



# AMERICA'S ESSENTIAL HOSPITALS

September 24, 2018

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Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
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Washington, DC 20201

**Ref: CMS-1695-P: Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model**

Dear Ms. Verma:

Thank you for the opportunity to submit comments on the above-captioned proposed rule. America's Essential Hospitals appreciates the 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—those that 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 providing high-quality care to all. Filling a vital role in their communities, our more than 325 member hospitals provide a disproportionate share of the nation's uncompensated care and devote nearly 70 percent of their outpatient care to uninsured patients and patients receiving insurance through public programs. Our members provide state-of-the-art, patient-centered care while operating on margins half that of other hospitals—4 percent on average compared with 7.8 percent for all hospitals nationwide.<sup>1</sup> Through their integrated health systems, members of America's Essential Hospitals offer a full range of primary through quaternary care, including trauma care,

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<sup>1</sup> Clark D, Roberson B, Ramiah K. Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2016 Annual Member Characteristics Survey. America's Essential Hospitals. June 2018. [www.essentialdata.info/](http://www.essentialdata.info/). Accessed August 13, 2018.

outpatient care in their ambulatory clinics, public health services, mental health services, substance abuse services, and wraparound services.

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 the proposed rule.

We are particularly concerned that CMS' proposed payment cut to office visits at excepted off-campus provider-based departments (PBDs) would drastically 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 also would impede 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 under 14 percent of 340B hospitals paid under the OPSS, would be disproportionately affected by the Part B drug payment policy, receiving more than 22 percent of the payment cut. Similarly, essential hospitals would receive 15 percent of the cuts to off-campus PBDs in CY 2019 while only representing 5 percent of all OPSS hospitals. In our detailed comments below, we urge CMS to withdraw its PBD and 340B payment proposals.

1. **CMS should reverse its Part B drug payment policy for hospitals participating in the 340B program. This proposal exceeds the agency's statutory authority, undermines the Public Health Service Act (PHSA), and has resulted in irreparable harm to 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 enacted in the calendar year (CY) 2018 Outpatient Prospective Payment System (OPSS) final rule. Under this policy, CMS reduced 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 continue to receive payment at 106 percent of ASP. **America's Essential Hospitals implores CMS to withdraw the policy to reduce payments for 340B drugs**

**and to return to its statutory default of 106 percent of ASP for all hospitals paid under the OPSS.**

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.”<sup>2</sup> Under the 340B program, covered entities can purchase certain outpatient drugs at discounted prices, enabling savings that are critical to the operations of hospitals that fill a safety-net role. The 340B program is structured by statute to offer 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 disadvantaged populations, including initiatives to reduce readmissions, ensure medication compliance, and identify high-risk patients in need of ancillary services. CMS’ ill-advised 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 takes money from the safety net and redirects it to hospitals that do not fill a safety-net role, including hospitals that are excluded by law from participating in the 340B program.

For a second year in a row, we urge the agency to reverse this policy. CMS’ policy is inconsistent with Medicare statute—a conclusion supported by reports from the Government Accountability Office (GAO) and Office of Inspector General (OIG)—and conflicts with section 340B of the PHSA, which governs the program.<sup>3,4</sup> This policy goes against the recommendation of the advisory panel on hospital outpatient payment, with which CMS is required to consult as a matter of law. In the year 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 provided to 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.

- 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 reduced payment for separately payable drugs purchased through the 340B program, because it is inconsistent with the agency’s**

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<sup>2</sup> H.R. Rep. No. 102-384, pt. 2 (1992).

<sup>3</sup> 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.

<sup>4</sup> 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.

**statutory authority under the SSA.** CMS should revert to its statutory default methodology, under which it had been paying 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 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.”<sup>5</sup> The Medicare Payment Advisory Commission (MedPAC) specifically recommended to Congress modifying Medicare payment for Part B drugs purchased through the 340B program.<sup>6</sup> OIG echoed 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.”<sup>7</sup> We agree with these experts that CMS does not have legal authority to implement a reduced payment rate for 340B drugs.

*i. CMS’ policy is an unlawful departure from the statutory default payment for separately payable Part B drugs.*

First, the payment policy 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.

Further, Congress already determined that ASP, as defined under section 1847A of the SSA, should not reflect that certain drugs are purchased at 340B discounts.<sup>8</sup> Because CMS does not have the authority to consider 340B drugs in calculating ASP plus 6 percent, it is unreasonable to conclude that CMS has the authority to make an adjustment to the statutory default based on 340B discounts.

*ii. CMS’ nearly 30 percent payment cut to a specific subset of hospitals does not constitute an “adjustment” under the SSA.*

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<sup>5</sup> 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, 2018.

<sup>6</sup> 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 28, 2018.

<sup>7</sup> 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.

<sup>8</sup> 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.

CMS purports to have statutory authority under section 1833(t)(14)(A)(iii)(II) to adjust payment rates for 340B drugs. However, section 1833(t)(14)(A)(iii)(II), which allows the secretary of health and human services to “calculate and adjust the average price,” does not give the secretary unlimited discretion to make a nearly 30 percent cut to drug payment rates. The adjustments 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 CY 2013 OPPS final rule.<sup>9</sup> Reducing payments by such a substantial amount is not an adjustment to ASP envisioned by the statute. Absent a specific directive from Congress allowing these types of adjustments, CMS’ reduction of Part B payments to 77.5 percent of ASP is inconsistent with its statutory authority.

*iii. CMS cannot attempt to pay at acquisition cost when it lacks acquisition cost data.*

CMS inappropriately adjusts payment rates by incorporating acquisition cost into a statutory methodology based on average price. In putting forth the payment policy for 340B drugs, CMS has justified the reduced payment amount by asserting it more appropriately reflects 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 on 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.”<sup>10</sup> 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 while using a payment method determined under 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

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<sup>9</sup> 77 Fed. Reg. 68210, 68386 (November 15, 2012).

<sup>10</sup> 77 Fed. Reg. 68210, 68386 (November 15, 2012).

hospitals at set rates for drugs, regardless of their costs for acquiring them, which CMS cannot alter based on hospitals' acquisition costs."<sup>11</sup>

*iv. CMS' use of 340B pricing as the sole determinant of acquisition cost is arbitrary and capricious.*

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 noted in last year's 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."<sup>12</sup> 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—that affects only a subset of hospitals, while not attempting to adjust for acquisition costs for other factors or for non-340B hospitals. Moreover, CMS' 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 fails 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 institute an across-the-board payment reduction for one subset of hospitals based on such incomplete and factually inaccurate analyses.

**b. CMS' payment methodology conflicts with another statute, the PHSA, and undermines Congress' intent in enacting the 340B program.**

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 Department of Health and Human Services (HHS) 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.<sup>13</sup> CMS' OPPS policy before 2018 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 policy as finalized in 2018 is inconsistent with and undermines the purposes of the 340B program.

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."<sup>14</sup> Congress specifically designated the entities that should benefit from the program, defining eligible DSH hospitals as

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<sup>11</sup> 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, 2018.

<sup>12</sup> 82 Fed. Reg. 59216, 59370 (Dec. 14, 2017).

<sup>13</sup> See, e.g., Statutory Interpretation: General Principles and Recent Trends (December 19, 2011) at page 29.

<sup>14</sup> H.R. Rep. No. 102-384, pt. 2 (1992).

those serving a disproportionately greater percentage of low-income (Medicaid and Medicare Supplemental Security Income) patients. These hospitals are intended to receive discounted drugs and are expected to stretch their resources, including Medicare reimbursement, to continue caring for low-income patients—among them, vulnerable Medicare beneficiaries.

By redirecting funds intended for 340B hospitals to other hospitals in the Medicare program, CMS' policy violates the intent of the 340B program. Not only has CMS' policy cut into the scarce resources of hospitals specified in statute, but CMS' budget neutrality adjustment also redistributes these funds to hospitals not participating in the 340B program. In essence, CMS is redirecting payment for 340B drugs to hospitals that are excluded from the program. Hospitals treating fewer low-income patients benefit at the expense of hospitals serving the most vulnerable patients. This is clearly not what Congress intended when it envisioned the 340B program.

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

**Before implementing a policy of such magnitude, CMS should ensure that it has calculated the policy's effect on hospitals and Medicare beneficiaries.** In the CY 2018 OPSS proposed rule, CMS includes very limited discussion of the impact of the 340B proposal on hospitals. The agency provides hospital-specific estimates of the effect of its proposed OPSS policies, as well as estimates of impact on groups of hospitals. Notably absent from these estimates was consideration of the Part B payment reduction for 340B hospitals.<sup>15</sup> This year, CMS has not performed any analysis of whether the policy has met its intended goals, how it has affected patient access, whether it has resulted in lower drug prices, or how it has affected hospital operations. It is irresponsible to continue with a policy that has an aggregate impact in the billions of dollars (in last year's final rule, CMS estimated that the policy would result in a \$1.6 billion cut to 340B hospitals after erroneously estimating the impact at \$900 million in the proposed rule) without any understanding of how it would impact hospitals or patients.

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

The 340B program is critical to ensuring that low-income and other disadvantaged people have access to the types of services best provided by essential hospitals. 340B hospitals already have begun to experience the effects of the \$1.6 billion cut in Medicare payments in CY 2018. 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 affected by the policy operate on an aggregate negative 15.9 percent margin, compared with negative 12.1 percent at non-340B hospitals. Accounting for the reduced OPSS reimbursement

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<sup>15</sup> 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.").

resulting from the Part B payment reduction, 340B hospitals' Medicare outpatient margins would drop even further, to negative 20 percent.<sup>16</sup> At the same time, because of the redistributive nature of the policy, non-340B hospitals likely 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.

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:

- maintain comprehensive care for and provide 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 high drug prices;
- establish clinical pharmacy programs, in which pharmacists interact with patients at bedside and in the emergency department (ED), ensuring patients understand and adhere to their medication regimen. Through these programs, essential hospitals have reduced excess readmissions;
- provide meaningful health care 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;
- provide mental health and substance abuse treatment;
- support free clinics in their communities; and
- reduce ED use through a medical home program providing primary care to uninsured, low-income patients.

The Part B drug payment reduction jeopardizes these critical programs and undermines the financial stability of essential hospitals. Not only does the policy 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 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

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<sup>16</sup> Data from internal analysis conducted for America's Essential Hospitals by Dobson DaVanzo & Associates. August 2018 (See appendix for a more detailed discussion of the methodology used to calculate Medicare outpatient margins).



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 any money. Because CMS is required to implement the policy in a budget-neutral manner, the cut in funding does not go back to the Medicare program 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. 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.<sup>17</sup> This means Medicaid covers copayments for more than 3 million beneficiaries who do not directly see the financial impact of this policy. Further, an estimated 25 percent of beneficiaries at 340B hospitals have Medigap coverage for copayments, and thus similarly do not receive much direct benefit from the policy.<sup>18</sup> In total, MedPAC has noted that 87 percent of Medicare beneficiaries are covered by some source of supplemental coverage, whether Medigap, Medicaid, or employer-sponsored supplemental coverage.<sup>19</sup> 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.

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<sup>17</sup> Data from internal analysis conducted for America's Essential Hospitals by The Moran Company. January 2016.

<sup>18</sup> Ibid.

<sup>19</sup> 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](http://www.medpac.gov/docs/default-source/data-book/jun18_databookentirereport_sec.pdf). Accessed August 29, 2018.

e. CMS' policy does not address 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 that are 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. OIG recently highlighted the connection between increasing 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.<sup>20</sup> This trend is bound to continue, with prescription drug spending projected to outpace overall health care spending growth through 2026, mainly due to rapid growth in drug prices.<sup>21</sup> 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 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. The 340B program has enabled essential hospitals to reduce 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 that 340B discounts provided by manufacturers only made up 1.3 percent of net U.S. drug spending in 2015, 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

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<sup>20</sup> 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 August 29, 2018.

<sup>21</sup> 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 August 29, 2018.

negotiate with health plan and pharmacy benefit managers accounted for 34 percent of all rebates and discounts.<sup>22</sup>

The sources CMS uses to link 340B and drug spending have serious methodological flaws. In fact, HHS previously argued against some of the conclusions in these reports. The GAO report on Part B spending at 340B 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.”<sup>23</sup> 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 in “excess” and “potentially inappropriate” and said these claims are “not supported by the study methodology.”<sup>24</sup> 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 withdraw its proposal to reduce payments for separately payable drugs administered at non-excepted PBDs, which exceeds its statutory authority under the SSA.**

CMS proposes to extend its unlawful payment policy for 340B drugs even further to include another category of hospital outpatient departments. Specifically, CMS is proposing to apply the 77.5 percent of ASP payment rate to 340B drugs administered in non-excepted off-campus PBDs, or those that are paid a reduced payment rate pursuant to section 603 of the Bipartisan Budget Act of 2015 (BBA). These PBDs are not paid for outpatient services pursuant to the OPPI, but instead under the Medicare Physician Fee Schedule (PFS) as adjusted. As we argue above, the policy to reimburse for 340B drugs

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<sup>22</sup> 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](http://www.340bhealth.org/files/340B_Financial_Impact_7_17.pdf). Accessed August 29, 2018.

<sup>23</sup> 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, 2018.

<sup>24</sup> Ibid.

at 77.5 percent of ASP under the OPSS is unlawful under the SSA. It's proposal to extend the policy to non-expected 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 payment for non-expected PBDs is the "significant incongruity" between payment for drugs at expected and non-expected PBDs, as well as the "perverse incentives and resulting distortions" that might result from the difference in payment across these settings.<sup>25</sup> 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 OPSS 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 OPSS. If CMS were to revert to its original methodology for paying drugs under the OPSS, there would be no difference between drug payments at expected and non-expected PBDs. Even if CMS were to double down on its 340B payment policy by attempting to set the payment rate at 77.5 percent of ASP for non-expected PBDs, it lacks the legal authority to do so, as we establish below.

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

Congress, in section 603 of the BBA, directed CMS to pay non-expected 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-expected PBDs in the annual PFS rule.<sup>26</sup> Therefore, the payment methodology for Part B drugs administered in these non-expected 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 biologics. 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-expected PBDs.

CMS's previous rulemaking on section 603 confirms that non-expected 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-expected 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."<sup>27</sup> CMS confirmed that the payment rate for these drugs should be set as if they were provided

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<sup>25</sup> 83 Fed. Reg. 37046, 37146 (July 31, 2018).

<sup>26</sup> 81 Fed. Reg. 79562, 79570 (Nov. 14, 2016).

<sup>27</sup> 81 Fed. Reg. 79562, 79723 (Nov. 14, 2016).

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).<sup>28</sup> 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 any 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 (erroneously) relied on by CMS 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.

Section 1833(t)(14)(iii)(II) falls under the section of the SSA that dictates OPSS payment and is therefore 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)."<sup>29</sup> Because non-excepted PBDs are no longer 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.

CMS attempts 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 does so by referencing 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 claims 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

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<sup>28</sup> 81 Fed. Reg. 79562, 79725 (Nov. 14, 2016).

<sup>29</sup> SSA 1833(t)(21)(C).

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 other than the PFS.

Finally, 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 proposes 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.

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

CMS’ proposal to reduce payment for outpatient clinic visits at excepted PBDs is contrary to the SSA and violates the payment structure of the OPSS. 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 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 implement a 60 percent payment cut 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 should withdraw this unprecedented non-budget neutral proposal, for which it lacks authority and which clearly contradicts congressional intent in passing section 603 of the BBA.

- a. 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, excepted PBDs that were not providing OPSS services before November 2, 2015. Section 603 excluded new off-campus PBDs from the OPSS while grandfathering existing clinics into the OPSS. By singlehandedly

deciding to use rulemaking to extend what Congress has limited through legislation, CMS upends this language and substitutes its own judgment for Congress'. In so doing, CMS usurps congressional authority. In disregarding Congress' judgment, this rule appropriates legislative authority for the executive branch in a clear violation of the separation of powers principle in the U.S. Constitution.

The proposed rule would effectively eliminate 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 that Congress did not intend for CMS to adjust payments to excepted PBDs. CMS tries to override congressional intent on the need to exclude these departments by proposing to cut 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.

- b. CMS' application of the volume-control methodology violates the SSA because it is required to be budget neutral.

CMS targets the payment reduction to a specific group of services (one HCPCS code). This targeted reduction falls outside of the normal scope of APC weight adjustments that CMS is permitted to make under the OPPS. Under the OPPS, CMS does not have the authority to selectively choose services and cut payment for those services outside of the regular rate setting process, which allows for the establishment of APCs and an annual reconfiguration of APC weights in a budget-neutral manner.<sup>30</sup>

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 equalizing payments between hospital outpatient departments and physician offices, CMS says it is implementing a volume-control

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<sup>30</sup> 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 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.”

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 maintains that it does not have to implement this method in a budget-neutral manner. However, applying the volume-control method provision of the SSA in a non-budget neutral manner conflicts with the rest of the provisions of the SSA on OPSS payment from year to year. Subparagraph 1833(t)(2)(F) falls under subsection 1833(t)(2), which outlines the overall requirements for the OPSS, including that changes to the OPSS are budget neutral. CMS does not have the authority to use the volume-control method in a way that violates a central tenet of the OPSS—budget neutrality. CMS is required to interpret this provision in the context of the larger OPSS statute and in a way that does not render any provisions “inoperative or superfluous, void or insignificant.”<sup>31</sup> By reading the volume-control provision as non-budget neutral, CMS bypasses the budget neutrality requirement and renders the entire statutory scheme of the OPSS inoperative.

Under section 1833(t)(9)(B) of the SSA, any adjustments referenced in subparagraph 1833(t)(9)(A) 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 OPSS statute. The full text of subparagraph (t)(9)(A) makes clear that Congress expected CMS to review the OPSS system annually and adjust to account for relevant developments in the overall health care system to ensure the accuracy and appropriateness of the OPSS 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 OPSS to be non-budget neutral or to not 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.

- c. CMS is required to develop a volume-control methodology before it can adjust payments through a conversion-factor update.

CMS proposed implementation of the volume-control methodology 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. 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 to the annual conversion-factor

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<sup>31</sup> Hibbs v. Winn, 542 U.S. 88, 101 (2004) (quoted in Corley v. United States, 556 U.S. 303, 314 (2009)).



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 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.” CMS has never established target amounts that then can be referenced to determine if a conversion-factor adjustment is warranted. CMS arbitrarily decides 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.<sup>32</sup> HCFA also suggested that packaging policies could be adopted and could take the place of any expenditure targets and conversion-factor updates, but that 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.”<sup>33</sup> 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’ proposal is unlawful, and CMS should withdraw it.

- d. CMS is required to consult with the advisory panel on hospital outpatient payment, which recommended against implementing the payment cut for hospital outpatient visits.

CMS omitted a critical procedural safeguard, which is that it must consult with the advisory panel on hospital outpatient payment before developing payment classifications and rates under the OPSS. The SSA requires CMS to consult with this panel as part of the annual rate setting process under the OPSS.<sup>34</sup> The panel, which is comprised of provider representatives who possess expertise in payment, billing, and

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<sup>32</sup> 63 Fed. Reg. 47552, 47586.

<sup>33</sup> 72 Fed. Reg. 66580, 66613 (Nov. 27, 2007).

<sup>34</sup> Social Security Act 1833(t)(9)(A).

APC groups, serves as an important advisory committee that provides technical assistance to CMS. In this case, CMS released a proposed rule containing the policy change before it was considered by the advisory panel. When the panel later met, at its August 20 meeting, it recommended that CMS not implement the clinic visit proposal and instead conduct additional study to better understand the reasons for increased utilization in the outpatient setting. **CMS should not move forward with finalizing this policy given this critical misstep and, most important, against the advisory panel's objections.**

- 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 OPSS, other than speculating that the shift in care to the hospital outpatient setting is driven by payment incentives. 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.

#### **4. 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 to essential hospitals and the vulnerable patients they serve. For example, CMS proposes that PBDs that expand services would lose their grandfathered payment for those new services, a limitation the BBA neither contemplated nor required. **CMS should use its statutory authority to offer flexibility and reduce burden on providers, particularly regarding expansion of services, relocation, and change of ownership.**

- a. CMS should follow Congress' original intent and continue to pay excepted off-campus PBDs at the full OPSS rate, even if they expand services.

Since CY 2017, CMS has paid excepted PBDs at the full OPSS rate. This year, CMS reinstates a proposal that it previously proposed and withdrew: it would categorize items and services provided at excepted PBDs as services provided before or after the date of enactment. Under CMS' proposal, excepted PBDs will only receive OPSS payment for items and services belonging to a clinical family of services that were provided by the PBD during a baseline period before the enactment of the BBA. If the PBD were to expand services beyond the types of services provided during the baseline period, these new services would be non-excepted and reimbursed at a rate other than OPSS. Effectively, this creates two categories of services at PBDs: those that will receive

OPPS reimbursement and any new services that will receive payment under the reduced PFS payment rate for non-excepted services. This categorization of excepted and non-excepted services at a given PBD is inconsistent with the text of the BBA. Further, it is a short-sighted policy proposal that fails to account for the changing needs of hospitals' communities and hospitals' long-term plans to meet these needs. **CMS should withdraw this proposal and clarify that, as defined in the BBA, any PBD that was billing for services provided before November 2, 2015, is an excepted PBD for all the services it provides.**

In support of its proposal to carve out certain types of items and services from the exception, CMS previously argued that the BBA “applies to off-campus PBDs as they existed at the time of enactment.”<sup>35</sup> But the statute neither states nor implies that this is the case. Section 603, titled “Treatment of Off-Campus Outpatient Departments of a Provider,” clearly states that for purposes of section 603, “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.<sup>36</sup> 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 the statute’s provisions. Additionally, the BBA contains no language that suggests PBDs are excepted only for services provided pre-enactment.

If there were any doubt about the clarity of the statutory text, one need only look to Congress’ own instructions to CMS on how it expected the agency to implement section 603. In a letter to CMS on the original implementation of section 603, a bipartisan group of more than 40 senators wrote that “nothing in the law was intended to preclude existing off-campus [hospital outpatient departments] from changing or expanding the types of outpatient services they provide to patients while receiving Medicare payment at the OPPS rate. We are interested in assuring that patients continue to have access to services they need at the facilities where they seek treatment.”<sup>37</sup>

CMS has referenced the provider-based regulations to support its claim that a PBD should be excepted only as it existed at the time of enactment. The regulatory language that CMS cites defines a PBD as including the physical facility as well as the personnel and equipment that are needed to provide services at the PBD. However, 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.”<sup>38</sup>

CMS states that its rationale for restricting the expansion of services at PBDs is to

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<sup>35</sup> 81 Fed. Reg. 45604, 45684 (July 14, 2016).

<sup>36</sup> Section 603 of Bipartisan Budget Act of 2015. Pub. L. 114-74, codified as Social Security Act §1833(t)(21)(B)(ii).

<sup>37</sup> Senate letter to CMS Acting Administrator Andrew Slavitt. October 3, 2016.

<sup>38</sup> 67 Fed. Reg. 49982, 50088 (August 1, 2002).

prevent the possibility of hospitals purchasing freestanding clinics and adding the physicians to their existing off-campus PBDs. However, section 603 was intended to prevent new practices from being created or acquired, not to prevent the expansion of existing ones. Moreover, there are many reasons why essential hospitals might need to expand or change their mix of services and there are many valid policy reasons to allow PBDs to do so. Most important, as the needs and composition of communities change, the types of services essential hospitals need to provide through their PBDs also change. Essential hospitals, already operating on negative Medicare outpatient margins, are motivated solely by the needs of their patients—patients who often do not have access to other providers in their communities. As directed by the Affordable Care Act, they constantly assess the needs of their communities and engage in population health programs to bring health care services into communities that previously lacked access. Ambulatory networks are an indispensable part of integrated hospital systems’ long-term vision to meet the needs of their community at large, particularly when they serve disadvantaged patients who live in underserved areas with limited access to transportation. By allowing hospital PBDs to re-evaluate the needs of their communities and add or remove services as appropriate, CMS will protect patient access and help to ensure care where it is needed.

CMS’ proposal to pay the non-expected rate for new service lines also will impose excessive administrative burden on providers and detract from time that should be spent on patient care. This administration has emphasized the importance of reducing provider burden and emphasizing patient care, as exemplified in its “Patients Over Paperwork” initiative.<sup>39</sup> CMS’ proposal is operationally complex, is bound to increase regulatory burden, and will strain hospital billing systems and staff resources. For example, CMS proposes implementing an entirely new health care service classification system of “clinical families.” Each hospital will have to manually reconcile the long list of services it provides with CMS’ new classification scheme.

Until now, excepted off-campus PBDs have appended modifier “PO” to all claim lines. To implement the reduced payment rate for non-expected PBDs under the BBA, CMS has required non-expected PBDs to append a “PN” modifier to their claims. CMS now proposes that excepted PBDs will have to append two different modifiers to services, depending on whether the service is excepted or non-expected. For services belonging to clinical families that were provided in the baseline period, an excepted PBD would continue to append the PO modifier. For services that are part of new clinical families, the PBD would have to append a PN modifier. As noted above, hospital staff first will have to perform a retrospective review of all of the services that were provided in each excepted PBD in the baseline period and cross-reference this list to CMS’ proposed clinical families. Once the hospital has determined which clinical families of services its PBDs were providing in the baseline period, it will have to evaluate all services provided to determine if any services fall under a new clinical family and require a PN modifier. Any time a hospital adds a new service to its system, it would have to repeat the process to ensure the modifier is in place. This process is impracticable and will be virtually impossible to implement by January 1, 2019. The modifier requirements represent an

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<sup>39</sup> 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 12, 2018.

additional burden, not only for coding efforts, but also for continuous review and compliance efforts.

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

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

**5. 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 chooses to move forward, the agency must revise its proposal 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: our analysis shows that in CY 2019, site neutral payments will result in essential hospitals' OPPS reimbursement being reduced by 2.2 percent compared to 1.5 percent at other hospitals.<sup>40</sup> For hospitals operating on narrow (often negative) margins, these drastically lower payments are unsustainable and will affect patient access in areas where there is most need for these services. Essential hospitals operate on a negative 22.7 percent Medicare outpatient margin, over eight percentage points lower than all OPPS hospitals nationally. **We strongly urge CMS to pay non-excepted PBDs of essential hospitals at a rate no lower than 75 percent of the OPPS rate; we have provided further comment in our separate letter on the CY 2019 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 to patients at other hospitals, a significantly higher proportion of patients treated at essential hospital PBDs are dually eligible for

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<sup>40</sup> Data from internal analysis conducted for America's Essential Hospitals by Dobson DaVanzo & Associates. August 2018.

Medicare and Medicaid, which is a key indicator of patient complexity. Over 37 percent of beneficiaries treated at essential hospital PBDs are dual eligibles, compared to 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.<sup>41</sup> 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 that CMS should promote—not stifle—through policies that protect patient access to vital clinic visits in essential hospital PBDs.

**6. 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 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 CY 2019 OQR Program measure set. For CYs 2020 and 2021, CMS proposes to remove a total of 10 measures and to adopt an additional factor to account for costs and benefits when evaluating measures for removal from the program. 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 support CMS' Meaningful Measures Initiative and encourage the agency to continue 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, the rapid growth in measures and measure reporting requirements has jeopardized the effectiveness of

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<sup>41</sup> 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](http://www.medpac.gov/docs/default-source/data-book/jun18_databookentirereport_sec.pdf). Accessed August 24, 2018.

efforts to make meaningful quality improvements. Although some measures provide useful information, their sheer number—as well as lack of focus, consistency, and organization—limits their overall effectiveness in improving health system performance. Further, the proliferation of measures combined with a lack of consistency often leads to inaccurate comparisons of providers and confusion for consumers.

Last year, CMS launched its Meaningful Measures Initiative to identify high-priority areas for quality measurement and improvement. **We applaud CMS' efforts to increase measure alignment across programs and reduce provider reporting burden. 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 that 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 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 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.<sup>42</sup>

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<sup>42</sup> 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 13, 2018.



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 clearly showing the connection between social risk factors and health care outcomes.<sup>43</sup> 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."<sup>44</sup> We urge CMS to closely examine the considerations provided by the Academies for risk adjustment in federal programs.

Like the growing body of research on socioeconomic risk adjustment, the Academies found that community-level elements outside providers' control can indicate risk unrelated to quality of care.<sup>45</sup> We urge CMS to examine these criteria, as identified by the Academies, when 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.

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<sup>43</sup> 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 September 13, 2017.

<sup>44</sup> National Academies of Sciences, Engineering, and Medicine. *Accounting for Social Risk Factors in Medicare Payment*. Washington, D.C.: The National Academies Press; January 2017.

<http://nationalacademies.org/hmd/Reports/2017/accounting-for-social-risk-factors-in-medicare-payment-5.aspx>. Accessed Sept. 13, 2018.

<sup>45</sup> 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 Sept. 13, 2018.

We urge CMS to examine the Academies' report for examples of 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 reduce health disparities across Medicare programs, including the OQR Program.

- c. CMS should provide flexibility in the application of the proposed additional factor (focused on the costs and benefits of a measure) and consider this factor when evaluating measures for removal from the OQR Program measure set.

CMS previously removed measures from its quality programs for a variety of reasons, including that measures were topped out, measures did not align with current clinical guidelines, or a more applicable measure became available. CMS uses seven factors to decide whether to remove measures in the OQR Program; these factors are considerations, not firm requirements. CMS proposes to adopt an eighth factor: whether the costs associated with a measure outweigh the benefit of its continued use in the program. Further, the agency has stated that it would remove measures based on this new factor on a case-by-base. **We support the addition of this factor and encourage CMS to provide flexibility in its application, as stakeholders might define costs and benefits in various ways.**

In proposing the additional removal factor, CMS has identified different types of costs, including, but not limited to, provider collection burden, CMS program oversight, and costs associated with participating in multiple programs. **We urge CMS to consider a broad variety of costs, both direct and indirect, associated with a measure that might create significant burden on essential hospitals and outweigh the benefit of its continued use.** For example, CMS might examine whether data to calculate the measure is collected from a single or limited number of data sources, as opposed to multiple different sources (charts, electronic health records [EHRs], claims, disease registries, etc.). Similarly, a burden or cost could be that hospitals must contract with (and pay for) external vendors to collect and report data. For essential hospitals already operating on low or negative margins, these costs have significant implications. Additionally, CMS should examine the indirect benefits of a measure, such as whether the data collected for reporting a measure can inform multiple measures. Conversely, if a measure does *not* inform other measures, perhaps it should be removed from the program.

**Additionally, we urge CMS to seek input from hospitals, physicians, and other stakeholders when evaluating costs and benefits.** Recently, CMS asked clinicians to participate in a study related to the Quality Payment Program (QPP). Specifically, the agency will study the burdens associated with reporting quality measures in the QPP by asking clinicians about their clinical workflows and data collection methods using different submission systems, as well as challenges to collecting and reporting quality data. We encourage CMS to promote this type of information sharing across its

programs so that the day-to-day “costs” of quality reporting are captured and incorporated into the agency’s considerations for measure removal.

- d. 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 from the OQR Program one quality measure beginning with the CY 2020 payment determination and nine quality measures beginning with the CY 2021 payment determination. 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 on essential hospitals.

CMS proposes to remove one measure from the CY 2020 OQR Program: OP-27: Influenza Vaccination Coverage Among Healthcare Personnel. For CY 2021, CMS proposes removal of these measures:

- OP-5: Median Time to ECG;
- OP 31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery;
- OP-29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients;
- OP-30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use;
- OP-9: Mammography Follow-up Rates;
- OP-11: Thorax Computed Tomography (CT)—Use of Contrast Material;
- OP-12: The Ability for Providers with Health Information Technology to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data;
- OP-14: Simultaneous Use of Brain CT and Sinus CT; and
- OP-17: Tracking Clinical Results between Visits.

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 proposed for removal in CY 2021 to be topped out: OP-11 and OP-14. America’s Essential Hospitals appreciates CMS’ efforts to reduce the reporting burden on hospitals. By removing measures that no longer show improvements in quality, and for which there is statistically indistinguishable difference in hospital performance, CMS will enable hospitals to use their limited resources for quality improvement instead of administrative reporting activities. CMS notes that removing these two measures will “reduce program burden, costs, and complexity,” adding that the burden associated with reporting these measures outweighs the benefit of keeping them in the program. 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 immediately remove topped-out measures.

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

CMS proposes to add three new C-APCs for CY 2019, bringing the total number of C-APCs to 65. 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.

**8. CMS should remove the communication about pain questions from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure under the Hospital Inpatient Quality Reporting (IQR) Program.**

In the FY 2018 Inpatient Prospective Payment System (IPPS) final rule, CMS finalized a refinement to the HCAHPS survey measure as used in the Hospital IQR Program. The change removed the previously adopted pain management questions and incorporated new communication about pain questions beginning with patients discharged in January 2018, for the FY 2020 payment determination and subsequent years. These questions relate to how providers communicate with patients about pain—e.g., how often did hospital staff talk with you about how to treat your pain?

CMS previously recognized the unintended consequences, related to influence on opioid prescribing practices, that could arise from the pain management dimension questions

in the Hospital Value-Based Payment (VBP) Program. The agency removed such questions for payment purposes under the Hospital VBP Program in FY 2018. CMS again proposes to modify the HCAHPS survey measure as used in the Hospital IQR program by removing the communication about pain questions entirely. This change would be effective with January 2022 discharges for the FY 2024 payment determination. **We support the removal of measures related to communication about pain and urge CMS to seek feedback from stakeholders on how best to assess quality of care related to pain management.**

Essential hospitals believe that pain management is a critical part of routine patient care and strive to engage with their physicians to judiciously prescribe opioids. For example, ED physicians at an essential hospital in Delaware have reduced narcotics prescriptions to half the national average by setting clear pain management expectations with patients before the pain starts and exploring other pain management tactics, such as spirituality, meditation, and yoga. These physicians even explored the use of virtual reality for pain management, a technique they have used in the health system's cancer center. **We encourage CMS to engage stakeholders about existing programs to manage pain and align incentives with compliance of evidence-based practices.** Before the development of future patient experience questions, CMS must do more to ensure it mitigates any unintended consequences, such as negative effects on provider behavior.

Another essential hospital in Ohio created an Office of Opioid Safety—focused on education, advocacy, and treatment—that has created physician-, practice-, and subspecialty-specific dashboards to collect data on prescribing practices. The data is used to educate providers on policy and best practices for safe opioid use. Further, residents and ED physicians at this health system undergo training in a simulation center, where they work with speaking mannequins to learn how to respond to patients who request more pain medication. **Hospitals and physicians should be able to monitor the administration of opioids and promote their evidence-based use through programs that are tailored to the needs of the hospital and its patient population.** We urge CMS to support and provide flexibility for hospitals that are working to increase compliance with prescribing protocols and pain management training. The agency should not add measures that increase administrative burden and have yet to be linked to improved outcomes.

#### **9. CMS should address cost and payment barriers to the use of non-opioid alternatives.**

In the proposed rule, CMS seeks comment on Medicare packaging policies for non-opioid alternative treatments and requests feedback on other policy, regulatory, and payment barriers to the use of non-opioid alternatives. Essential hospitals are national leaders in reducing opioid dependence through the implementation of clinical practices that encourage the use of non-opioid alternative treatments. An essential hospital in New Jersey was the first hospital to develop an alternatives-to-opioids program in its ED that prioritizes the use of non-opioid treatments to manage acute pain. In the first two years of the program, the hospital decreased opioid prescriptions by 82 percent while continuing to meet patients' needs for pain relief for ailments such as renal colic

pain, sciatica, headaches, musculoskeletal pain, and extremity fractures. These non-opioid treatments include other medications, ultrasound-guided nerve blocks, nitrous oxide, and trigger-point injections. While this essential hospital and others are developing pioneering approaches to combat the opioid crisis, there are prevailing cost and payment barriers to the use of non-opioid alternatives; CMS can reduce such barriers to encourage the adoption of these alternative treatments.

CMS packages payment for non-opioid medications—such as Exparel, a post-surgical analgesic injection—into payment for the rest of the surgical procedure. Packaging a supply into payment for an overall surgical procedure results in underpayment for the supply. When a hospital receives a single, packaged payment for a surgical procedure, the payment rate is based on the average cost of providing the surgery and the associated bundle of services across all hospitals. Packaged payment does not account for the higher costs of an individual service or supply, such as a non-opioid alternative, at a given hospital. In many cases, the cost of a non-opioid alternative is prohibitive and is more than the cost of a comparable opioid treatment. **To eliminate this issue, we urge CMS to pay for Exparel and other non-opioid alternative treatments separately and to discontinue packaging these treatments into payment for the surgical procedure.**

As essential hospitals have demonstrated, non-opioid alternatives often can be effective tools for pain management. In instances for which a non-opioid treatment is clearly preferable to an opioid-based treatment, there are payment and cost barriers that discourage the use of such alternative methods. Outside of the limited scope of packaging policies, CMS should work to ensure adequate payment for non-opioid alternatives and develop policies that counter rising drug prices. In addition to inadequate Medicare payment, the rising cost of drug list prices strains hospital budgets. For example, intravenously administered acetaminophen often is a viable alternative to opioids, but the list price increase of this drug might discourage some providers from using it, especially if the comparable opioid is more affordable. Ultrasound-guided nerve blocks and compartment blocks, likewise, are insufficiently reimbursed. **CMS should evaluate its payment policies to ensure sufficient payment for non-opioid alternative treatments, while simultaneously working with stakeholders to address the root causes of rising drug list prices.**

**10. CMS should ensure any efforts to improve transparency account for existing reporting requirements, as well as sociodemographic variation among patients served by essential hospitals, and do not add administrative burden to providers.**

America's Essential Hospitals appreciates the opportunity to respond to CMS' request for information (RFI) about price transparency. We support CMS' efforts to improve transparency and ensure patients have access to vital information to make informed decisions about their care. However, we are concerned that CMS' proposal to require that hospitals make available a list of standard charges (either in the form of the chargemaster itself or another form of the hospital's choice) via the internet in a machine-readable format might be misleading to patients and cause excess administrative burden on essential hospitals.

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. The following are specific recommendations to ensure transparency measures provide patients with appropriate and usable information, without duplication or additional administrative burden.

- 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 work in partnership 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 that information provided to patients is relevant as they navigate their care decisions and does not create additional uncertainty. What hospitals charge and what they receive from payers can—and often does—vary significantly. Medicare and Medicaid, for example, pay administratively determined rates that often fall well short of a hospital's true cost of care. Despite this, the law requires hospitals to maintain uniform charges for all patients, regardless of their economic or insurance status—the rate represented on their charge description master (CDM). This means that 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. In response to the FY 2019 IPPS proposed rule, America's Essential Hospitals opposed the new requirement that hospitals post a list of their standard charges online in a machine-readable format.

Hospital pricing is complex. The final amount paid by patients often is dependent on insurance benefit design, including deductibles, coinsurance, copayments, out-of-pocket maximum amounts, and how the payer has negotiated a contract with the provider. Prices listed in the CDM are no more useful for patients without insurance, as they are often eligible for hospital charity care policies or other significant discounts. No single list at an institution can capture this information. Posting gross prices will have the effect of creating more confusion for patients and ultimately will generate more administrative costs and burden on hospitals.

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.

Essential hospitals strive to ensure that their patients receive the most timely and accurate information regarding the cost of their care, including through their 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 that 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.

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 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 limited English proficiency (LEP) experience significant communication barriers when they enter the health care system.<sup>46</sup> 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 along with 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.

**Any 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 that are vital to the community, such as trauma or behavioral health care, will

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<sup>46</sup> 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.

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.

- b. Transparency requirements should not increase administrative or regulatory burden on essential hospitals.

America's Essential Hospitals commends the administration for its attempts to reduce regulatory and administrative burden. Last year, CMS announced its Patients over Paperwork initiative to increase efficiency in the delivery system by allowing providers to focus their time and resources on patient care. We urge CMS to consider the administrative burden that its policies on transparency would impose on essential hospitals.

A variety of hospital regulatory requirements increase the demand on resources to deliver care, and ultimately the cost of care, without necessarily improving quality. 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. Efforts should be taken to examine the usefulness of data already reported. If stakeholders are required to report specific data beyond what currently is reported, we urge CMS to mitigate the administrative burden associated with additional reporting requirements.

The implementation of new transparency requirements would likely require significant investment of time and resources from essential hospitals—time and resources that otherwise could be spent providing care to patients. Hospitals might have to purchase new systems, such as price estimating systems, to comply with new requirements.

**Sharing patient-specific information on their own out-of-pocket costs is a more accurate and less burdensome use of hospital resources and will lead to less confusion among patients, especially those with complex needs and low health literacy or LEP.**

- c. CMS should encourage transparency, while recognizing that essential hospitals already comply with multiple transparency requirements on both the state and federal level.

Essential hospitals, many of which are fully or partially governed by state or local governments, are, by definition, more transparent than most other hospitals. Public hospitals often are subject to more stringent requirements under state and/or local laws intended to increase accountability to the public. For example, public hospitals often must periodically report to local government entities and government audits; conform

to open meeting and open records laws; take part in competitive bidding before entering contracts; and follow stringent procurement requirements to ensure appropriate spending of public dollars.

In addition, other essential hospitals (including some public hospitals) are nonprofit organizations under section 501(c)(3) of the Internal Revenue Code. In 2009, Congress and the IRS implemented reforms on nonprofit hospitals to ensure greater transparency in their activities. These transparency requirements include the creation of the IRS Form 990, Schedule H, which requires that nonprofit hospitals disclose financial assistance and means-tested government program information and other benefits to their communities. Section 501(r) also requires nonprofit hospitals to publicize their financial assistance policies and limit the amount they charge patients who are eligible for financial assistance. Nonprofit hospitals face the very real threat of losing their tax-exempt status if they do not comply with these requirements.

In addition to federal regulations, hospitals face transparency requirements from their state and local governments. In some states, data on hospital prices for common procedures are posted online to allow consumers to compare potential charges at hospitals in their area. Any new reporting requirements should not be duplicative of other efforts to increase transparency.

Hospitals also face a multitude of quality reporting standards intended to improve quality and reduce costs. America's Essential Hospitals supports quality improvement initiatives; however, we caution that many quality reporting standards serve only to increase administrative burden without necessarily meeting their goals. Hospital cost reports, filed annually by all hospitals, also collect detailed records and create significant burden. **Before implementing new price transparency guidelines, CMS should consider the full scope of reporting requirements with which hospitals already comply.**

**11. CMS should encourage improved communication between providers and patients, as well as improved care transitions, without putting further burden on essential hospitals by requiring additional information exchange through Conditions of Participation (CoPs).**

America's Essential Hospitals appreciates the opportunity to respond to CMS' RFI on the potential use of Medicare and Medicaid CoPs to further advance the electronic exchange of information. We support the agency's efforts to improve interoperability amongst providers and the use of EHR technology to improve the flow of information between providers and patients. However, the proposed changes do not account for the unique patient population served by essential hospitals or the challenges to interoperability and information exchange that have yet to be addressed. Further, these changes would create administrative burden and duplicative reporting requirements.

We support CMS' goal of promoting communication between providers and improving care transitions and outcomes by highlighting the importance of discharge planning. Essential hospitals understand the need for providers across the care continuum to have ready access to patients' health information. However, there are obstacles—many of

which are outside of the control of hospitals—that inhibit their ability to seamlessly exchange information. The GAO pointed to the many remaining challenges to attaining a truly interoperable nationwide health information technology infrastructure.<sup>47</sup> There are multiple private- and public-sector initiatives to improve the interoperability landscape, but there still is much work to be done to allow providers to easily exchange information. Requiring such information exchange through CoPs—for which noncompliance might result in the inability to participate in the Medicare and Medicaid programs—would hold providers to an exacting standard for health information exchange that is not in line with the reality of nationwide progress with this technology.

Regarding the discharge planning process, we urge CMS to consider the special challenges essential hospitals face in caring for those who require a more extensive discharge planning process—one that accounts for complex needs, such as socioeconomic and literacy barriers, limited access to medications, and little availability of non-health care services—and to not add administrative burden.

- a. To avoid duplicative reporting requirements, CMS should not require the electronic exchange of information through CoPs.

CMS has listed relieving administrative and regulatory burden from providers as an agency priority. As part of the Patients over Paperwork initiative, the agency issued an RFI on ways to reduce regulatory burden on providers. Further, as part of CMS' Meaningful Measures Initiative, the agency proposed in this rule the elimination or de-duplication of a significant number of measures across its quality programs. We applaud the administration's efforts to allow essential hospitals to focus more of their time and resources on patient care instead of onerous administratively burdensome actions. However, **the addition of new CoPs would be a step backward and represent a new administrative challenge for essential hospitals.**

As major providers of care to Medicaid and Medicare patients, essential hospitals adhere to the regulatory requirements and CoPs they must meet to participate in these programs. CoPs are process-oriented and cover every hospital service and department. These requirements were put in place to protect the health and safety of patients. However, compliance with frequently changing CoPs can place administrative burden on some hospitals, as well as financial stress to invest funds into compliance efforts. CoPs also are typically restrictive in acceptable approaches for meeting the condition, thereby limiting essential hospitals' flexibility to test and implement novel approaches based on the unique patient populations they treat.

CMS already requires hospitals to electronically exchange information with other providers and to provide patients access to their health records as part of the PI Program. If they fail to meet these requirements, they face financial penalties. CMS now is considering adding CoPs for hospitals to ensure a patient's right and ability to electronically access his or her medical information without undue burden. Imposing duplicative requirements through CoPs would force essential hospitals to use resources

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<sup>47</sup> U.S. Government Accountability Office. Nonfederal Efforts to Help Achieve Health Information Interoperability. GAO-15-817. September 2015. <http://www.gao.gov/assets/680/672585.pdf>. Accessed September 4, 2018.

to report the same information twice and would not benefit patients. **The addition of CoPs to improve the electronic exchange of information is overly burdensome to hospitals and an inappropriate means to improve patient access to health records.**

Moreover, adding requirements for health information exchange and patient access through CoPs is premature, given that hospitals currently are focused on updating their systems and training their staff to meet Stage 3 requirements. In Stage 3, CMS has added new requirements for health information exchange and patient access, including the use of application programming interfaces (APIs) for enabling patient access to their records. Stage 3 also includes requirements for hospitals to both send and receive health information from other providers. Hospitals are focusing their resources on ensuring they have implemented the appropriate version CEHRT and that they can successfully report on these measures. As such, **CMS should not impose similar requirements through CoPs while hospitals work to ensure readiness for Stage 3 and have yet to gain familiarity with reporting more challenging Stage 3 measures.**

- b. CMS should recognize and mitigate the barriers that prevent health information exchange before imposing new requirements.

The commitment essential hospitals make to serve 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 electronic patient information, including poverty, homelessness, language barriers, and low health literacy. Many patients served at essential hospitals struggle to access technology that would enable them to access discharge planning documents electronically. Members of America's Essential Hospitals predominantly serve a diverse mix of patients who face significant socioeconomic challenges and who are uninsured or covered by public programs. Some of these patients are homeless and seek care at programs designed for their needs, including respite programs at essential hospitals. In addition to homelessness, patients' ability to access the technology is affected by a variety of other sociodemographic factors, including income, education, and primary language. Many of our members' patients do not have electronic access to their health information outside of the hospital. While internet service might be readily available in most urban areas, many families do not have a computer at home or cannot afford the monthly cost of internet access. **We urge CMS to recognize the patient challenges that make sharing information even more difficult for essential hospitals serving this population.**

In addition to the challenges they face due to their unique patient populations, essential hospitals struggle with difficult measures in the PI Program, such as the measure requiring electronic exchange of a summary of care document and the measure requiring a certain percentage of patients to electronically access their health information. The consequences for failing to report or meet benchmarks through CoPs would be even more damaging to hospitals. The result of noncompliance with CoPs is far more punitive when compared with the PI Program and could result in hospitals losing the ability to participate in the Medicare program. With the multitude of challenges essential hospitals still face in ensuring their EHR technology is properly

implemented, the use of CoPs in this area could be devastating to the communities these hospitals serve.

ONC has conducted important work in promoting new technology for providers and encouraging increased interoperability. As directed in the 21st Century Cures Act, the Office of the National Coordinator (ONC) in January 2018 released the Trusted Exchange Framework and Common Agreement, which outlines a set of principles for trusted exchange and is intended to enable interoperability.<sup>48</sup> ONC should be allowed to continue its work of promoting interoperability. However, a great deal of progress needs to be made before seamless health information exchange is possible.

In addition to creating the TEFCA, CMS must allow ONC to complete additional work as directed in the 21st Century Cures Act—including rulemaking on information blocking and APIs—before taking further action on interoperability. This rulemaking would provide much-needed clarification on standards for APIs and activities that are not considered information blocking. It is inappropriate for CMS to suggest incorporating information exchange requirements in CoPs when ONC has yet to complete statutorily required work in this area. Further, CMS has failed to define important terms that would determine how interoperability requirements in CoPs affect essential hospitals. **Without the required rulemaking from ONC and sufficient clarity from CMS, adding interoperability requirements into CoPs would result in significant confusion and additional burden for essential hospitals.**

- c. CMS should encourage patient-centered care and care transitions while recognizing the challenges essential hospitals face in caring for vulnerable patients with complex postdischarge needs and in implementing certified EHR technology (CEHRT).

In 2015, CMS proposed revisions to discharge planning requirements for hospitals. In response, America’s Essential Hospitals urged CMS to consider the additional challenges faced by essential hospitals and their patients in the discharge planning process. The patients treated at essential hospitals are among the most vulnerable and require extensive time and resources to ensure the discharge planning process is tailored to their clinical needs. Discharge planning for this population also requires consideration of social risk factors outside the control of the hospital, such as homelessness, cultural and linguistic barriers, and low literacy.

Members of America’s Essential Hospitals understand the critical contribution non-health care social services make to achieving effective care transitions and improved outcomes, including reduced readmissions. One member in Missouri developed a care transitions program that reduced hospital admissions, ED visits, and costs. This essential hospital identified the need for a multidisciplinary team, bringing together licensed clinical social workers, client-community liaisons, and advanced-practice registered nurses, among other staff, to address both the clinical and social issues affecting their patient population.

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<sup>48</sup> Office of the National Coordinator for Health Information Technology. Draft Trusted Exchange Framework. January 2018. <https://www.healthit.gov/sites/default/files/draft-trusted-exchange-framework.pdf>. Accessed September 4, 2018.

In caring for vulnerable populations, essential hospitals face special challenges, such as identifying a patient's or caregiver's capability and availability to provide necessary postdischarge care, as well as the availability of community-based support, including transportation, meals, housing, and other non-health care services. For example, the successful transfer of patients from one level of care to another, or from one setting to another, requires careful attention to patient care goals and treatment preferences, in combination with consideration of the availability of postdischarge services. Further, patients served by essential hospitals might have language-related access barriers. As such, **identifying language needs is important in accurately capturing the patient's care goals and treatment preferences, which form the core of the discharge planning process.**

CMS' discharge planning proposed rule was never finalized, and yet the agency's proposals under consideration for this RFI seek to go beyond the proposed rule by requiring electronic sharing of discharge planning information. This introduces additional complexity and resource allocation for essential hospitals. Existing EHR technology remains a challenge for essential hospitals as they adapt to the Promoting Interoperability (PI) Programs. While many essential hospitals are leaders in implementing CEHRT, the health care field in general has not reached a point where CMS can reasonably expect the seamless sharing of information, particularly between hospitals and community providers.

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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](mailto:eomalley@essentialhospitals.org).

Sincerely,

Bruce Siegel, MD, MPH  
President & CEO

**APPENDIX**  
**Dobson DaVanzo & Associates, LLC**  
**OPPS Analysis Methodology**