AMERICA'S ESSENTIAL HOSPITALS

Sept. 12, 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-1832-P: Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program

Dear Administrator Oz:

Thank you for the opportunity to comment on the above-captioned proposed rule. 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. However, we are concerned that some changes in the proposed rule would disproportionately harm essential hospitals that at the forefront of the administration's efforts to make Americans healthy again. As CMS finalizes this rule, we ask the agency to consider our recommendations on how to mitigate the disproportionate impact. We also provide ways to more effectively support hospitals that face great financial challenges and serve as pillars 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 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 overall. 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. Additionally, about three-

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quarters of essential hospital patients are uninsured or enrolled in Medicaid or Medicare.[1] To meet the needs of all patients, essential hospitals constantly engage in initiatives to improve quality, increase care access, and combat chronic health conditions, all while lowering health care costs.

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%).[2] 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." [3]

We appreciate CMS' proposed steps to reduce burdensome regulations and support positive health outcomes. However, we remain concerned that CMS' proposed policies do not go far enough to ensure essential hospitals can continue filling their safety net role. To better support essential hospitals and their mission of helping make all Americans healthy, this letter highlights the following areas for agency action:

- Establishing an essential health system designation
- Supporting essential hospital participation in value-based care models
- Ensuring sufficient payment for physician services provided in facility settings
- Expanding access to telehealth services
- Ensuring compliance with 340B Drug Pricing Program requirements and the Inflation Reduction Act (IRA)

Establishing an Essential Health System Designation

Essential hospitals long have led the way in value-based care delivery before financial incentives existed. Because of their commitment to their mission, essential hospitals always seek to use their limited resources to provide timely access to care in the most appropriate settings. For example, many essential hospitals have become vertically integrated systems that provide a full range of primary and specialty care, assistance with whole-person care, and access to essential services that other hospitals are unable or unwilling to provide.

Value-based payment models such as the Medicare Shared Savings Program (MSSP) intend to align financial incentives to support these efforts and provide flexibility for providers to innovate and evolve care delivery to meet patient needs. However, essential hospitals have struggled to take advantage of the MSSP and other Medicare value-based payment models because structural barriers in model design make it more difficult for them to participate.

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[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. 21, 2025

[2] Ibid.

[3] 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 Aug. 8, 2025.

To understand how policymakers can better structure incentives to support essential hospital participation in value-based care models, America's Essential Hospitals convened its policy committee of hospital leaders to update its value-based care policy principles. Overall, the committee urged policymakers to take a more nuanced view of the potential unintended consequences of poorly designed models. The committee noted that, "**without proper attention to the unique needs of essential hospitals and the communities they serve, value-based payment systems could further exacerbate disparities in resources and negatively affect patient outcomes."**[4]

Based on these principles, we offer feedback on CMS' proposals related to MSSP participation, population adjustments, and quality reporting requirements. We continue to raise concerns about CMS' proposed mechanisms to assess challenges for hospitals filling a safety net role. We urge CMS to recommit to its goal of engaging with safety net providers when designing measures to support them.

1. The electronic clinical quality measure (eCQM) Merit-based Incentive Payment System (MIPS) reporting incentive and the Complex Organization Adjustment do not capture the complexities essential hospitals face.

In the calendar year (CY) 2026 Medicare Physician Fee Schedule (PFS) proposed rule, CMS proposes removing the health equity benchmark adjustment from accountable care organization (ACO) quality scores beginning in performance year 2025. Instead, the agency will rely on existing mechanisms, such as the Complex Organization Adjustment and eCQM/MIPS CQM reporting incentives, to account for the challenges safety net providers face. While CMS notes that these mechanisms aim to recognize the complexities essential hospitals face, we believe the mechanisms are not sufficient to ensure meaningful participation in value-based care for these institutions.

While the Complex Organization Adjustment and eCQM/MIPS reporting incentives may target specific aspects of quality reporting and care complexity, they do not account for the broader operational and structural challenges faced by essential hospitals. For instance, the Complex Organization Adjustment is tied to eCQM reporting, but it fails to capture the full spectrum of challenges that essential hospitals encounter. These institutions serve a high proportion of high-risk, low-income, and medically complex patients, often with limited resources and under lower reimbursement structures.

While the adjustment provides upward points for reporting eCQMs, it does not consider the financial, administrative, and operational burdens these hospitals face in managing such complex patient populations. It also does not acknowledge essential hospitals' unique infrastructure needs. These hospitals often struggle with technology investments or face greater administrative costs tied to serving high-need communities. In this context, the Complex Organization Adjustment, while helpful in targeting some reporting complexity, does not adequately adjust for the full range of challenges that impact quality outcomes in these settings.

Similarly, the eCQM/MIPS CQM reporting incentive, while an important tool for encouraging quality measure reporting, inherently favors organizations with more advanced health IT

[4] Value-Based Care Policy Principles. America's Essential Hospitals. https://essentialhospitals.org/wp-content/uploads/2024/08/2024-VBC-Principles.pdf. Accessed Aug. 25, 2025.

systems and infrastructure. Essential hospitals might not have the same level of technological capability or access to health data systems as other organizations, so they have a disadvantage in earning these incentives.

The eCQM incentives are primarily focused on specific clinical measures, which may not fully reflect the complexity of the populations essential hospitals serve. These clinical measures also do not account for the nonclinical factors that influence care delivered to communities with high social and economic needs. Thus, these incentives, while valuable for encouraging certain types of data reporting, do not provide a sufficiently broad or comprehensive support mechanism for essential hospitals to thrive in a value-based care environment.

Given the limitations of these proposed adjustments, **we strongly recommend that CMS consider a more tailored and comprehensive framework that better supports the unique role of essential hospitals in the health care system.** We believe this could be achieved through the creation of an "essential health system" designation.

2. CMS should adopt a formal essential health system designation using proven measures to account for the challenges safety net providers face.

We believe the above-mentioned policy shift underscores the urgent need for CMS to formally designate essential health systems in Medicare programs and to provide targeted support for their participation in the MSSP and other models. Without a clear designation, CMS risks applying one-size-fits-all incentives that do not reflect the financial and operational realities of hospitals serving the nation's most complex patients.

CMS should use Section 1886(d)(5)(I) authority to designate essential health systems to ensure that Medicare payment policy appropriately considers the unique needs of these hospitals and the patients that they serve. More than two decades ago, the IOM reported that America's safety net is "intact but endangered" and recommended the creation of a federal definition of hospitals that serve a safety net role.[5]

More recently, the Medicare Payment Advisory Commission (MedPAC) also recommended that CMS create a new metric to identify and invest in safety net providers.[6] 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 complement other existing Medicare hospital designations. 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., critical access hospital, sole community hospital, or Medicare dependent hospital

[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 Aug. 14, 2025.

[6] 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-1.pdf. Accessed Aug. 14, 2025.

status).[7] A federal essential hospital definition would help recognize and support all hospitals that are providing access to low-income patients no matter where they are located.

The IOM's clarion call in 2000—to ensure safety net providers are "sustained and protected"—is even more relevant today than it was two and a half decades ago.8 Hospital closures, physician shortages, and shuttered services in communities across the country have made the role of essential hospitals more important than ever. CMS must act to ensure essential hospitals are able to provide the care on which their communities depend. By implementing an essential hospital designation, CMS could call upon a tested measure to target resources more efficiently and effectively to hospitals that serve a safety net role.

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. In 2022, when the Medicare Payment Advisory Commission (MedPAC) initially developed its framework for identifying safety net providers, it also acknowledged policymakers should also consider Medicaid and uninsured patients when assessing whether a provider serves a safety net role.[9]

To further inform development of measures to identify essential hospitals, America's Essential Hospitals convened hospital leaders in 2022 to discuss practical considerations for implementing 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.[10]

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

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[7] 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. 14, 2025.

[8] 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 Aug. 14, 2025.

[9] 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 Aug. 14, 2025.

[10] 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. 15, 2025.

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.[11]

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
- A **Medicaid inpatient utilization rate (MIUR)** 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.

We urge CMS to consider the bipartisan approach to designating essential health systems laid out in the Reinforcing Essential Health Systems for Communities Act and implement it using Section 1886(d)(5)(I) authority.

Supporting Essential Hospital Participation in Value-Based Care Models

3. We urge CMS to consider how proposed Medicare Shared Savings Program (MSSP) changes could discourage new participation in the program.

a. CMS should maintain greater flexibility in the progression to two-sided risk in the MSSP.

America's Essential Hospitals appreciates CMS' continued efforts to refine participation requirements in the MSSP to improve accountability and program integrity. However, we are concerned that two proposals—shortening the allowable duration in one-sided risk arrangements for inexperienced ACOs and requiring faster progression to two-sided risk—could unintentionally discourage new program participation.

[11] 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.

We recognize the value of incentivizing greater accountability for cost and quality. However, we believe CMS' current glide path structure, which includes the ability to remain in a one-sided risk arrangement for up to seven years across two agreement periods, appropriately balances program goals with the realities of readiness among new and safety net ACOs. We are concerned that the proposal to shorten the one-sided risk period to five years, limited to a single agreement period, removes a critical entry ramp for safety net providers and may reduce overall MSSP participation. Essential hospitals and their partners need sufficient time to build the infrastructure and experience necessary to succeed in value-based arrangements. By requiring inexperienced ACOs to assume two-sided risk earlier, even with the option of BASIC Level E, CMS risks deterring new entrants from joining the program at all.

We urge CMS to reconsider this proposal and maintain greater flexibility in the progression to two-sided risk. This includes preserving the current policy that permits up to seven performance years in one-sided models. We also urge CMS to enable ACOs to advance at a pace that reflects their operational and financial readiness, not on a fixed timeline. In addition, we request clarification on how CMS intends to apply the definition of "inexperienced with performance-based risk" moving forward. We seek clarification on whether safety net ACOs with minimal prior MSSP involvement would be expected to advance more quickly even absent demonstrated readiness.

While we support the agency's goal of strengthening the MSSP, **any effort to accelerate the risk assumption should include tailored support for lower-resourced providers**, including technical assistance, up-front funding mechanisms, and risk-adjustment policies that accurately reflect patient complexity. Without such support, shortening the glide path likely will disadvantage the very providers CMS seeks to engage.

b. CMS should preserve flexibility for safety net providers related to minimum beneficiary eligibility.

America's Essential Hospitals supports CMS' proposal to revise the MSSP's minimum beneficiary eligibility requirement. The proposal would allow ACOs entering agreement periods beginning on or after Jan. 1, 2027, to meet the 5,000-assigned beneficiary threshold in only the third benchmark year, rather than in all three benchmark years. This proposal provides needed flexibility and reflects a more practical approach to the variation in beneficiary assignment over time, particularly for smaller ACOs and those in regions with fluctuating Medicare populations.

However, we are concerned that the associated policy changes would significantly weaken the value of this flexibility. CMS proposes that ACOs with fewer than 5,000 assigned beneficiaries in any benchmark year would (1) be restricted to participation in the BASIC track, (2) have shared savings and losses capped throughout the agreement period, and (3) be excluded from low-revenue ACO policy flexibility under the BASIC track.

These restrictions may discourage participation from ACOs that would otherwise qualify under the revised threshold. Limiting track options and capping shared savings reduces the potential return on investment, which may lead some providers—particularly those without large beneficiary pools or financial reserves—to forgo participation altogether. This would be counterproductive to the agency's stated goal of broadening MSSP participation.

The proposal to exclude ACOs with fewer than 5,000 beneficiaries in any benchmark year from BASIC track flexibilities for low-revenue ACOs is especially concerning. Many hospital-led ACOs operate with relatively low revenue and face inherent volatility in patient attribution.

Removing access to existing flexibility for this group undermines the value of the proposed eligibility change.

We urge CMS to preserve current BASIC track flexibility for low-revenue ACOs regardless of the benchmark year's beneficiary counts. We also urge CMS to reconsider the across-the-board cap on shared savings and losses. Additionally, we request that CMS publish its actuarial analysis justifying the proposed restrictions, including data on financial variation among ACOs with lower benchmark year attribution. In short, we support the revised eligibility proposal but recommend that CMS avoid layering restrictions that undercut its potential impact.

4. CMS should finalize changes that streamline and reduce burden in the MSSP.

America's Essential Hospitals supports CMS' proposal to revise the definition of a "beneficiary eligible for Medicare CQMs" beginning in performance year 2025. Aligning the definition to require at least one primary care service during the performance year from an ACO professional who is a primary care physician; a designated specialty under § 425.402(c); or a physician assistant, nurse practitioner, or clinical nurse specialist will improve the alignment between CQM-eligible beneficiaries and those assignable to an ACO. This change should streamline patient matching and reduce administrative burden in quality reporting.

We also support the proposed transition to a web-mail-phone protocol for the Consumer Assessment of Healthcare Providers and Systems for MIPS Survey, starting in performance year 2027. This multimodal approach reflects current communication preferences, has the potential to increase response rates, and modernizes the survey process. CMS should monitor whether shifting away from the mail-phone protocol affects response rates for certain populations, particularly older beneficiaries, and adjust outreach strategies accordingly.

America's Essential Hospitals agrees with CMS' proposal to expand extreme and uncontrollable circumstances (EUC) policies to include relief for ACOs affected by cyberattacks, including ransomware or malware incidents. Given the significant operational and data integrity disruptions such events can cause, extending EUC protections in these scenarios is reasonable and consistent with maintaining fair quality and financial performance assessments. **We recommend that CMS provide clear guidance on documentation requirements and timelines for MIPS EUC Exception applications to avoid delays in relief.**

5. CMS should finalize changes to refine the Quality Payment Program.

We appreciate CMS' continued efforts to provide stability for MIPS participants by maintaining the performance threshold at 75 points for the CY 2026 performance period (payment year 2028) through performance year 2028/payment year 2030. A stable threshold gives clinicians and their organizations a predictable benchmark for planning investments in infrastructure, staffing, and reporting processes. Essential hospitals depend on such predictability to sustain participation in the program while continuing to serve patients with complex medical and social needs.

We support CMS' addition of six new MIPS Value Pathways (MVPs): Diagnostic Radiology, Interventional Radiology, Neuropsychology, Pathology, Podiatry, and Vascular Surgery. They provide specialty-specific pathways that can better align measures with clinical practice. Specialty-relevant MVPs have the potential to reduce reporting burden and make performance

data more meaningful. We encourage CMS to provide adequate outreach, education, and technical assistance during the rollout of these new MVPs to promote successful uptake.

We recognize CMS' proposal to retire 10 current MIPS quality measures and replace them with five outcome-based measures, including two eCQMs, with greater emphasis on chronic condition prevention and management. Outcome-based measures, such as Patient-Reported Falls and Plan of Care and Hepatitis C Virus: Sustained Virological Response, can better capture the care outcomes. However, their implementation must account for varying patient populations and care contexts to avoid penalizing providers serving patients with greater clinical complexity. We recommend that CMS continue to assess measure specifications and risk-adjustment methodologies to ensure they reflect differences in patient acuity and resource needs.

We support CMS' decision not to add new cost measures now and agree with its proposed two-year testing period before incorporating new measures into scoring. This approach allows for refinement and validation of measures before they affect payment, reducing the likelihood of unintended consequences for providers.

Ensuring Adequate Reimbursement for Care Costs

In the face of significant financial headwinds, essential hospitals consistently find innovative ways to provide cost-effective and high-quality health care services to all patients. However, by nature of their commitment to supporting all patients, essential hospitals bear a disproportionate burden, because federal payers consistently pay less for health care services than it costs to deliver them—especially in hospital and facility settings.

We appreciate the opportunity to provide feedback on CMS' proposals related to hospital and facility financing for CY 2026, and **we urge CMS to ensure its policies adequately reimburse for all care provided in facility settings.**

6. CMS should maintain its historic policy of parity for practice expense (PE) relative value unit (RVU) calculations.

Essential hospitals and the physicians they employ are committed to delivering high-quality care to all patients. We are concerned that the proposed changes to CMS methodology for calculating indirect PE RVUs for facility-based settings under the Physician Fee Schedule will reduce beneficiaries' access to care. While we support CMS' goals of improving accuracy in PFS payment, we are deeply concerned that the proposed changes to indirect PE RVU allocation will destabilize safety net providers and threaten patient access to essential health care services. This proposal is based on a flawed assumption that physicians practicing in hospital settings incur minimal indirect costs compared with practice-based physicians.

While we acknowledge differences in cost structures between sites of service, this binary approach fails to reflect the modern realities of hospital-based practice and the financial and operational burdens that essential hospital physicians bear. **We urge CMS to withdraw this proposal and maintain its longstanding methodology that more accurately reflects the costs associated with providing care in facility settings.**

a. Facility-based physicians have increased practice expenses because they must comply with the Emergency Medical Treatment and Labor Act (EMTALA).

While CMS argues that the facility fee covers hospital overhead, that approach overlooks financial and professional burdens that fall on physicians practicing in facility settings like essential hospitals. For example, essential hospital physicians must comply with EMTALA, which ensures that patients with emergent care needs receive medical care, regardless of their ability to pay. This translates to substantial practice expenses for which facility costs do not account. Because essential hospitals treat such a disproportionate number of uninsured and low-income patients, facility-based physicians in essential hospital settings bear the greatest costs of EMTALA responsibilities.

As Medicare already pays less for the care provided to beneficiaries, reducing payments for facility-based physicians will have a disproportionate impact on essential hospitals with higher Medicare and Medicaid payer mixes. These costs are especially high in essential hospital emergency departments (EDs). Due to essential hospitals' disproportionate share of Medicare, Medicaid, and uninsured patients, every dollar Medicare pays for services is critical for maintaining access to care for all patients. EDs already face immense challenges, as demonstrated by national trends in ED closures. Facility fees are clearly insufficient to EDs and other hospital units and cuts to practice expense RVUs will only exacerbate these problems.

b. Facility-based physicians provide more coordinated care and face additional standby burdens.

Physicians practicing in essential hospitals routinely provide more complex, multidisciplinary care than their peers based in offices and even other acute-care hospitals. We analyzed the American Hospital Association's annual survey data from 2018–2023. Despite a 0.2% decline in inpatient days at acute-care hospitals, inpatient days at essential hospitals rose by 5.7% during that period.

Due to their unique roles in their communities, essential hospitals are more likely than other acute-care facilities to treat complex patients with intensive inpatient care needs. Thus, physicians at essential hospitals must coordinate with inpatient teams, specialists, and care managers to treat patients with severe comorbidities and social risk factors. This coordination often occurs outside of billable encounters but consumes significant clinical time and staff resources—both of which are indirect practice expenses.

Reducing indirect PE allocations in facility settings ignores these added responsibilities and penalizes clinicians treating the most medically and socially complex patients.

c. Facility-based physicians may require highly specialized equipment and/or training for that equipment that facilities do not provide.

For highly specialized physicians—such as those working in the high-acuity trauma, neonatal intensive care, burn, and obstetric units at essential hospitals—facility payments do not uniformly cover the costs of equipment and training. These costs often are borne in part by the physicians or physician groups themselves. CMS' proposal would bluntly reduce PE inputs without recognizing these context-specific cost drivers, which are essential to the functioning of safety net hospitals. Despite CMS claims to the contrary, practice expenses such as equipment costs are not uniformly higher or lower across different settings. **CMS should more**

carefully examine indirect practice expenses incurred in various settings and across specialties before making sweeping reforms.

7. CMS should not expand its proposed changes to PE RVU calculations to include maternal health care services.

We appreciate CMS' request for stakeholder input on the effect of proposed changes to PE RVU calculations on maternal health care services. CMS explicitly acknowledges that MMM global period codes are unique under the PFS. These codes span nearly a year of care and include prenatal visits, imaging, delivery, and postpartum services. MMM codes are valued using a building-block methodology that assumes a significant share of care occurs in office-based settings.

National trends in rural hospital closures and provider shortages have driven more patients to hospital-based clinics and outpatient departments. Essential hospitals are playing a key role in sustaining patients' access to these critical services.[12] These facility-based maternity providers continue to incur administrative and clinical practice expenses typically covered in full or part by indirect PE RVUs. Cutting those inputs now could destabilize access to obstetric care at a time when maternal health deserts are expanding.

Moreover, because Medicaid relies heavily on Medicare rates as a benchmark, the proposed cuts would ripple beyond the PFS. The cuts would result in lower reimbursement from state Medicaid programs, which covered more than 41% of all births nationwide in 2023.[13] In essential hospitals, where Medicaid represents a significantly higher share of the payer mix, the proposed change would be devastating.

We strongly urge CMS to exclude MMM codes from the proposed indirect PE RVU adjustment. This is consistent with CMS' own recognition of maternity care's special characteristics and is critical to ensuring continued access to perinatal services for communities in need.

8. CMS should finalize the proposals to advance access to behavioral health services.

We support the proposal to create optional add-on codes for Advanced Primary Care Management (APCM) services that allow providers to furnish complementary behavioral health integration or psychiatric Collaborative Care Model services. This approach has the potential to improve care management, enhance patient follow-up, and reduce fragmentation, particularly for patients with co-occurring physical and behavioral health conditions.

We also support the establishment of three new G-codes (GPCM1, GPCM2, and GPCM3) to be billed as add-on services when the APCM base code is reported by the same practitioner in the same month. The ability to bill these codes would appropriately recognize the additional time, resources, and clinical expertise required to provide behavioral health integration alongside

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[12] 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. Aug. 8, 2025

[13] Kaiser Family Foundation. 5 key facts about Medicaid and pregnancy. *Kaiser Family Foundation*. May 29, 2025. https://www.kff.org/medicaid/issue-brief/5-key-facts-about-medicaid-and-pregnancy/. Accessed Aug. 21, 2025.

primary care management. However, **CMS should ensure the operational requirements for these add-on codes allow consistent application across settings, including those that serve high volumes of patients with complex needs.**

We urge CMS to consider the administrative and financial implications for hospitals and health systems when implementing these codes. Many essential hospitals operate integrated primary care and behavioral health services, often in resource-constrained environments. Clear guidance on documentation, cost reporting, and supervision requirements will be necessary to support adoption without creating undue burden.

Regarding cost sharing for APCM services, **we recommend CMS evaluate the implications of including preventive services within APCM bundles.** If preventive behavioral health services are included, CMS should ensure that cost-sharing rules do not create barriers to patient access, particularly in cases where early intervention can mitigate the need for more intensive, higher-cost care. Aligning cost-sharing policies with the preventive nature of certain behavioral health interventions could help improve uptake and care continuity.

9. CMS should rescind its proposed "efficiency adjustment" for specific non–time-based CPT codes.

America's Essential Hospitals supports CMS' goal to incentivize efficient, high-quality care. However, we are concerned that the proposed "efficiency adjustment" for select CPT codes appears speculative and is not supported by publicly available data or transparent rationale. CMS should not move forward with a payment reduction absent a clear and evidence-based explanation that justifies the policy's necessity and design. **We urge CMS to withdraw the proposed efficiency adjustment and commit to a data-driven process** with ample stakeholder engagement before finalizing any similar payment changes in future rulemaking cycles.

As CMS acknowledges, the proposed policy intends to "adjust work RVUs for codes that do not have a time component," based on a ratio of indirect PE RVUs to work RVUs, to mitigate potential overvaluation. But CMS has not demonstrated that the selected services are overvalued, nor has it provided a transparent methodology that would allow stakeholders to replicate or evaluate the efficiency determination. This approach lacks the rigor CMS typically applies to RVU valuation. It raises serious concerns for essential hospitals that operate under persistent financial pressure and depend on stable, predictable reimbursement. While we oppose the proposal generally, if it does move forward, **CMS should provide a full list of affected codes before finalizing this proposal.**

Essential hospitals consistently operate on negative margins, both due to inadequacies in federal reimbursement and the increased time, energy, and attention that complex patients require. Applying uniform efficiency adjustment to these services and providers would undervalue care coordination, transportation support, and social services on which beneficiaries rely and that essential hospitals provide.

Expanding Access to Innovative Health Care Delivery Services through Telehealth

We appreciate CMS' continued efforts to modernize telehealth policies and sustain beneficiary access to services delivered via telecommunication technologies. We support the proposals in this rule to streamline the Medicare Telehealth Services List, codify a definition of direct supervision, and maintain payment parity. These are each significant steps toward ensuring equal access to health care for all patients and improving health care outcomes. However, we urge CMS to maintain parity for resident supervision via telehealth across all settings. **CMS should finalize these proposals and continue payment equity under the PFS for telehealth services.**

10. CMS should finalize the proposals to simplify the Medicare Telehealth Services List.

The development and growth of telehealth services in recent years have benefited patients and health care providers alike. The continued success of telehealth services is contingent on a Telehealth Services List that is up-to-date and reflects best practices. Simplifying the review process by eliminating steps three to five of the review and eliminating the provision status for telehealth services will enhance physicians' ability to use and provide the most appropriate care in the most appropriate setting. **We encourage CMS to finalize its proposed policies to ensure that services included on the Medicare Telehealth Services List represent best available practices.**

Removing the provisional status category will reduce administrative ambiguity and provide long-term certainty for providers and researchers seeking to evaluate or expand telehealth services. We agree with stakeholders that provisional designations have inhibited innovation and long-term planning. Finalizing this change will help align Medicare policy with real-world practice and ensure a durable framework for telehealth coverage moving forward. **We encourage CMS to finalize this element of the proposed rule.**

11. CMS should finalize and codify the definition of direct supervision via use of two-way audio/video communications technology included in the proposed rule.

CMS requires that certain services be administered under specified levels of minimum supervision by a physician or other practitioner to qualify for Medicare payment. We support CMS' proposal to permanently codify a definition of direct supervision that includes real-time audio/video telecommunications for certain services. In recent years, CMS has provided a temporary definition for "direct supervision," only for the duration of the COVID-19 public health emergency, to include supervision via telehealth.

CMS wisely took an incremental approach to expanding these policies in recent years. Outcomes of these incremental expansions have demonstrated that remote supervision via two-way audio-vision communication technologies is appropriate and safe for a range of services. **We encourage CMS to finalize its proposal to permanently include supervision via two-way telehealth services in the definition of "direct supervision."**

Unfortunately, the proposed policy excludes audio-only telehealth from the definition of direct supervision. We are concerned CMS does not provide adequate justification to prohibit the use of audio-only telehealth services for circumstances when video supervision is not necessary. The proposed 2026 policy represents continued incremental change. Absent inclusion of audio-

only telehealth in the CY 2026 final rule, **CMS should study how audio-only telehealth services can provide effective opportunity for remote supervision and include it in future rulemaking.**

12. CMS should maintain its existing policy on resident supervision requirements.

We appreciate CMS' efforts to eliminate temporary waivers and establish permanent policies where appropriate in telehealth. However, we are concerned that the proposal to eliminate the waiver authorizing urban teaching institutions to provide resident supervision via telehealth harms resident education access. We strongly support efforts to strengthen rural training pathways and find opportunities to encourage physicians to practice in rural settings. **CMS should promote consistent policies when they are appropriate and reflect the reality of capable resident supervision.**

We recognize that flexibility for rural settings is necessary to continue developing qualified health care professionals with experience working in rural communities, but that does not necessitate a different policy for teaching physicians practicing in urban areas. In practice, residents practicing in urban facilities are more likely to have additional support due to the broader capacity of large urban teaching hospitals. **CMS should not discriminate against urban teaching institutions and should maintain its existing policy for resident supervision.**

13. CMS should finalize its proposed policies that maintain payment equity for telehealth services, including audio-only telehealth.

Recent years have demonstrated that telehealth can deliver quality health care services and outcomes while reaching patients in geographically diverse settings. We support CMS' proposal to maintain payment parity across telehealth and in-person services. Sustaining telehealth access is especially critical for essential hospitals, which serve patients who face transportation, geographic, or mobility barriers that make in-person visits difficult. To continue providing telehealth services, essential hospitals—which operate on negative margins far lower than those of peer acute-care hospitals—must be reimbursed for telehealth at parity with in-person services. This should include audio-only telehealth services, an effective tool for reaching rural and elderly patients that cannot use video-based telehealth services.

We welcome CMS' proposal to maintain payment equity for telehealth services in CY 2026 and **encourage CMS to continue upholding parity across service types**. Reimbursement cuts would reduce access to safe and effective care through telehealth.

Ensuring Compliance with 340B Program Requirements and the Inflation Reduction Act

The 340B program is a critical tool allowing essential hospitals to expand access to lifesaving services and medications for all patients. However, careless implementation of new prescription drug recognitions could severely jeopardize access to 340B discounts and the services essential hospitals provide to qualifying patients. **As CMS implements new prescription drug policies, it must not interfere with the administration of this vital program.**

14. CMS should implement inflation rebate calculations in a manner that builds on the success of the 340B program.

Based on feedback from the CY 2025 rulemaking process, CMS proposes a revised methodology and data sources for identifying and excluding 340B drugs when determining Medicare inflation rebates, added by the Inflation Reduction Act (IRA) of 2023. We support the IRA's goal of achieving access to affordable medications for all patients and encourage CMS to continue implementing these rules in ways that build on the 340B program's success.

It is important for CMS to ensure that the new rules do not create more administrative burden and complexity for providers participating in the 340B program. We appreciate that the proposed rule includes a clear role for CMS, as opposed to individual manufacturers, in identifying drugs subject to both a 340B discount and an IRA rebate. This is a notable departure from the proposed implementation of the IRA maximum fair price requirements. We also appreciate that CMS acknowledges key operational realities, such as the fact that 340B retail claims are often identified retrospectively rather than at the point of sale. We continue to support CMS' decision not to require a claims modifier for Part D claims.

We appreciate CMS' thoughtful process, driven by stakeholder feedback, to identify and exclude the units of drugs eligible for Part D rebates for which manufacturers provide a 340B discount. In CY 2025, CMS proposed applying an estimation percentage. This calculation used 340B Prime Vendor program data on 340B sales as a share of total sales for a particular national drug code. CMS now proposes a claims-based methodology, intended to address accurate concerns related to the estimation method. The agency acknowledges that this alternative also would entail certain data limitations and ultimately still serve as an estimate of 340B units. Whether CMS pursues the estimation methodology, the proposed "Prescriber-Pharmacy Methodology," or the alternative "Beneficiary-Pharmacy Methodology," **we continue to urge CMS to ensure that any final implementation (1) allows for retrospective claim identification, (2) prioritizes simplicity, and (3) limits new burden and complexity for providers.**

In the proposed rule, CMS also considers establishing a Medicare Part D Claims Data 340B Repository. Repository submissions would be voluntary at first but may become mandatory replacements for the aforementioned methodologies. We encourage CMS to act on its suggestion to test the repository and implement user and industry feedback before making further decisions on the repository's future.

15. CMS should finalize proposed claims-based methodology for identifying and excluding 340B units from rebate calculations.

CMS proposes to identify 340B-eligible drug units based on (1) the affiliation of the National Provider Identifier of the prescriber with a registered 340B covered entity, and (2) the designation of the dispensing pharmacy as a 340B contract pharmacy (the "Prescriber-Pharmacy Methodology"). CMS also requests feedback on an alternative claims-based model, known as the "Beneficiary-Pharmacy" method, which would identify drugs (1) dispensed by a 340B contract pharmacy and (2) for beneficiaries who receive care from a 340B covered entity affiliated with that pharmacy.

We appreciate and strongly support either of these claims-based methodologies, as both would account for retroactive claim identification and would limit new

burdens on and complexity for providers. For example, we appreciate the claims-based methodologies relying on existing data sources, and that they would be used only to identify 340B drugs for exclusion from IRA rebate calculations and not to question the underlying 340B eligibility of a particular claim.

Regardless of which methodology is finalized, **we urge CMS to continue its transparency regarding the methodology's limitations. We ask CMS to avoid applying the methodology or results for purposes beyond excluding drugs from IRA rebate calculation.** CMS acknowledges that the methodology could significantly overestimate the share of 340B drugs by capturing drugs as 340B-eligible even if the unit had not actually received a discount. This could be caused because (1) manufacturer restrictions on the entity's use of contract pharmacies result in a non-340B price; (2) the covered entity determined that the prescription was not provided for a "patient" of a covered entity under 340B rules; (3) the drug was unavailable or in shortage; or (4) the covered entity did not accumulate enough units to replenish the full package. We are wary that policymakers could draw incorrect conclusions due to the likelihood of undercounting 340B units under this methodology. We urge CMS and other policymakers to acknowledge these realities when considering the role of 340B discounts in the Medicare Part D program or when developing other 340B-related policy.

Similarly, neither methodology would be appropriate for verifying whether a particular claim should be considered 340B eligible. CMS acknowledges that the methodologies do not account for the complexities of the 340B patient definition. CMS also acknowledges that the methodology may not capture 340B eligible drugs dispensed through entities' own pharmacies. This is because the 340B Office of Pharmacy Affairs Information System database lists all contract pharmacies but does not similarly list in-house pharmacies. We appreciate that CMS acknowledges these realities does not propose to validate 340B eligibility based on the dataset it constructs.

For more detailed feedback, we refer CMS to the shared comments of America's Essential Hospitals and other 340B covered entity groups.[14]

16. CMS should finalize its proposed voluntary 340B repository.

We continue to support CMS' consideration of a repository model and appreciate that the current proposal reflects feedback from America's Essential Hospitals and other 340B hospital organizations. CMS now proposes to create "a repository to receive voluntary submissions from covered entities of certain data elements from Part D 340B claims to allow CMS to assess such data for use in identifying units of Part D rebatable drugs for which a manufacturer provides a discount under the 340B program in a future applicable period."

First and foremost, **we appreciate that the proposed repository would allow users to retrospectively identify claims as 340B-eligible and urge CMS to maintain this feature.**

a. CMS must protect confidentiality of claims information from manufacturers.

[14] Krenrich S, Thompson M, Schreiber E, et al. Letter to Meena Seshamani on July 2, 2024. https://essentialhospitals.org/wp-content/uploads/2024/07/Joint-Comments-on-5.3.24-IRA-Draft-Guidance-7.2.24.pdf. Accessed Aug. 21, 2025.

It is also critical that CMS proposes to collect the data directly from covered entities or their vendors and acknowledges the need to maintain the confidentiality of the data submitted—particularly by not sharing the information with manufacturers. We appreciate that CMS addressed the concerns raised by America's Essential Hospitals and others in response to last year's rule. However, we remain concerned that manufacturers might use claims information for purposes outside the scope of the Medicare Drug Price Negotiation Program and wholly unrelated to removing 340B units from inflation rebate calculations.

For example, a manufacturer might use the data to manage its voluntary rebate agreements with Part D plans, including disputing whether it owes rebates to a plan. It would also be inappropriate for the manufacturer to use that information to police covered entity compliance with 340B requirements. Neither purpose pertains to manufacturers' legal obligations under Part D or 340B. In fact, the latter purpose is contrary to the 340B program's design.

The Health Resources and Services Administration (HRSA), not manufacturers, is responsible for overseeing covered entities' compliance with 340B program requirements. Additionally, the IRA does not require CMS to share 340B claims data with manufacturers. **We urge CMS to continue to protect confidentiality as it moves forward with a repository.**

We also appreciate that CMS is storing 340B data to identify claims for IRA rebate exclusion and not for validating or questioning 340B eligibility. CMS instead would require a certification from covered entities that choose to submit data to the 340B repository that the data is from verified 340B claims. **We encourage CMS to finalize these proposed provisions.**

b. CMS should allow revision of claim status on claims submissions.

In the proposed rule, CMS identifies the possibility that claims status might need to be revised after initial submission. CMS proposes to allow covered entities additional time to submit data to reflect a revision to the 340B determination of a claim where (1) resubmission of data for a claim that the covered entity previously submitted to the 340B repository in error or with errors in the requested data fields, or (2) new submission of data for a claim for a drug that the covered entity had previously determined was not purchased under the 340B Program, but later identified was purchased under such program. This is a feature of the state repository referenced by CMS and crucial to the workability of the proposal for covered entities. **CMS should finalize a policy that permits these revisions and allows the most accurate claims data possible.**

c. CMS should ensure sufficient testing of the repository before making it mandatory.

We commend CMS for its intention to test the repository through voluntary submission before making it mandatory for covered entities. We also appreciate the agency's acknowledgment that it will need to work with users to reduce the burden of submission; identify complexities that could require adjustments; and ensure sufficient time for covered entities to gather, validate, and submit the specified data. The data from the voluntary submissions will be used to assess the usability of the repository to identify drug units for removal from IRA rebates.

CMS proposes that the testing period would include claims with dates of service on or after Jan. 1, 2026. However, the repository would not be available to accept submissions until fall 2026, at which point data back to Jan. 1 would be due within three months. CMS does not propose a length for the testing period.

CMS states that it expects disproportionate share hospitals, critical access hospitals, and federally qualified health centers to participate during the testing period and recommends that covered entities generally take advantage of the opportunity. We urge CMS to consider that providers are facing a stream of new requirements and challenges, including changes resulting from H.R. 1. **If participation is lower than anticipated, CMS should work directly with stakeholders to understand why and to improve voluntary participation.** Providers might be more able and willing to participate with more technical support from CMS, and CMS should work with providers to understand challenges and hiccups in reporting and troubleshoot accordingly. Ultimately, the testing period is critical for assessing CMS' and providers' investment of time and resources into a repository.

17. CMS should consider additional uses of the repository.

The proposed rule indicates that CMS may use the repository in the future as an alternative to the methodologies proposed above when calculating the total rebate amount for a Part D rebatable drug to exclude drugs provided with a 340B discount. In addition, investing in the repository could serve as a helpful alternative to individual manufacturer requirements to address de-duplication issues more broadly, including IRA compliance for maximum fair price purposes (e.g., an alternative to HRSA's rebate pilot).

For additional feedback, we refer CMS to the shared comments of America's Essential Hospitals and other 340B covered entity groups.

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

Sincerely,

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