2018 and 2019 OQR Program measure sets. For CYs 2020 and 2021, CMS proposes to remove a total of six measures and delay the five survey-based measures derived from the Outpatient Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) survey. 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. CMS should account for sociodemographic factors, including socioeconomic status, by risk adjusting the measures used in the OQR Program.

America's Essential Hospitals supports the creation and implementation of measures that lead to quality improvement. We are pleased CMS is seeking comment on 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 other existing measures, and risk adjusted for sociodemographic factors. CMS should not include measures in outpatient quality performance standards until those measures have been appropriately risk adjusted for sociodemographic factors, including socioeconomic status.

In previous comments on hospital inpatient quality reporting programs, we urged CMS to consider the sociodemographic factors—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.[31] Outcome measures, especially those focused on readmissions, do not accurately reflect quality of care if they do not account for sociodemographic factors that can complicate outcomes. For example, patients who do not have a reliable support structure are more likely to be readmitted to a hospital or other institutional setting. Reducing preventable readmissions is of paramount concern to America's Essential Hospitals and its members. We believe that any program directed at reducing readmissions and improving beneficiaries' health through an episode of care must target readmissions that are preventable and include appropriate risk-adjustment methodology.

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.

As required by the Improving Medicare Post-Acute Care Transformation Act, HHS' Office of the Assistant Secretary for Planning and Evaluation (ASPE) in December 2016 released a report in which the connection between social risk factors and health care outcomes was clearly shown.[32] The report provides evidence-based confirmation of what essential hospitals and other providers have long known: Patients' sociodemographic and other social risk factors matter greatly when assessing the quality of health care providers. We urge CMS to further examine the recommendations found in the ASPE report for future incorporation in the OQR Program.

As noted by the National Academies of Sciences, Engineering, and Medicine (the Academies), in its series of reports on accounting for social risk factors in Medicare programs, "achieving good outcomes (or improving outcomes over time) may be more difficult for providers caring for patients with social risk factors precisely because the influence of some social risk factors on health care outcomes is beyond provider control."[33] We urge CMS to closely examine the considerations provided by the Academies for risk adjustment in federal programs.

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[31]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 August 2017.

[32]Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Washington, D.C.; December 2016. https://aspe.hhs.gov/system/files/pdf/253971/ASPESESRTCfull.pdf. Accessed April 7, 2017.

[33]National Academies of Sciences, Engineering, and Medicine. *Accounting for Social Risk Factors in Medicare Payment*. Washington, DC: The National Academies Press; January 2017. http://nationalacademies.org/hmd/Reports/2017/accounting-for-social-risk-factors-in-medicare-payment-5.aspx. Accessed April 7, 2017.

Like the growing body of research on socioeconomic risk adjustment, the Academies found that community-level elements that providers are unable to change can indicate risk unrelated to quality of care.[34] We urge CMS to examine these criteria, as identified by the Academies, for choosing the risk factors for an adjustment methodology:

- conceptual relationship with the outcome of interest;
- empirical association with the outcome of interest;
- risk factor presence at the start of care;
- risk factor modifiability through the provider's actions; and
- risk factor resistance to manipulation or gaming.

We urge CMS to examine the Academies' report for examples of currently available data to include in measure risk adjustment in the OQR Program. The agency also 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 determining how to best measure and incorporate those factors into payment systems is a complex task, but doing so is necessary to ensure better outcomes, healthier populations, lower costs, and transparency. We look forward to working with CMS to account for social risk factors and reducing health disparities across Medicare programs, including the OQR Program.

b. CMS should delay implementation of the OP-37-a-e: OAS CAHPS survey measures for the OQR Program.

In previous rulemaking, CMS finalized the adoption of five survey-based measures derived from the OAS CAHPS Survey for the CY 2020 payment determination to assist in collection of information about patients' experiences of care in hospital outpatient departments and ambulatory surgery centers. The survey initially was implemented as a voluntary national reporting program in January 2016; it will conclude in December 2017. The survey covers access to care, communications, experience at a facility, and other topics. As set forth in the CY 2017 OPPS final rule, hospitals would be required to begin collecting data for these measures on January 1, 2018. **We support CMS' proposal to delay implementation the OAS CAHPS survey measures beginning with the CY 2020 payment determination—i.e., CY 2018 reporting.**

In prior comments to CMS, we voiced concerns about factors that influence survey administration and that might create undue hardships for essential hospitals, including additional resources needed to effectively communicate with people who have limited English proficiency. A growing body of evidence demonstrates that language concordance between patients and caregivers increases patient satisfaction, patient-reported health status, and adherence with medication and follow-up visits.[35] Vulnerable patients treated by essential hospitals might have difficulty completing

[34]America's Essential Hospitals. Sociodemographic Factors Affect Health Outcomes. April 18, 2016. http://essentialhospitals.org/institute/sociodemographic-factors-and-socioeconomic-status-ses-affect-health-outcomes/. Accessed May 2017.
[35]Manson A. Language Concordance as a Determinant of Patient Compliance and Emergency Room Use in Patients with Asthma. *Med Care.* 1988;26(12):1119–28.

surveys due to language barriers and low health literacy, and they will require additional support and outreach from facilities administering the survey. **We urge CMS to closely examine the necessity and utility of the proposed OAS CAHPS measures and adjust for all factors that could influence how patients respond to the survey, but that are beyond the control of the hospital and not directly related to hospital performance.**

America's Essential Hospitals supports efforts to better understand patients' experiences in the outpatient setting. However, we continue to believe further development of the OAS CAHPS survey is necessary. We encourage CMS to continue refining the OAS CAHPS survey, with input from stakeholders, to ensure the information collected accurately reflects patient experience in a meaningful way. For these reasons, **we urge CMS to finalize its proposed delay of the OAS CAHPS survey measures implementation date to allow further measure development.**

c. CMS should promptly remove topped-out measures from the OQR Program to ensure quality of care and patient safety, and to reduce administrative burden.

CMS proposes to remove certain measures for the CYs 2020 and 2021 payment determination for the OQR Program. Measures are considered topped out when measure data show: statistically indistinguishable performance levels at the 75th and 90th percentiles; and a truncated coefficient of variation less than 0.10. We urge CMS to remove measures promptly, when topped out, to avoid further reporting and its associated burden by essential hospitals.

CMS proposes to remove these measures from the CY 2020 OQR Program:

- OP-21: Median Time to Pain Management for Long Bone Fracture; and
- OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures.

For CY 2021, CMS proposes removal of these measures:

- OP-1: Median Time to Fibrinolysis;
- OP-4: Aspirin at Arrival;
- OP-20: Door to Diagnostic CMS-1678-P 45 Evaluation by a Qualified Medical Professional; and
- OP-25: Safe Surgery Checklist Use.

CMS proposes to remove these measures from the OQR Program for various reasons, including: potential misinterpretation of the intent of the measure, performance or improvement on the measure does not result in better patient outcomes, a measure exists that is more strongly associated with a desired patient outcome, or the measure is considered topped out.

CMS considers two measures to be topped out and proposes their removal in CY 2021: OP-4 Aspirin at Arrival and OP-25 Safe Surgery Checklist Use. America's Essential Hospitals appreciates any efforts by CMS to reduce the reporting burden on hospitals. By removing measures that no longer show improvements in quality, CMS will enable hospitals to use their limited resources for quality improvement as opposed to administrative reporting activities. CMS notes that removing such measures would

"alleviate the maintenance costs and administrative burden to hospitals associated with retaining them." That being the case, we seek clarification regarding the agency's delay in removal of these two topped-out measures until CY 2021. **We urge CMS to finalize its proposed removal of measures, and to immediately remove topped-out measures.**

4. **CMS should mitigate concerns about the effect of removing TKA procedures from the IPO list on Medicare payment models.**

Procedures found on the IPO list usually are performed only in the inpatient setting and are reimbursed at inpatient rates, not under the OPPS. Each year, CMS reviews this IPO list for procedures that should be removed because they can be provided in the outpatient setting. Based on developments and innovations in TKA technique and patient care, which allow the procedure to be performed on an outpatient basis, CMS proposes to remove TKA from the IPO list for CY 2018.

We have concerns about the effect the proposed removal of TKA would have on Medicare payment models. The TKA 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 TKA procedure has been on the IPO list, CMS does not have claims history for beneficiaries receiving TKA on an outpatient basis. If CMS were to remove TKA from the IPO list, some patients who previously would have received a TKA 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 TKA procedures.

Modifications to current Medicare payment models would be required if the TKA procedure is removed from the IPO list. This would lead to confusion among hospitals and CMS, as well as issues of accuracy and fairness in setting target prices.

Additionally, there are differences in patient population for which the TKA 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. Further, many Medicare patients have comorbidities and would require intensive rehabilitation after a TKA procedure, making it best performed in an inpatient setting. As such, TKA 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 further study the differences in performing it in both settings to ensure patient safety for all Medicare beneficiaries, as well as fairness among participants in episode-based payment models.**

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

For the first time since instituting its policy of packaging payment for services into C-APCs, CMS is not proposing to add any new C-APCs for CY 2018. Under the C-APC payment policy, CMS packages payment for the primary procedure with other services that appear on the claim and were provided in association with the primary procedure. 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 OPPS but under a separate fee schedule, including payment for durable medical equipment, also are paid under the OPPS as part of C-APC payment.

We appreciate CMS' decision to not add new C-APCs, but we continue to urge the agency 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 receiving treatment is, or the number and cost of adjunctive services actually provided in conjunction with the primary procedure.

Such a policy 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. [36] 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

[36]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.

resources. **Therefore, CMS should account for these factors by adjusting for patient complexity in the C-APC methodology.**

In addition to adjusting for patient complexity, CMS should revise its complexity adjustment methodology that 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 for 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. [37] **We urge the agency to evaluate other types of procedures for complexity adjustments—a practice it does not currently do—to avoid potentially underpaying hospitals for the cost of performing resource-intensive procedures in conjunction with the primary procedure on the claim.**

CMS should also move a C-APC to the next-highest C-APC in 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 to the next-highest level—that is, two levels higher than the originating C-APC—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 one level 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.

6. Before considering any payment changes, CMS should work with providers to better understand the difference between services performed in the inpatient and outpatient settings.

In the proposed rule, CMS refers to differing payment rates across the inpatient and outpatient settings and seeks comment on ways to "identify and eliminate inappropriate payment differentials for similar services provided in the inpatient and outpatient settings."[38] **America's Essential Hospitals urges CMS to work with providers to understand the reasons for performing a service in an inpatient setting, rather than outpatient.** Implementing policies that seek to minimize the payment differential

[37]Status indicator N denotes services that are packaged and therefore do not have a separate APC payment amount.
[38]82 Fed. Reg. 33558, 33704 (July 20, 2017).

or equalize the payment rate would fail to account for the many case-specific reasons a hospital might need to admit a patient.

CMS attempted to resolve the issue of short inpatient stays and excessively long outpatient stays through its two-midnight policy, but ultimately provided additional flexibility and exceptions that would defer to the clinician's judgment on the most appropriate care setting. In deciding whether to treat a patient in the inpatient or outpatient setting, a provider accounts for the patient's specific needs and comorbidities. Any policies that undermine clinician judgment run counter to CMS' stated goals of moving toward patient-centered care and "ensur[ing] that patients and their providers and physicians are making the best health care choices possible."[39] **Therefore, we recommend that CMS defer to clinicians' judgment and the individual needs of the patient in making any future policy recommendations on inpatient and outpatient payment policy.**

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

Sincerely,

Bruce Siegel, MD, MPH
President and CEO

[39]Ibid.

APPENDIX: Dobson DaVanzo & Associates, LLC - OPPS Analysis Methodology

Dobson | DaVanzo

Dobson DaVanzo & Associates, LLC 450 Maple Avenue East, Suite 303, Vienna, VA 22180 703.260.1760
www.dobsondavanzo.com

This document summarizes the methodology used in analyzing the proposed reduction in payment for 340B drugs that Dobson | DaVanzo completed for America's Essential Hospitals (AEH) for the 2018 Hospital Outpatient Prospective Payment System (OPPS) Notice of Proposed Rulemaking (NPRM).

Methodology for the 340B Drug Analysis

The 340B Drug Pricing Program, administered by the Health Resources and Services Administration (HRSA), requires drug manufacturers to provide outpatient drugs to eligible health care organizations or covered entities at reduced prices. To participate in the 340B Program, eligible organizations or covered entities must register and be enrolled with the 340B program and must comply with all 340B program requirements.

When Congress first enacted the 340B program in 1992, it targeted disproportionate share (DSH) hospitals that provide high levels of care to Medicaid and low-income Medicare beneficiaries. Hospitals that treat high levels of low-income beneficiaries have often been referred to as "safety net" hospitals. The 340B program was established to provide "safety net" hospitals an avenue for purchasing outpatient drugs at a lower cost. Congress intended for the savings from these discounted prices to enable covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients, and providing more comprehensive services." This suggests that congressional intent was for resources to be targeted toward specific hospitals and toward low-income patient populations.

Drugs included in the 340B program generally comprise prescription drugs administered by physicians in an outpatient setting, excluding vaccines. Specific 340B prices are determined by statutory formulas based on manufacturers' rates. Because Medicare reimbursement rates are similar across all providers, the dollar difference between discounted drug costs to the provider and Medicare payment to 340B covered entities allows for hospitals to provide services not otherwise paid for by their low-income patients using this source of income.

The purpose of this 340B analysis for America's Essential Hospitals was to model the cash flow impact of the proposal made by CMS to reduce Medicare payment to 340B hospitals for Part B drugs purchased under the 340B Drug Discount Program. This analysis required modeling the reduction in payment for Part B drugs to 340B hospitals by 22.5 percent of ASP, and comparing this to current Medicare payment for outpatient drugs for each hospital and in aggregate. Furthermore, CMS projected that reducing the payment for Part B drugs to 340B hospitals would increase non-drug OPPS payment rates by 1.4 percent, but it did

not include impacts of these increases into the NPRM. This analysis also considered how the increase in the conversion factor will affect payment for other OPPS services.

Step 1: Identify 340B Hospitals

To model this reduction in payment for Part B drugs purchased under the 340B Drug Discount Program, we first identified 340B hospitals. Two criteria were applied to identify 340B hospitals: (1) active participation in the 340B program, based on a current (August 2017) update of the HRSA Office of Pharmacy Affairs (OPA) Drug Pricing Program Database; and (2) inclusion in the OPPS NPRM Impact File for CY 2018. We note that this methodology for identifying 340B hospitals is different than that used by CMS in the NPRM; however, this is a method that we have used successfully in the past, and we feel is appropriate here. CMS has assumed that every governmental-owned, cancer, and children's hospital, as well as those hospitals with a DSH percentage greater than 11.75 percent, sole community hospitals with a DSH percentage greater than 8 percent, and rural referral centers with a DSH percentage greater than 8 percent, all participated in the 340B program. However, we note that participation is voluntary and therefore included just those hospitals that are currently participating in the 340B program.

Step 2: Create Working Dataset

Once the 340B DSH hospitals were identified, a beneficiary-level working claims database was developed using the CY 2018 OPPS NPRM data file, which contains line-level claims for CY 2016. This is the dataset that CMS used in its analysis for the NPRM. Using this beneficiary-level database, we extracted all beneficiary claims for care paid under OPPS. Table 1 provides a list of the status indicators that were present in the 2018 NPRM data and identifies which were eligible to be paid under OPPS. Status indicators were determined by crossing the HCPCS on the line-level claim with the Hospital Outpatient Prospective Payment System Proposed Rule Addendum D1. All claims with these status indicators indicating that the service was eligible for payment under OPPS were retained. The subset of claims for separately billable Part B drugs from 340B hospitals was identified from here.

Table 1. Status Indicators Present in 2016 OPPS NPRM Data

Not Paid Under OPPS	Paid Under OPPS
A	G
B	J1
C	J2
E	K
E1	N
E2	P
F	R
L	S
M	T
Y	U
	V

Separately billable Part B drugs were defined as Part B drugs with a status indicator of "G" (pass-through drugs and biologicals) and "K" (non-pass-through drugs and non-implantable biologicals, including therapeutic radiopharmaceuticals, brachytherapy, and blood and blood products). We assumed that all drugs with these status indicators were purchased through the 340B Program at the identified 340B hospitals. (We recognize that some hospitals may elect to carve-out drugs for their Medicaid patients, in which case drugs for dual-eligible beneficiaries may not be purchased under the 340B program. Given the limitations of our data, however, it was not possible to model this scenario.)

We only considered those drugs paid using the ASP methodology and with status indicator "K" to be affected by the proposed reduced payments under the NPRM. Drugs paid under the ASP methodology were identified using the April 2017 ASP Drug Pricing List from CMS. Additional adjustments were made to further exclude any vaccine or immunization from the universe of drugs affected by the proposal, as these products cannot be purchased at a discounted rate by 340B hospitals.

For each of the separately billable Part B drugs included in this analysis, total payments (including Medicare reimbursement and beneficiary responsibility) were obtained using the payment amount located in the NPRM data file. Using the patient-level linked claims database, the payments were summed across patients within each 340B hospital to obtain the total payment amount to that hospital for 2016. The aggregate amount these payments by hospital represents the total amount of money that a hospital received for separately billable Part B drugs in 2016.

Step 3: Calculate hospital-specific financial impact

To model the financial impact of the proposal made by CMS, it was necessary to model a reduction in payment by 22.5 percent of ASP for affected drugs. We made the following assumptions to calculate this payment reduction:

(1) Total payment consists of 80 percent Medicare reimbursement and 20 percent beneficiary responsibility

(2) Reimbursement rates were ASP plus six percent in 2016

(3) The Medicare reimbursement subjected to a 2 percent reduction due to sequestration.

Following these assumptions, reimbursement rates were reduced to ASP and further reduced by 22.5 percent for these drugs. Thus, used the following formula to model the reduction, which includes the additional 2 percent reduction from the Medicare reimbursement:

$$Reduced\ payment = 0.775 * \frac{Current\ Payment}{(0.8 * 0.98 * 1.06) + (0.2 * 1.06)}$$

The difference in total payment and proposed payment methodologies for affected drugs represents the loss in revenue that the hospital will face under the proposed payment reduction.

CMS notes in the NPRM that reducing payment for 340B drugs to ASP minus 22.5 percent would increase non-drug OPPS payment rates by approximately 1.4 percent in CY 2018. We attempted to replicate this number by calculating the total dollar amount of the reduction in reimbursement for eligible separately payable Part B drugs, divided by the total Medicare Part B non-drug OPPS revenue. That is:

$$Payment\ Rate\ Percent\ Change = \frac{340B\ Payment\ Cut}{Medicare\ Part\ B\ Non\ Drug\ OPPS\ Revenue} \times 100$$

In addition, we looked at the results of this analysis in various contexts for each hospital, including:

1. The total dollar amount of the reduction in reimbursement for separately payable Part B drugs, for each 340B hospital individually and in aggregate for all 340B hospitals, and all AEH member hospitals. We also modeled the difference in OPPS payments for non-drug services as currently paid and after accounting for increased payments due to the budget neutrality requirement.

2. The total hospital separately payable Part B drug payment as a percent of current total hospital Medicare Part B OPPS revenue. This was done using the current (2016) drug payment, as well as the modeled (reduced) drug payment under the NPRM methodology. Total hospital Medicare Part B OPPS revenue was obtained by summing the payments for all eligible claims from the 2016 NPRM data.

3. The total dollar amount of the reduction in reimbursement as a percentage of total hospital Medicare Part B OPPS revenue.

4. The total payment for affected separately payable Part B drugs (i.e., excluding vaccines and pass-through drugs) as a percentage of the total payment for all separately payable Part B drugs (including vaccines and pass-through drugs).

5. The total dollar amount of the reduction in reimbursement as a percentage of the current (2016) separately payable Medicare Part B outpatient drug payment (including vaccines and pass-through drugs).

In addition to examining the proposal on a hospital level, we aggregated the results by hospital type to determine the differential effects of CMS' proposal on different types of hospitals.

Step 4. Compare Medicare Outpatient Margins Before and After 340B Cut for Hospitals

After calculating the magnitude of the proposed 340B drug payment reduction on 340B and AEH member hospitals, we used this information to calculate Medicare Part B OPPS margins. Margins were calculated two ways: (1) without adjusting for the proposed reduction in 340B drug payments; and (2) adjusting for the proposed reduction in 340B drug payments and corresponding increase in non-drug payments.

We calculated the unadjusted Medicare Part B OPPS margin using data from the FY 2015 MCR, as follows:

$$Medicare\ Part\ B\ OPPS\ Margin = \frac{Medicare\ Part\ B\ OPPS\ Revenue - Medicare\ Part\ B\ OPPS Costs}{Medicare\ Part\ B\ OPPS Revenue}$$

Medicare Part B revenue and costs were obtained from the FY 2015 Medicare cost reports (July 2017 HCRIS update) using Worksheet E, Part B. Revenue was calculated using Lines 24, 34, 35 and 40.01 for the hospital and all subproviders (Revenue = Line 24 + Line 35 – Line 34 – Line 40.01), while costs were obtained from Line 2 for the hospital and all subproviders.

To calculate the adjusted Medicare outpatient margin, i.e., to account for the proposed reduction in 340B drug payments, we subtracted the amount of the revenue loss, resulting from the Part B drug payment reduction for each hospital as calculated in Task 7, from the hospital's Medicare Part B outpatient revenue. We then added in the net increase resulting from higher non-drug reimbursement rates. This was done separately for two non-drug increase percentages: 1.4 percent, as estimated by CMS in the NPRM, and 3.6 percent, as estimated by Dobson | DaVanzo as part of this analysis. The margin was then recalculated as described above.

In addition to calculating margins at the hospital level, we produced aggregate margins for each different types of hospitals. Margins for hospital groups were case-weighted; that is, an overall group margin will be calculated by summing the revenues and costs over the entire group of hospitals and using these group sums in the overall margin calculation.

Step 6. Create Summary Tables

A set of summary tables was created in Excel for AEH, providing the results of our analysis. Estimates of the impact of the reduction in payment and associated statistics provided by CMS, both in the NPRM and the associated 2018 OPPS NPRM impact file, are presented in Table 1 below.

Table 1. CMS Estimates

Line	CMS Estimates	
1	2018 340B Drug Payment Decrease (NPRM)	$900,000,000
2	2018 Non-Drug Payment Increase (NPRM)	1.40%
3	2018 Non-Drug Payment Total for OPPS Hospitals (Extrapolation)	$64,285,714,286
4	2018 Estimated OPPS Payments (NPRM)	$70,000,000,000
5	2018 Estimated OPPS Payments (Impact File)	$55,003,489,015

We note that the estimates of total 2018 OPPS payments provided by CMS in the NPRM and associated impact file are not internally consistent. We also note that our estimates, a summary of which is in Table 2 below, are not consistent with those provided by CMS (i.e., $70 billion versus $55 billion for 2018 estimated OPPS payments). We note that our estimates are provided in 2016 dollars and have not been inflated to 2018 rates.

Table 2. Dobson | DaVanzo Estimates

Line	Dobson | DaVanzo Estimates	
1	2016 340B Drug Payment	$5,934,930,516
2	Proposed 340B Drug Payment (2016 dollars)	$4,409,774,457
3	**340B Drug Payment Decrease (2016 dollars)**	**$1,525,156,059**
4	2016 Non-340B Drug Payment for OPPS Hospitals[a]	$2,605,404,260
5	2016 Non-Drug Payment Total for OPPS Hospitals	$42,153,352,762
6	2016 OPPS Payments for OPPS Hospitals in 2016 OPPS NPRM Data (Line 1 + Line 4 Line 5)	$50,693,687,537

[a] Includes drugs from non-340B hospitals and non-340B drugs from 340B hospitals
[b] Includes payments for all claims, including those with status indicators not paid under OPPS
[c] There were 106 hospitals with claims in the OPPS NPRM data file that were not included in the OPPS Impact file. These hospitals were included in the total here.
Note: All estimates from Dobson | Davanzo are in 2016 dollars. Individual lines may not sum to total due to rounding.

Detailed results of our analysis are found in the accompanying Excel workbook. The spreadsheets contained within can be divided into two separate models. The first, identified with blue tabs, uses the Dobson | DaVanzo estimate of reduction in 340B drug payments at $1.525 billion, as seen in Table 2. It then utilizes a 1.4 percent increase to non-drug OPPS payments, as estimated by CMS and documented in the NPRM. The first spreadsheet provides hospital-specific data, and the second aggregates this data by hospital type. We note that, despite using the estimate from CMS of 1.4 percent for the increase in non-drug OPPS payments, we have not scaled the 340B drug payment reduction down to $900 million to match that estimate from CMS, nor have we scaled the non-drug payments up to match the $64 billion CMS is anticipating (see Line 3, Table 1). That is, all modeled policy payments reflect the findings of our analyses, aside from the use of the 1.4 percent from CMS.

The second model, identified with green tabs, again uses the Dobson | DaVanzo estimate of reduction in 340B drug payments at $1.525 billion, as seen in Table 2. However, this model utilizes a 3.6 percent increase to non-drug OPPS payments, as estimated by our analysis. Again, the first spreadsheet provides hospital-specific data, and the second aggregates this data by hospital type.