AMERICA'S ESSENTIAL HOSPITALS

September 11, 2023

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

Ref: CMS-1786-P: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction

Dear Administrator Brooks-LaSure:

Thank you for the opportunity to comment 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 and to close the existing health equity gap. As the agency finalizes Medicare outpatient payment policies, we ask that it consider the following comments on supporting the unique role essential hospitals play in promoting health equity and increasing access for marginalized communities by crafting policies that protect these hospitals from payment cuts and ensure their continued stability.

America's Essential Hospitals is the leading champion for hospitals and health systems dedicated to high-quality care for all. Our more than 300 member hospitals fill a vital role in their communities. They provide a disproportionate share of the nation's uncompensated care (UC), 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 less than half that of other hospitals—3.2 percent on average compared with 7.7 percent for all hospitals nationwide.[1] These narrow operating margins result in minimal reserves and low cash on hand—circumstances exacerbated by financial pressures related to COVID-19. As essential hospitals attempt to rebound from the pandemic, they remain prepared for new surges in

[1] Clark D, Ramiah K, Taylor, J, et al. *Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2020 Annual Member Characteristics Survey*. America's Essential Hospitals. September 2022. https://essentialdata.info. Accessed August 22, 2023.

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

hospitalizations while facing other challenges, such as rising workforce costs and shortages, rising supply costs, and supply shortages.

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. Essential hospitals are uniquely situated to target these social determinants of health (SDOH) and are committed to serving these marginalized patients. These circumstances, however, compound our members' challenges and strain their resources, requiring flexibility to ensure essential hospitals are not unfairly disadvantaged for serving marginalized populations and can continue to provide vital services in their communities.

Essential hospitals offer comprehensive, coordinated care across large ambulatory networks to bring vital services to where patients live and work. These ambulatory networks are a central part of essential hospitals' efforts to combat the structural racism ingrained in the health care system at large by bringing culturally competent care to patients who otherwise lack access to care. These networks allow essential hospitals to bring care closer to where their underserved patients live, which is an important step in ensuring continuity of care for patients whose health is shaped by lack of transportation, unstable housing, and other social risk factors. Our members' ambulatory networks of hospital-based clinics 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 have been a critical asset in essential hospitals' response to COVID-19, as well.

We urge the agency to implement policies that will ensure stability for hospitals serving marginalized patients and promoting health equity. We are pleased that CMS for a second year intends to restore full Part B drug payments to 340B hospitals. We are, however, concerned about several provisions of the proposed rule that would have a disproportionately negative impact on essential hospitals. The insufficient outpatient payment update, coupled with continued cuts to off-campus provider-based departments (PBDs), will impede the ability of essential hospitals to remain financially solvent. This will undermine their ability to serve as primary points of care in underserved communities, including for people of color and others disproportionately affected by public health crises. To ensure our members have sufficient resources to respond to future challenges and are not unfairly disadvantaged by their commitment to serve medically complex patients, CMS should consider the following recommendations when finalizing the above-mentioned proposed rule.

1. CMS should define a category of hospitals that disproportionately serve marginalized patients and implement policies to protect and support these essential hospitals' critical work.

Essential hospitals form the fiber of the nation's health care safety net. **CMS should adopt payment policies that recognize the unique role of essential hospitals in promoting health equity and should protect essential hospitals from the adverse effects of payment cuts and other policies that affect patient access.** The administration has prioritized tackling structural racism and promoting equity throughout the

federal government.[2] From low payment rates in Medicare and Medicaid—insurance on which low-income people rely—to worse health outcomes for people of color, the lingering effects of structural racism drive health disparities and represent a continued public health threat.

We are encouraged that, in a request for information (RFI) in the fiscal year (FY) 2024 Inpatient Prospective Payment System (IPPS) proposed rule, CMS heeded our calls to define and support safety net hospitals through Medicare payment policies. As CMS noted in that rule, these hospitals "play a crucial role in the advancement of health equity by making essential services available to the uninsured, underinsured, and other populations that face barriers to accessing healthcare, including people from racial and ethnic minority groups, the LGBTQ+ community, rural communities, and members of other historically disadvantaged groups."[3]

The need to define this core group of hospitals and ensure they have stable, sustainable support to continue fulfilling their missions is long overdue and goes beyond the limited context of the IPPS. The Institute of Medicine's 2000 clarion call to ensure safety net providers, which rely on tenuous funding sources, are "sustained and protected" is as relevant today as it was when it was made more than two decades ago.[4] The same issues the safety net faced in 2000—chronic underfunding, reliance on an unstable patchwork of funding sources, a higher uninsured and public payer mix, and treating complex patients—continue to undermine the viability of safety net hospitals and pose an equally, if not more dire, threat in 2023. **To further the administration's and essential hospitals' shared goals of tackling health disparities and promoting health equity, it is imperative CMS recognize these hospitals when crafting Medicare payment and other policies.**

a. Essential hospitals are distinguished by the vital role they serve in their communities and the unique challenges they face.

Essential hospitals are defined by their indispensable role in their communities, the diversity of the patients they serve, and the unique challenges they face that threaten their viability. Essential hospitals, by virtue of their very mission and diverse communities, are experts in targeting SDOH and advancing health equity. This expertise stems from essential hospitals' firsthand experience witnessing and tackling the effects of structural racism and how it routinely disadvantages and produces cumulative and chronic adverse outcomes for people of color. In 2020, racial and ethnic minorities made up more than half of member discharges.[5] Essential hospital patients are challenged by SDOH that affect their health, well-being, and quality of life. Our members reached nearly 16 million people who live below the federal poverty line, 370,000 individuals experiencing homelessness, and nearly 8 million people experiencing food insecurity.[6]

As essential hospitals, our members are committed to ending health disparities and providing high-quality care to all, including underrepresented and marginalized populations. But the ability to sustain this critical work is hampered by challenges, including financial instability

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[2] Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, E.O. 13985 (2021).
[3] 88 Fed. Reg. 26658, 27187 (May 1, 2023).
[4] Institute of Medicine Committee on the Changing Market, Managed Care, and the Future Viability of Safety Net Providers. Lewin ME, Altman S, eds. *America's Health Care Safety Net: Intact but Endangered*. Washington, D.C.: The National Academies Press; 2000.
[5] Clark D, Ramiah K, Taylor, J, et al. *Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2020 Annual Member Characteristics Survey*. America's Essential Hospitals. September 2022. https://essentialdata.info. Accessed August 22, 2023.
[6] Ibid.

driven by insufficient payments and skyrocketing costs. Essential hospitals are chronically underfunded, due to their lower share of commercially insured patients relative to other hospitals and their high level of uninsured patients and patients insured by public payers. The disproportionately high amount of UC they provide and the chronic underfunding of the disparate payment sources on which they rely make it challenging for these hospitals to fulfill their mission. Federal policy changes, such as site-neutral payment cuts, disproportionately affect these hospitals, which already operate on financial margins narrower than the average hospital. Such policy changes also undermine Medicare beneficiaries' access to the linguistically and culturally competent care essential hospitals provide.

Essential hospitals are distinguished by the diverse patients they treat, serving high proportions of Medicaid, Medicare, and uninsured patients, in addition to racial and ethnic minorities. Due to their payer mix, they also provide a much higher share of UC than the average hospital. In addition to this vital safety net role, essential hospitals serve other key roles in their communities. They:

- Provide specialized, lifesaving services, such as level I trauma and neonatal intensive care, emergency psychiatric services, and burn treatment.
- Train the next generation of health care professionals to ensure the community's supply of doctors, nurses, and other caregivers meets demand.
- Deliver comprehensive, coordinated care across large ambulatory networks to bring services to where patients live and work.
- Meet public health needs by improving population health and preparing for and responding to natural disasters, public health emergencies, and other crises.
- Advance health equity to meet the needs and challenges of patient populations that face the greatest disparities and barriers to receiving quality care.

By providing this array of services, essential hospitals serve as anchor institutions and providers of choice for their communities. In the RFI in the IPPS rule, CMS cited many of these characteristics as defining qualities of safety net hospitals, including playing a crucial role in advancing health equity by treating the uninsured, underinsured, and other populations facing barriers to health care; providing burn and trauma care; partnering with local health departments to target SDOH; and providing culturally and linguistically competent care in their underserved communities.[7]

b. CMS must define the select group of hospitals with a safety net mission that provide a substantial share of UC and serve a high number of low-income patients across payers.

To further the administration's and essential hospitals' shared goals of tackling health disparities and promoting health equity, it is imperative CMS recognize these hospitals when crafting Medicare payment and other policies. It is critical for the agency to develop a reliable, cross-cutting definition of a safety net hospital that ensures these hospitals are defined and supported, not just for IPPS or Medicare payment more broadly but also for other payments under CMS' purview. CMS has expressed interest in supporting safety net hospitals in various contexts:

[7] 88 Fed. Reg. 26658, 27187 (May 1, 2023).

- CMS has incorporated health equity adjustments into quality programs related to accountable care organizations (ACOs), as well as the determination of advance investment payment amounts for ACOs.
- The CMS Innovation Center, through its initiative to advance health equity, seeks to increase participation of safety net providers in payment and service delivery models.
- In the Medicaid managed care context, CMS acknowledges the financing challenges safety net hospitals face and proposes to allow states to design directed payments that increase reimbursement for these hospitals.

Other payers, too, will look to CMS' work to define safety net hospitals, elevating the importance of holistically defining this group of hospitals. Instead of adopting a piecemeal approach with disparate definitions of safety net hospitals both within and outside CMS, it is imperative that any adopted definition be comprehensive and broadly applicable to all public policy and public health purposes. Once CMS has defined safety net hospitals, it can tailor policies to support these hospitals that are specific to each payer and payment system. That is, the underlying definition should be consistent across payers, with the policies meant to support these providers differing by payer and context. Appropriately defining the full scope of the nation's safety net hospitals is the first step in developing policies that target these hospitals for sustained support.

With a clear definition, CMS can identify providers that fill these specific roles in the health care system and assess how current and future policies affect them. This identification will ensure CMS can target support to this specific group of hospitals and protect them from harmful policies. **In crafting a definition of safety net hospital, we urge CMS to look beyond the limited context of Medicare policy and create a definition applicable across all payers, agencies, and policymakers so that CMS and other stakeholders can consistently identify this singular group of hospitals for targeted support.**

There is precedent for uniformly designating a group of safety net providers, such as federally qualified health centers (FQHCs). FQHCs are defined in both the Medicare and Medicaid statutes and receive dedicated payment rates specific to their provider class. Beyond Medicare and Medicaid, policymakers have used the FQHC definition to provide targeted support, such as Provider Relief Fund assistance, during the COVID-19 public health emergency (PHE). Policymakers also recognized FQHCs as the only provider type eligible to distribute free vaccines to underinsured children through the Vaccines for Children program. Additionally, the Health Resources and Services Administration automatically designates FQHCs as health professional shortage areas (HPSAs). This designation provides special treatment for payment purposes, such as special consideration for certain grant programs.

Like FQHCs, essential hospitals serve a safety net role by caring for marginalized patients. Codifying a definition of safety net hospital will be critical to ensuring support for all safety net provider types. Ensuring safety net hospitals receive reliable, consistent support will be predicated on an aligned definition of "safety net hospital" across payers and policies, like the aligned definition of FQHC across payment systems.

In addition to the vital roles cited above, safety net hospitals are defined by their commitment to fulfilling their mission of serving all patients, regardless of economic circumstance, while operating on narrow margins. Their fulfillment of this mission is reflected in their payer mix—they treat a disproportionately high share of uninsured and publicly insured patients, and as a result, provide substantially high levels of UC relative to the average hospital. Three quarters of essential hospitals' patients are publicly insured or uninsured, and essential hospitals provide

eight times as much UC, on average, compared with other hospitals. Thus, unlike other hospitals, their share of commercially insured patients is small, resulting in an average margin 40 percent that of other hospitals.[8] **To capture essential hospitals' safety net mission and the types of low-income patients they serve, we urge CMS to incorporate these metrics into the definition:**

- The Medicare disproportionate patient percentage (DPP). The DPP captures a hospital's proportion of Medicaid inpatient days and low-income Medicare inpatient days.
- A measure of a hospital's share of UC costs relative to all hospitals' UC costs, such as the Medicare uncompensated care payment factor (UCPF). CMS currently measures each hospital's share of UC costs using the Medicare UCPF.
- Designation as a deemed disproportionate share hospital (DSH). Defined in the Medicaid statute, the deemed DSH designation identifies hospitals with high Medicaid and low-income utilization rates.

CMS currently uses these three metrics in different contexts to identify hospitals with a high level of need and that qualify for additional financial support. The DPP is an established metric CMS has used to define which hospitals qualify for traditional Medicare DSH payments. CMS uses the relative share of UC costs to target Medicare DSH UC-based payments to hospitals with high UC levels. It is derived from Medicare cost report data and is annually audited. Finally, defined by statute, the deemed DSH designation identifies hospitals with high Medicaid and low-income utilization rates.[9]

Together, these metrics are a suitable proxy for hospitals serving patients that face social and economic barriers to care, and by association, treating very few commercial patients relative to other hospitals. By using these metrics, CMS will ensure it captures the full breadth of the safety net by not focusing on one segment of low-income patients but instead capturing the full scope of low-income patients safety net hospitals treat. Further, all our proposed metrics are vetted, reliable data sources with historical context; the DPP and DSH have been in use for decades, and the UCPF has been in use for nearly 10 years.

CMS can use these data sources without requiring additional revisions to methodology to ensure their reliability, unlike many of the new, less-tested metrics CMS has previously considered, such as the Medicare safety net index and area-level indices such as the area deprivation index. As we have expressed in detail in our response to the IPPS RFI, both metrics are untested and have significant methodological flaws that fail to capture the full cohort of the country's safety net hospitals. **They should not be used to identify this group of hospitals for any purpose.[10]**

c. Once CMS has defined this group of hospitals, the agency should implement Medicare program policies that can support these hospitals and change policies that disproportionately harm them.

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[8] Clark D, Ramiah K, Taylor, J, et al. *Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2020 Annual Member Characteristics Survey*. America's Essential Hospitals. September 2022. https://essentialdata.info. Accessed August 22, 2023.
[9] 42 U.S.C. § 1396r–4(b).
[10] America's Essential Hospitals Comment Letter to CMS on FY 2024 IPPS Proposed Rule. June 9, 2023. https://essentialhospitals.org/wp-content/uploads/2023/06/FINAL-AEH-FY-2024-IPPS-Comment-Letter-6-9-23.pdf. Accessed August 21, 2023.

With a safety net hospital definition in hand, CMS could turn to portions of the proposed rule that offer policymaking opportunities to target support for essential hospitals. These opportunities include ensuring stable access for low-income patients to ambulatory networks by exempting essential hospitals from excepted off-campus PBD clinic visit cuts and ensuring an adequate payment rate for non-excepted, off-campus PBDs of essential hospitals. We discuss these policies in the respective sections of our comment letter below.

In addition to implementing our specific Outpatient Prospective Payment System (OPPS) recommendations throughout this letter, CMS should continue in future rulemaking to evaluate policies to support and protect hospitals serving a safety net role. CMS should define this group of safety net hospitals within its jurisdiction so it can target policies to support these providers across Medicare's distinct payment systems (including fee-for-service and Medicare Advantage), in the Medicaid program, and through demonstration projects under the purview of the Innovation Center. For example, CMS should consider the following policy approaches to supporting essential hospitals:

- Ensuring stable Medicare DSH funding by insulating essential hospitals from year-over-year decreases.
- Implementing the Value-Based Purchasing Program health equity adjustment.
- Incorporating an essential hospital definition in peer grouping methodology for the Hospital Readmissions Reduction Program.
- Adding hospital characteristics, including classification as an essential hospital, to the confidential reporting of across-hospital disparity method results.
- Ensuring essential hospitals are supported in efforts to address disparities and promote equity measurement.
- Ensuring adequate networks and rate sufficiency for essential hospitals in Medicare Advantage.
- Prioritizing the availability of new graduate medical education slots to essential hospitals.
- Targeting Medicaid DSH funds to hospitals serving a safety net role to better align the program with statutory intent.
- Identifying Innovation Center models to support safety net hospital participation.

The Medicare statute gives CMS wide latitude to implement these changes through existing authority. There is precedent in both this rule and previous rulemaking for CMS to protect certain hospitals from financial losses or to increase payments to all hospitals or groups of hospitals.

In working to identify and support essential hospitals, CMS would advance its commitment to health equity, protect the interests of the Medicare program, and preserve access to care for the most disadvantaged Medicare beneficiaries. We urge CMS to follow these recommendations, and we look forward to working with the agency to advance our shared goals.

2. CMS should increase its proposed annual hospital payment update to account for rapidly rising costs of hospital goods and services.

CMS proposes a net annual payment update of 2.8 percent, resulting from a 3 percent market basket update minus a 0.2 percentage point productivity adjustment. **We urge CMS to adjust its methodology for calculating the annual payment update for calendar**

year (CY) 2024 to ensure it provides a robust payment update that adequately incorporates the effects of inflation and rising workforce costs on hospitals.

Hospitals continue to incur soaring costs as they recover from the COVID-19 pandemic, feel the effects of inflation, experience unprecedented increases in labor costs, and encounter supply chain issues and shortages. One analysis found hospitals' per discharge labor costs increased 37 percent from 2019 to 2022.[11] The pressure on hospital input costs has continued into 2023, with one analysis of hospital finances citing increased material costs and increased labor costs attributable to persistent workforce shortages. This analysis shows a 4 percent increase in hospital expenses in June 2023 compared with June 2022 and a 22 percent increase in expenses so far in 2023 compared with 2020.[12]

These trends are not expected to abate anytime soon, with clinical labor costs expected to outpace inflation and increase by 6 to 10 percent over the next two years.[13] Essential hospitals have incurred considerable costs associated with hiring bonuses, retention bonuses, and increased salaries to recruit and retain nurses and other staff in short supply. These challenges have persisted even as COVID-19–related hospitalizations decrease and stabilize. Ongoing challenges from the protracted battle against COVID-19 and the consequential emotional toll on staff remain evident. The pandemic has led to burnout on an unprecedented scale, and essential hospitals have expended significant resources to recruit and retain clinical and nonclinical staff—a costly undertaking in the already competitive marketplace for health care workers.

In the context of historical inflation and workforce challenges, a net 2.8 percent payment update is insufficient to truly capture year-over-year changes in hospital costs. **To that end, we encourage CMS to implement a fee schedule increase factor of at least 5 percent, to use its statutory authority to waive the productivity adjustment in CY 2024, and to make a one-time retrospective adjustment to account for the insufficiency of the market basket update in CY 2022.**

In determining the annual fee schedule increase factor for hospitals, CMS typically uses the inpatient market basket update figure. The CMS Office of the Actuary (OACT) estimates the market basket percentage increase, which reflects the annual change in the mix of goods and services used for providing inpatient hospital services. OACT's use of the IHS Global Inc. forecast of the market basket rate of increase clearly does not account for the true cost increases hospitals face, particularly when there are sudden increases in prices attributable to unprecedented circumstances, such as the COVID-19 pandemic, as well as a historic level of inflation.

CMS is not bound to use the IPPS market basket update. The OPPS statutory provision at 1833(t)(3)(C)(iv) authorizes CMS to deviate from the IPPS update by "substituting for the market basket percentage increase an annual percentage increase that is computed and applied with respect to covered OPD services furnished in a year in the same manner as the market

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[11] Kaufman Hall. The Financial Effects of Hospital Workforce Dislocation. A Special Workforce Edition of the National Hospital Flash Report. May 2022. https://www.kaufmanhall.com/sites/default/files/2022-05/KH-NHFR-Special-Report-2.pdf. Accessed August 22, 2023.
[12] Kaufman Hall. National Hospital Flash Report. July 2023. https://www.kaufmanhall.com/sites/default/files/2023-07/KH-NHFR_2023-07.pdf. Accessed August 22, 2023.
[13] Fleron A, Krishna A, Singhal S. The gathering storm: The transformative impact of inflation on the healthcare sector. *McKinsey & Company*. September 19, 2022. https://www.mckinsey.com/industries/healthcare/our-insights/the-gathering-storm-the-transformative-impact-of-inflation-on-the-healthcare-sector. Accessed August 22, 2023.

basket percentage increase is determined and applied to inpatient hospital services for discharges occurring in a fiscal year." Instead, CMS could consult alternative cost data sources, such as Medicare cost report data, as a truer representation of hospital-reported cost increases to support providing a market basket update of at least 5 percent.

CMS also should waive the negative 0.2 percent productivity adjustment. While this adjustment is required by statute, CMS can waive the productivity adjustment it applied to the IPPS market basket update (which then applies to the OPPS payment update) using its Section 1886(d)(5)(I)(i) equitable adjustment authority. **Furthermore, CMS can use this authority to implement a one-time retrospective adjustment to account for the underestimate of the CY 2022 market basket update, which was finalized at 2.7 percent.** CMS should implement an adjustment equal to the difference between the most up-to-date market basket data for CY 2022 and the finalized market basket update of 2.7 percent. **We emphasize that this should be a one-time adjustment to account for the rapid increase in costs in CY 2022 attributable to the COVID-19 pandemic and inflation.** By adjusting the annual payment update to account for increasing hospital input costs, CMS can ensure hospitals can continue to provide high-quality care and meet the needs of their patients.

3. CMS should continue paying hospitals in the 340B Drug Pricing Program the statutory default payment of average sales price (ASP) plus 6 percent and promptly repay 340B hospitals for the five years of unlawful cuts.

America's Essential Hospitals is pleased that in CY 2024, CMS proposes to continue paying 340B hospitals using the pre-2018 methodology of paying all OPPS hospitals at ASP plus 6 percent. **CMS should finalize this proposal and continue to ensure this payment rate for 340B hospitals and non-340B hospitals alike. We also urge CMS to finalize its separate rulemaking to craft a remedy to make 340B hospitals whole for the past five years of payment cuts.**

a. CMS should pay ASP plus 6 percent for 340B-acquired drugs for CY 2024 onwards.

From January 1, 2018, through September 27, 2022, CMS reimbursed certain separately payable drugs purchased through the 340B program at 77.5 percent of ASP, amounting to $10.5 billion in reduced drug reimbursement. This policy represented a nearly 30 percent reduction in Part B 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. In June 2022, the Supreme Court unanimously struck down CMS' unlawful 2018 and 2019 policy, unequivocally holding that "under the text and structure of the statute, this case is therefore straightforward," and that "HHS acted unlawfully by reducing reimbursement rates for 340B hospitals."[14] This decisive ruling marks the culmination of yearslong litigation challenging CMS' authority to institute these cuts and resolves any doubt about whether these cuts can continue.

In the CY 2023 OPPS final rule, CMS acknowledged the unlawfulness of its 340B hospital payment reduction and restored the 106 percent of ASP payment rate for 340B hospitals. CMS proposes to continue paying 340B hospitals at 106 percent of ASP in 2024. **We support the agency's position of continuing its prior, longstanding policy of paying ASP plus 6**

[14] *American Hospital Association et al. v. Becerra*, 596 U.S. ___, slip op. at 10 (2022).

percent for 340B-acquired drugs in CY 2024 and urge CMS to finalize this policy in the OPPS final rule.

By sustaining adequate payment rates for 340B hospitals, the agency will align with the Biden administration's priorities to mitigate health inequities and promote the health of the nation's marginalized communities. We urge CMS to ensure continuity in the ASP plus 6 percent payment rate going forward to maintain adequate funding and parity for 340B hospitals. That is, CMS should ensure 340B hospitals are paid at 106 percent of ASP, as was the case before 2018. Adequate and equitable reimbursement is consistent with the intent of the 340B program and vital for hospitals serving a safety net role to continue to serve the marginalized communities that turn to them for care.

Congress created the 340B program, codified in the Public Health Service Act, to allow covered entities to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[15] 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. These savings also enable essential hospitals to target the social determinants shaping their patients' health, such as food insecurity, homelessness, and lack of transportation. 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.

Statute structures the 340B program 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. The Supreme Court acknowledged this very point in its opinion, stating that in setting Part B drug reimbursement rates in 2003, "Congress was well aware that 340B hospitals paid less for covered prescription drugs" but "did not see fit to differentiate 340B hospitals from other hospitals when requiring that the reimbursement rates be uniform under option 2."[16] We believe preserving the intent of the 340B program by ensuring adequate Part B drug payment rates serves low-income Medicare beneficiaries and the Medicare program at large and aligns with the administration's policy goals.

b. CMS should promptly finalize and implement a remedy for 340B hospitals.

In separate rulemaking, CMS has proposed a remedy for the nearly five years of Part B cuts. In that rule, CMS states that it intends to finalize a remedy before it issues the CY 2024 OPPS final rule. **We strongly urge CMS to adhere to this timeline and to finalize a rule in accordance with our recommendations in our separate comment letter.** In that comment letter, we urge CMS to:

- Swiftly finalize its proposed lump-sum repayments to 340B hospitals, including the methodology and timeline for repaying 340B hospitals, which does not need to be conditional on a budget neutrality recoupment.

[15] H.R. Rep. No. 102–384, pt. 2 (1992).
[16] *American Hospital Association et al. v. Becerra*, 596 U.S. __, slip op. at 12 (2022).

- Separately resolve other important issues, such as the fact that CMS is not authorized to recoup money from hospitals as part of a retroactive budget neutrality adjustment, requiring CMS to pay hospitals interest on the Part B underpayments, and urging it to consider the effect of its policies on Medicare Advantage payments to hospitals.

By following these recommendations for a remedy and for future payment rates, CMS would adequately compensate 340B hospitals and support, rather than undermine, our shared priorities of mitigating health inequities and promoting the health of the nation's marginalized communities.

c. CMS should discontinue the use of claims-based modifiers to identify 340B drugs.

To identify which Part B drugs are subject to the reimbursement cuts, CMS has required since January 1, 2018, the use of claims modifiers JG and TB on OPPS claims with 340B-acquired drugs. CMS used the JG modifier to reduce reimbursement for 340B drugs and the TB modifier as an informational modifier on claims for 340B drugs not subject to the payment reduction (e.g., pass-through drugs and drugs administered at exempt hospitals, such as rural sole community hospitals). Because CMS plans to revert to its pre-2018 policy, it no longer needs to distinguish between 340B and non-340B drugs.

The use of these modifiers burdens hospitals, requiring them to distinguish between their 340B discounted drugs and non-340B drugs, as well as between 340B drugs subject to the payment reduction and 340B drugs not subject to the payment reduction. The difficulty is further compounded in cases when 340B hospitals purchase drugs at list price, or wholesale acquisition cost, because they are unable to purchase drugs through a group purchasing organization. CMS states that it will continue using these modifiers in 2024 and in 2025 will require all hospitals to report their 340B drugs using solely the TB modifier. CMS says the modifier will be used to exclude 340B drugs from Part B inflation rebates under the Inflation Reduction Act (IRA). **Because the use of these modifiers no longer will be relevant when CMS reverts to paying at ASP plus 6 percent, we urge CMS to discontinue their burdensome use. CMS can use other methods to exclude 340B drugs for the purposes of the IRA, such as excluding from inflationary rebates all units of separately payable drugs on Part B claims submitted by 340B hospitals.**

4. 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 certain site-neutral payment policies to PBDs, which disproportionately affect essential hospitals and the patients they serve. **CMS should use its authority to protect essential hospitals, as defined in section 1, from payment cuts to their PBDs. Specifically, CMS can exempt essential hospitals' excepted, off-campus PBDs from the clinic visit policy and pay non-excepted, off-campus PBDs of essential hospitals subject to Section 603 of the Bipartisan Budget Act of 2015 (BBA) at a rate no lower than 75 percent of the OPPS rate.**

To align with the administration's policy goals, the agency must revise its site-neutral policies to the fullest extent permitted by statute to protect essential hospitals and their patients, rather

than causing further harm. Essential hospital PBDs are disproportionately affected 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 24 percent Medicare outpatient margin—13 percentage points lower than OPPS hospitals nationally.[17] Continuing these cuts without revision would reduce essential hospitals' outpatient margins even further.

Shielding essential hospital PBDs from the detrimental effect of these cuts would ensure essential hospital PBDs can continue to cover the costs associated with providing comprehensive, coordinated care to complex patient populations in underserved areas and advance the administration's health equity goals.

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 beneficiaries dually eligible for Medicare and Medicaid. 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. Inadequate payment rates affect patient access by limiting the ability of essential hospitals to bring health care into these communities of need. CMS' implementation of Section 603—especially the inadequate payment rate—already has caused essential hospitals to reevaluate plans to expand their provider networks into underserved areas.

CMS' site-neutral payment policies have played an undeniable role in limiting health care access for the country's most disadvantaged patients and will only further exacerbate health disparities. Essential hospitals are committed to advancing the Biden administration's goal of advancing racial equity throughout the federal government, including by eliminating health disparities.[18] The patients treated at essential hospitals' off-campus PBDs typically are low-income people and people of color. 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 poorer in health, more likely to be disabled, and costlier to treat compared with other Medicare beneficiaries.[19] 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 restrictive policies on essential hospitals' PBDs undoubtedly 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 emergency department (ED) visits, manage patients with chronic conditions, provide follow-up care to patients to avoid readmissions, and,

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[17] External analysis of CY 2022 OPPS Proposed Rule conducted for America's Essential Hospitals. 2021.
[18] Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, E.O. 13985. (2021).
[19] Medicare Payment Advisory Commission. *Data Book: Health Care Spending and The Medicare Program*. July 2022. https://www.medpac.gov/wp-content/uploads/2022/07/July2022_MedPAC_DataBook_SEC_v2.pdf. Accessed August 22, 2023.

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.

It also is worth noting there are key differences between PBDs and freestanding physician offices that warrant a higher payment rate for PBDs, generally. PBDs incur additional compliance costs freestanding physician offices do not bear. As integral parts of hospitals, PBDs must comply with provider-based regulations, which include requirements pertaining to billing, medical records, and staffing. For example, an outpatient department must be clinically and financially integrated with the main provider and offer full access to services at the main hospital to qualify as a provider-based facility and receive Medicare reimbursement. The department also must integrate its medical records into the main provider's system. Further, PBDs must maintain standby capacity to provide emergency services stemming from their obligations under the Emergency Medical Treatment and Active Labor Act of 1986. They also undergo rigorous licensing and accreditation requirements, in addition to compliance with the Medicare conditions of participation, by which freestanding physician offices are not bound.

CMS has acknowledged it cannot directly compare payment to hospital PBDs and freestanding clinics because payment under the OPPS accounts for the cost of packaging ancillary services to a greater extent than payment under the Physician Fee Schedule (PFS). For many services paid under the OPPS, including comprehensive ambulatory payment classifications, CMS makes a single payment for the main service and related packaged services. Comparing payment under the OPPS and PFS without accounting for the higher level of packaging that occurs under the OPPS understates the costs of services in hospital PBDs.

The Medicare Payment Advisory Commission (MedPAC) in a June 2022 report discussed equalizing payment across ambulatory settings. MedPAC noted that adjustment in payment rates to hospital PBDs should account for the higher level of packaging in the hospital setting by paying the hospital department at a higher rate than the physician freestanding office. The report also acknowledged that low-income beneficiaries rely on PBDs as their primary source of care, and that site-neutral payment policies targeting these PBDs could adversely affect access for low-income beneficiaries, necessitating policy adjustments to protect such PBDs.[20]

a. CMS can use its authority under Section 603 of the BBA to set an appropriate payment rate for non-excepted PBDs of essential hospitals.

As mandated by Section 603 of the BBA, CMS on January 1, 2017, discontinued paying certain off-campus PBDs under the OPPS. The BBA instructed CMS to pay these non-excepted PBDs under a Part B "applicable payment system" other than the OPPS but not did prescribe a specific payment system or amount. CMS designated the PFS as that system and has the authority to determine the payment rates within that payment system. **America's Essential Hospitals urges CMS to reimburse non-excepted PBDs of essential hospitals at no lower than 75 percent of the equivalent OPPS payment rate.** This would lessen the effect of the cuts so essential hospital PBDs can continue to cover the costs associated with providing comprehensive, coordinated care to complex patient populations in underserved areas and advance the administration's health equity goals.

[20] Medicare Payment Advisory Commission. Report to the Congress: Medicare and the Health Care Delivery System. June 15, 2022. https://www.medpac.gov/wp-content/uploads/2022/06/Jun22_MedPAC_Report_to_Congress_v4_SEC.pdf. Accessed August 22, 2023.

Since 2018, CMS has established an interim payment rate under the PFS for non-excepted items and services provided at non-excepted, off-campus PBDs that is equivalent to 40 percent of the OPPS payment rate. To public knowledge, CMS has not analyzed how reduced reimbursement would affect patient access to care in PBDs or the differences between the patients treated at PBDs and physician-owned offices. Reduced payments to off-campus PBDs have impeded essential hospitals' ability to care for under-resourced patients in these facilities.

By paying non-excepted PBDs at 40 percent of the OPPS rate, CMS grossly undercompensates essential hospitals for services they provide to complex patients. **We urge CMS to increase the payment rate for non-excepted PBDs of essential hospitals (as defined in section 1 of this letter) to adequately account for the higher acuity of patients they treat compared with physician offices and promote access to care in the nation's most marginalized communities.** Payment rates also should reflect the requisite resources, staff, and capabilities necessary for PBDs both to comply with other CMS regulations and provide high-quality care to all patients. Essential hospital PBDs offer culturally and linguistically competent care tailored to the disadvantaged patients in their communities. Whether due to the clinical complexity of their patients or the additional resources needed to provide translators and wraparound services, essential hospitals incur higher costs than other facilities. By considering the recommendations above, CMS can lessen the negative effect of Section 603 on disadvantaged patients' access to care.

b. CMS should finalize its policy to reimburse intensive cardiac rehabilitation services at the full OPPS rate and identify other services that should be paid at the full OPPS rate to preserve beneficiary access.

We urge CMS to preserve beneficiary access to vital services by finalizing its proposal to pay intensive cardiac rehabilitation (ICR) services provided in non-excepted, off-campus PBDs at 100 percent of the OPPS rate. CMS also should conduct a comprehensive review of services provided in the physician office and PBD settings to identify other services that should be paid at the OPPS rate to preserve beneficiary access.

In the rule, CMS proposes to revise the payment rate for certain services furnished at off-campus, non-excepted PBDs. CMS notes that. since implementation of Section 603, it has paid for ICR services (health care common procedure coding system (HCPCS) codes G0422 and G0423) provided in non-excepted PBDs at the lower PFS rate. However, when these services are provided in the physician office setting and paid under the PFS, the Medicare statute requires they be paid at 100 percent of the OPPS rate. Therefore, in applying the PFS relativity adjuster to ICR services since 2017, CMS has inadvertently paid less for these services when provided in a non-excepted PBD (40 percent of the OPPS rate) than when provided in a physician office (100 percent of the OPPS rate). To eliminate this discrepancy and to address potential beneficiary access issues, CMS proposes to pay for ICR services at 100 percent of the OPPS rate and exclude them from application of the PFS relativity adjuster.

We applaud CMS for identifying this discrepancy and for acknowledging the access issues it has created. Similarly, other services provided in both the freestanding office and PBD setting are not appropriate to be paid at the physician office rate. In its recent report, MedPAC acknowledged that many services, such as those provided more frequently in the PBD setting than the physician office, should not be subject to site-neutral payment policies. MedPAC suggested that these services are more safely provided in the PBD setting and that limiting

payment for these services could limit beneficiary access. **CMS should identify these ambulatory payment classifications and exclude them from reduced reimbursement under Section 603. Furthermore, CMS should identify those payment codes for which payment to freestanding physician offices under the PFS is higher than 40 percent of the OPPS rate and not subject these codes to the 40 percent relativity adjuster.**

c. CMS should exempt essential hospitals' excepted PBDs from its clinic visit policy.

Separately, CMS can ensure access for patients that rely on off-campus, excepted PBDs by excluding essential hospital PBDs from its discretionary clinic visit policy. Since 2019, CMS has reduced payment rates for excepted PBDs. The agency has called this practice its method to control unnecessary increases in the volume of clinic visit services furnished at these off-campus, excepted PBDs. CMS states that hospitals' utilization related to the clinic visit service has increased rapidly compared with other services and resulted in shifts in sites of service from other lower-cost settings. Again, PBDs serve a unique role in their communities, incurring costs and providing services freestanding physician offices do not provide. Essential hospitals' diverse patient communities turn to these PBDs as a source of primary and specialty care to which they otherwise would not have access. As described in section 1, essential hospitals are anchor institutions for their marginalized patients, providing a range of services and serving low-income patients. Their payer mix results in narrow financial margins relative to other hospitals. This tenuous financial predicament is only worsening due to the new pressures imposed by COVID-19 and unprecedented workforce and supply challenges.

Once CMS has defined the group of essential hospitals that serve a safety net role, it can use this definition to exempt associated PBDs from the clinic visit policy. Because the clinic visit policy is a discretionary policy CMS has implemented since 2019—not one mandated by statute—CMS can use its regulatory authority to reverse the cuts for essential hospitals' PBDs. In fact, in the CY 2023 OPPS rule, CMS exempted PBDs of rural sole community hospitals (SCHs), highlighting their financial troubles, as well as unique access challenges their patients face, and noting they "are often the only source of care in their communities."[21] These challenges are not unlike the struggles essential hospitals face nationwide; the difference is that SCHs are easily identified through an existing definition. Essential hospitals face equally dire financial challenges and have patients who similarly rely on their PBDs as their usual source of care. **Therefore, CMS should define a group of essential hospitals and exclude those essential hospitals' excepted PBDs from its clinic visit policy to ensure continued access for marginalized communities without other reliable sources of care.**

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

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

[21] 87 Fed. Reg. 71748, 72048 (November 23, 2022).

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

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

There are many external forces that could compel a hospital to relocate a clinic. For example, hospitals needed to relocate PBDs during the COVID-19 pandemic to increase access for patients and to triage care. In recognition of this need, 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 required hospitals to move the PBD back to its original location after the COVID-19 PHE expired. To allow hospitals to meet the needs of their communities and to respond to new outbreaks of COVID-19 or other future public health crises, CMS should allow hospitals to relocate their PBDs permanently if relocation is in the best interest of their patients and communities.

There are other reasons 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 closure of a building 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 an excepted PBD if it continues to meet the provider-based requirements.

b. CMS should permit 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 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 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 vital outpatient services. Because excepted PBDs that change ownership operated before the date of enactment and are not newly created, they should remain excepted.

6. CMS should adopt a flexible stance on data reporting, reconsider publicizing enforcement actions, and implement a safe harbor policy for accuracy in response to its new price transparency proposals.

CMS has incrementally introduced price transparency regulations for hospitals over the past few years, beginning with requirements in 2021 for hospitals to publish standard charge information and shoppable service prices online. To strengthen compliance and enforcement, CMS now proposes additional provisions requiring a standardized template for data reporting, publicizing actions against noncompliant hospitals, and mandating certification of data accuracy. While increased transparency aims to empower consumers and drive competition, essential hospitals remain concerned about the unintended consequences for hospitals striving to comply amid data complexities. Thus, CMS must take a balanced approach that provides flexibility in implementation, focuses on good faith over perfection, and contextualizes disclosed data to avoid misleading comparisons.

a. We urge CMS to allow continued flexibility in what data is reported under price transparency requirements and how it is reported.

In the CY 2024 OPPS rule, CMS proposes requiring hospitals to use a machine-readable file (MRF) template to present standard charge information. While we recognize CMS's intent to establish a uniform approach, we urge the agency to take a flexible approach to hospital charge data reporting that accommodates the diverse contracting methodologies essential hospitals employ. CMS now proposes that hospitals list drug units (e.g., one dose) and measurement types (e.g., tablet) separately. This additional detail aims to improve transparency but may pose implementation challenges for hospitals with less standardized charging practices. CMS also conceded this point in the proposed rule, noting that this alteration "may introduce a burden on some hospitals."[22]

Similarly, the required use of specific data elements, such as payer contracting method and charge display as dollar amounts or algorithms, also aims to add context but may not fit all hospitals' contracting approaches. Allowing some flexibility prevents hospitals from incurring major burdens in reconfiguring systems. **We urge CMS to consider retaining flexibility in the CY 2024 OPPS rule to accommodate diverse hospital contracting methodologies and charging practices to mitigate potential implementation challenges and major burdens while still enhancing transparency and standardization in charge data reporting.**

b. CMS should reconsider its proposal to publicize information about enforcement actions related to price transparency regulations, as it could unfairly stigmatize hospitals that strive to comply but face resource and technical limitations.

CMS proposes to publicize information related to hospital compliance with price transparency requirements on its website. It proposes publishing any compliance actions taken against a

[22] 88 Fed. Reg. 304. 45,147 (July 31, 2023).

hospital, the status of such compliance actions, and the outcomes. **We urge CMS not to publish such information, as it might unfairly stigmatize a hospital that makes a good-faith effort to comply with the requirements but, due to limited resources and information technology capabilities, may require additional time to become fully compliant.**

In the rule, CMS acknowledged that, when deliberating whether to require hospitals to display their standard charge information using only the JavaScript Object Notation (JSON) format, the agency ultimately decided that flexibility was needed due to "variability in hospital sophistication and technical expertise."[23] CMS now proposes that hospitals post this information in either JSON or Comma-Separated Values (CSV) formats. **We urge CMS to take a similar flexible approach to publicizing enforcement actions.**

The task of collecting, maintaining, and regularly updating the data required for posting standardized charges using a MRF will exert a considerable burden on essential hospitals. While we acknowledge CMS' intention to provide technical guidance, we stress that the work needed to align hospitals' data with the new CMS template will be a time-consuming endeavor. Moreover, it may demand skills and resources that hospitals currently lack. Additionally, CMS has not provided clarity regarding the required frequency of template updates and the strategies for managing these updates.

Considering these challenges, **we request that CMS refrain from publishing enforcement actions while essential hospitals diligently work towards complying with the proposed rule. This would greatly assist hospitals in navigating the transition and achieving full compliance.**

c. CMS should implement a safe harbor policy that acknowledges hospitals' good faith efforts to ensure accuracy amid health care billing and contracting data complexities, avoiding undue burdens and penalties for minor inconsistencies.

CMS proposes requiring each hospital to formally affirm that their publicly reported standard charge information is complete and accurate. CMS proposes to include the affirmation statement directly in the MRF file rather than on a hospital's website or in a separate document. CMS notes that the intent of this change is to provide assurance related to the standard charge data in that particular file.

Essential hospitals undoubtedly will strive to ensure the accuracy of their pricing data within the MRF. **However, asserting on record that their data, which is exceedingly intricate and constantly evolving, is completely accurate, precise, and comprehensive might prove operationally unfeasible.** The realm of health care billing and contracting encompasses numerous variables and data elements that can, at times, inadvertently result in discrepancies or unintentional exclusions within the MRF.

CMS has proposed a requirement for hospitals to affirm the completeness and accuracy of their publicly reported standard charge information. The agency suggests including the affirmation statement directly in the MRF file instead of on the hospital's website. While essential hospitals will strive to ensure accuracy, the intricate and evolving nature of pricing data makes it operationally difficult to claim complete precision. This raises concerns about potential legal

[23] 88 Fed. Reg. 306. 45,147 (July 31, 2023).

implications and shifts the focus from acknowledging good faith compliance efforts to mandating perfection.

The proposed MRF format poses challenges for hospitals in indicating instances where standard charges are not established for specific items or services. The rigid structure of the format mandates displaying standard charge information within predetermined fields or columns, making it cumbersome to signify intentional blanks or inapplicability. The lack of a clear designation for nonapplicable fields complicates hospitals' validation efforts, hinders transparency, and adds to the administrative burden of ensuring accurate and comprehensive data representation.

Additionally, the requirement for frequent MRF updates with the latest standard charge data creates a significant administrative burden, particularly for hospitals operating with limited resources and filling a safety net role. Verifying thousands of data points each time an update is required is labor-intensive and repetitive work.

We urge CMS to provide a safe harbor policy for hospitals that make a good faith effort on accuracy while contending with the inherent complexity of billing and contracting data. This balanced approach would still ensure reasonable accuracy without imposing undue burdens on hospitals or penalizing them for unintentional and minor data inconsistencies.

d. We urge CMS to consider a more nuanced approach in presenting negotiated rate data that recognizes the unique factors influencing hospital rates. Rather than solely focusing on disclosing broad contracting methodologies for payer-specific negotiated charges, CMS should consider incorporating the following nuanced approach suggestions.

CMS proposes that hospitals indicate the contracting method they used to establish each payer-specific negotiated charge. This contracting method would describe the general methodology, including the fee schedule, case rate, per diem, and percentage of charges. For rates expressed as algorithms, hospitals would be required to provide the actual algorithm used. CMS said this proposal seeks to provide additional context about how each negotiated rate was developed through high-level methodology identification.

Even with this additional contextual information, true comparisons of negotiated rates between hospitals still may not be accurate or meaningful. This is because each hospital likely negotiates rates uniquely with payers based on individualized factors such as service mix, location, and market leverage. Describing methodologies provides only limited context and not the full parameters of each negotiation.

Essential hospitals negotiate rates uniquely with each payer based on their mission to provide comprehensive services to all patients, regardless of ability to pay. A simple description of general contracting methodologies fails to account for the many factors that drive their costs higher than other hospitals, such as providing trauma care, operating behavioral health services, and caring for patients with social risk factors. Aggregated or comparative rate data as collected by CMS would be misleading and fail to consider these important contextual factors.

Moreover, requiring public disclosure of sensitive rate information could undermine essential hospitals' ability to sustain programs that meet the health-related social needs of their communities. They struggle to cover the high costs of uncompensated care through limited

resources. Publicly divulging aspects of their private contracts could hamper their future negotiations.

We urge CMS to consider a more nuanced approach that recognizes the unique factors influencing hospital rates, such as complex patient populations and contextual differences, rather than solely relying on disclosing broad contracting methodologies for payer-specific negotiated charges. A nuanced approach would anonymize hospital and payer names to prevent discernment of individual contracts from disclosed data. It also would allow hospitals to provide context for their rates without divulging exact price points by mentioning factors affecting costs, such as the proportion of uninsured patients or specialized services. This type of presentation balances transparency with appropriate rate protection.

7. CMS should continue to refine the Outpatient Quality Reporting (OQR) Program to include measures that provide valid, accurate, and meaningful information to consumers about care quality.

The COVID-19 pandemic has highlighted the importance of vaccination for health care professionals. Getting vaccinated protects health care workers and their patients by reducing virus transmission. CMS proposes to modify the COVID-19 Vaccination Coverage Among Healthcare Personnel measure in the OQR program. The proposed changes would update the definition of COVID-19 vaccination status to align with Centers for Disease Control and Prevention (CDC) recommendations on booster doses. While CMS intends to encourage higher vaccination rates, **essential hospitals have concerns about the feasibility of tracking ever-evolving CDC guidelines and the potential unintended consequences for hospitals' performance scores.**

a. CMS should revise its proposed COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) measure by reducing its reporting frequency and not publicly reporting it.

CMS proposes to modify the COVID-19 Vaccination Coverage Among HCP measure to update the definition of being "up to date" with COVID-19 vaccination to align with CDC recommendations for booster doses. Specifically, CMS proposes modifying the measure to use the term "up to date" in the HCP vaccination definition and updating the numerator to specify the timeframes within which an HCP is considered up to date with CDC-recommended COVID-19 vaccines, including booster doses, beginning with CY 2024 reporting period/CY 2026 payment determination for the Hospital OQR Program. We recognize and appreciate the proposed modifications' intent and agree that COVID-19 vaccination is a crucial part of maintaining public health. However, we foresee potential burdens these modifications may unintentionally impose on health care facilities.

Our primary concern is the proposed modification to replace the term “complete vaccination course” with “up to date.” While we understand the need for alignment with the CDC's guidelines, the interpretation of "up to date" may introduce additional challenges. The changing nature of the definition, reflective of evolving CDC guidelines, could lead to significant logistical and administrative difficulties for health care facilities.

Additionally, we are apprehensive about the practicality and feasibility of tracking the timely receipt of primary and booster vaccine doses. The burden of such a task could be considerable,

especially given variations in vaccination schedules, doses, and types across the diverse population of HCP.

America's Essential Hospitals supports revising the current measure, which captures up-to-date vaccination information per CDC recommendations. However, the proposed reporting frequency of one week a month may pose an undue burden on hospitals, as they would have to regularly, on an employee-by-employee basis, access an "up to date" status, and parse out those granted medical and religious exemptions as well as newly hired employees. **We urge CMS to revise the proposed reporting requirements for the COVID-19 Vaccination Coverage Among HCP to a single annual reporting.** Shifting to an annual reporting frequency will alleviate burden, enabling hospitals to track employee vaccination statuses, exemptions, and new hires efficiently and comprehensively.

America's Essential Hospitals firmly believes vaccination is a critical part of the nation's continued strategy to combat COVID-19, and our members continue to promote widespread vaccination within their organizations and communities. However, it is unclear whether CMS plans to address factors contributing to variation among hospitals' reported vaccination rates and the potential for confusion among consumers if publicly reported. For example, some hospitals have implemented a vaccination requirement policy for all employees, while others have limited requiring vaccination to those with specific job functions, and still others require only two of the initial doses recommended under the previous policy. We urge CMS to refrain from publicly reporting this data given potential variation in hospital policies regarding employee vaccination requirements, which might lead to confusion among consumers.

b. CMS should not finalize its proposal to restore the Hospital Outpatient Department Volume Data on Selected Outpatient Surgical Procedures (formerly OP-26) to the OQR program.

CMS proposes to adopt the Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures measure beginning with the voluntary CY 2025 reporting period and mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination.

Essential hospitals continue to see an increase in the volume of outpatient services, partly due to the continued shift of complex surgical procedures from the inpatient to the outpatient setting (e.g., knee replacement). America's Essential Hospitals and its members understand the value of reliable quality measures for patients when deciding where to seek care. However, volume as a proxy for care quality is a poor indicator and should not be substituted for properly risk-adjusted clinical outcomes as a measure of care quality.

In the CY 2018 OPPS final rule, CMS removed OP-26, stating, "there is a lack of evidence to support this measure's link to improved clinical quality." Specifically, the number of surgical procedures does not offer insight into a facility's overall performance or quality improvement. Further, CMS reasoned that the burden of reporting this measure outweighs any potential value.[24] Given the complex relationship between volume and quality and the lack of evidence linking volume to improved clinical outcomes, the public reporting of volume as an indicator of where to seek care is misguided. **We urge CMS to refrain from reimplementing a volume measure in the Hospital OQR program.**

[24] 82 Fed. Reg. 217, 214 (November 13, 2017).

c. CMS should finalize its proposal to limit survey instruments for the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery (OP-31) measure.

The OP-31 measure was originally adopted in the CY 2014 OPPS final rule. The measure evaluates the percentage of patients who had improvement in visual function achieved within 90 days following cataract surgery, based on completing both a pre- and post-operative survey. The measure has been voluntarily reported for several years. In 2022's OPPS proposed rule, CMS stated it would be appropriate to require hospitals to report on OP-31 for the CY 2023 reporting period. However, after receiving comments expressing concern about making this measure mandatory, given the additional burden reporting the measure would create during the COVID-19 pandemic, CMS finalized a two-year delay in implementing this measure, requiring mandatory reporting in CY 2025.

The proposed rule attempts to make it easier for patients and doctors to report on vision quality. CMS proposes to allow only three standard surveys for X: the NEI VFQ-25, VF-14, and VF-8R. The agency believes that survey standardization will make the results more reliable. Patients will also have more options for taking the surveys, like phone, mail, or email. This is meant to be more convenient for both patients and doctors. The changes are set to start January 1, 2024.

While limiting the survey instruments and allowing flexible administration might simplify data collection, measures that require cross-setting coordination among clinicians of different specialties (i.e., surgeons and ophthalmologists), such as OP-31, add complexity and burden to essential hospitals already under tremendous strain. **We support CMS' proposal to limit survey tools and urge the agency to finalize this measure.**

d. We urge CMS to proceed with the proposed elimination of the Left Without Being Seen (LWBS) measure from the Hospital OQR Program.

CMS proposes to remove the LWBS measure from the Hospital Outpatient Quality Reporting Program beginning with the 2024 reporting period/2026 payment determination. The measure assesses the percentage of emergency department (ED) patients who leave without being evaluated by a clinician. CMS believes removal is warranted because the measure provides limited evidence of improved patient outcomes, may reflect issues outside of hospital control like access to care, and does not furnish sufficiently granular data to facilitate quality improvement. A replacement measure, Median Time from ED Arrival to Departure, is considered a better measure of ED performance and throughput by presenting stratified data on length of stay.

America's Essential Hospitals support this change. During the June 2022 National Quality Forum Measure Applications Partnership (MAP) Health Equity Advisory Group, hospitalists pointed out that tracking the percentage of patients who leave without being seen provided limited insight into quality of care and patient outcomes.[25] A major reason patients leave the ED relates to wait times, which can be influenced more by external factors beyond hospital control, such as surges in patient demand that occurred during the COVID-19 PHE.[26]

[25] National Quality Forum. Measure Applications Partnership Health Equity Advisory Group 2022 Measure Set Review Meeting. June 15, 2022. https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=97369. Accessed August 10, 2023.
[26] Ibid.

The median time from ED arrival to ED departure for discharged ED patients measure captures the time in minutes from registration to when the patient physically leaves the ED.[27] The measure provides insight into ED throughput and efficiency by capturing how long it takes on average for nonadmitted patients to be evaluated, treated, and released from the ED.

The measure is stratified into four categories to provide more granular data: all ED patients combined, patients discharged to home, patients discharged to another site of care but not admitted to the hospital, and patients who expire in the ED. This stratification allows facilities to identify specific patient populations or discharge processes that may contribute most to delays.

CMS should remove the LWBS measure from the Hospital OQR Program, as proposed. While tracking patients who leave the ED prematurely initially intended to provide insights into quality of care, it is now clear the LWBS measure has significant limitations. It does not reliably correlate to patient outcomes or facilitate targeted quality improvements. Factors like wait times, which influence LWBS rates, are often beyond hospital control. The replacement Median Time from ED Arrival to Departure measure captures throughput in a more granular, actionable way.

e. We urge CMS to finalize the change to the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients quality metric as it matches national guidelines and is expected to impose a limited new burden on hospitals.

The Normal Colonoscopy in Average Risk Patients measure currently assesses the percentage of patients ages 50 to 75 receiving a colonoscopy who had a follow-up interval of at least 10 years recommended. CMS aims to change the measure's denominator to cover patients ages 45-75 instead. This aligns with the updated guidelines from the U.S. Preventive Services Task Force and other groups that recommend starting colorectal cancer (CRC) screening at age 45 instead of 50 for average-risk adults.[28] The change would apply beginning with the 2024 reporting period. **We urge CMS to finalize this change as it matches national guidelines and is expected to impose a limited new burden on hospitals.**

CMS notes that the data collection and reporting processes and methodologies would remain the same. Hospitals are only required to abstract data on a maximum number of cases between 63 to 96, depending on hospital size. In addition, this change aligns with CMS' health equity goals. Lowering the age of appropriate follow-up interval for normal colonoscopy in average-risk patients from 50 to 45 could be key to mitigating disparities in CRC screening and early detection among different sociodemographic groups. For instance, African Americans have the highest CRC incidence and mortality rates among all racial groups in the United States, with a 20 percent higher likelihood of CRC diagnosis and a 40 percent higher death rate.[29]

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[27] Ibid.
[28] U.S. Preventive Services Task Force. Screening for colorectal cancer: U.S. Preventive Services Task Force recommendation statement. May 18, 2021. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening. Accessed August 11, 2023.
[29] American Cancer Society. Colorectal Cancer Rates Higher in African Americans, Rising in Younger People. September 3, 2020. https://www.cancer.org/cancer/latest-news/colorectal-cancer-rates-higher-in-african-americans-rising-in-younger-people.html. Accessed August 11, 2023.

f. We urge CMS to extend for two years voluntary reporting on Risk-Standardized Patient-Reported Outcomes After Elective Primary Total Hip and Total Knee Arthroplasty measures. This will enable a thorough evaluation of its effect on resource-constrained hospitals with complex patients and help improve risk adjustment and benchmarks.

CMS proposes to adopt both the Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty measure in OQR. It proposes voluntary reporting in FYs 2025 and 2026, followed by mandatory reporting starting in FY 2028. We appreciate the efforts to improve the quality of care and patient outcomes through the implementation of performance measures. However, we believe that further consideration is needed before mandating this measure for all hospitals. Essential hospitals serve a unique and vulnerable patient population, **and we request that the patient-reported outcome performance measures (PRO–PM) remain voluntary for an additional two years until CMS gathers more information on its impact.**

A significant percentage of the patients essential hospitals treat live below the poverty line with socioeconomic challenges that profoundly affect outcomes and chronic conditions complicating recovery. The PRO-PM relies on patient surveys, but factors limiting health literacy and access can impede participation, disadvantaging essential hospitals despite best efforts.

Patients in safety net hospitals may have a higher prevalence of risk factors, such as substance abuse, hepatitis C virus infection, and human immunodeficiency virus infection, which can increase the risk of complications associated with hip and knee surgeries.[30,31,32] While CMS' risk adjustment on this measure may account for some patient population factors, it may not fully capture this increased baseline risk or key social determinants of health influencing outcomes. Prematurely mandating the measure could unfairly penalize hospitals for circumstances outside their control.

Delaying mandatory reporting on the measure an additional two years will allow the agency and hospitals more time to conduct additional testing and analysis around risk adjustment approaches, stratification criteria, statistical modeling, and performance benchmarks.

g. CMS should not finalize its proposal to publicly report data for the Median Time for Discharged ED Patients—Transfer Patients and Median Time for Discharged ED Patients—Overall Rate, as this change could unfairly impact essential hospitals facing unique challenges with ED overcrowding and complex patient populations.

CMS proposes publicly reporting data for the Median Time for Discharged ED Patients—Transfer Patients and Median Time for Discharged ED Patients—Overall Rate measures on the Care Compare website. These measures evaluate the time between arrival to and departure

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[30] Jergesen, HE, Thielen ZP, Roever JA, et al. Primary Hip and Knee Arthroplasty in a Safety Net Hospital: Substance Abuse and Other Factors Affecting Short-term Complications. *The Journal of Arthroplasty*. 2018;33(9):3003–3008. https://doi.org/10.1016/j.arth.2018.05.007. Accessed August 11, 2023.
[31] Ibid.
[32] Cheng T, Yang C, Hao L, et al. Hepatitis C virus infection increases the risk of adverse outcomes following joint arthroplasty: A meta-analysis of observational studies. *Orthopaedics & Traumatology: Surgery & Research*. 2022;108(2):102947. https://doi.org/10.1016/j.otsr.2021.102947. Accessed August 11, 2023.

from the ED, also known as ED throughput time. The Median Time for Discharged ED Patients measure calculates throughput time for different types of patients:

- Median Time for Discharged ED Patients—Reported Measure excludes psychiatric/mental health and transferred patients.
- Median Time for Discharged ED Patients—Psychiatric/Mental Health Patients includes only psychiatric/mental health patients.
- Median Time for Discharged ED Patients—Transfer Patients includes only transferred patients.
- Median Time for Discharged ED Patients—Overall Rate contains data for all patients.

Currently, only the Median Time for Discharged ED Patients—Reported Measure is publicly reported on the Care Compare website. CMS now proposes also to report publicly the Median Time for Discharged ED Patients—Transfer Patients and Median Time for Discharged ED Patients—Overall Rate measures.

CMS believes displaying these additional elements will highlight issues in behavioral health and care coordination. Publicly reporting throughput times for transferred patients and overall rates can reveal gaps in care for patients needing specialized services. CMS proposes to begin publicly reporting data for the Median Time for Discharged ED Patients—Transfer Patients and Median Time for Discharged ED Patients—Overall Rate measures on the Care Compare website and in downloadable files starting with CY 2024 data. This will provide throughput time information on patients transferred from the ED and overall rates for all patients.

CMS should not finalize this proposal to publicly report the additional ED throughput time measures at this time. Essential hospitals have limited resources that serve an under-resourced, uninsured patient population, and our members may lack the reporting infrastructure and staff needed to track and submit these chart-abstracted measures accurately. Essential hospitals need more time to properly develop systems to collect and verify these data points before publicly reporting them on Care Compare. Rushing implementation risks presenting incomplete or inaccurate information that misrepresents ED performance and quality of care.

8. CMS should consider essential hospital operational challenges as it confronts workforce safety under the OQR program.

CMS seeks public feedback on incorporating patient and workforce safety measures into the Hospital OQR Program. Specifically, CMS is interested in understanding safety outcome priorities across various outpatient settings and services, potential harms, and methodological approaches to identify these harms. Furthermore, the agency is looking into the significance of workforce safety in maintaining an effective health care environment and how emerging technologies might affect patient safety, either by presenting new risks or by facilitating improved safety and quality measurement.

While America's Essential Hospitals support the aim of promoting safety and zero preventable harm, measuring and reporting on additional workforce safety metrics could burden an already overstretched staff and scarce resources. Essential hospitals care for vulnerable patient populations that face greater risks of adverse events due to socioeconomic challenges and complex medical and psychosocial needs.

Workforce safety is critically important, but America's Essential Hospitals is concerned about the potential introduction of new measures for violent or traumatic incidents involving human factors beyond a hospital's control. Additional reporting may unintentionally detract from mitigation efforts. **Given these challenges, we request that CMS not introduce new workforce safety measures to the OQR program.**

9. CMS should cover the costs of maintaining a buffer stock of medicines and ensure these policies do not exacerbate drug shortages.

CMS seeks comments on providing separate payment through the IPPS and the OPPS to cover the costs of maintaining a three-month buffer stock of essential medicines so hospitals would have an available supply in the event of drug shortages. CMS could start paying hospitals under the IPPS as soon as cost reporting periods beginning January 1, 2024, for the costs of maintaining a three-month stock of essential medications. These payments would cover the resource costs of establishing and maintaining a buffer supply of essential medicines, including for hospitals contracting with wholesalers or distributors to maintain a buffer stock of medicines. Payment would supplement the reimbursement hospitals receive for the costs of the medicines themselves and could be paid as biweekly interim lump-sum payments that would be reconciled at cost report settlement.

We are pleased that CMS is exploring how to mitigate drug shortages, which affect essential hospitals. Drug shortages impose significant burdens on hospitals serving that safety net role, especially those with a high proportion of Medicaid, dual-eligible, and uninsured patients. These hospitals already confront multiple challenges, including limited resources, complex patient needs, purchasing power constraints, staffing and workload pressures, and health disparities. It is critical that we recognize the role these hospitals play as community anchors and work together to find solutions that mitigate the effect of drug shortages on under-resourced patient populations. By targeting the unique challenges essential hospitals face, we can ensure equitable access to quality care for all individuals, regardless of their socioeconomic status or insurance coverage.

Paying for the costs of establishing and maintaining a buffer stock of essential medicines is an incremental step toward addressing drug shortages. **CMS should finalize such a policy to reimburse hospitals for these costs because it will allow hospitals to readily access lifesaving medicines, provide timely care to patients, and improve health outcomes. CMS should consider covering costs of establishing a buffer stock for a longer period, such as six months.**

However, while CMS presents the idea of covering hospital costs of maintaining and establishing a buffer supply, it would not cover the costs of acquiring these drugs upfront, which is a significant expense for hospitals with limited cash on hand. **CMS should consider covering additional costs, such as upfront drug purchase costs, as well as investments in infrastructure to store drugs onsite.** For essential hospitals with limited resources, providing funds to make these investments will be critical.

Furthermore, we recognize the potential supply shortages that could result from hospitals stockpiling drugs that are already in limited supply or subject to shortages. **As such, CMS should ensure any policies it proposes do not further worsen the drug shortage problem.** For example, CMS could phase in the establishment of buffer stocks of medicines to lessen the potential for a demand surge that would lead to drug shortages as hospitals purchase

bulk quantities of drugs. CMS also should continuously monitor the list of essential medicines to ensure that drugs that are in short supply are excluded to not exacerbate shortages. Finally, we urge CMS to continue to work across the Department of Health and Human Services, with Congress, and with other relevant drug supply chain stakeholders to find lasting, actionable solutions to the drug shortage problem.

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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.

Sincerely,

Bruce Siegel, MD, MPH
President and CEO