AMERICA'S ESSENTIAL HOSPITALS

Sept 15, 2025

Mehmet Oz, MD
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-1834-P: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Overall Hospital Quality Star Ratings; and Hospital Price Transparency

Dear Administrator Oz,

America's Essential Hospitals appreciates and supports the efforts of the Centers for Medicare & Medicaid Services (CMS) to improve health care quality and reduce regulatory burden for hospitals; we appreciate this opportunity to comment on the proposed rule. However, we are concerned that some of the changes included in the Calendar Year 2026 Outpatient Prospective Payment Systems (OPPS) proposed rule would disproportionately harm essential hospitals at the forefront of the administration's efforts to make Americans healthy again. As CMS finalizes this rule, we ask the agency to consider these comments on ways to mitigate the disproportionate impact and more effectively support hospitals facing the greatest financial challenges while serving as a core pillar of health care delivery services in their communities.

America's Essential Hospitals is the leading association and champion for hospitals dedicated to high-quality care for all, including those who face social and financial barriers to care. Since 1981, America's Essential Hospitals has advanced policies and programs that promote health and access to health care. We support our more than 350 members with advocacy, policy development, research, education, and leadership development. Communities depend on essential hospitals for care across the continuum, health care workforce training, research, public health, and other services. Supported by the Essential Hospitals Institute, the association's research and education arm, essential hospitals innovate and adapt to lead all of health care toward better outcomes and value.

The mission of essential hospitals closely aligns with President Trump's vision to make all Americans healthy—while reducing patient costs and national health care expenditures alike. Essential hospitals are committed to serving people in all communities that need access to quality care. Although essential hospitals account for only 5% of acute-care hospitals nationwide, in 2022 they provided 28% of the nation's charity care. About three-quarters of the

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patients our members serve are uninsured or enrolled in Medicaid or Medicare.[1] To meet the needs of all patients, essential hospitals constantly engage in robust quality improvement initiatives and have created programs that improve quality and access, including efforts to combat chronic health conditions, all while lowering health care costs and health care spending.

Unfortunately, **low Medicare and Medicaid payment rates threaten essential hospitals' ability to provide care.** Because these rates are lower than other payers' rates, essential hospitals have lower operating margins than other hospitals. In 2022, members of America's Essential Hospitals had an aggregate operating margin of -9.0%, which was far worse than the aggregate operating margins for all other hospitals (-2.8%). Over time, this underinvestment also has limited the capital available to these hospitals to invest in needed infrastructure for delivery system reform. As the Institute of Medicine (IOM) acknowledged in its landmark report more than two decades ago, America's safety net is "intact but endangered.

We appreciate the steps CMS proposes to take to reduce burdensome regulations and support positive health outcomes. However, we remain concerned CMS' proposed policies do not go far enough to ensure essential hospitals can continue serving their safety net role. To better support essential hospitals' role in making all Americans healthier, this letter highlights the following areas for agency action

- Establishing a federal designation for essential hospitals
- Preventing cuts that disproportionately impact essential hospitals
- Providing adequate funding for essential hospitals
- Ensuring appropriate payment for hospital administered drugs
- Reducing administrative burden on essential hospitals

Establishing a Federal Designation for Essential Hospitals

CMS' annual updates to Medicare hospital outpatient payment policies provide an opportunity for the agency to ensure adequate support for the hospitals that need it the most. **We urge CMS to use their authority to establish a federal designation of an essential hospital system and then use that designation to ensure essential hospitals can continue providing vital services in their communities.**

Recently, the Medicare Payment Advisory Commission (MedPAC) also recommended that CMS create a new metric to identify and invest in safety net providers.[2]Although we disagree with MedPAC's proposed metrics, **we strongly support the concept of establishing a federal designation of safety net providers and using the designation as a tool to target increased funding to providers that need it most**.

A federal definition of essential hospitals would help complement other existing Medicare hospital designations, none of which specifically identify hospitals fulfilling this safety-net role. For example, in 2022, 64% of essential hospitals provided access to care in rural areas but only 23% of essential hospitals qualified for existing Medicare designations based on rurality (i.e.,

[1] Miu R, Kelly K, Nelb R. *Essential Data 2024: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2022 Annual Member Characteristics Survey*. America's Essential Hospitals. December 2024. essentialdata.info. Accessed Aug. 10, 2025

[2] Medicare Payment Advisory Commission. Report to the Congress. Medicare Payment Policy. March 2025. https://www.medpac.gov/wp-content/uploads/2025/03/Mar25_MedPAC_Report_To_Congress_SEC.pdf. Accessed May 20, 2025.

critical access hospital, sole community hospital, or Medicare dependent hospital status).[3] A federal essential hospital definition would help recognize and support all hospitals that are providing access to all patients no matter where they are located. This letter reviews the association's proposed principles for identifying essential hospitals and ways that CMS could use this designation to more effectively target Medicare funding and other CMS policies.

1. CMS should finalize a new overarching designation for essential hospital systems.

Policymakers have developed a range of designations to identify health care providers that serve important roles and depend on federal payers. CMS uses existing designations—like Critical Access Hospital, Rural Emergency Hospital, Medicare Dependent Hospital, Sole Community Hospital, and Children's Hospital—to support key providers of certain health care services or those in certain prescribed locations; however, these existing identifiers already overlap and are an incomplete depiction of the range of safety-net providers. **CMS should establish a new essential hospital designation to identify and support safety-net providers.**

In MedPAC's 2024 Report to Congress, the commission observed that Medicare payments to hospitals with high shares of low-income patients may be insufficient, and went further to recommend the creation of a new metric to identify safety net providers. [4] Essential hospitals are unique in their reliance upon federal payers, including Medicare, to sustain their ability to provide cost-effective and high-quality care to all patients.

An essential hospital system designation would be additive to CMS' stable of hospital identifiers and would provide CMS with a ready and targeted tool to mitigate specific challenges faced by hospitals serving a disproportionate share of uninsured, Medicare, and Medicaid patients. Elsewhere in this comment letter, we provide suggestions for how CMS could use an essential hospital designation to preserve, promote, and improve patient health.

i. No existing mechanism in OPPS supports hospitals the serve a disproportionate share of low-income patients

Policymakers have long recognized the need for increased payments to hospitals that serve a disproportionate share of low-income patients. Shortly after the creation of the Inpatient Prospective Payment System in 1983, Congress created the Medicare disproportionate share hospital (DSH) program to account for the increased care needs of low-income patients and the financial vulnerability of hospitals that care for them. Essential hospitals depend and rely upon Medicare DSH, which allows essential hospitals to provide the immense share of charity care they take on.

Unfortunately, t**here is no similar adjustment for Medicare outpatient payments despite outpatient care accounting for a growing share of hospital volume**. In recent years, patient care trends have changed as a matter of preference and public policy.

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[3] America's Essential Hospitals. Policy Brief: Essential Hospitals Ensure Access to Care in Rural Areas. March 2025. https://essentialhospitals.org/wp-content/uploads/2025/03/2025-Access-to-Care-in-Rural-Areas-Brief.pdf. Accessed Aug. 5, 2025.

[4] Medicare Payment Advisory Commission. *Report to the Congress. Medicare Payment Policy*. March 2024. https://www.medpac.gov/wp-content/uploads/2024/03/Mar24_MedPAC_Report_To_Congress_SEC-2.pdf. Accessed Aug. 6, 2025

Inpatient care has declined in both relative and absolute terms nationwide, and the trend has benefited patients and taxpayers alike. Treatments that once required inpatient hospitalization can now be delivered in lower-acuity and lower-cost outpatient settings. However, due to essential hospitals' unique roles in their communities, these trends have impacted hospitals differently.

According to our analysis of the American Hospital Association's annual survey data from 2018-2023, all-payer inpatient days have remained relatively level—declining less than .2% since 2018--while outpatient visits have increased by nearly 7% over the same period. Essential hospitals experienced a notably different trend over the same time frame. Due to their patients' more complex care needs and other factors, at essential hospitals the number of inpatient days increased by 5.7% over that same period and outpatient visits increased by 9.6%.

Essential hospitals' safety net roles mean they are disproportionately taking on more complex patients than other acute care hospitals. **Yet as their relative share of outpatient visits increases, Medicare DSH payments are leaving essential hospitals with greater levels of under-reimbursed care for Medicare beneficiaries**. The lack of a DSH-like adjustment under OPPS and the increasing rates of outpatient care relative to inpatient care means Medicare payments have fallen out of step with essential hospitals' role in providing care to all patients—regardless of their ability to pay.

2. CMS should establish an essential hospital designation using practical and evidence-backed measures developed in coordination with safety-net hospitals.

For decades, there has been broad consensus that safety net providers should be identified based on the share of all types of low-income patients they serve. In 2000, the IOM convened a wide variety of stakeholders and experts to develop a consensus definition of safety net providers as those that serve a high share of uninsured, Medicaid, and other disadvantaged patients.[5] In 2022, when MedPAC initially developed its framework for identifying safety net providers, it also acknowledged that Medicaid and uninsured patients should be considered when assessing whether a provider serves a safety net role.[6]

To further inform development of measures to identify essential hospitals, America's Essential Hospitals convened hospital leaders in 2022 to discuss practical considerations for the implementation of a new federal designation. In addition to reaffirming the importance of considering payer mix, these leaders also identified the importance of using available metrics, focusing on mission-driven institutions, and considering state variation.[7]

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[5] 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. https://nap.nationalacademies.org/catalog/9612/americas-health-care-safety-net-intact-but-endangered. Accessed August 5, 2025.

[6] Medicare Payment Advisory Commission. *Report to the Congress: Medicare and the Health Care Delivery System, Chapter 3*. June 2022. https://www.medpac.gov/wp-content/uploads/2022/06/Jun22_Ch3_MedPAC_Report_to_Congress_SEC.pdf. Accessed August 5, 2024.

[7] Dickson E, Purves S, Shields C. To Protect America's Safety-Net Hospitals, Establish A New Federal Designation. Health Affairs Forefront. Oct. 3, 2022. https://www.healthaffairs.org/content/forefront/protect-america-s-safety-net-hospitals-establish-new-federal-designation. Accessed Aug. 5, 2025

As CMS considers establishing an essential hospital designation, it should use metrics that reflect the full scope of the safety-net—inclusive of Medicare beneficiaries, Medicaid patients, the uninsured, and dual-eligible enrollees. This designation should parallel longstanding metrics used in Medicare and Medicaid DSH programs. Through it, CMS would gain a more accurate picture of the financial risk and the role essential hospitals play in their communities.

3. CMS should meaningfully engage with essential hospital leaders to develop an essential hospital designation.

CMS has signaled its interest in strengthening the safety net. However, in previous rulemaking cycles, the agency dismissed proposals for a federal designation of essential hospitals as beyond the scope of payment policy. Given the impact of the proposed OPPS rule on essential hospitals, **CMS should use it's authority to ensure hospitals that shoulder the greatest burden of uncompensated and undercompensated care can continue providing care to those that need it.**

In the 119th Congress, a bipartisan group of lawmakers introduced the Reinforcing Essential Health Systems for Communities Act (H.R. 7397), which would create a comprehensive definition of essential health systems that is consistent with the principles outlined by essential hospital leaders and the IOM. The Reinforcing Essential Health Systems for Communities Act used these three tested measures to identify and qualify essential hospitals:

- **Disproportionate patient percentage (DPP),** which captures a hospital's proportion of Medicaid and low-income Medicare patients. This measure has long been used in the Medicare DSH program.

- **Medicare uncompensated care payment factor (UCPF),** which is a measure of a hospital's share of UC costs relative to all hospitals' UC costs and can help identify the costs of care delivered to uninsured individuals. This measure also is currently used to distribute UC-based Medicare DSH payments.

- **Deemed DSH hospital status**, which reflects a commitment to serving a high percentage of Medicaid and low-income patients and accounts for differences in Medicaid programs among states. Defined in the Medicaid statute, the deemed DSH designation has long been used to identify hospitals that are statutorily required to receive Medicaid DSH payments, because they serve a high share of Medicaid and low-income patients.[8]

Medicaid deemed DSH status is based on one of two measures CMS could calculate through Medicare cost reports or require states to report as part of their implementation of the statutory Medicaid DSH requirements:

- A **low-income utilization rate (LIUR)** of at least 25%, which is measured based on charity care and Medicaid revenue for services provided in the inpatient or outpatient setting

[8] Medicaid and CHIP Payment and Access Commission. *Annual Analysis of Medicaid Disproportionate Share Hospital Allotments to States*. https://www.macpac.gov/publication/annual-analysis-of-medicaid-disproportionate-share-hospital-allotments-to-states-3/. Accessed Sept. 3, 2025.

- A **Medicaid inpatient utilization rate (MIUR)** of at least one standard deviation above the mean for all hospitals in the state (a measure that accounts for state variation in decisions about whether to expand Medicaid)

These measures are already available to CMS and have long been used in Medicare and Medicaid payment programs. In addition, our proposed use of multiple metrics helps to account for state variation, focuses on mission-driven institutions, and balances the needs of small and large hospitals in urban and rural areas.

Overall, these measures help identify hospitals that serve a high share of low-income and uninsured patients. These measures also help identify hospitals that face increased financial challenges because of their payer mix, which makes it difficult for these hospitals to participate in delivery system reform initiatives and maintain access to essential services. For example, according to the Medicaid and CHIP Payment and Access Commission (MACPAC), deemed DSH hospitals provide more uncompensated care and access to essential services than other hospitals, but they had much lower operating margins of –4.6% in fiscal year (FY) 2021.[9]

We urge CMS to commit to implementing a federal designation for essential hospitals using these described metrics. While implementing that process, CMS should provide a clear articulation of how such a designation will be used to adjust outpatient payments. CMS should also explore ways to integrate essential hospital status into other Medicare programs, including value-based purchasing, quality reporting, and alternative payment models. Doing so will help ensure that safety net providers are not disadvantaged in systems designed for providers with more favorable payer mixes.

America's Essential Hospitals remains ready to collaborate with CMS on defining and implementing an essential hospital designation. We believe this proposal is consistent with CMS' legal authority and past precedent and represents an important opportunity to improve access to cost effective, high quality care for all Americans. A federal designation would be a critical step toward aligning OPPS policy with the reality of the modern health care landscape—and ensuring that essential hospitals remain able to serve those who need them most.

Preventing Cuts that Disproportionately Impact Essential Hospitals

We appreciate CMS' concern with patients' health care costs. As CMS looks to reduce beneficiary cost-sharing and overall expenditures under OPPS, **we urge the agency to avoid cuts that would disproportionately harm essential hospitals that serve this necessary role in their communities.**

4. CMS should withdraw its proposal to cut payments for drug administration services provided in Provider Based Departments (PBDs)

CMS proposes a significant cut to outpatient drug administration services administered in Provider Based Departments (PBDs) citing its volume control authority under Social Security Act Sec. 1833(t)(2)(f). This section requires that the secretary develop mechanisms *under the*

[9] Ibid.

OPPS payment system to control unnecessary increases in the volume of covered OPD services. We are deeply concerned that CMS' proposal to align payments across settings for health care services does not account for the higher costs associated with maintaining a PBD, contravenes both congressional intent and the plain letter of the statute, and will threaten beneficiaries' access to services in their communities.

a. Extending additional cuts to excepted off-campus PBDs exceeds CMS' statutory authority under Sec. 603 of the Bipartisan Budget Act of 2015.

Congress created OPPS as a distinct payment methodology from the Medicare Physician Fee Schedule (PFS). This separation reflects the higher regulatory standards, broader service capacity, and unique public safety obligations borne by hospital-affiliated departments. PBDs, like other hospital outpatient departments, must comply with the Emergency Medical Treatment and Labor Act (EMTALA), hospital licensure and accreditation requirements, quality reporting standards, and hospital-level infection control protocols. These obligations are embedded in OPPS rates but are absent from PFS cost calculations.

Congress has also explicitly addressed site-neutral payment reforms. Section 603 of the Bipartisan Budget Act of 2015 (BBA 2015) drew a clear statutory distinction between "excepted" and "non-excepted" off-campus PBDs. Non-excepted PBDs are paid under the PFS (or another applicable system), while excepted PBDs—both on-campus and certain grandfathered off-campus locations—remain within OPPS. Congress deliberately protected excepted PBDs from PFS-level payments and has not amended §1833(t) to authorize CMS to apply PFS-equivalent rates to these services. The current proposal would override that protection by regulation, contrary to the statute's plain language and intent. **We urge CMS to withdraw this policy to comply with federal law and protect Medicare beneficiaries' access to services.**

b. The proposal fails to recognize fundamental differences between care settings

The proposed cut to PBD drug administration services relies on a flawed premise that services administered in hospital PBDs are equivalent to services administered in independent physician offices. This policy ignores the realities of hospital-supported care: the higher regulatory and operational costs associated with PBDs, the unique patient populations served by essential hospitals, and how PBDs maintain a higher standby capacity for unexpected patient events.

i. Unique Patient Populations with higher acuity

PBDs in essential hospitals treat disproportionately high shares of patients with complex medical needs, multiple comorbidities, and limited access to alternative sites of care. As previously noted, despite a nationwide decline in inpatient days between 2018 and 2023, essential hospitals saw a 5.7% increase in inpatient days. Correspondingly, patients of essential hospitals require closer monitoring, the availability of more intensive services, and other care that necessitate more staff time. Many patients of essential hospitals rely on hospital-based care, and our members are committed to providing it—regardless of their patients' ability to pay. OPPS payment rates reflect the resource intensity of these populations and applying PFS-level payments ignores these differences.

ii. Additional Costs are associated with operating a PBD compared to a PFS-aligned setting

Furnishing and operating an outpatient PBD comes at substantially higher fixed and variable costs than when those same services are furnished in a freestanding physician's office. PBDs are obligated to comply with a full-range of hospital-level licensure, accreditation, and quality reporting requirements, must meet EMTALA obligations, and must uphold hospital-level infection control and safety standards. These obligations are embedded in OPPS payment rates but are excluded from the cost basis used to establish PFS rates. Simply put, a hospital PBD and a freestanding physician's office do not provide the same service due to these underlying costs. PFS payment rates cannot sustain a hospital PBD; that fact is why PFS payment rates are lower and Congress created separate payment schedules.

iii. OPPS Payment Rates Support Standby capacity

Hospital-based PBDs maintain standby capacity to respond to acute events like emergent patient needs that arise during outpatient encounters such as infusion and chemotherapy. In these circumstances, adverse reactions may require immediate intervention. Maintaining this level of readiness is a core safety obligation and a characteristic unique to PBDs over physician offices. OPPS cost calculations recognize this capacity, while PFS does not. Essential hospital PBDs provide critical capacity for large scale emergency situations—including both manmade and natural emergencies. Sustaining this capacity, with OPPS payment rates and facility fees, is the intent of the OPPS fee schedule outlined by Congress; cuts to PBD payment will reduce that capacity.

c. The policy would hit the most vulnerable patients hardest

CMS estimates the proposed reductions to PBD drug administration will slash Medicare payments to hospitals by $210 million. According to CMS' own estimates of how these cuts will be distributed, the 870 hospitals CMS identifies as having the highest DSH patient percent would see a -.4% adjustment to payments. Essential hospitals, which serve a high share of Medicare, Medicaid, and low-income patients—as already stated—have razor thin operating margins. These cuts would directly harm essential hospitals' ability to invest in and maintain outpatient services.

CMS' proposed exemption for rural Sole Community Hospitals is insufficient. There are many safety-net hospitals that serve similarly vulnerable communities, which would be severely harmed by this policy. According to our analysis, essential hospitals made up less than 5% of OPPS hospitals in the country in 2022, yet would make up 14.8% of the cuts using CMS' proposed methodology and 2022 Medicare claims data..

CMS has clearly not considered how cuts to PBD drug administration will impact care delivery at essential hospitals and other providers of safety net care. Our analysis also shows that in 2022 more that 43,000 Medicare claims were submitted using the PO modifier for services provided in emergency department settings. Cuts to emergency departments, which according to Centers for Disease Control admissions data are disproportionately likely to be used by patients over the age of 65, will impact vulnerable Medicare beneficiaries the most.[10]

[10] National Center for Health Statistics. National Hospital Ambulatory Medical Care Survey: 2022 Emergency Department Summary Tables. Centers for Disease Control and Prevention. 2024. https://www.cdc.gov/nchs/data/nhamcs/web_tables/2022-nhamcs-ed-web-tables.pdf. Accessed Sept. 3, 2025.

d. CMS could use an essential hospital designation to protect providers of safety-net services

CMS acknowledges that its payment cuts to drug administration services will have negative impacts on hospitals, and it proposes to insulate rural sole community hospitals from these cuts. However, essential hospitals provide similar access to services in their communities and **CMS should use the aforementioned essential hospital designation to protect essential hospitals from these deleterious impacts.** Essential hospitals' PBDs are creating access that otherwise would not exist, and CMS should use an essential hospital designation to insulate them from this harm.

Protecting care delivery in all outpatient settings

Essential hospitals provide outpatient care in many outpatient settings. They triage emergency patients, support on-and off- campus physician offices, and operate remote off-campus locations. Using innovative care delivery, like the Acute Hospital Care at Home program, mobile clinics, and telehealth, essential hospitals are meeting patients where they are. Essential hospitals open and operate outpatient locations to expand access into medical care deserts. Cuts to Medicare outpatient reimbursement would directly impact access to care in places that already have limited access.

Medicare pays, on average, 84 cents on the dollar for care delivered to Medicare beneficiaries.[11] At essential hospitals—for whom 24% of services were delivered to Medicare beneficiaries and have an average operating margin of -9%—further cuts to Medicare reimbursement would be devastating.

5. CMS should not cut payments for common procedures administered in on-campus settings

We appreciate the opportunity to provide feedback on CMS' Request for Information on the potential expansion of its aforementioned volume control methodology to on-campus hospital outpatient departments, starting with clinic visits. **We are deeply concerned by CMS' consideration of extending any cuts to outpatient services for on-campus locations and urge CMS to abandon any attempts to alter reimbursement in on-campus settings**. There are vast differences in the care provided and the regulatory obligations of hospital outpatient departments and independent physician offices; those distinctions—and alternative payment policies that account for those differences—have been a cornerstone of Medicare payment policy for decades. Cutting payments for clinic (or other) services in on-campus PBDs to align with independent physician offices disregards decades of precedent and the Medicare statute.

a. There is no statutory basis for on-campus "site-neutrality"

Congress has declined to allow CMS to reduce reimbursement for care delivered in on-campus settings, when it has considered this issue in recent years. Section 1883(t) of the Social Security

[11] American Hospital Association. Fact Sheet: Underpayment by Medicare and Medicaid. American Hospital Association. 2020. https://www.aha.org/fact-sheets/2020-01-07-fact-sheet-underpayment-medicare-and-medicaid. Accessed Sept. 3, 2025.

Act establishes a specific, detailed, mandatory payment framework for "covered OPD services" under the OPPS. In Sec. 603 of the BBA, Congress redefined "covered OPD services" to exclude certain "applicable items and services" furnished in PBDs as further specified in section 1883(t)(21), but only for PBDs "off-campus."[12] Congress did not in any way authorize the exclusion of services furnished in on-campus locations from reimbursement as a "covered OPD service" under the OPPS. No other aspect of 1883(t) provides a broad license to jettison the OPPS formula altogether and replace it with an unrelated methodology from the PFS. If Congress intended to authorize CMS to shift payment in on-campus settings from OPPS to an alternative methodology, it would have done so explicitly, as it did in Sec. 603 of the BBA 2015 for off-campus non-excepted PBDs. **CMS should not move forward with any cuts to on-campus settings.**

b. Courts have rejected similarly broad redistributive policies that contradict clear statutory commands

If CMS were to move forward with cuts for services delivered in on-campus settings, it would run afoul of existing statute in a similar manner to that for which CMS was recently rebuked by the Supreme Court. In *Bridgeport Hospital v. Becerra,* the Supreme Court determined that CMS cannot "jettison" a "highly specific formula" ascribed by Congress.[13] SSA section 1883(t), as amended by Sec. 603 of the BBA, creates clear classes of facilities, each subject to a reimbursement methodology specified by Congress: on-campus departments, which are "covered OPD services" that must be reimbursed pursuant to "a regime of highly specific formulas" under the OPPS; "excepted" off-campus PBDs, which are not subject to payment reductions under BBA Sec. 603 and must be paid under the OPPS; and non-excepted off-campus PBDs, that are subject to Sec. 603 reductions under another "applicable payment system," as determined by CMS. Paying for services delivered in hospital outpatient departments by any fashion other than the methodologies described above would be ignoring the formulas required by Congress and would be against statutory intent.

The D.C. Circuit's decision in *American Hospital Association v. Azar* did not grant CMS blanket authority to replace Congress' generally prescribed OPPS formula for assigning payment to Ambulatory Payment Classifications (APCs). APCs associated with on-campus services are squarely within the complex and "intricate" statutory framework set by Congress.[14] CMS cannot override the required statutory framework for setting APC rates through the broad application of its section 1883(t)(2)(F) authority to adopt volume-control methods.[15] It is clear from the preamble to the RFI that CMS is taking the limited authority sanctioned in *American Hospital Association v. Azar*—cuts to a single Healthcare Common Procedure Coding System (HCPCS) code for clinic visits in off-campus PBDs—and proposing to expand it.[16]

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[12] 42 U.S.C. 1395*l*(t)(1)(B)(v).
[13] Bridgeport Hospital v. Becerra, No. 22-5249, 2024 WL 3504407 (D.C. Cir. July 23, 2024). 22-5249-2065938.pdf. Accessed Aug. 22, 2025 [hereinafter *Bridgeport*].
[14] Am. Hosp. Ass'n v. Azar, 964 F.3d 1230, 1234 (D.C. Cir. 2020).
[15] Bridgeport at 13-14 (prohibiting CMS from "overrid[ing] a statutory command as specific as the congressionally required formula in the [Medicare inpatient] wage-index provision" through an adjustments provision similar in nature to the volume-control authority here).
[16] It is worth noting that *American Hospital Association v. Azar* was decided under the *Chevron* doctrine, which required significant deference to agency decision-making. In a subsequent June 2024 decision, *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024), the Supreme Court overruled *Chevron*, requiring courts to instead "exercise their independent judgment" in reviewing agency statutory authority. Under the less deferential *Loper Bright* standard of review, even CMS' existing clinic visit policy for excepted PBDs might not survive a court's review.

Unlike the more limited policy considered in *American Hospital Association v. Azar*, in this rule, CMS first proposes to use its section 1883(t)(2)(F) to cut payments for multiple APCs for drug administration services in off-campus PBDs. CMS then envisions extending cuts to services furnished on hospital campuses—far beyond the authority granted to CMS by Congress as described above. As in *Bridgeport*, CMS is unlawfully proposing to adjust payments using a "'severe restructuring of the statutory scheme" that is neither "low in cost nor narrow in scope."[17] CMS itself acknowledges that its proposal to extend clinic visit cuts into on-campus settings has the potential to slash payment for "the most utilized service across the OPPS," over 60% of which is furnished on-campus.[18] A proposal to align on-campus APCs with PFS rates would effectively jettison the OPPS mechanism entirely. **CMS has no statutory authority to make wholesale substitutions of OPPS payment rates.**

c. On-campus cuts have the potential to devastate hospital emergency departments

Emergency departments (EDs) at essential hospitals are already struggling across the country. Insufficient Medicare reimbursement already creates challenges for essential hospitals, and reductions in ED reimbursement will only exacerbate these problems. Recent analysis conducted by America's Essential Hospitals has shown that EDs are a frequent point of service for the very APCs MedPAC has previously identified as common and that are more likely to be considered for cuts by CMS.

Cuts to these services would harm not just hospitals broadly, but EDs specifically and the patients who rely on them. Patients frequently arrive in emergency departments with non-emergent care needs—either in addition to their emergent needs, or because they lack access to other points of care. Based on America's Essential Hospitals' analysis of 2022 Medicare claims data, we identified that nearly half(47%), of services that occurred in EDs and were billed to Medicare were associated with the 57 APCs identified in MedPAC's June 2023 report as "common," and that CMS could attempt to cut using its volume-control rationale. Our analysis shows cuts to these APCs would have cut payments to emergency departments by $935 million in 2022 alone. Cuts of this magnitude would be devastating for patient access and care. **CMS should not, under any circumstances, move forward with cuts to payments for on-campus services.**

6. CMS should rescind its attempt to adjust the 340B remedy recoupment methodology

We are deeply concerned by CMS' proposal to abruptly reverse its recently finalized policy to gradually offset repayments to hospitals necessitated by a 2022 Supreme Court decision declaring CMS' OPPS payment policy for 340B covered entities from 2018-2022 to be unlawful. CMS now proposes to cut payments for non-drug items and services by 2% for an estimated six years instead of by 0.5% for an estimated 16 years. This proposed policy represents a significant and unjustified deviation from the prior policy, which was finalized through a lengthy and thoughtful notice and comment process less than two years ago. No changes have occurred since that time that warrant the reversal CMS proposes. **We request that CMS rescind its proposed changes to the already finalized 340B remedy and resume its planned**

[17] Bridgeport at 12-14.
[18] Proposed Rule at 33691.

recoupment that has already undergone extensive stakeholder input with court oversight.

d. CMS does not have the grounds to suddenly reverse its previously finalized 340B Remedy offset

The 0.5% cuts that CMS previously finalized are set to take effect in a mere five months. Hospitals have had several years to prepare for those cuts and adjust their business plans accordingly. CMS' new, proposed timeline for recoupment—3 times faster than previously established, with immediate cuts of 2%—is substantially more harmful to 340B hospitals and will require significant shifts in short- and long-term financial planning without meaningful notice. **The sudden reversal, which has occurred absent any meaningful change in statute, court ruling, or substantive facts, amounts to a bait-and-switch that threatens the solvency of essential hospitals.**

The reversal is all the more troubling given that CMS expressly considered a 5-year recoupment strategy in the course of its 2023 rulemaking and rejected it. While hospitals might have had time to better prepare for a shorter recoupment period with years of advance notice, they certainly do not have a reasonable opportunity to do so in a matter of months. To resurrect a policy flatly rejected by the agency just two years ago threatens hospitals' stability, and undermines the procedural protections afforded regulated entities by the Administrative Procedures Act (APA).

iv. CMS specifically rejected shorter recovery periods when the remedy policy was finalized

More specifically, less than two years ago, after issuing a 19-page proposed rule and a 45-page final rule—with meaningful input from stakeholders and under the watchful eyes of the courts monitoring CMS' implementation of the Supreme Court's decision—CMS concluded that its policy of cutting non-drug payments by 0.5% for an estimated 16 years applied budget neutrality principles in a manner that "restore[d] matters as closely as possible to where they would have been absent the policy the Supreme Court determined to be unlawful."[19] **CMS made this choice after seeking comment on alternative options, including recovery in a single year and recovery over a shorter 5- or 10-year period.** CMS specifically rejected two comments to recover the remedy offset over a 5-year period, concluding that "the proposed 0.5 percent annual reduction (and resulting 16-year implementation timeframe) properly reverses the increased payments for non-drug items and services to comply with statutory budget neutrality requirements while at the same time accounting for any reliance interests and ensuring that the offset is not overly burdensome on impacted entities."[20]

In 2023, CMS properly cited *Shands Jacksonville Md. Ctr.*, 959 F.3d at 1120, for the proposition that the "agency need not 'precisely compensate each hospital for payments that were reduce,' and the agency's task is to "properly appl[y] the budget neutrality principle in a fair, reasonable manner, even if it results in some unavoidable imprecision."[21]

[19] 88 Fed. Reg. 77150, 77154 (Nov. 8, 2023).
[20] *Id.* at 77179.
[21] *Id.*

By contrast, in the proposed OPPS rule, in less than 3 pages, CMS rescinds its finalized policy, purportedly choosing an option that "best achieves the overarching goal of the Final Remedy rule, which is to restore hospitals as close to the financial position they would have been in had the 340B Payment Policy never been implemented." Of course, the policy that best achieves that goal is another rejected policy not acknowledged in the proposed rule—reprocessing of all claims for the period in which the unlawful policy was in effect**. So, CMS' sole rationale for shrinking the recovery period to 5 years is without any rational basis**.

v. CMS provides no factors or circumstances that justify this abrupt change in policy

In the proposed OPPS rule, **CMS also fails to offer any new facts or circumstances that would warrant an abrupt change in policy**. Laughably, CMS explains that 2041 is further from 2018 than 2031, and that a "16-year timeframe is more than three times longer than the 5-year period the 340B Payment Policy was in place." The operation of the passage of time has not changed since 2023; those same facts were true when CMS finalized its policy in 2023 and do not justify a reversal.

At the same time, CMS completely fails to consider other legally relevant factors and past stakeholder concerns, including hospitals' reliance interests on previously finalized policies, especially in light of "extraordinary financial challenges caused by unprecedented workforce shortages, inflation, supply chain disruptions, eroding margins, cost increases due to increases in supplies and staffing costs and the lingering effects of the COVID-19 PHE."[22] While hospitals are two years further removed from COVID, all other reliance interests remain equally urgent – if not more so – than in 2023. And unlike in 2023, hospitals are facing imminent and unprecedented financial hardships associated with the Medicaid policies enacted in the One Big Beautiful Bill Act. CMS cannot ignore these considerations, which informed CMS' choice in 2023 to adopt a lengthy recovery period and to extend the implementation of even a 0.5% reduction from 2025 to 2026, giving hospitals over two years to prepare.

Under the APA, agencies must supply a reasoned basis for their actions and consider all relevant factors, or their policies will be deemed "arbitrary and capricious" by courts.[23] **The bar is even higher when an agency rescinds a previously finalized policy, as CMS is proposing to do here.**[24] In the proposed OPPS rule, CMS has failed to provide <u>any</u> reasoned basis, much less satisfying the higher burden associated with a reversal in policy. The APA also requires agencies to account for and respond to stakeholder concerns expressed through notice and comment rulemaking.[25] Many of those concerns are known here, thanks to CMS' thorough rulemaking process in 2023. Yet CMS is ignoring those concerns completely in its proposal. Moving forward with the proposed cuts of 2% over a 6-year period, on the eve of the effective date of CMS' 2023 final policy after an intentional 2-year delay in implementation to allow for adequate preparation by hospitals, would make a mockery of the APA's required notice and comment procedures.

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[22] *Id.*
[23] 5 U.S.C. § 706(2)(A); Motor Vehicle Mfrs. Assn. of the U.S., Inc. v. State Farm Mutual Automobile Ins. Co., 463 U.S. 29 (1983).
[24] Motor Vehicle Mfrs. Assn. of the U.S., Inc. v. State Farm Mutual Automobile Ins. Co., 463 U.S. 29, 42 (1983) ("an agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not [so] act in the first instance.").
[25] 5 U.S.C. § 706(2)(D) (requiring courts to overturn agency actions "found to be…without observance of procedure required by law").

The proposal to apply a 2% offset over five years will harm essential hospitals and the patients they serve, is legally unsupported, and should be abandoned.

e. The Proposed Remedy Offset Would Outweigh Any Positive Adjustments for Essential hospitals

CMS' own analysis of the cumulative impacts of all the polices included in the proposed rule—including the proposed reduction on providers subject to the 340B remedy offset—is a net 0% adjustment, on average, for all providers.[26] However, different classes of hospitals will see different impacts. CMS' proposed policies will devastate rural hospitals that lack specific designation, the largest urban hospitals, major teaching hospitals, and those with the greatest DSH patient percentage alike. According to CMS' own analysis, each of these categories of hospitals will see a net reduction in payment for CY 2026 compared to CY 2025, mainly due to the proposed 340B remedy offset.

Reports indicate 25 hospitals and emergency departments closed in 2024 and CMS' proposed policies would do nothing to reverse this trends.[27] Essential hospitals, already operating on negative margins that far exceed other acute care hospitals, cannot afford a net payment cut in CY 2026 and continue to meet the needs of their communities. CMS estimates the annual losses associated with the proposed rule would exceed $1 billion in CY 2026, climbing to $1.6 billion in CY 2030. Based on our analysis of Medicare costs reports, we expect our members, representing less than 6% of OPPS hospitals, to face $136 million in cuts, or 12.4% under the proposed policy in 2026. **These cuts would have devastating impacts for essential hospitals and their patients and CMS should rescind this proposed policy.**

f. The 340B Remedy need not be budget neutral

If CMS does in fact reopen its consideration of the 340B Remedy, rather than imposing deeper and more immediate cuts on hospitals that will ultimately harm patients, CMS should instead exercise its authority to provide the remedy without a budget neutrality adjustment. Doing so would be consistent with both CMS and legal precedent. For instance, in *H. Lee Moffitt Cancer Ctr. & Res. Inst. Hosp., Inc. v. Azar, (D.D.C. 2018),* the courts determined HHS may make a retroactive adjustment without applying the budget-neutrality requirement to cancer hospitals that received a statutorily mandated adjustment later than the law required. Similarly, in *Shands Jacksonville Medical Center v. Burwell, (D.D.C. 2015)*, HHS compensated hospitals for three years of across-the-board cuts with a one-time prospective increase of .6%.

CMS is not obligated to apply budget neutrality to the 340B remedy, and if CMS is revisiting the 340B remedy, it should forgo any recoupment whatsoever and hold facilities harmless for CMS' illegal policies.

7. CMS should maintain its historic approach to the IPO list.

CMS has consistently reviewed procedures included on the Inpatient-Only (IPO) list and added or removed services as it deems appropriate. In the CY 2026 proposed rule, CMS proposes the

[26] Table 112. Proposed CY2026 OPPS Rule, 90 FR 33476, 33843 (July 17, 2025). 2025-13360.pdf Accessed Aug. 22, 2025

[27] Ashley, Madeline. 25 hospital closures in 2024. Becker's Hospital Review. 2024. https://www.beckershospitalreview.com/finance/5-hospital-closures-in-2024/. Accessed August 22, 2025.

elimination of the IPO list over three calendar years. For CY 2026, CMS proposes to eliminate 285 services from the list as a first step. America's Essential Hospitals supports the goal of providing more choice for patients and providers regarding care setting; however, as we have commented in previous years, we are concerned that elimination of the IPO list will have unintended ramifications for essential hospitals and patients. **CMS should maintain its historic approach to the IPO list and rescind the IPO list's proposed termination**. If CMS insists on moving forward with removal of the proposed services for 2026, it should study the impacts of removal before removing additional services at scale.

As the landscape of medicine changes, CMS should continue updates as they are appropriate. However, wholesale removal of the IPO list risks patient access—and hospital reimbursement—for services in inpatient settings when needed. Additionally, changes to the IPO list, especially when occurring at the proposed scale, necessitates significant administrative effort from hospitals. Hospitals and providers will need time to adjust to the removal of these 285 procedures, including preparing criteria for site selection, developing criteria for patient selection, and updating billing systems.

We also are concerned that some payers may resist reimbursement for these services if they are provided in inpatient settings. As previously highlighted, despite a national trend towards outpatient care, away from inpatient care, essential hospitals are still seeing increased inpatient care volumes over recent years. As hospitals are more likely to treat more complex patients, it is vital that services are still provided in the most appropriate setting.

Ensuring Sufficient Payments to Essential Hospitals for Outpatient Services

8. CMS should increase its proposed annual hospital payment update to account for historically high–and rising–costs of hospital goods and services.

CMS must ensure payment for services provided to Medicare beneficiaries is sufficient to ensure no "undue limitation of access to needed services." hHowever, years of inadequate adjustment have now compounded such that fee for service (FFS) Medicare margins are near record lows. In its March 2025 report to Congress, MedPAC determined "payments for inpatient and outpatient services continued to be below hospitals' costs in FY 2023," and that hospitals FFS Medicare margin was -13%.[28] These margins represent a dire threat to beneficiaries' access to services—particularly for essential hospitals which care for a disproportionate share of low-income beneficiaries.

CMS proposes a net annual OPPS payment update of 2.4% for CY 2026, stemming from a 3.2 %market basket update offset by a 0.8% productivity adjustment. We urge CMS to revisit this approach and consider alternative data sources to better reflect the true cost pressures facing hospitals, particularly essential hospitals. A more robust update is necessary to ensure that

[28] Medicare Payment Advisory Commission. March 2025 Report to the Congress: Medicare Payment Policy — Section 1. Medicare Payment Advisory Commission. 2025. https://www.medpac.gov/wp-content/uploads/2025/03/Mar25_MedPAC_Report_To_Congress_SEC-1.pdf. Accessed August 22, 2025.

Medicare outpatient payments keep pace with rapidly escalating labor and input costs that threaten the financial stability of safety-net providers. **We urge CMS to adjust its methodology for calculating the annual payment update for FY 2026 to ensure it provides a sufficient payment update to adequately incorporate the effects of inflation and rising workforce costs on hospitals.**

Specifically, we urge CMS to consider the context of historic and ongoing rates of inflation. According to recent industry analysis, total hospital expense per calendar day has increased 15% since 2022, and 6% since 2025..[29] A 2.4% adjustment is woefully inadequate to compensate for the real costs hospitals will bear in CY 2026 and is significantly less than updates in other payment rules. For example, in its recent CY 2026 Rate Announcement for Medicare Advantage and Medicare Part D Prescription Drug Programs, CMS finalized a MA payment rate increase of 5.06%, recognizing increased costs for MA plans, more than double the proposed rate for hospitals.[30] **CMS should, at a minimum, match the 5.06% rate finalized for Medicare Advantage plans for OPPS payments.**

Ensuring Appropriate Payment for Hospital Administered Drugs

Maintaining Congressional Intent within the 340B Program

In the OPPS proposed rule, CMS states its intent to conduct a survey of the acquisition costs for each separately payable drug acquired by all hospitals paid under the OPPS, including Specified Covered Outpatient Drugs (SCODs), and drugs and biologicals CMS historically treats as SCODs. CMS has historically set payment rates for these drugs using an alternative permitted under statute, rather than setting rates based on acquisition costs determined through a statutorily prescribed survey process.

CMS has been charged with developing an acquisition cost survey plan.[31] CMS proposes to field a survey in early calendar year 2026 and to use the survey results to inform policymaking beginning in the CY 2027 OPPS/ASC proposed rule.

Given the Administration's goal of reducing administrative burdens, we urge CMS to reconsider the necessity and timing of the proposed survey. CMS has never conducted a survey meeting the statutory requirements because such a survey would impose significant administrative burdens on CMS, essential hospitals, and other safety net providers. Both CMS and the Government Accountability Office (GAO) have acknowledged that conducting this survey imposes a significant documentation and operational burden, especially for hospitals with limited administrative resources. Furthermore, simultaneous and ongoing policy changes to prescription drug policies, including implementation of negotiated drug prices, 340B drug pricing program rebate policies, and the most-favored nation policy, will

[29] Kaufman, Hall & Associates, LLC. National Hospital Flash Report: May 2025 Metrics. Kaufman Hall. 2025. https://www.kaufmanhall.com/sites/default/files/2025-07/KH-NHFR-Report_May-2025-Metrics.pdf. Accessed Aug. 22, 2025.
[30] 90 Fed. Reg. 25,678 (April 15, 2025)
[31] Executive Order, "Lowering Drug Prices by Once Again Putting Americans First" (April 15, 2025), *at* https://www.whitehouse.gov/presidential-actions/2025/04/lowering-drug-prices-by-once-again-putting-americans-first/. Accessed Aug. 22, 2025

preclude a survey conducted in CY 2026 from serving as an accurate basis for future Medicare reimbursement policies.

CMS should take this time to conduct a test survey, incorporate stakeholder feedback, and learn from GAO's findings of technical challenges while these changes are implemented. CMS acknowledged in the proposed rule that it cannot compel hospitals to complete the survey, nor may CMS fill in proxy cost information for hospitals that do not respond. GAO had significant concerns that prohibited it from evaluating how rebates implicate acquisition costs, among other concerns; we outline these concerns in more detail below.

We further urge CMS to revise the proposed survey design to capture other hospital characteristics that might influence drug acquisition costs, rather than the singular focus on the difference between 340B and non-340B acquired drug costs. When GAO conducted the earlier surveys in 2004 and 2005, it did not consider 340B status as a relevant characteristic and did not ask about drugs' 340B status at all.

Finally, CMS should not use the survey as a basis to reduce future OPPS payments to 340B hospitals. The 340B program enables eligible hospitals to provide critical services to underserved patients. Using acquisition cost surveys to set Medicare payment rates would undermine this goal, and given the budget neutral nature of the OPPS, would simply shift funds to non-drug services by hospitals treating fewer low-income Medicare beneficiaries and other vulnerable patients. CMS should instead continue using average sales price (ASP)-based methodologies to ensure predictable reimbursement and protect program stability for providers that rely on 340B savings to support patient care without adding excessive burden.

9. The proposed survey is unduly burdensome on hospitals and CMS without culminating in accurate results.

As CMS notes in the OPPS proposed rule, the agency has never "conducted a survey of the acquisition costs for each SCOD for all hospitals paid under the OPPS."[32] CMS has historically opted out of conducting this survey for several reasons—including undue burdens and inaccuracy of results—and these realities have not changed.

As required by statute, surveys were first conducted by GAO in 2004 and 2005. After conducting the survey, GAO researchers highlighted the significant burden it had on hospitals, because "to submit the required price data, [the hospitals] had to divert staff from their normal duties, thereby incurring additional costs."[33] The burden was so significant that GAO recommended that the survey be used only to validate "ASP data that manufacturers report to CMS for developing SCOD rates."[34] CMS declined to conduct a survey between 2006 and 2019, influenced by GAO's analysis, and cited the survey's burden on both hospital staff and the agency.[35]

[32] 2026 proposed rule at 33653
[33] GAO-06-372.
[34] GAO 06-372.
[35] When the agency ultimately decided to conduct its first hospital acquisition cost survey in 2020 during the covid-19 pandemic, it (1) only sent it to a subset of hospitals and (2) allowed those hospitals to complete a "quick survey" in lieu of a "detailed survey" and has not proposed to use those results. 85 Fed. Reg. 85866, 86044-86045.

As recently as November 2021, HHS publicly acknowledged the significant burden the survey has on the agency and hospitals. During a Supreme Court oral argument, HHS stated that the surveys are "very burdensome on the study takers," "very burdensome on the hospitals," and "do not produce results that are all that accurate."[36] The hospital acquisition cost survey would divert resources from patient care, contribute to inefficiencies, and create financial strain on hospitals at a time when it is a CMS priority to actively reduce such inefficiencies and burdens.

For 340B covered entities, who stand to be most impacted by the survey results and who depend on drug reimbursement as a core part of their financial sustainability, the burden of survey completion would be greater. Not only do 340B hospitals often have limited administrative resources, but the proposed OPPS rule would require 340B hospitals to report twice the amount of data as other hospitals.

10. If CMS insists on conducting the survey, it should delay the survey to a time when the administration is not making other regulatory changes to drug pricing policy

CMS proposes to open the survey at the end of CY 2025/early CY 2026. However, the administration is actively taking steps and implementing regulatory changes that will not be fully reflected before the targeted survey completion date. For example, uncertainty in the supply chain resulting from proposed pharmacy benefit manager (PBM) reform, Medicare fair price negotiations, a pilot 340B Rebate Model program, and international price matching—to name just a few changes—will have an unknown impact on hospital acquisition costs. Indeed, the Administration is in the process of implementing the first year of price negotiations beginning January 2026.

Conducting the survey at a time when drug reimbursement and pricing is in significant flux will not produce accurate results. Acknowledging the incredible burden found by GAO when the survey was previously conducted, CMS proposes repeating the survey only once every five years, so this initial survey would be used to inform reimbursement policies for years when the Administration's efforts related to prescription drugs will already have resulted in significant change in the drug market.

CMS should instead take this time to conduct a test survey, incorporate stakeholder feedback, and learn from GAO's technical findings. GAO provided extensive technical feedback on their learnings from the experience in conducting the survey, including that accuracy was increased for drugs purchased by larger volumes of hospitals, that rebates or payments from GPOs significantly reduce the accuracy of calculations—to the degree GAO only considered purchase prices and not factors such as rebates, chargebacks, and statutory discounts such as 340B —and notes that these prices are only a snapshot of costs during the time of the survey.[37]

President Trump's executive order instructs CMS to publish a plan to conduct a survey by a certain date but does not instruct the agency to conduct the survey or change OPPS payment rates to reflect acquisition costs by a specified time.[38] **CMS' published plan, in complying**

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[36] *American Hospital Association et al. v. Becerra*, 59 U.S. 724, 729 (2022).
[37] Government Accountability Office. Medicare: Drug Purchase Prices for CMS Consideration in Hospital Outpatient Rate-Settings. June 30, 2005. https://www.gao.gov/assets/gao-06-372.pdf. Accessed Aug. 22, 2025.
[38] Executive Order, *supra fn* 1.

with President Trump's executive order, should provide opportunity to incorporate stakeholder feedback and GAO's recommendations before CMS conducts the survey. Rushing the survey will only produce inaccurate results, to the detriment of patients, hospitals, and taxpayers.

11. CMS should not make responding to the survey a mandatory requirement of all hospitals paid under the OPPS.

In the proposed OPPS rule, CMS seeks feedback on whether it should make responding to the survey a mandatory requirement of all hospitals paid under the OPPS through section 1833(t)(14)(D)(iii).[39] **CMS should not make responding to the survey a mandatory requirement for payment.**

First, when GAO previously conducted the survey, it provided no incentives or penalties to encourage participation. Even without any incentives in place, GAO received usable data from 83% of the hospitals.[40] Thus, there is no need for CMS to make the survey mandatory.

Second, hospitals should not be punished for not responding to the survey. As noted above, responding to the survey is an extremely burdensome process for hospitals. Hospitals' non-response is often due to lack of administrative or operational capacity available to them. Hospitals, especially essential hospitals which operate with limited capacity and on thin margins, should not be punished for the inability to complete the survey. Refusing to provide OPPS payments for such hospitals would significantly harm their bottom line and would specifically harm 340B hospitals already doubly burdened by the survey requirements.

Third, CMS lacks the authority to condition payment on completion of the survey. Section 1833(t)(14)(D)(iii) of the Act merely requires that the surveys "have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug." The statute neither explicitly nor implicitly gives CMS the power to condition OPPS payments on hospitals completing the survey. CMS should not mandate survey participation in regulation as a mandatory condition of participation in OPPS as it would exceed CMS' authority under the statute.

12. CMS should not fill in proxy costs for hospitals that do not respond to the survey.

As an alternative to making the survey mandatory, CMS requests feedback on alternatives to address potential hospital non-response. CMS wrongly suggests it could interpret non-responses to the survey to mean that a hospital has minimal acquisition costs, and reporting proxy data for the hospital would be used in the overall calculation of hospital acquisition costs. This assumption is not valid and substitution of a non-response with a proxy response reflecting minimal acquisition costs would be inaccurate and misleading. Such a methodology would render the survey results unsound and would run afoul of Congress's intent in ensuring a statistically sound survey through explicit survey requirements in the OPPS statute. **The agency should not interpret or factor in non-responses to the survey for any reason.**

[39] OPPS proposed rule at 33654
[40] GAO-06-372

As CMS notes, section 1833(t)(14)(D)(i)(II) requires the Secretary to take into account recommendations from the Comptroller General regarding the methodology of the survey. When GAO conducted the survey, it did not include non-response data in its price calculations. The agency explicitly excluded non-responses from its calculations stating it was "not appropriate for [its] purpose."[41]

The statute also does not contemplate CMS filling in gaps from non-responses. The statute instructs the agency to collect data from "a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered drug."[42] CMS cannot manipulate an otherwise insufficient sample by using other hospitals' proxy data for hospitals that do not respond.

Moreover, the methodology CMS posits to interpret non-responses has no comprehensible reasoning. CMS points to no evidence for the conclusion that groups of hospitals that do not respond to the survey have lower acquisition costs, and certainly no justification for why "us[ing] the lowest acquisition cost reported among otherwise similar responding hospitals as a proxy" would be a remotely accurate methodology.[43] Congress, in 1395l(t)(14)(A)(iii), dictates drug reimbursement be based on either hospital acquisition cost data, or the average price of the drug. Substituting data such as "pricing from the Federal Supply Schedule (FSS); 340B ceiling price; ASP plus 6 percent, 0 percent or another percentage; or other recognized drug pricing for payment of hospitals"[44] would contravene explicit congressional intent.

13. CMS should not penalize hospitals for non-response by eliminating their separate reimbursement for the applicable drugs and instead packaging payment into the payment for the hospital encounter/episode.

As another alternative approach to hospital non-response, CMS requests feedback on an option to use hospitals' non-response to the survey to identify hospitals that should not receive separate payment for these drugs and instead assume the costs are packaged into the payment for the associated hospital outpatient service. Specifically, the proposed rule states that CMS might "conclude that hospitals who do not report their drug acquisition costs lack meaningful additional, marginal costs related to the acquisition of these drugs and, as such, their drug costs should not be paid separately but rather should be packaged into the payment for the associated service."[45]

Once again, CMS does not cite any evidence that non-response means minimal acquisition costs. GAO and CMS acknowledge the burden of this survey, which could clearly be a reason for non-response. This proposal is instead an attempt to make the survey effectively mandatory, even though CMS does not have the authority to do so. CMS is aware that the drugs at issue can be prohibitively expensive, particularly for hospitals serving disproportionate shares of low-income individuals. If CMS does not pay adequately for hospitals' drug costs it will not only undermine the financial stability of hospitals but will impact Medicare patients' access to critical medications. Moreover, the OPPS statute requires CMS to pay for these drugs either based on the survey or based on ASP; **CMS does not have the authority to eliminate payment for these drugs.**

[41] GAO-05-581R at 17
[42] SSA 1833(t)(14)(D)(iii).
[43] Proposed OPPS rule 33654
[44] Proposed OPPS rule 33654
[45] Proposed OPPS rule at 33654

14. CMS should further consider and address the methodology recommendations and challenges identified by the Comptroller General.

CMS claims to have "reviewed and taken into account the Comptroller General's recommendations regarding the frequency and methodology of these surveys in developing [its] proposed survey."[46] Such consideration is not reflected in the proposed OPPS rule.

First, when GAO conducted the survey, it did not require 340B costs to be reported separately despite the program being in existence at the time. GAO identified several relevant characteristics that impact acquisition costs, and 340B status was not included in that list. A large number of factors outside of covered entity status implicate drug acquisition costs; it's unreasonable to base payments on 340B status alone.

Second, CMS does not address a critical flaw in the GAO survey that would undermine the accuracy of results and misleadingly inflate the difference in relative acquisition cost between 340B and non-340B hospitals. CMS proposes that hospitals would be required to report the total acquisition cost of each drug, net of rebates and discounts.[47] In its report, however, GAO stated "we found that we could not obtain data that would permit calculation of hospitals' acquisition costs, because, in general, hospitals were unable to report accurately or comprehensively on rebates."[48] CMS does not acknowledge this issue or address how it proposes to assist hospitals in more accurately reporting on rebates. To the extent non-340B hospitals are more likely to receive discounts through rebates, the survey results will reflect higher than actual acquisition costs for this group as well as an overestimate of the difference from 340B hospital acquisition costs. A survey that does not address this flaw should be questioned by policymakers as a basis for rate setting.

Third, GAO recommended that the survey be conducted only once or twice per decade and be used only to validate "ASP data that manufacturers report to CMS for developing SCOD rates."[49] It appears that CMS' intention is to conduct the survey periodically and use the hospital acquisition cost data on its own to set payment rates rather than use the survey to validate ASP data that is already used for payments.

15. CMS should not use the proposed survey to set OPPS rates.

The proposed rule discusses use of the survey results in future rate-setting in ways that could be inconsistent with the OPPS statute. For example, while CMS acknowledges the statutory requirement to conduct a survey of acquisition costs on a periodic basis, CMS does not clarify how it would adjust payments outside of survey periods. By contrast, current policy updates payments quarterly based on Medicare's average sales price (ASP), ensuring payment rates reflect current market drug costs. The proposed rule includes no such similar adjustment for routine adjustments to costs.

[46] Proposed OPPS rule at 33653
[47] Proposed OPPS rule at 33832
[48] GAO-06-372
[49] GAO 06-372.

Section 1833(t)(14)(A)(iii)(I) requires that the payment for a specified covered outpatient drug should be equal to the average acquisition cost for the drug for that year. Given the significant changes being implemented by and further proposed by this Administration— such as changes resulting from proposed PBM reform, Medicare fair price negotiations, and international price matching, as noted above—a survey fielded at the start of CY2026 is unlikely to reflect the acquisition cost even in CY2027, never mind future years.

16. CMS should not use the survey to reduce OPPS payments for 340B hospitals.

While the OPPS proposed rule does not explicitly state CMS' intent to use the survey to lower payments to 340B-acquired drugs only, the proposed structure of the survey foreshadows CMS' future actions. CMS previously lowered OPPS payments to only 340B-acquired drugs in 2018 and 2019. **We urge CMS not to revive this unwise and illegal policy.**

CMS should not use the survey to lower payments to 340B hospitals. A reduction in Medicare payment rates to 340B hospitals significantly erodes the intent of the 340B program. The 340B program is critical to ensuring that low-income and other disadvantaged people have access to the types of services best provided by essential hospitals. Essential hospitals participating in the 340B program operate on margins significantly narrower than margins of other hospitals, with many operating at a loss. These hospitals, which serve a high number of low-income individuals, are already struggling under insufficient Medicare and Medicaid payments. Given the fragile financial position of essential hospitals, policy changes that jeopardize any piece of the patchwork of support on which they rely, including the 340B program, can threaten their ability to maintain critical services.

Reducing Medicare payments for 340B hospitals would have many negative consequences for patients and providers and would not save the Medicare program any money. Any changes to OPPS must be made in a budget-neutral manner. Thus, a cut in funding for 340B hospitals does not go back to the Medicare program or directly to beneficiaries; instead, the funds would be redistributed to non-340B hospitals at the expense of 340B hospitals and their patients.

Reducing Administrative Burden

Hospital Price Transparency Requirements

17. CMS should not finalize changes to requirements for Hospital Price Transparency

America's Essential Hospitals supports CMS's ongoing efforts to improve price transparency and provide patients with meaningful, actionable information about hospital charges. We recognize the importance of empowering consumers through clearer pricing data, consistent with Executive Order 14221. However, we urge CMS to carefully consider the operational realities and data complexities faced by hospitals, particularly those fulfilling safety-net roles, in implementing these proposed changes.

CMS's proposal to require hospitals, beginning January 1, 2026, to disclose the tenth, median, and ninetieth percentile allowed amounts in machine-readable files (MRFs), including counts of allowed amounts used in these calculations, aims to better reflect the distribution of actual prices hospitals receive. We agree with the agency's goal of increasing transparency, but we caution that this approach also introduces significant technical and administrative challenges. Calculating these percentiles requires hospitals to rely heavily on electronic remittance advice (ERA) data and apply detailed methodologies that may not capture the full complexity of payer contracts, particularly those involving formulas such as percentage-of-charge, case rates, or bundled payments.

Essential hospitals often serve patient populations covered by contracts with varied and dynamic reimbursement structures that do not lend themselves to straightforward dollar amount representations. The requirement to encode allowed amounts using EDI 835 ERA data as proposed will necessitate substantial cross-departmental coordination and ongoing resource investment. For many hospitals operating under constrained financial and IT capacities, these demands are nontrivial and may lead to inconsistencies or delays in reporting despite best efforts.

Moreover, the proposal to require hospital chief executives or senior officials to attest to the inclusion of all applicable payer-specific negotiated charges underscores the need for a reasonable compliance framework. We strongly encourage CMS to continue emphasizing good-faith efforts and to establish safe harbor provisions that recognize the inherent complexities and evolving nature of payer contracts and hospital billing systems. Absolute certification of "accuracy" and "completeness" should be understood as a point-in-time assessment based on available data and reasonable methodologies, rather than an inflexible standard that could expose hospitals to disproportionate penalties.

We support CMS's proposal to encode national provider identifiers (NPIs) within MRFs, as this will improve data interoperability and support efforts to integrate pricing data with broader health care information systems. However, CMS should provide sufficient lead time and technical guidance for hospitals to update internal systems and vendor configurations to accommodate these changes.

Regarding enforcement, we recommend this be paired with expanded technical assistance, enhanced validator tools, and a clear, graduated approach to enforcement that prioritizes education and corrective action over punitive measures. The CMS validator tool should be improved to flag formatting issues, data inconsistencies, and missing elements before data publication, ideally through a sandbox environment enabling hospitals to pre-test MRF submissions. Public enforcement actions should be reserved for cases of egregious noncompliance to avoid unjust reputational harm to hospitals making substantial good-faith efforts.

Finally, we reiterate the importance of CMS pursuing insurer-side reporting of actual payment data as a critical complement to hospital-reported MRFs. Shifting some transparency responsibilities to payers would reduce hospital administrative burden and provide a more comprehensive and accurate picture of negotiated payment rates across markets. Insurer-reported data could help illuminate reimbursement disparities that are often driven by market dynamics rather than hospital performance, an issue of particular significance for safety-net hospitals.

In conclusion, we urge CMS to ensure its hospital price transparency requirements are implemented with flexibility, clear technical guidance, and a supportive compliance framework that acknowledges the complexity of hospital pricing arrangements and the operational challenges faced by essential hospitals. Doing so will enhance the accuracy and usefulness of price transparency data without imposing undue burdens that could detract from hospitals' primary mission of delivering care.

Outpatient Quality Reporting Requirements

18. CMS must incorporate suitable risk adjustment in new quality measures.

We support CMS' efforts to ensure that quality measures remain clinically relevant, reliable, and administratively feasible, and we offer the following comments on the proposed removals, additions, and requests for information.

We support the proposal to remove the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients and the Left Without Being Seen measures beginning with the CY 2028 reporting period/CY 2030 payment determination. These measures, while useful in certain contexts, capture limited dimensions of ED performance and do not fully account for operational realities in high-volume urban emergency departments, where throughput is strongly influenced by inpatient capacity constraints and post-acute care availability.

The proposed adoption of the Emergency Care Access & Timeliness electronic clinical quality measure (eCQM) warrants careful consideration in this context. This measure aggregates multiple access and timeliness indicators into a single score, potentially magnifying the effect of system-level barriers and patient complexity. For safety-net hospitals, which often operate at or near capacity, factors such as inpatient boarding, delays in transferring patients to post-acute facilities, and shortages of behavioral health beds can substantially influence ED timeliness independent of clinical performance. Without appropriate risk adjustment, the measure risks conflating resource limitations with quality of care.

We urge CMS to incorporate robust risk adjustment that accounts for patient case mix, acuity, and the availability of post-acute care services within the hospital's service area. This is particularly important for hospitals serving large numbers of patients who require complex discharge planning—such as those awaiting skilled nursing facility placement, rehabilitation, or long-term care—where community resource constraints can significantly extend ED and inpatient lengths of stay. A fair methodology must distinguish between delays within the hospital's control and those driven by systemic capacity issues.

Regarding the removal of the COVID-19 Vaccination Coverage Among Healthcare Personnel measure from the OQR and Rural Emergency Hospital Quality Reporting programs, we agree that this measure has limited ongoing utility in capturing actionable quality improvement opportunities for outpatient hospital departments. Its removal will reduce reporting burden and allow greater focus on measures with a direct link to clinical processes and outcomes.

We support the proposed update to the Extraordinary Circumstances Exception policy to explicitly include extensions as a type of relief. This clarification will improve administrative

efficiency and provide hospitals with more flexible options during disruptive events that affect data collection and reporting.

Finally, regarding CMS' request for information on potential measures related to well-being and nutrition, we encourage the agency to proceed cautiously. While these concepts are important, their operationalization in hospital outpatient settings is challenging, and reliable, validated tools applicable to diverse patient populations remain limited. If CMS pursues these concepts, the agency should ensure measures are evidence-based, standardized, and impose minimal additional burden on reporting entities.

19. CMS should not finalize changes to the Overall Hospital Quality Star Rating

America's Essential Hospitals appreciates CMS' continued commitment to improving patient safety and transparency in public reporting. We agree that patient safety should be a central component of the Overall Hospital Quality Star Rating and that the current methodology can, in some cases, result in high overall ratings despite low performance in the Safety of Care measure group. However, we have significant concerns about the proposed approach to address this issue—particularly its reliance on blunt quartile-based penalties without sufficient adjustment for hospital case mix, patient acuity, and community resource constraints.

Safety-net hospitals—by virtue of their mission and patient populations—often care for individuals with higher clinical complexity, greater comorbidity burden, and more frequent social and structural barriers to recovery. These factors can directly influence outcomes in the Safety of Care measure group, which includes measures such as health care-associated infection rates, postoperative complications, and serious safety events. For example, patients with chronic illness, malnutrition, or unstable housing may have elevated infection risk or slower recovery trajectories despite adherence to evidence-based safety protocols. Without robust risk adjustment for these clinical and contextual factors, the proposed quartile-based reduction will disproportionately penalize hospitals serving the most medically and socially complex patients.

The proposed Stage 1 four-star cap in CY 2026 and Stage 2 blanket one-star reduction in CY 2027 and beyond also risk amplifying the impact of small measurement differences. Because quartile placement depends on relative ranking, a hospital could move between penalty and no penalty year-to-year based on marginal changes in peer performance, even when its own performance is stable. This volatility may undermine the credibility and interpretability of the Star Ratings for patients and policymakers.

We urge CMS to incorporate measure-specific and group-level risk adjustment for factors such as patient comorbidity, infection risk profile, and case mix, to ensure ratings reflect true safety performance rather than patient population characteristics. We also recommend that CMS evaluate alternative statistical thresholds, such as performance below a fixed benchmark, to reduce volatility and avoid penalizing hospitals that perform well in absolute terms but rank lower relative to a shifting peer set. Finally, CMS should conduct impact analyses stratified by hospital type, including safety-net and rural hospitals, and provide transparent methodological documentation on how quartile cut points are calculated and how changes in the national distribution of Safety of Care scores affect rating assignments.

While we support CMS' goal of elevating the role of patient safety in the Star Rating methodology, the agency must ensure that the approach differentiates between preventable safety lapses and outcome variation driven by patient acuity or system capacity constraints.

Public ratings must remain a fair and reliable signal of performance—not a proxy for the complexity of the population a hospital serves.

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America's Essential Hospitals appreciates the opportunity to submit these comments. If you have questions, please contact Evan Schweikert, at 202-585-0124 or eschweikert@essentialhospitals.org.

Sincerely,

Bruce Siegel, MD, MPH
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