



# AMERICA'S ESSENTIAL HOSPITALS

October 5, 2020

Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building, Room 445-G  
200 Independence Avenue SW  
Washington, DC 20201

Ref: CMS-1736-P: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-Owned Hospitals

Dear Administrator 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, which provide stability and choice for people who face barriers to care. The steep cuts to hospitals in the 340B Drug Pricing Program, coupled with the cuts to off-campus provider-based departments (PBDs), will impede the ability of essential hospitals to remain financially solvent and continue to serve as the primary point of care for vulnerable communities. Further, these cuts come at a particularly inopportune time, as hospitals recover from the financial losses incurred during the COVID-19 pandemic.

America's Essential Hospitals is the leading champion for hospitals and health systems dedicated to high-quality care for all, including the vulnerable. Our more than 300 member hospitals fill a vital role in their communities. They provide a disproportionate share of the nation's uncompensated care, and three-quarters of their patients are uninsured or covered by Medicare or Medicaid. Essential hospitals provide state-of-the-art, patient-centered care while operating on margins one-third that of other hospitals—2.5 percent on average compared with 7.6 percent for all hospitals nationwide.<sup>1</sup> These narrow operating margins result in minimal reserves and low cash on hand—circumstances exacerbated by financial pressures related to COVID-19.

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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 2018 Annual Member Characteristics Survey. America's Essential Hospitals. May 2020. <https://essentialdata.info/>. Accessed September 12, 2020.

Essential hospitals' commitment to serving all people, regardless of income or insurance status, and their diverse patient mix pose unique challenges. A disproportionate number of their patients face sociodemographic challenges to accessing health care, including poverty, homelessness, language barriers, and low health literacy. Ten million people in essential hospital communities have limited access to healthy food, and nearly 24 million live below the poverty line.<sup>2</sup> Essential hospitals are uniquely situated to address these social determinants of health and are committed to serving these vulnerable patients; however, these circumstances compound our members' challenges and strain their resources. As such, it is crucial the administration offer flexibility to ensure essential hospitals are not unfairly disadvantaged for serving the vulnerable and can continue to provide vital services in their communities.

We are encouraged by CMS' proposals on overall hospital quality star ratings. America's Essential Hospitals, along with our members, have engaged fully in listening sessions as well as the technical expert panel convened by the agency to address flaws in the current methodology. We are pleased to see that those conversations led to proposals to stratify and use peer grouping in an effort to provide better comparisons of hospitals. This is the direction in which the program needs to go—accounting for differences among hospitals that are outside their control. We encourage CMS to go further by adjusting for social risk factors at the measure level. Additionally, we support the removal of the complex latent variable modeling approach to improve reliability and predictability within the star ratings.

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.

These ambulatory networks are a critical asset in essential hospitals' response to coronavirus. They have enabled essential hospitals on the front lines to screen, test, and treat COVID-19 patients in their communities. Our members have invested substantial resources in preparing for and responding to the COVID-19 public health emergency (PHE)—including by increasing capacity through alternative care sites, maintaining sufficient quantities of personal protective equipment and other critical supplies, and ensuring staff capacity. These efforts are far from over.

Hospitals have made these investments while facing double-digit drops in revenue due in part to decreasing the number of planned and elective procedures and other ancillary services to stand ready for COVID-19 patients. As a result, essential hospitals face an uncertain financial future and many other challenges as they continue to respond to and recover from the COVID-19 PHE.

CMS' proposed outpatient cuts would further exacerbate essential hospitals' uncertain financial future. Continuing reduced payment to office visits at excepted off-campus PBDs will severely limit the ability of essential hospitals to provide comprehensive, coordinated care to disadvantaged populations. 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.

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<sup>2</sup> Ibid.

The Part B drug payment policy would disproportionately affect essential hospitals—although they represent just 12 percent of 340B hospitals paid under the Outpatient Prospective Payment System (OPPS), essential hospitals would receive 25 percent of the payment cut. Similarly, essential hospitals would receive a disproportionate portion of the cuts to off-campus PBDs in calendar year (CY) 2021. In our detailed comments below, we urge CMS to withdraw its PBD and 340B payment proposals.

1. For CY 2021, CMS should pay hospitals in the 340B program the statutory default payment of average sales price (ASP) plus 6 percent. CMS' proposed alternative payment methodology exceeds the agency's statutory authority and undermines the Public Health Service Act (PHSA), and the cuts to 340B hospitals have irreparably harmed low-income patients and the hospitals committed to treating them.

America's Essential Hospitals implores CMS to withdraw its proposed policy because the payment cut is based on an unlawful application of CMS' authority to set payment rates for specified covered outpatient drugs (SCODs) under the Social Security Act (SSA) and would have devastating consequences for vulnerable communities. CMS proposes to reimburse certain separately payable drugs purchased through the 340B program at 65.3 percent of ASP, with a 6 percentage point add-on, amounting to 71.3 percent of ASP. This constitutes an even deeper cut than the agency's previous policy initially enacted in the CY 2018 OPPS final rule, under which it has paid 340B hospitals at 77.5 percent of ASP. The new policy represents a 33 percent reduction in payments from the statutory default methodology for hospitals in the 340B program, while hospitals not in the program continue to receive payment at 106 percent of ASP. To effectuate this policy, CMS invokes a different provision of the SSA than it has used since 2018; this provision directs the agency to set payment rate for SCODs based on average acquisition cost (AAC) collected through a robust, methodologically sound survey of hospitals.

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

For the fourth consecutive year, we urge the agency to reverse Part B payment cuts to 340B hospitals. CMS' proposal to use AAC data to set payment rates for 340B hospitals violates the SSA's prescribed methodology for determining payments based on AAC. We continue to believe CMS' alternative methodology to reduce payments to 77.5 percent of ASP violates the Medicare statute. Continuing for an additional year with steep payment cuts to hospitals, particularly during a pandemic, is ill-advised and detrimental to hospitals and their patients. In the three years since CMS first proposed this sweeping policy change, the agency has yet to demonstrate that the policy lowers drug prices,

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<sup>3</sup> H.R. Rep. No. 102-384, pt. 2 (1992).

financially helps beneficiaries, or improves access to or quality of care for Medicare beneficiaries. On the contrary, as we establish in more detail in the following sections, CMS' drug reimbursement policy already has begun to undermine a key policy lever that has proved effective in combating high drug prices.

- a. CMS' proposed policy violates the plain language of the SSA and is impermissible under the Administrative Procedure Act (APA).

For CY 2021, CMS proposes to reimburse 340B hospitals for non-pass through separately payable Part B drugs at 71.3 percent of ASP, asserting this represents the average acquisition cost for 340B drugs across all 340B hospitals. CMS collected AAC data during a survey of 340B hospitals earlier this year; using the survey data, as well as ceiling price data for hospitals that did not submit AAC data, CMS calculated the volume-weighted geometric mean 340B discount. CMS notes that, due to the confidential nature of 340B ceiling prices, the agency will not set the payment rate for each SCOD separately, as doing so could reveal confidential pricing data about an individual drug's 340B ceiling price and average manufacturer price. While CMS proposes to pay 340B hospitals at the rate that it believes approximates their AAC, the agency will continue to pay non-340B hospitals at the statutory default rate of 106 percent of ASP. CMS' interpretation and application of the payment methodology for SCODs violates the SSA for the following reasons.

- i. To pay hospitals based on AAC, CMS first must conduct a robust survey of a statistically valid sample of all OPPS hospitals.

CMS' proposed payment methodology violates the Medicare statute because the agency did not collect the survey data using the prescribed methodology for collecting acquisition costs for SCODs. CMS described its acquisition cost survey as a "hospital survey for SCODs." The agency, however, required only 340B hospitals to report acquisition costs through the survey; non-340B hospitals were not required to report their acquisition costs because CMS asserts ASP data is "an adequate measure of the drug acquisition costs" of these hospitals.<sup>4</sup> The selective collection of drug acquisition costs based on an arbitrarily selected hospital characteristic (in this case, participation in the 340B program) conflicts with the acquisition cost collection methodology that Congress outlined for CMS in the Medicare statute.

The provision of the SSA which authorizes CMS to collect drug acquisition costs, section 1833(t)(14)(D), first required the comptroller general of the Government Accountability Office (GAO) to conduct a hospital acquisition cost survey in 2004 and 2005 to determine the hospital acquisition cost for each SCOD. Then, based on GAO's recommendations, CMS was directed to "conduct periodic subsequent surveys to determine the hospital acquisition cost for each [SCOD] for use in setting the payment rates under subparagraph (A)." The survey requirement is for the collection of hospital acquisition costs of each SCOD—there is no reference to only 340B drugs or 340B hospitals, or authority to exclude non-340B drugs or hospitals.

More significantly, the Medicare statute has specific requirements that surveys are conducted using a "large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each [SCOD]." When GAO conducted its survey of hospitals, it used a thorough process and rigorous statistical methods to ensure the survey results were representative of hospital acquisition costs by SCOD. GAO created a stratified random sample of the 3,450 hospitals that

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<sup>4</sup> CMS Supporting Statement A. Hospital Survey for Specified Covered Outpatient Drugs. CMS-107-0; OMB 0938-New.

had charged Medicare for SCODs at some point in the previous year. That is, GAO's survey sample was selected to represent all OPPS hospitals—not just one subset of hospitals, such as 340B hospitals. Hospitals in the 340B program account for only a portion of all OPPS hospitals. CMS states in the proposed rule that it administered the survey to 1,442 340B hospitals, which is less than half of the more than 3,600 hospitals paid under the OPPS.

It is worth noting that hospitals not in the 340B program can benefit from additional discounts that allow them to purchase drugs at prices significantly below the list price. Hospitals that are part of large systems leverage their size to procure volume discounts. Non-340B hospitals can use group purchasing organizations—which 340B hospitals are statutorily prohibited from using for 340B drugs—to negotiate sizable discounts on their drugs. For CMS to gather data on and pay hospitals based on acquisition cost, it must collect information for all hospitals to capture the different types of discounts that can affect acquisition cost—the agency did not do this in its survey. Because the survey only focused on one type of hospital, it did not satisfy statutory sampling requirements and, ultimately, did not accurately capture average acquisition costs of all OPPS hospitals.

- ii. CMS cannot selectively reimburse one group of hospitals using AAC data while paying another group of hospitals using ASP-based payment.

For a given SCOD, the SSA directs CMS to either pay based on AAC (if accurate AAC data are available as collected through a survey) or using ASP when AAC data are not available. Specifically, the SSA provision on SCOD reimbursement states “payment . . . for a SCOD” is to be equal:

- (I) to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D); or
- (II) if hospital acquisition cost data are not available, the average price for the drug in the year established under section 1842(o), section 1847A, or section 1847B, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of this paragraph.

This provision is clear that CMS cannot arbitrarily pick and choose between these two provisions—that is, the agency cannot pay one group of hospitals based on AAC and another group based on ASP. Instead, CMS is to base the payment rate for a given SCOD across all hospitals using one of the two prescribed methodologies.

The statute does provide CMS with discretion to vary payment by hospital group but only if it uses the option to pay based on AAC. But, if CMS chooses to go this route, it first must collect AAC data for all hospitals to vary the payment rate. If CMS intends to exercise its authority to vary payment by hospital group, that authority lies strictly under the subclause (I) AAC methodology. Under that methodology, CMS first must collect the requisite data to set AAC-based payment, determine if there are variations in AAC across hospitals with certain characteristics, and then set differential payment rates to these groups of hospitals using their respective AAC data. Instead of doing this, CMS bypasses the requirement that it collect AAC data for non-340B hospitals and proposes to continue paying them using the statutory default methodology under subclause (II) at 106 percent of ASP. By conflating two different methodologies for SCOD payment under the SSA, CMS incorrectly varies payment for hospital groups.

- iii. CMS failed to implement adequate safeguards to ensure the accuracy of its survey data.

Setting aside the fact that CMS did not follow the statute’s statistical sampling requirements, CMS’ survey was rife with other procedural deficiencies. For example, CMS did not provide hospitals with ample notice of the survey. While CMS did seek public comment on the information collection request, it launched the survey the day after receiving Office of Management and Budget approval, providing no lead time and only three weeks for hospitals to complete the survey. Neither CMS nor Medicare administrative contractors actively shared the news of the survey’s launch through existing channels, other than posting it on the OPPS website. Many hospitals had been unaware of the survey launch and others remained unclear about the instructions in the survey, especially given that CMS had changed the survey and survey instructions from proposed to final form. This lack of notice was exacerbated by the poor timing of the survey, launched at the end of April, when hospitals were singularly focused on responding to the surge of COVID-19 patients.

The unreliability of the survey is underscored by the fact that only 7 percent of surveyed hospitals completed the detailed inquiry, with the remainder either substituting ceiling price data instead or not responding. CMS cannot set payment rates for more than 1,000 hospitals based on unreliable data submitted by only 99 hospitals. In comparison, the GAO survey, which is meant to serve as a model for future CMS surveys of AAC, received an 83 percent response rate.

In contrast to the rigorous methodology employed by GAO in its 2004 survey, CMS’ survey followed hardly any methods that could be used to ensure the accuracy of the data. When GAO conducted its survey of hospitals, it sought a larger sample than needed, expecting a response rate lower than 100 percent. GAO took numerous steps to ensure the accuracy of its data. It pretested the survey with a small group of hospitals before officially launching the survey and once it launched the survey, it communicated with each individual hospital on average of 8 to 15 times to ensure accurate and complete data submission. GAO took eight months from its pretesting stage to receipt of all survey responses, in addition to time taken to verify and analyze the data.<sup>5</sup> Without taking similar steps, CMS cannot certify that its data are reliable and valid. Given the numerous procedural deficiencies in CMS’ survey of AACs, CMS cannot vouch for the reliability of its AAC data and must withdraw its proposed policy.

- iv. Participation in the 340B program is not a relevant hospital characteristic that can be used to vary drug payment.

Even if CMS did have the necessary AAC information for all hospitals to set payment by hospital groups, participation in the 340B program is not one of the characteristics Congress envisioned to be used to vary payment. Subclause (I) of the SCOD provision says CMS may vary payment by hospital group “as defined by the Secretary based on volume of covered OPD services or other relevant characteristics.” The only characteristic explicitly mentioned in the statute is the volume of outpatient services. Although CMS has discretion to choose other “relevant” characteristics, 340B participation is not one of these characteristics.

GAO’s analysis of variations in AAC by hospital characteristic is instructive in illustrating the types of characteristics CMS can use to vary payment. The part of the SSA that directs GAO to conduct surveys

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<sup>5</sup> GAO. Medicare Hospital Outpatient Drug Prices. GAO-05-581R. June 2005.

on AAC contains a clause on “differentiation in cost.”<sup>6</sup> This clause states GAO shall “determine and report to Congress if there is (and the extent of any) variation in hospital acquisition costs for drugs among hospitals based on the volume of covered OPD services performed by such hospitals or other relevant characteristics of such hospitals (as defined by the Comptroller General).” In conducting the surveys of AAC, GAO identified teaching status, location, and size as three factors that affected AAC.<sup>7</sup> Notably, GAO did not even include 340B-priced drugs in its calculation of AAC.<sup>8</sup> GAO’s analysis was intended to serve as the foundation for future AAC surveys by CMS. The fact that GAO did not include 340B participation as a relevant hospital characteristic and also deliberately excluded 340B drugs from the AAC calculation demonstrates that 340B participation is not one of the characteristics intended as the basis for variation in Medicare Part B drug payment.

Moreover, Congress made it clear that it did not intend 340B prices to lower Medicare Part B payment rates when it explicitly excluded the use of 340B prices from the calculation of ASP. Specifically, under section 1847A(c)(2)(A) of the SSA, Congress determined CMS should not include sales exempt from best price calculations in the calculation of ASP. Because drugs purchased under 340B are exempt from the best price calculation, they are exempt from inclusion in ASP as well. GAO clearly interpreted the statute the same way and decided to exclude 340B prices from the calculation of the AAC so as not to lower any future payment rates based on AAC, thus preserving the benefit of the 340B discount for 340B hospitals.

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 undermines 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>9</sup> CMS’ policy prior to 2018 aligns with this premise, demonstrating it is possible to implement a reasonable interpretation of Medicare rate-setting authority consistent with 340B program intent. Despite CMS’ assertions, the policy to reduce 340B hospital drug reimbursement is inconsistent with and undermines the purposes of the 340B program.

Congress stated 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>10</sup> Congress specifically designated the entities that should benefit from the program, defining eligible DSH hospitals as those serving a disproportionately greater percentage of low-income patients (determined through Medicaid and Medicare Supplemental Security Income). 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

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<sup>6</sup> Social Security Act. Section 1833(t)(14)(D)(iv).

<sup>7</sup> GAO. Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS. GAO-06-372. April 2006.

<sup>8</sup> Ibid at page 36.

<sup>9</sup> See, e.g., Statutory Interpretation: General Principles and Recent Trends (December 19, 2011) at page 29.

<sup>10</sup> H.R. Rep. No. 102-384, pt. 2 (1992).

hospitals specified in statute, but CMS' budget neutrality adjustment also redistributes these funds to hospitals not 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 enacted the 340B program; as referenced above, Congress did not envision that the Medicare program would benefit from 340B discounts when it excluded 340B prices from the calculation of ASP.

- c. CMS' alternative methodology violates the plain language of the SSA and is impermissible under the APA.

CMS seeks comment on continuing its 77.5 percent of ASP payment rate for 340B hospitals instead of its proposal to pay at 71.3 percent of ASP. We oppose this alternative and urge CMS to revert to paying all hospitals at 106 percent of ASP. More specifically, as we have established in greater depth in our CYs 2018 through 2020 comments, CMS lacks the authority for using the subclause (II) methodology to approximate AAC for these reasons:

- CMS' policy since 2018 is an unlawful departure from the statutory default payment for separately payable Part B drugs, which requires the agency to pay at ASP plus 6 percent if it does not have acquisition cost data;
- CMS' nearly 30 percent payment cut to a specific subset of hospitals does not constitute an "adjustment" under section 1883(t)(14)(A)(iii)(II) of the SSA. The payment reduction is excessive and would have to be applied to all OPPS hospitals, not just one subset of hospitals;
- CMS cannot attempt to pay at acquisition cost when it lacks acquisition cost data and has been paying under the ASP methodology in section 1833(t)(14)(A)(iii)(II); and
- CMS' payment methodology conflicts with another statute, the PHSA, and undermines Congress' intent in enacting the 340B program. By redirecting funds intended for 340B hospitals to other hospitals in the Medicare program, CMS' policy violates the intent of the 340B program.

Because litigation on the 2018 and 2019 policy is pending, implementing the reduced payment rate for another year not only will impede patient access and hospital operations but also will impose an ongoing unnecessary burden on hospitals if the Court of Appeals later invalidates this policy.

- d. CMS' drug payment policy harms essential hospitals and their patients while doing nothing to counter astronomically rising drug prices.

Since CMS implemented this policy, which has reduced drug payments to 340B hospitals by nearly \$5 billion over three years, the agency has not provided evidence that the policy has benefited Medicare beneficiaries or improved access to and quality of health care. CMS has not analyzed whether the policy has met its intended goals, how it has affected patient access, whether it has lowered drug prices, or how it has affected hospital operations. In fact, drug prices have continued to rise since the implementation of the policy and hospitals continue to see their operations affected by their declining outpatient margins.

It is especially irresponsible to further deepen payment cuts already totaling in the billions of dollars during a pandemic, which has strained hospital operations and finances. During the COVID-19 pandemic, hospitals on the front line of response efforts have experienced tens of billions of dollars in lost revenue and increased expenses per month. The Medicare Payment Advisory Commission



(MedPAC) estimates that in the aggregate, hospitals lost up to \$30 billion in the month of April alone.<sup>11</sup> Other estimates have monthly losses at \$50 billion, with total projected losses for the year over \$300 billion.<sup>12</sup> MedPAC underscored how the financial impact of the pandemic has been more pronounced for nonprofit hospitals compared with for-profit hospitals. It would be devastating for these public and nonprofit 340B hospitals to face an additional \$2 billion in cuts in 2021 on top of the hundreds of billions of dollars in losses they experience due to the pandemic. The brunt of these cuts will be felt by the low-income and other disadvantaged people who rely on 340B hospitals for their care.

As America's Essential Hospitals has expressed in its CYs 2018–2020 comments, in addition to being unlawful, the 340B payment cut is a counterproductive policy for several reasons:

- The cuts jeopardize the patchwork support on which essential hospitals rely, threatening their ability to maintain critical services. 340B hospitals' Medicare outpatient margins are substantially lower than non-340B hospitals, at negative 16 percent for 340B hospitals compared to negative 12 percent for non-340B hospitals. Accounting for the reduced OPPS reimbursement resulting from the Part B payment reduction, 340B hospitals' Medicare outpatient margins would drop even further, to negative 20 percent.<sup>13</sup> At the same time, because of the redistributive nature of the policy, non-340B hospitals will see their Medicare outpatient margins increase;
- Patients do not benefit from CMS' payment cuts. Because CMS implements this policy in a budget-neutral manner that raises OPPS rates for other ambulatory payment classifications (APCs), all beneficiaries pay higher copays for other services. Additionally, most beneficiaries have some form of third-party coverage that covers unpaid Medicare copays; and
- The payment cuts undermine the administration's efforts to counter astronomically rising drug prices. While the evidence is clear that drug list prices have risen from year to year, CMS provides 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.

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. 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 not reduce payments for separately payable drugs purchased through the 340B program and administered at non-excepted PBDs, as doing so exceeds the agency's statutory authority under the SSA.

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<sup>11</sup> MedPAC September 2020 meeting. The coronavirus pandemic and Medicare. [http://medpac.gov/docs/default-source/meeting-materials/medpac\\_covid\\_sept\\_2020\\_rev.pdf](http://medpac.gov/docs/default-source/meeting-materials/medpac_covid_sept_2020_rev.pdf). Accessed September 12, 2020.

<sup>12</sup> American Hospital Association. Hospitals and Health Systems Continue to Face Unprecedented Financial Challenges due to COVID-19. June 2020. <https://www.aha.org/system/files/media/file/2020/06/aha-covid19-financial-impact-report.pdf>. Accessed September 12, 2020.

<sup>13</sup> Data from internal analysis conducted for America's Essential Hospitals by Dobson DaVanzo & Associates. September 2020 (See appendix for a more detailed discussion of the methodology used to calculate Medicare outpatient margins).

CMS proposes to continue its unlawful payment policy for 340B drugs to non-excepted PBDs, as it did for the first time in CY 2019. Specifically, the agency plans to pay at 71.3 percent of ASP for 340B drugs administered in non-excepted off-campus PBDs under section 603 of the Bipartisan Budget Act of 2015 (BBA). These PBDs are not paid for outpatient services at the full OPPS rate but instead under the Medicare Physician Fee Schedule (PFS), as adjusted. As we argue above, the policy to reimburse for 340B drugs at 71.3 percent of ASP under the OPPS is unlawful under the SSA. Extending this policy to non-excepted PBDs is equally untethered from the statute, which also precludes payment at a rate other than 106 percent of ASP for these clinics in these ways:

- The Medicare PFS is the applicable payment system for non-excepted PBDs, and it requires payment for drugs at 106 percent of ASP under section 1842(o)(1)(c);
- This section does not contain adjustment authority similar to section 1833(t)(14)(A)(iii) and therefore bars CMS from paying anything other than 106 percent of ASP; and
- 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 pay hospital off-campus PBDs at 106 percent of ASP—the same as it pays physician offices. Instead, CMS wants to pay these off-campus PBDs even less than physician offices. This policy choice is out of line with the rationale behind its site-neutral payment policy.<sup>14</sup>

For these reasons, CMS should pay non-excepted PBDs at 106 percent of ASP under the PFS payment methodology for separately payable drugs.

3. CMS should withdraw its proposal to continue reducing payments for clinic visits at excepted off-campus PBDs, as doing so exceeds its authority under the SSA.

As mandated by section 603 of the BBA, CMS discontinued paying certain off-campus PBDs under the OPPS on January 1, 2017; the statute instructs CMS instead to pay these PBDs under another Part B “applicable payment system.” In CY 2017 OPPS rulemaking, CMS decided 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. Since CY 2019, CMS has cut payment for outpatient clinic visits to these excepted PBDs, which are clearly outside the reach of the reduced payment amount under section 603. 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 emergency department.

CMS' proposal to continue to reduce payment for outpatient clinic visits at excepted PBDs to 40 percent of the OPPS rate is contrary to the SSA and violates the payment structure of the OPPS. Litigation is ongoing on the lawfulness of the cuts to excepted PBDs. Despite a recent ruling of a panel of judges for the U.S. Court of Appeals for the District of Columbia, we fully expect the courts ultimately to find extending site-neutral payment policies to excepted clinics unlawful. As America's Essential Hospitals established in further detail in its comments on the CYs 2019 and 2020 proposed rules, the cut to excepted PBDs is unlawful for various reasons summarized below.

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<sup>14</sup> See America's Essential Hospitals Comment Letter on CY 2020 OPPS Proposed Rule. September 27, 2019. <https://essentialhospitals.org/wp-content/uploads/2019/09/FINAL-AEH-CY2020-OPPS-Comment-Letter-9-27-19-for-archive.pdf>. Accessed September 27, 2020.

First, CMS' extension of payment cuts to excepted PBDs violates the SSA, as amended by the BBA. Congress did not intend CMS to adjust payments to excepted PBDs. CMS contravened congressional intent by cutting payments for excepted departments at the same rate as if they were non-excepted. In so doing, CMS effectively has 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.

Second, although CMS justified the cuts to excepted PBDs by claiming it is implementing a volume-control mechanism under section 1833(t)(2)(F) of the SSA, the manner in which it is implementing this policy violates the SSA. The SSA states “the [HHS] Secretary shall develop a method for controlling unnecessary increases in the volume of covered [outpatient department] services” only after services exceed an established target and only through a conversion factor update. CMS' proposed implementation of the volume-control methodology through this rule is contrary to statutory requirements. 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 volume-control targets under this subparagraph are exceeded does HHS have the authority to make a payment adjustment through (9)(C), which allows an adjustment only in the form of an annual conversion-factor update in a subsequent year.

Finally, CMS' reduction of the clinic visit payment rate violates the SSA because adjustments to specific services under the OPPS must be budget neutral. CMS targets the payment reduction to excepted clinics for a specific type of service (one HCPCS code). This targeted reduction falls outside the normal scope of APC weight adjustments CMS is permitted to make under the OPPS. Under the OPPS, CMS does not have the authority to selectively choose services and cut payment for those services outside the regular rate setting process, which allows for the establishment of APCs and an annual reconfiguration of APC weights in a budget-neutral manner.<sup>15</sup>

In addition to being unlawful, CMS' policy has and will continue to undermine the ability of essential hospitals to serve vulnerable populations in underserved areas. Many essential hospitals have off-campus clinics in federally designated areas with shortages of providers, including health professional shortage areas (HPSAs) and medically underserved areas (MUAs). Further, these clinics are more likely to serve patients dually eligible for Medicare and Medicaid, as well as uninsured patients and those on Medicaid, compared with freestanding physician offices. These clinics face severe cuts due to CMS' policy, and their closure would restrict access to care for communities in which access to health care already is limited and cannot be provided by freestanding physician offices.

For these reasons, CMS should withdraw this site-neutral proposal, for which it lacks authority and which clearly contradicts congressional intent in passing section 603 of the BBA, and revert to paying excepted PBDs the full OPPS rate for clinic visits.

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

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<sup>15</sup> See, e.g., Social Security Act 1833(t)(9)(B), stating, “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.”

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 unnecessarily expanded the law's scope beyond Congress' original intent; this will further harm essential hospitals and the vulnerable patients they serve. CMS should use its statutory authority to offer flexibility and reduce burden on providers, particularly regarding relocation and change of ownership.

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

CMS should allow PBDs to retain their excepted status, even if they relocate, if they continue to meet the provider-based requirements. In the CY 2017 OPPI final rule, CMS created 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. One of the most glaring examples has been the need for hospitals to relocate PBDs during the COVID-19 pandemic to increase access for patients and to triage care. In recognition of the need for hospitals to relocate PBDs during the pandemic, CMS allowed on-campus PBDs and excepted off-campus PBDs to relocate while maintaining their excepted status during the COVID-19 PHE. However, this relocation exception is temporary, and CMS will require hospitals to move the PBD back to its original location once the PHE expires. To allow hospitals to meet the needs of their communities and to respond to potential outbreaks of COVID-19 in the future, CMS should allow hospitals to permanently relocate their PBDs once the COVID-19 PHE expires if it is in the best interests of their patients and communities.

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

For these reasons, CMS should lift the burdensome limitation on relocation and clarify that a hospital can relocate a PBD that is excepted if it continues to meet the provider-based requirements.

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

In the CY 2017 OPPI 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 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 operating an off-campus PBD unsustainable 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 are not 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 does not revert to the full payment rate for PBDs, the agency must revise its policy in a way that protects essential hospitals and their patients, rather than causing further harm. Essential hospital PBDs are disproportionately impacted by site-neutral payment policies. For hospitals operating on narrow (often negative) margins, these substantially lower payments are unsustainable and will affect patient access in areas with the greatest need for these services. Essential hospitals operate on a negative 23 percent Medicare outpatient margin—9 percentage points lower than OPPS hospitals nationally.<sup>16</sup> We strongly urge CMS to pay non-excepted PBDs of essential hospitals at a rate no lower than 75 percent of the OPPS rate.

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 full primary and specialty services.

The patients treated at essential hospitals' off-campus PBDs typically are low-income and racial and ethnic minorities. Compared with patients at other hospitals, a significantly higher proportion of patients treated at essential hospital PBDs are dually eligible for Medicare and Medicaid, which is a key indicator of patient complexity. 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>17</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

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<sup>16</sup> Data from internal analysis conducted for America's Essential Hospitals by Dobson DaVanzo & Associates. September 2020 (See appendix for a more detailed discussion of the methodology used to calculate Medicare outpatient margins).

<sup>17</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 September 12, 2020.

through ambulatory networks. Providing care in the outpatient setting allows hospitals to avoid unnecessary emergency department visits, manage patients with chronic conditions, provide follow-up care to patients to avoid readmissions, and, in the process, reduce costs for the health care system at large. These are goals CMS should promote—not stifle—through policies that protect patient access to vital clinic visits in essential hospital PBDs.

6. CMS should address stakeholder concerns about eliminating the inpatient only (IPO) list, including burden on providers, time frame for removal, and impact on patient-mix for Medicare models.

Procedures on the IPO list usually are performed only in the inpatient setting and are reimbursed at inpatient rates—not paid for under the OPSS. Each year, CMS reviews this IPO list for procedures that should be removed because they can be provided in the outpatient setting.

For example, based on developments and innovations in total knee arthroplasty (TKA) technique and patient care—allowing the procedure to be performed on an outpatient basis—CMS finalized the removal of TKA from the IPO list for CY 2018. The agency also finalized the removal of total hip arthroplasty (THA) from the IPO list in the CY 2020 OPSS final rule.

CMS in 2021 proposes to begin the process of fully eliminating the IPO list with the removal of approximately 300 musculoskeletal-related services; the agency would remove all remaining services from the list over a three-year transition period.

- a. CMS should extend the timeline for eliminating the IPO list to allow providers adequate time to prepare and gain experience with newly removed procedures.

CMS proposes to eliminate the IPO list in its entirety (all 1,740 services) by January 1, 2024. As part of a three-year transition period, the agency identified 266 musculoskeletal services, such as hip and knee arthroplasty and spine procedures, for removal in CY 2021. America’s Essential Hospitals supports the goal of providing more choice to patients and providers regarding the care setting. However, we are concerned about the potential for unintended consequences associated with eliminating the IPO list, and the proposed three-year time frame for removal.

Along with physician judgment, the IPO list serves as a tool to indicate which services are appropriate to furnish in the outpatient setting. The removal of almost 300 services in 2021 represents the largest one-time removal of services from the IPO list. Hospitals and providers will need time to adjust to the removal of these procedures from the list. For example, providers need time to prepare clear criteria for surgical site selection, develop criteria for patient selection, update their billing systems, and gain experience with newly removed procedures eligible to be paid under either the Inpatient Prospective Payment System or OPSS.

Additionally, the COVID-19 PHE has strained the health care community. This sweeping change—eliminating the IPO list—would only add complexity and burden to a workforce already under immense pressure. We urge CMS to extend the transition time frame to at least five years to allow for adequate preparation.

- b. CMS should address concerns about the effect of elimination of the IPO list on current Medicare payment models.

We have concerns about the effect the proposed elimination of the IPO list would have on current Medicare payment models. In comments to CMS on its proposed removal of the TKA and THA procedures, we noted that these services on the IPO list are included in two episode-based payment models: Comprehensive Care for Joint Replacement (CJR) and Bundled Payment for Care Initiative (BPCI). In the BPCI and CJR models, services are paid on a fee-for-service basis with retrospective reconciliation against target prices based on historical costs associated with the procedure, for a defined time period. Being that TKA/THA was on the IPO list, we raised concern to CMS that the agency did not have claims history for beneficiaries receiving these procedures on an outpatient basis.

Similarly, but on greater scale, if CMS were to eliminate the IPO list in its entirety, patients who previously would have received procedures included in Medicare models in an inpatient setting may receive those procedures on an outpatient basis. Therefore, establishing an accurate target price based on historical data becomes more complicated within the CJR and BPCI models. Further, the historical episode spending data might not accurately predict episode spending for beneficiaries receiving the procedure as an inpatient.

Removing procedures from the IPO list will require modifications to the current Medicare payment models, leading to confusion among hospitals and CMS, as well as issues of accuracy and fairness in setting target prices. We urge CMS to provide clarification and guidance as to the impact on Medicare models, and plans to ensure hospitals are not negatively impacted by the removal of all services from the IPO list.

Additionally, we know there are differences in patient population for TKA/THA procedures performed on an outpatient basis—i.e., younger, active, fewer complications, and having more support at home than most Medicare beneficiaries. Further, many Medicare patients have comorbidities and would require intensive rehabilitation after a TKA/THA procedure, best performed in an inpatient setting. As such, TKA/THA procedures performed on an outpatient basis might only be appropriate for a small number of Medicare beneficiaries. CMS will need to identify a methodology for payment model participants that appropriately adjusts target prices for inpatient procedures to reflect the shift of less complex procedures to the outpatient setting. We urge CMS to study the differences in performing procedures in both settings to ensure patient safety for all Medicare beneficiaries, and fairness among participants in episode-based payment models, before removing hundreds of services at one time from the IPO list.

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

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

CMS made changes to the two-midnight rule in past years that are positive steps toward preserving clinician judgment and addressing these concerns.

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

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

7. CMS should continue to refine the overall hospital quality star ratings to ensure usability, predictability, and fairness. The agency should replace the complex latent variable modeling with an explicit approach, stratify the readmissions measure group, use peer grouping to compare hospitals, and further examine ways to risk adjust at the measure level to account for factors outside hospitals' control.

CMS proposes to update and simplify the methodology that would impact public release of overall hospital quality star ratings in CY 2021 and subsequent years.

America's Essential Hospitals took part in various listening sessions held by CMS and other stakeholders, including the National Quality Forum, as well as having member hospitals provide valuable input as part of the agency's technical expert panel. We applaud CMS' recognition of the need to increase predictability, stability, and comparison within the star ratings methodology.

America's Essential Hospitals remains committed to working with CMS and others on better ways to empower patients and their families with information about health care quality.

- a. CMS should ensure the star ratings do not oversimplify a complex and individualized decision—a patient's choice of care—while potentially exacerbating disparities in care.

Essential hospitals know the importance of sound data to reduce disparities in care, and they lead efforts to close gaps in quality for racial and ethnic minorities. By involving patients as active



participants in their own care, hospitals can better help identify care choices, as well as respond to clinical and social needs that might improve health outcomes.

However, a single rating for a hospital oversimplifies what is inherently a complex and personalized decision—the choice of where to seek care. Assigning a single, simplified rating might fail to capture a hospital’s particular expertise in an area of care most important to a given patient. For example, a hospital’s complication rate after an orthopedic procedure provides little useful information to a woman deciding where to give birth. Because each patient’s circumstances differ, so, too, will the measures that matter to them.

CMS should explore a rating system based on specific clinical conditions, instead of one overall rating. In 2019, CMS hosted a listening session with a broad variety of stakeholders, during which concerns were raised about the usability of ratings that do not provide information important to patients’ health care decision making—location or condition-specific data, for example.<sup>18</sup> We urge CMS to further examine the methodology for the star ratings and ensure patients receive information on coherent sets of hospital quality measures in a way that is most relevant to their individualized care choices.

- b. CMS should finalize its proposal to stratify the readmissions group scores based on proportion of dual-eligible patients, and further examine ways to risk adjust at the measure level to account for socioeconomic and sociodemographic factors that complicate care for vulnerable patients.

In previous comments, America’s Essential Hospitals called for improvements to the star ratings methodology to account for differences among hospitals and the populations they treat. Essential hospitals go above and beyond medical treatment to care for disadvantaged patients every day. The current ratings do not adjust for factors outside the control of the hospital. We support the public release of valid measures of care quality. However, it is counterproductive to release ratings that misrepresent the actual quality of care provided; this is particularly damaging to the nation’s public health if misrepresentation hurts hospitals that primarily care for disadvantaged patients and communities.

We support CMS’ proposal to stratify the readmissions group score using a hospital’s proportion of dual-eligible patients, as a first step on the path to true risk adjustment. In doing so, the agency will align with methodology in the Hospital Readmissions Reduction Program. However, we urge CMS to continue to explore risk adjustment at the measure level for factors outside a hospital’s control.

More than two-thirds of the star rating summary score is linked to outcome measures—mortality, readmission, and patient experience, for instance—which research shows are influenced by social risk factors. A large and growing body of evidence shows sociodemographic factors—age, race, ethnicity, and language, for example—and socioeconomic status, such as income and education, can influence health outcomes.<sup>19</sup> These factors can skew results on certain outcome measures, such as those for readmissions. To measure outcomes performance in the overall star ratings, we strongly urge CMS to

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<sup>18</sup> Overall Hospital Quality Star Ratings Listening Session Meeting Summary Report (revised November 7, 2019). <https://www.cms.gov/files/document/overall-hospital-quality-star-ratings-listening-session-summary-report>. Accessed September 18, 2020.

<sup>19</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 September 11, 2020.

include methodology that incorporates risk adjustment for socioeconomic and sociodemographic factors, so results are accurate and reflect varying patient characteristics across hospitals. Without proper risk adjustment, an essential hospital serving a disproportionate share of low-income patients with compounding sociodemographic factors might receive a lower rating for reasons outside its control. Further, this misrepresentation could compromise potential patients' decisions on and access to necessary medical services.

While America's Essential Hospitals supports the inclusion of measures that cover multiple dimensions of quality, certain measures in the methodology—including those in the readmission group—are biased against essential hospitals for reasons beyond the control of the hospital. Risk adjusting measures for these factors will ensure patients receive accurate information about a hospital's performance. America's Essential Hospitals urges CMS to include factors related to a patient's background—including sociodemographic status, language, and postdischarge support structure—in the risk-adjustment methodology for star ratings.

- c. CMS should remove the statistical latent variable model and instead use a simple average methodology to calculate measure group scores, while monitoring for unintended consequences.

A flawed methodology—not actual hospital performance—drives the current star ratings. The underlying and complex statistical technique at the heart of the methodology lacks transparency and creates uncertainty by disproportionately and inconsistently weighting measures within groups. CMS uses a latent variable model (LVM) to calculate a numerical “loading factor” for each star ratings measure. The higher a measure's loading factor, the more it drives performance within a particular measure group.

We believe the methodology—with its use of an LVM—remains overly sensitive to subtle changes in the underlying data. This is problematic because it means a hospital's rating could hinge on measures that reflect only a narrow aspect of hospital care (e.g., hip/knee replacements) and that critical, universal quality measures, such as the infection measures, might have almost no importance in determining the star rating. Further, it is difficult for hospitals to identify high priority areas for improvement given the sensitivity of the LVM used in the current methodology.

Due to the questionable application of and difficulty in interpreting results from the current statistical model, we urge CMS to eliminate the LVM from the star ratings system completely and instead apply consistent weights for each measure and evaluate weight allocation annually. This would provide scoring stability and easier interpretation for hospitals and the public.

- d. CMS should move forward with its use of peer grouping by number of measure groups, and further consider additional factors (e.g., bed size) that might allow better comparison among hospitals.

Currently, CMS compares all hospitals that meet the minimum measure requirements (three measure scores, within at least three measure groups, including one measure group related to outcomes) regardless of differences in hospital characteristics, such as teaching or safety-net status, number of beds, or variety of services provided. By virtue of essential hospitals' mission, they treat a disproportionate share of our nation's vulnerable and complex patients—both medically and socially. It

is misleading to the consumer to portray all hospitals as being alike, with the same patient mix or services provided.

CMS proposes to use peer grouping by number of measure groups where hospitals are grouped by whether they have three or more measures in three, four, or five measure groups. In conversations with stakeholders, CMS sought input on a variety of characteristics (e.g., teaching hospitals, safety-net hospitals, critical access hospitals) to group similar hospitals and generate their own rating. The agency chose number of measures reported as a proxy for hospital size—i.e., larger systems likely to report more measures.

We support peer grouping as an interim step on the way to true risk adjustment. Directionally, this is where the star ratings program should be headed—acknowledging and accounting for the differences in hospitals, unrelated to the quality of care they provide, that impact measure performance and ratings. As we have seen, specialty hospitals often receive five stars, whereas major teaching hospitals—having a substantially different patient mix and breadth of services—do not receive the same recognition.

Further, we agree that hospitals that report few measures are qualitatively different from hospitals that report all measures—particularly in the sense of being niche, specialty hospitals rather than essential hospitals with emergency departments and significant charity care missions. However, we encourage CMS to look at bed size in conjunction with number of measure groups reported when creating peer groups.

Additionally, CMS should monitor the use of peer grouping to ensure appropriate placement of hospitals in groups and to avoid disproportionately disadvantaging certain hospitals. As the agency implements changes to the star ratings system, ongoing engagement with the broader stakeholder community is necessary to ensure ratings are useful to patients and fair to hospitals.

- e. CMS should not publish star ratings until the agency appropriately resolves issues with the underlying methodology.

We support CMS' efforts to continue to refine and enhance the star ratings system. Proposed changes to the methodology should avoid disproportionately disadvantaging any category of hospitals and ensure the ratings give patients meaningful and accurate hospital quality information. It is imperative that essential hospitals, as well as CMS, have adequate time to understand proposed changes to the methodology and review the potential effects modifications might have on different types of hospitals. Given the need to address outstanding, significant concerns with the star ratings methodology, we urge CMS to suspend publication of ratings until such a time as key stakeholders can agree on appropriate peer grouping, an explicit measure approach to modeling, and a stratified reporting structure that does not penalize essential hospitals.

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

CMS proposes to require prior authorization for two categories of services beginning July 1, 2021: cervical fusion with disc removal and implanted spinal neurostimulators. In last year's final rule, CMS for the first time required prior authorization for OPPS services. CMS cited section 1833(t)(2)(F) of the SSA as its authority for implementing prior authorization, which is the same authority the agency cited

for implementing its payment cut to office visits at excepted off-campus PBDs. We urge the agency to withdraw this proposal because it is an unlawful exercise of its statutory authority, it would hinder patient access to timely care, and it would impose excessive administrative burden on the agency and hospitals.

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

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

CMS must first demonstrate that certain services have experienced unnecessary increases in volume before it can use this authority. In this instance, CMS has not shown that the two categories of services it intends to subject to prior authorization have had unnecessary increases in utilization. CMS looks at data from 2007 to 2018 and points to increases in volume but fails to consider the underlying reasons that could drive the volume increases. For example, CMS postulates it is unaware of reasons other than financial incentives for the increase in volume. However, there are many reasons for increase in utilization of outpatient services—for instance, CMS failed to consider developments in clinical research that demonstrate the benefits of such services and drive utilization. CMS also did not consult with clinical experts who could explain the necessity of these services and the evolution in their use over the past decade.

Prior to CY 2021, CMS only required prior authorization for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) but not for OPPTS services. However, it is granted explicit statutory authority for prior authorization under the DMEPOS fee schedule, which it does not have under the OPPTS statute. Section 1834(a)(15) of the SSA clearly gives CMS the ability to require authorization for certain DMEPOS items by developing and updating a list of services to be subject to prior authorization. The volume control methodology CMS cites under the OPPTS does not confer the same authority to the agency to use prior authorization. Even if it were to use prior authorization, CMS would have to demonstrate that the increase in utilization was unnecessary, which it has not done in the rule.

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

CMS' prior authorization process will result in delays in patients accessing timely care, including in cases of genuine medical necessity. For a hospital to receive Medicare reimbursement for one of the services on CMS' list, it first must submit a prior authorization request to CMS or its contractors, which will have 10 business days to review before responding with a decision. If the service is approved, the provider will receive a provisional affirmation. However, payment for the service still may be denied once the hospital submits a claim for the service. In cases for which a hospital requests an expedited review due to risks to the beneficiary's life, health, or ability to regain maximum function, CMS or the contractor has two business days to respond with a decision. This timeline would seriously jeopardize beneficiary access to care, even in cases of expedited review. For example, in a case where a beneficiary presents to a hospital outpatient department with a condition that requires immediate treatment on a Friday afternoon, CMS would have until Tuesday—four calendar days later—to respond with a decision. This

scenario does not account for additional time the provider will need to gather the necessary documentation and submit the required prior authorization paperwork. Additionally, there is no appeals process through which a provider could contest an adverse decision from CMS once a denial is issued. CMS should withdraw the prior authorization proposal because it creates unnecessary obstacles to Medicare beneficiaries receiving timely care deemed necessary by experienced clinicians.

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

CMS' proposal is administratively burdensome for providers and for the agency. This administration has emphasized the importance of reducing provider burden and emphasizing patient care, as exemplified in its "Patients Over Paperwork" initiative. CMS' proposal is operationally complex, is bound to increase regulatory burden, and will strain hospital systems and staff resources. Before a service is provided to a beneficiary, the provider must submit a detailed prior authorization request with documentation demonstrating the service meets Medicare coverage, coding, and payment rules. Hospital staff will require extensive training on the list of services subject to prior authorization, as well as the procedures for submitting these requests. Providers also will need to spend time explaining to patients the need for prior authorization and will need to develop educational materials for patients on these new requirements. The proposal will also strain CMS and its contractors' resources at a time when they already face a backlog in case reviews. For these reasons, CMS should not finalize its prior authorization proposals.

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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 and CEO

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