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Submitted electronically via www.regulations.gov

September 15, 2025

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1834-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: 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,

The AAMC welcomes this opportunity to comment on the proposed rule entitled "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," 90 Fed. Reg. 33476 (July 17, 2025), issued by the Centers for Medicare & Medicaid Services (CMS or the agency).

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, clinical care, biomedical research, and community collaborations. Its members are all 160 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 Canadian medical schools accredited by the Committee on Accreditation of Canadian Medical Schools; nearly 500 academic health systems and teaching hospitals, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools, academic health systems and teaching hospitals, and the millions of individuals across academic medicine, including more than 210,000 full-time faculty members, 99,000 medical students, 162,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Through the Alliance of Academic Health Centers International, AAMC membership reaches more than 60 international academic health centers throughout five regional offices across the globe.

The following summary reflects the AAMC's comments on CMS' proposals regarding hospital payment, quality proposals, graduate medical education, and requests for information (RFIs) in the Calendar Year (FY) 2026 Outpatient Prospective Payment System (OPPS) Proposed Rule.

- **Payment Update:** CMS should increase the OPPS payment update for CY 2026 to reflect higher growth in labor and supply costs amid financial uncertainty.
- **Adjustment to OPPS Payments for Non-Drug Items and Services:** CMS should not move forward with implementing the 340B remedy claw back policy. If CMS chooses to move forward with the claw back, it should not accelerate the existing claw back timeline.
- **OPPS Drug Acquisition Cost Survey**: CMS should withdraw the OPPS drug acquisition cost survey due to the significant burden associated with collecting data that quickly becomes outdated from frequent acquisition cost changes and should not base Part B drug reimbursement rates on the results of any future survey.
- **Site Neutral Policies - Payment for Drug Administration Services at Provider-Based Departments**: The AAMC opposes CMS' proposal to extend site-neutral policies to drug administration services in excepted off-campus provider-based departments as these payment cuts are likely to reduce access to care, particularly for the sickest and most complex patients.
- **Site Neutral Policies - Requests for Information (RFI):** The AAMC has significant concerns with the expansion of site neutral payment policies to on-campus clinic visits or for other services provided at on- or off-campus HOPDs as these significant cuts in payment would reduce access to care.
- **Inpatient Only (IPO) List**: Given the breadth of services included on the IPO list, the AAMC urges CMS not to eliminate the IPO list. Instead, CMS should continue to solicit stakeholder feedback to comprehensively evaluate on an annual basis which procedures should remain in the inpatient setting, balancing concerns about beneficiary safety and outcomes, and evolving standards of care.
- **Ambulatory Surgical Center (ASC) Covered Procedures List (CPL):** CMS should not eliminate the current criteria for identifying procedures for the ASC CPL in the interest of patient safety.
- **Market Basket Weights for the Inpatient Prospective Payment System (IPPS):** CMS should not require hospitals to report median payer-specific Medicare Advantage (MA) negotiated rates on the cost report and should not use those rates as the basis for the MS-DRG weights in the future.
- **Price Transparency:** CMS should review and streamline the existing price transparency policies, rather than continuing to add requirements as proposed in this rule.
- **Virtual Supervision:** CMS should finalize the proposal to make permanent virtual direct supervision of cardiac rehabilitation services (CR), intensive cardiac rehabilitation services (ICR) and pulmonary rehabilitation services (PR), and diagnostic services.
- **Wage Index**: CMS should finalize realignment of the IPPS and OPPS wage indexes.
- **Definition of "Approved Medical Residency Programs":** CMS should not finalize the proposed changes to the definition of approved medical residency program.
- **Changes to the Outpatient Quality Reporting (OQR) Program***:* CMS should adopt proposed measures with modifications, finalize measure modifications and removals as proposed, and align Extraordinary Circumstances Exception (ECE) policies with the ECE policies adopted for CMS inpatient hospital quality reporting and performance programs.

- **Emphasizing Patient Safety in the Overall Hospital Quality Star Ratings:** CMS should ensure policies to emphasize patient safety best reflect patient priorities and appropriately balance safety with important areas like patient experience and mortality.

PAYMENT PROPOSALS

PAYMENT UPDATE

CMS Should Increase the OPPS Payment Update for CY 2026 to Reflect Higher Growth in Labor and Supply Costs Amid Financial Uncertainty

For CY 2026, CMS is proposing an OPPS conversion factor update of positive 2.4 percent for CY 2026. The proposed OPPS payment update is based on the fiscal year (FY) 2026 Inpatient Prospective Payment System (IPPS) proposed rule[1] market basket increase of 3.2 percent and a total factor productivity adjustment of minus 0.8 percentage points. (P. 33507). As highlighted in our response to this year's IPPS proposed rule, we remain concerned the data used to calculate the FY 2026 market basket update is not representative of the significantly higher growth in labor and supply costs hospitals continue to experience.[2] The FY 2026 IPPS final rule finalized a market basket update of 3.3 percent minus a total factor productivity adjustment of 0.7 percentage points, which equated to a final update of 2.6 percent.[3] We anticipate CMS will adopt a similar update in the OPPS final rule. However, even with the final FY 2026 IPPS market basket increase, we believe the update does not adequately account for the financial challenges hospitals continue to face. We recommend CMS look to utilize alternative data sources updated at a faster cadence to better reflect true labor and input cost increases**.** The data CMS is currently using to calculate the FY 2026 inpatient market basket update, which is also used to calculate the OPPS conversion factor update, do not appropriately reflect the dramatic cost increases that hospitals and health systems have experienced.

Hospitals continue to experience substantial annual increases in their expenses, with year-over-year labor increases at 4 percent and supply expenses up 9 percent.[4] In its March 2025 report, the Medicare Payment Advisory Commission (MedPAC) found Medicare fee-for-service margins of negative 13 percent in 2023, virtually unchanged from the record-low negative 13.1 percent margins in 2022.[5] The financial outlook for academic health systems is even more grim—AAMC member hospital overall Medicare fee-for-service margins were negative 18.2 percent in fiscal year 2022.[6] We do not see these cost trends lessening in CY 2026 or the foreseeable future. Instead, due to continued economic and supply chain uncertainty stemming from tariffs,

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[1] 90 FR 18002
[2] AAMC, Comments to CMS on the FY 2026 IPPS Proposed Rule (June 2025)
[3] 90 FR 36536
[4] Kaufman Hall June 2025 National Hospital Flash Report. August 11, 2025.
[5] MedPAC March 2025 Report to Congress. Chapter 3.
[6] Note: AAMC margin data for 2023 are not yet available for comparison to MedPAC's 2023 all-IPPS hospital Medicare margins. Source: AAMC analysis of the FY2022 Hospital Cost Reporting Information System (HCRIS) released in July 2024. AAMC membership data, September 2024.

substantial changes to Medicaid and the Health Insurance Marketplaces, and other external pressures, we expect these conditions to worsen in 2026. MedPAC continues to recognize these challenges, and for a third year in a row is recommending Congress direct CMS to provide a payment update 1 percent above the market basket update to ensure beneficiary access to care and hospital access to capital.[7] CMS has opted not to pursue this recommendation in the proposed rule.

Costs have also been further exasperated by the widespread effect of newly introduced tariffs on the supply chain, with the details of several of these tariffs still being negotiated. In CY 2026, hospitals will inevitably experience significant price increases due to new tariffs on items such as pharmaceuticals, medical supplies, medical devices, and building materials used in capital projects.[8] Experts anticipate that tariffs could increase supply costs for health systems by 15 percent over the next six months, with 90 percent of healthcare supply chain professionals expecting significant disruptions in procurement processes.[9] Recently, the administration has pivoted from their exemption of tariffs on pharmaceuticals and has begun exploring imposing tariffs of up to 250 percent on pharmaceuticals and pharmaceutical ingredients, ratcheting rates up over the course of one to two years.[10] We see the impact of such polices on drug expenses already playing out with year over year drug expenses increasing twelve percent in June 2025 compared to previous years, making drug expenses the main driver of expense growth.[11] These increased costs must be accounted for in CMS' calculations of the CY 2026 OPPS conversion factor.

The AAMC has previously flagged the insufficiency of annual market basket increases when compared to actual costs. Our prior comments have showcased the gap between forecasted and actual market data, highlighting the impact of CMS' underestimation of actual cost increases.[12] Additionally, underestimating the market basket becomes amplified due to the compounding nature of payment updates. So, if one year's payment update lags behind actual costs, it builds each year creating an even greater gap. Due to the continued implementation of inadequate market-basket updates coupled with the growing financial pressures for providers, it is necessary for CMS to issue a course correction to ensure Medicare payments are accurately updated to reflect hospital input costs and maintain continued access to care. We urge CMS to reconsider their proposed conversion factor increase by taking these additional factors into account. **For these reasons, we again urge CMS to reconsider the CY 2026 OPPS market basket to reflect these financial challenges by substituting inpatient market basket data used to set the outpatient update with more relevant and updated data sources.** [13] Specifically, under section 1833(t)(3)(C)(iv) of the Social Security Act, CMS can "substitute[e] for the market

[7] MedPAC March 2025 Report to Congress. Chapter 3.
[8] Healthcare Dive. Tariffs send healthcare industry into 'unchartered waters'. April 4, 2025.
[9] Becker's Hospital Review, Hospital finance, supply leaders predict 15% increase in tariff-related costs (March 2025)
[10] The Hill, Trump threatens pharma tariffs of up to 250 percent (August 2025)
[11] Kaufman Hall June 2025 National Hospital Flash Report. August 11, 2025.
[12] AAMC, Comments to CMS on the FY 2026 IPPS Proposed Rule (June 2025)
[13] AAMC, Comments to CMS on the CY 2025 OPPS Proposed Rule (September 2024)

basket percentage increase an annual percentage increase that is computed and applied with respect to covered OPD services furnished in a year in the same manner as the market basket percentage increase is determined and applied to inpatient hospital services for discharges occurring in a fiscal year." An increased market basket would protect Medicare beneficiaries' access to health care by enabling health systems to continue to provide essential care to beneficiaries.

AAMC member health systems continue to experience financial challenges, including workforce shortages, capacity constraints, insufficient reimbursement by payers, supply chain disruptions, and significant growth in expenses such as labor costs. These challenges are expected to be worsened by recent legislative actions and the other proposals within this rule impacting reimbursement rates. Most recently, the One Big Beautiful Bill Act (OBBBA), which was signed into law on July 4, 2025, included a historic $1 trillion cut to federal spending on Medicaid and the Health Insurance Marketplaces over the next decade. This law is expected to increase the number of uninsured by over 10 million in 2034.[14] This will result in increases in uncompensated care, charity care, and ultimately lead to higher care costs due to delayed care. Additionally, the law would reduce funding sources and reimbursement for state Medicaid programs, further reducing payments to hospitals and other providers. These negative forces have already begun pushing academic health-systems to explore difficult financial decisions in order to maintain the least disruption to patient access to care.[15] In addition to these planned cuts, the OBBBA is expected to result in Medicare cuts via the Statutory Pay-As-You-Go (S-PAYGO) Act sequester. The S-PAYGO requires Congress to ensure new legislation is budget neutral. If it is not and new legislation increases the federal deficit, then sequestration is triggered.[16] Reductions in Medicare spending through S-PAYGO would equate to 4 percent of total program spending, which the Congressional Budget Office (CBO) estimates would result in nearly $500 billion in reductions from 2027 thought 2034.[17] This is in addition to the Budget Control Act of 2011 (BCA) sequester that reduces Medicare payment by two percent and is currently in effect through fiscal year 2032.[18] Congress may waive or suspend the mandatory sequester before the end of the current congressional session in December. However, without congressional approval of such a waiver, CBO will be required to implement the sequester beginning in early 2026. The potential for these cuts to Medicare program, in addition to the $1 trillion cut in federal spending on Medicaid and the Health Insurance Marketplaces, presents another layer of budget constrain and concern to providers following the enactment of the OBBBA. These financial challenges highlight the importance and need for CMS to accurately update the current market basket and correct errors in prior year's updates to ensure beneficiaries retain access to their providers and needed services.

[14] Congressional Budget Office, Estimated Budgetary Effects of Public Law 119-21, to Provide for Reconciliation Pursuant to Title II of H. Con. Res. 14, Relative to CBO's January 2025 Baseline (July 21, 2025)
[15] AAMC, Hospitals make painful choices as federal cutbacks add to economic headwinds (August 7, 2025)
[16] P.L. 111-139
[17] CBO, CBO's Estimates of the Statutory Pay-As-You-Go Effects of Public Law 119-21 (August 15, 2025)
[18] P.L. 112-25

In addition, CMS includes a higher-than usual total productivity adjustment of negative 0.8 percentage points, further reducing an already inadequate payment update. The proposed productivity adjustment is the largest CMS has used since FY 2019 and is the second largest in the last 15 years CMS has published data. Productivity adjustments are based on a 10-year rolling average of data CMS acquires from the Bureau of Labor Statistics. Due to this rapid and significant increase for CY 2026, CMS should evaluate why and how the rolling average experienced such a significant increase when compared with the productivity adjustments from prior years ranging from 0.2 to 0.5 percentage points.[19]

Lastly, the CY 2026 OPPS market basket update is weakened, and almost completely eliminated, by CMS' proposal to accelerate the claw back for increased payment of OPPS non-drug items and services from January 1, 2018, through September 22, 2022. (P.33631). Further rendering the payment update insufficient. Our comments below further discuss the challenges associated with this proposal.

ADJUSTMENT TO OPPS PAYMENTS FOR NON-DRUG ITEMS AND SERVICES

CMS Should Not Move Forward with Implementing the 340B Remedy Claw Back Policy

In the CY 2018 OPPS final rule,[20] CMS finalized a policy to reduce reimbursement for drugs acquired under the 340B Program from average sales price plus 6 percent (ASP +6%) to average sales price minus 22.5 percent (ASP-22.5%) beginning January 1, 2018. CMS discussed the litigation history related to these cuts in the rule's preamble (p.33632). This litigation resulted in a unanimous decision by the U.S. Supreme Court on June 15, 2022, which held that absent a survey of hospital acquisition costs, CMS did not have the authority to reduce payments under the OPPS for 340B-acquired drugs and therefore would need to remedy the underpayments hospitals received for these drugs.[21] On September 28, 2022, the D.C. District Court ruled that CMS must begin reimbursing covered entities for 340B-acquired drugs immediately and not wait for a remedy to be finalized.[22]

Following this decision, in November 2023, CMS finalized a remedy to repay hospitals for the unlawful reimbursement cuts for drugs acquired under the 340B Program for the period between January 1, 2018, through September 27, 2022. At the time CMS finalized a budget-neutral policy to address the underpayment for drugs acquired under the 340B Program and the increased payment for non-drug items and services under the OPPS. Under this remedy, hospitals received lump sum payments for separately payable Part B drugs purchased through 340B during the impacted timeframe between January 1, 2018, through September 27, 2022. CMS argued that it was required to make these additional payments budget neutral and adopted a claw back of the increased payment of non-drug items and services under the OPPS during that same time period, totaling $7.8 billion, set to begin in CY 2026. The finalized claw back would recoup payment for

[19] CMS actual regulation market basket updates file. FY 2026 productivity adjustment is from proposed rule. Productivity adjustments are subtracted from the market basket update to yield the payment update—therefore, larger values in the graph indicate larger reductions.
[20] 82 FR 52356
[21] American Hospital Association v. Becerra, 142 S. Ct. 1896 (2022)
[22] Am. Hospital Ass'n v. Becerra, Case No. 1:18-cv-2084, Dkt. 78 (September 28, 2022)

non-drug items and services between January 1, 2018, through September 27, 2022, by adjusting the OPPS conversion factor by reducing it by 0.5 percentage points each year until the $7.8 billion was recovered, estimated to be over a period of sixteen years.[23]

Despite CMS having already finalized a policy to recoup the increased payment for non-drug items and services under the OPPS between January 1, 2018, through September 27, 2022, the agency is now proposing to accelerate this recoupment. Under this acceleration, CMS is proposing to reduce the otherwise applicable update for non-drug items and services by 2.0 percentage points over six years, as opposed to CMS' previously finalized policy which would reduce the otherwise applicable annual update for non-drug items and services by 0.5 percentage points over sixteen years (p. 33634). CMS further suggests an alternative policy option to reduce the otherwise applicable annual update for non-drug items and services by five percentage points over three years (p. 33635).[24]

The AAMC does not believe there is any statutory authority for CMS to adopt a claw back at all, much less of the magnitude it proposes. **The AAMC opposes the proposed acceleration of the claw back and urges CMS to not finalize the proposal.** As the AAMC commented in response to the original proposal for the 340B remedy, the AAMC agreed with American Hospital Association's (AHA's) comments[25] and believes CMS does not have the legal authority to implement a claw back policy at all much less the increased reduction of 2.0 percentage points.[26]

A claw back policy also introduces financial unpredictability for providers and ultimately harms patients by negatively impacting health systems and hospitals' ability to improve or maintain access to care. Health systems and hospitals should not have to withstand additional financial strain as a result of the agency's previous mistake. The increase in payment for non-drug items and services occurred at a time when hospitals were utilizing all of their available resources to take care of patients during the COVID-19 public health emergency. Despite this increase in payment for non-drug items and services, hospitals still faced significant negative margins during this time. Any "additional" money health systems and hospitals received during this time from the adjustment to payments was spent to care for and meet the needs of their patients and communities. These funds were not budgeted to be re-couped at a later date.

Reducing reimbursement for non-drug items and services will further financially strain health systems and hospitals that continue to struggle with supply chain and workforce issues. In Table 112 of the proposed rule, CMS included an estimated payment update for all hospitals after accounting for all factors including the 340B recoupment adjustment of just 0.1 percent (p.

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[23] 88 FR 77150

[24] AAMC notes that in several places in the preamble to the OPPS proposed rule, CMS describes the proposal as a 2.0 percent reduction to the *conversion factor* rather than a 2.0 percent to the otherwise applicable annual *update to the conversion factor* as the adjustment is presented in 42 CFR § 419.32(b)((1)(iv)(B)(12). AAMC recommends CMS be more precise in the description in the preamble language to make clear that CMS intends to adopt a reduction to the otherwise applicable update and not the conversion factor itself.

[25] American Hospital Association, Comments to CMS on the Remedy for the 340BAcquired Drug Payment Policy for Calendar Years 2018-2022 Proposed Rule (August 2023)

[26] AAMC, Comments to CMS on the Remedy for the 340BAcquired Drug Payment Policy for Calendar Years 2018-2022 Proposed Rule (August 2023)

33843). The impact of the combined proposed policies would be even worse for major teaching hospitals with an overall estimated payment update of negative 0.2 percent for CY 2026 (p.33845). As discussed in response to the inadequacy of the proposed conversion factor update, health systems and hospitals are continuing to experience financial challenges in light of inadequate payment updates, increased costs, and the introduction of upcoming significant cuts to the federal funding of state Medicaid programs and the Health Insurance Marketplaces. These challenges are exacerbated by proposals to further reduce payment updates, effectively cutting Medicare rates, and rendering reimbursement rates to be even more insufficient.

Additionally, CMS' current remedy policy has been finalized since November 2023, giving hospitals two years to prepare for an expected decrease in the annual update of 0.5 percentage points for non-drug items and services each year over the course of the next sixteen years. The agency's decision to now quadruple the current reduction to the conversion factor update for non-drug items and services is rash and arbitrary, giving health systems and hospitals only two months to prepare if finalized. CMS' assertion that the alteration of this policy prior to the start of CY 2026 would yield minimal harm to "hospitals' reliance interest" in the original policy is false. (p.33635). Many health systems aim to conduct financial and strategic planning several years in advance, and prior to 2020 it was common practice for these systems to develop plans three to five years in advance.[27] However, due to the uncertainty many health systems and hospitals have faced due to payment polices such as this one, it has become challenging for providers to plan in advance. This financial unpredictability ultimately harms patients as health systems and hospitals are unable to plan and invest in new endeavors to improve, streamline, or even maintain access to care.

CMS Must Account for the Impact of a Claw Back on Future MA Payments to Hospitals

Lastly, the agency has not considered the impact the proposed aggressive fee-for-service claw back policy will have on Medicare Advantage (MA) rates. Medicare Advantage Organizations craft their reimbursement rates based on Medicare FFS rates. Over time the decrease in the OPPS conversion factor will carry over to MA plans and result in lower MA reimbursement rates, despite these plans never issuing repayment for the original unlawful reductions to Medicare payments for 340B drugs. Decreased reimbursement from MA plans would double the adverse impact of the proposed recoupment on health systems and hospitals and potentially jeopardize access to care for beneficiaries. As more Medicare beneficiaries choose to enroll in MA plans, the agency must weigh the impact of this policy on MA plans.

OPPS Drug Acquisition Cost Survey

CMS Should Withdraw the OPPS Drug Acquisition Cost Survey Due to the Significant Burden Associated with Collection for Data That Quickly Becomes Outdated from Frequent Acquisition Cost Changes

In this proposed rule, CMS includes a notice that the agency will conduct a survey by early CY 2026 on the acquisition costs for each separately payable drug acquired by all hospitals paid

[27] Becker's Hospital Review, Health systems' strategic plans adjust to 'new financial realities' (July 29, 2025)

under the OPPS. The data collected in this survey will be used to inform reimbursement of separately payable drugs under OPPS in future rulemaking as soon as CY 2027 (p. 33653). While the proposed rule is light on specific details around the estimated burden or level of detail that hospitals will be required to provide, CMS issued draft survey materials separate from the OPPS proposed rule containing additional details.[28] Within these additional materials, CMS indicated that hospitals will be asked to report total acquisition cost, net of all rebates and discounts, of each separately payable drug acquired, by National Drug Code (NDC), and separated by 340B and non-340B acquired drugs from July 1, 2024, through June 30, 2025.[29] Under this proposal hospitals would be expected to report the acquisition cost data for approximately 700 Healthcare Common Procedure Coding System (HCPCS) codes, with most HCPCS codes having multiple NDCs per HCPCS code. This is a tremendous undertaking requiring tens of thousands of units of data a hospital would need to account for. We believe CMS has grossly underestimated the expenditure of time and resources hospitals will incur in order to collect and submit the data. Currently, CMS is estimating each hospital will require just 73.5 hours to complete the survey in its entirety.[30] Retrieving acquisition cost data involves not just hospital staff and resources but collaboration with external partners that have access to this data, such as wholesalers and other distributors. Acquiring this data would require hospitals to evaluate their contracts with their wholesalers to ensure the data can be shared and to ensure their wholesalers have access to the data for the period in question, as many wholesaler agreements limit the lookback period for when acquisition cost data can be downloaded. To complete this survey and other requirements, hospitals will likely be forced to redirect financial resources that would otherwise be used for patient care.

The initiation of such a large collection of information also places greater burden on the agency itself to facilitate the collection, evaluation, and resolution of any missing or incorrectly reported data. It is ironic, however, that this proposal comes at a time where the agency seeks to eliminate and reduce overly burdensome regulations in order to streamline the American health care system. Moreover, beyond the burden of such a survey, the results reported from hospitals will only reflect drug acquisition costs at a single point in time. Ebbs and flows in the market, further complicated by recent economic initiatives such as the Most Favored Nation drug pricing[31] and pharmaceutical tariffs[32], result in drug acquisition costs changing as frequently as day-to-day. Any data collected from this survey would rapidly become obsolete requiring additional efforts to survey in the future to ensure accurate data. **For these reasons, we request CMS withdraw its notice to survey OPPS drug acquisition costs**.

Further, CMS does not include a requirement for hospitals to respond but seeks feedback on whether the agency should mandate hospitals' response (p. 33654). Under Section 1833 (t)(14)(D) of the SSA, the agency is empowered to conduct OPPS drug acquisition cost surveys; however, the statute does not authorize the agency to mandate that hospitals respond to such

[28] CMS-10931; OMB 0938-New
[29] *Id.*
[30] *Id.*
[31] White House, Fact Sheet: President Donald J. Trump Announces Actions to Get Americans the Best Prices in the World for Prescription Drugs. (July 2025)
[32] Sullivan, D, *et al.*, The consequences of pharmaceutical tariffs in the United States, JMCP (May 6, 2025).

surveys. Absent this language, we do not believe CMS has the statutory authority to compel hospital responses. We suspect CMS is anticipating non-response due to the lack of statutory authority to mandate such a response. As a result, CMS is proposing various assumptions the agency may make around a hospitals' drug acquisition cost in the event of non-response. These assumptions include using the lowest reported amount among similar hospitals as a proxy, using supplemental data from the Federal Supply Schedule, using the 340B ceiling price, and using ASP plus a percentage. CMS even goes so far as to consider interpreting non-response as a hospital having insignificant or low acquisition costs, so the agency should always package drug costs, and never pay separately (p. 33654).

The AAMC views these considerations as an extreme overreach by the agency, as none of these assumptions are explicitly authorized by statute and the assumptions CMS is considering would be arbitrary in the extreme. Section 1833 (t)(14)(A)(iii) of the Act permits the agency to establish payment amounts for specified covered outpatient drugs based on the average acquisition cost of a drug as identified by a drug acquisition cost survey, or the ASP of that drug in a given year. However, if the agency wishes to utilize a survey for this purpose, it must "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."[33] Absent a statistically significant number of responses, CMS cannot implement changes to reimbursement rates that vary by groups of hospitals for separately payable drugs under the OPPS.[34] Without explicit statutory authority or instruction, CMS cannot artificially manufacture survey responses in order to meet the statistically significant threshold to use the drug acquisition cost survey results to implement changes to OPPS drug reimbursement. Utilizing arbitrary assumptions as the proposed rule contemplates would not yield statistically sound survey results and could render the survey unusable for the purpose of informing reimbursement of separately payable drugs under OPPS in future rulemaking. **Therefore, CMS should not finalize its proposals to assume drug acquisition costs for non-responsive hospitals.**

CMS Should Not Base Part B Drug Reimbursement Rates on The Results of Any Future Survey

As mentioned above, CMS builds on its notice to survey hospitals for drug acquisition costs of separately payable OPPS drugs by stating the agency's plans to utilize the collected survey data to inform reimbursement of separately payable drugs under OPPS in future rulemaking as soon as CY 2027 (p. 33653). As highlighted, a survey of drug acquisition costs for a single point in time may not accurately reflect a hospitals' drug costs. This is further complicated if CMS chooses to continue with its proposal to make assumptions on acquisition cost for non-response. These factors may skew the data collected and negatively impact reimbursement for separately payable drugs under OPPS. Cuts to reimbursement have the potential to negatively impact patient access to care. This is especially true for hospitals that treat a large number of low income individuals, such as hospitals participating in the 340B Program. The 340B program allows participating hospitals to provide vital support and access to vulnerable patients and communities

[33] 42 U.S.C. Sec.1395l(t)(14)(D)(iii)
[34] *American Hospital Association v. Becerra*, 142 S. Ct. 1896 (2022)

by allowing participating hospitals to utilize savings from drugs acquired under the 340B Program. Furthermore, Congress did not design the 340B Program to pay hospitals at acquisition costs. For these reasons, drug acquisition costs should not be the basis of reimbursement cuts. Cuts to drug reimbursement based on drug acquisition cost pose the risk of jeopardizing hospitals' ability to stretch scarce resources as far as possible, reach more patients, provide comprehensive services, and invest in the needs of their local communities. **The AAMC urges CMS not to pursue changes or cuts to reimbursement for separately payable drugs under OPPS using drug acquisition cost data, even if only to a subset of hospitals, especially those serving large volumes of low income patients.**

SITE NEUTRAL POLICIES - PAYMENT FOR DRUG ADMINISTRATION SERVICES AT PROVIDER-BASED DEPARTMENTS

Extending Site-Neutral Policies to Drug Administration Services in Excepted Off-Campus Provider-Based Departments Is Likely to Reduce Access to Care, particularly for the Sickest and Most Complex Patients

Section 603 of the Bipartisan Budget Act of 2015 (BBA) required that services furnished in off-campus provider-based departments (PBDs, interchangeably referred to as hospital outpatient departments, or HOPDs) that began billing under the OPPS on or after November 2, 2015, and that do not meet the 21st Century Cures "mid-build" exception (collectively referred to as non-excepted services) be paid under another applicable Part B payment system instead of the OPPS (Section 1833(t)(21) of the Act). In rulemaking, CMS determined that the payment amount for these non-excepted services would be set at 40 percent of the OPPS rate.

In the CY 2019 OPPS final rule, citing its authority under section 1833(t)(2)(F) of the Act, CMS established a policy to apply the site neutral rate to outpatient clinic visits provided in excepted off-campus PBDs deeming that there had been an unnecessary increase in the volume of outpatient services provided in the HOPD setting, resulting from a shift of services from the physician office to the HOPD. [35] CMS implemented the policy in a non-budget neutral manner. At that time, the AAMC strongly opposed the reduction in payments to excepted off-campus HOPDs, as these reductions are detrimental to the important care provided by teaching hospitals to vulnerable Medicare beneficiaries. In addition, the AAMC questioned CMS' statutory authority to implement the payment reductions, and the agency's authority to impose cuts that are not budget neutral. The AAMC urged CMS to withdraw its CY 2019 proposal based on these concerns. Despite the many concerns and objections raised by the AAMC and other commenters, CMS finalized the proposal in its CY 2019 OPPS final rule and cut payments to excepted off-campus PBDs in a non-budget neutral manner.

In this rule, CMS is proposing to use its authority under section 1833(t)(2)(F) of the Social Security Act to expand its existing site-neutral payment policies to include drug administration services furnished at all off-campus hospital outpatient locations. CMS states that it has the authority to "develop a method for controlling unnecessary increases in the volume of covered"

[35] 83 Fed. Reg. 59076 (November 21, 2018)

outpatient services. Specifically, CMS proposes to apply the PFS equivalent rate (40 percent of the OPPS rate) for any HCPCS codes included in drug administration ambulatory payment classifications (APCs 5691, 5692, 5693, 5694) when provided at excepted off-campus PBDs**.** Off-campus PBDs that are not excepted are already subject to the PFS-equivalent payment rate for these services. CMS proposes to exclude rural sole community hospitals from this policy. CMS' rationale for this policy is that the agency has noticed a substantial shift over time from drug administration in physician offices to administration in PBDs and has concerns about the higher costs when these services are provided at HOPDs. CMS proposes to implement this proposal in a non-budget neutral manner, which it estimated would result in a reduction of $280 million in hospital payments under the OPPS in 2026, and a reduction of $8.150 billion in payments to hospitals and $2.770 billion reduction in beneficiary coinsurance over 10 years.[36]

The AAMC opposes CMS' proposal to extend site-neutral policies to drug administration services in excepted off-campus provider-based departments as these payment cuts are likely to reduce access to care, particularly for the sickest and most complex patients that are cared for by AAMC member academic health systems and teaching hospitals. Drug administration services are a critical part of cancer care, and patients rely on hospitals, including off-campus departments, to provide these vital services. These off-campus departments enable patients to receive their care in locations closer to home that are integrated with the main hospital. Off-campus departments may be located in regions where there are a limited number of physicians available to treat patients. These off-campus departments are critical to enabling hospitals to improve access to care, especially for some of the sickest and most medically complex patients.

Significantly reducing payment for drug administration services would disproportionately harm academic health systems and teaching hospitals, many of which are safety net providers. While representing only seven percent of OPPS hospitals nationwide, AAMC member academic health systems and teaching hospitals would shoulder 60% of the Medicare HOPD cuts to drug administration services.[37] Reducing Medicare payments for care provided in these settings would threaten patients' access to critical services, particularly in rural and underserved communities, and diminish the ability of our members to provide cutting-edge treatments and sustain their missions.

These reductions to payment would come at a time when AAMC-member academic health systems and teaching hospitals and their affiliated physician faculty practices are facing profound financial challenges that already seriously endanger their ability to care for patients and train the next generation of physicians. Historic workforce shortages, unprecedented capacity constraints, insufficient reimbursement from payers, supply chain disruptions, and growth in expenses all

[36] As we describe further below in the comment letter, we believe CMS may have erred in its calculation of the impact of the payment reduction beginning with the second year of the proposed policy being in effect by assuming an unrealistic increase in baseline utilization. This overestimate could be resulting in an error in CMS' estimate of the cumulative impact of these cuts. We urge CMS to clarify its estimates so the public can better understand the impact of this proposed policy.

[37] Analysis of CY2024 outpatient claims data by AAMC and Watson Policy Analysis. Includes a claims completion and trending factor to project CY2026 impacts.

contribute to the acute financial pressures currently facing academic medicine. These challenges are expected to be exacerbated by significant price increases due to tariffs on items such as pharmaceuticals, medical supplies, medical devices, and building materials used in capital projects. According to MedPAC, hospitals 'overall fee-for-service Medicare margins dropped to a record low of -13.1% in 2022 and remained at -13%in 2023.[38] The financial outlook for academic health systems and teaching hospitals is even more grim: AAMC member hospitals' overall Medicare fee-for-service margins were -18.2% in fiscal year 2022. We don't see these trends improving in CY 2026 or the foreseeable future.

These financial challenges will be further exacerbated by the enactment of the One Big Beautiful Bill Act (OBBBA) on July 4, 2025, which included a historic $1 trillion cut in federal spending on Medicaid and the Health Insurance Marketplaces over the next decade. According to the Congressional Budget Office, the law is projected to result in an increase of approximately 10 million uninsured people by 2034, most of whom would have been covered by Medicaid and the Affordable Care Act's health insurance marketplaces.[39] It is likely that these patients will shift from being covered under Medicaid or having insurance through the exchanges to receiving uncompensated care provided by academic health systems, which currently account for 29 percent of Medicaid inpatient days and 33 percent of uncompensated care costs.

Taken together, the expansion of site-neutral payment policies as proposed, the anticipated increase in uncompensated care due to provisions in the OBBBA, and the anticipated future effect of new tariffs, will undoubtedly reduce hospital margins further. Academic health systems and teaching hospitals cannot absorb additional cuts without dire consequences for patients, communities, and the future of the physician workforce. **We urge CMS not to make these reductions in payment for drug administration services to ensure that our nation's most vulnerable patients continue to receive the high-quality care they need and deserve.**

"Site-Neutral" Policy Does Not Account for Fundamental Differences Between the Patients Cared for HOPDs Versus Physician Offices

This proposal inappropriately assumes that the care provided in outpatient hospital clinics is equivalent to the less complex care that is provided in physician offices. The policy does not account for the fundamental differences between the patients cared for HOPDs and physician offices, as well as the greater licensing, accreditation, and regulatory requirements for hospitals.

HOPDs Treat More Clinically Complex and Economically Challenged Patients

HOPDs often provide different services to patients than a typical physician office does. Compared to physician offices, patients treated in HOPDs are more clinically and socially

[38] MedPAC March 2025 Report to Congress. Chapter 3. https://www.medpac.gov/wp-content/uploads/2025/03/Mar25_Ch3_MedPAC_Report_To_Congress_SEC.pdf
[39] Congressional Budget Office, Estimated Budgetary Effects of Public Law 119-21, to Provide for Reconciliation Pursuant to Title II of H. Con. Res. 14, Relative to CBO's January 2025 Baseline (July 21, 2025). https://www.cbo.gov/publication/61570

complex. Specifically, data show that patients treated in HOPDs have more severe chronic conditions, are two times as likely to have had a prior inpatient hospital stay, are almost twice as likely to have prior emergency department use, are more likely to live in low-income areas, are one and a half times more likely to be under 65 and disabled, and over one and a half times more likely to be dually eligible for Medicare and Medicaid.[40]

For patients with cancer, differences among patients treated in HOPDs compared to physician offices are even more pronounced. Cancer patients treated in HOPDs are:

- Over two times more likely to be dually eligible for Medicare and Medicaid,
- Over two times more likely to be under 65 and disabled,
- Two times more likely to have a prior inpatient hospital stay,
- Nearly twice as likely to have had a prior ED visit; and
- Live in counties with lower median income than beneficiaries seeking treatment at a physician office.

Treating these patients requires greater use of resources.[41]

For safety reasons, physicians often refer sicker patients with higher-risk conditions to outpatient hospital settings for their care since hospitals are equipped with additional resources that enable them to better manage complications and emergencies than other settings. For patients with severe chronic conditions and comorbidities, even minor procedures can have an increased likelihood of complications. Examples of comorbid conditions that would increase risk include morbidly obese patients, patients with dementia and other mental health issues, and patients with disabilities. If a complication occurs during drug administration or another procedure, HOPDs are prepared to care for patients in a manner that physician's offices are not. They have access to code teams and other emergency response services whereas in a physician's office the response is usually to call 911. This is especially important with regard to drug administration as there are many chemotherapies that can cause hypersensitivity reactions, which are immune responses to a drug that can range from mild symptoms to life-threatening anaphylaxis. Additionally, hospitals offer important services such as laboratory, imaging, surgical and many other services that the patient may need that are not readily available in physician offices or ASCs.

There are many situations in which patients are referred to HOPDs rather than physician offices or ASCs for clinical and safety reasons. For example, consider a cancer treatment that requires large volumes of IV fluid administered with the chemotherapy (e.g., Cisplatin based regimens that are commonly part of the treatment for many different cancers, including lymphoma, lung, bladder, head and neck and others), to avoid nephrotoxicity and cardiotoxicity. Imagine an

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[40] Comparison of Care in Hospital Outpatient Departments and Independent Physician Offices: Updated Findings for 2019-2024. KNG Health Consulting LLC analysis for American Hospital Association using 2018Q4-2024Q2 Medicare Inpatient, Outpatient, and Carrier Standard Analytical Files and Denominator files. September 2025.
[41] Comparison of Care in Hospital Outpatient Departments and Independent Physician Offices among Cancer Patients: Updated Findings for 2019-2024. KNG Health Consulting LLC analysis for American Hospital Association using 2018Q4-2024Q2 Medicare Inpatient, Outpatient, and Carrier Standard Analytical Files and Denominator files. September 2025.

otherwise healthy 35-year-old with lymphoma receiving this treatment, who has no other medical conditions or chronic diseases, a strong heart, healthy lungs, and normal kidney function. This patient might easily handle receiving several liters of IV fluids over a short period of time without fear of complication and could in many circumstances be treated in a physician's office. Now consider the same treatment, but this time in a 70-year-old with diabetes, congestive heart failure, and chronic kidney disease (a very common clinical scenario). That same treatment with identical IV fluids creates significant risk of acute pulmonary edema or other cardiopulmonary complications. The ability to manage any potential complications would, in most circumstances, require the higher level of resources associated with a HOPD that a physician's office would not generally have.

Hospitals Must Comply with Licensing, Accreditation and Other Regulatory Requirements that Increase Costs

Hospitals must comply with a much more comprehensive scope of licensing, accreditation and other regulatory requirements compared to physician offices. Hospitals must comply with more stringent building codes, life-safety codes, and hospital-level staffing requirements. For drug administration, hospitals are required to take many additional measures to make certain that medications are prepared and administered safely for their patients. Unlike other settings, hospitals must ensure that a licensed pharmacist supervises drug preparation, rooms are cleaned with positive air pressure to prevent microbial contaminations, and employees are protected from hazardous drugs. Hospitals must comply with the Medicare conditions of participation,[42] standards established by the Joint Commission, Food and Drug, Administration, and U.S. Pharmacopeia. Hospital payment rates must be sufficient to support the higher standard of care that compliance with these standards requires.

The ASHP and AHA developed a chart (included below) that includes information on the additional measures that hospitals are required to take for drug administration compared to other settings. Complying with these requirements requires significantly more resources in the form of staff time and supplies, resulting in higher costs incurred by HOPDs compared to other ambulatory settings.

[42]See 42 C.F.R. section 413.65(a),(e) , requiring PBDs to comply with the same conditions of participation as their affiliated hospital.

	REQUIREMENTS	HOSPITAL	PHYSICIAN OFFICE	FREE-STANDING SITE
SAFE PREPARATION	Clean room with positive air pressure to prevent microbial contamination	✓	✗	✗
	Environmental sampling to ensure sterile conditions	✓	✗	✗
	Drug preparation supervised by a licensed pharmacist	✓	✗	✗
	Employee protections from exposure to hazardous drugs	✓	✗	✗
	Drug Supply Chain Security Act rules prevent use of counterfeit or mishandled drugs	✓	✗	✗
SAFE ADMINISTRATION	Drug barcoding and EHR integration reduce administration errors	✓	✗	✗
	Hospital pharmacist confirms safe dosing and checks for drug-drug interactions	✓	✗	✗
	On-site physician for prompt response to adverse reactions	✓	✓	✗
CARE COORDINATION	On-site pharmacy prevents delays accessing medication	✓	✗	✗
	On-site pharmacy can modify dosing on day of infusion based on therapeutic needs	✓	✗	✗
	Provides care for the most complex patients	✓	✗	✗
	Provides access to care 24 hours per day	✓	✗	✗
	Provides care to uninsured and underinsured patients	✓	✗	✗
SAFETY OVERSIGHT	Food and Drug Administration, state boards of pharmacy, U.S. Pharmacopeia, and The Joint Commission	✓	✗	✗

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Hospitals Offer Unique Services to the Community, Impacting Cost of Care

In addition to the regulatory, accreditation, and licensing requirements, health systems and hospitals provide unique services to their communities that impact the cost of care delivered. For example, hospitals invest in the infrastructure to manage disasters and public health emergencies. They are the only type of health care provider that delivers emergency care 24 hours a day, 365 days a year to the community, regardless of their patients' insurance coverage or ability to pay. This "standby capacity" is costly and is supported by revenue from direct patient care. Additionally, academic health systems and teaching hospitals provide access to critical services and programs that may not be otherwise available. Academic health systems and teaching hospitals provide highly specialized care that is often unavailable in other settings, including oncology services, transplant surgery, trauma care, burn care, pediatric specialty care, and treatment for rare and complex conditions. These site neutral policies can endanger a hospitals' ability to continue to provide 24/7 access to care, capacity for disaster response, and other critical services to the community.

CMS Does Not have the Statutory Authority to Make Reductions in Payment for Drug Administration Services

Section 603 of the BBA required that services furnished in off-campus PBDs that began billing under the OPPS on or after Nov. 2, 2015, or that do not meet the 21st Century Cures "mid-build" exception (referred to as non-excepted services) will be paid under another applicable Part B payment system instead of the OPPS (Section 1833(t)(21) of the Act). In rulemaking, CMS

determined that the payment amount for these non-excepted services would be set at 40 percent of the OPPS rate.

In this proposed rule, CMS describes increases in the volume of drug administration services provided in HOPDs and cites its authority under section 1833(t)(2)(F) of the Act to establish a "method" for "controlling unnecessary increases in the volume of covered OPD services. CMS' "method" is to pay 40 percent of the OPPS rate for these services. CMS proposes to implement this policy in a non-budget neutral manner, resulting in $280 million reduction in hospital payment under the OPPS in 2026.

Congress explicitly included language specifying that excepted off-campus PBDs would not be paid at the reduced rates that would apply to non-excepted PBDs in section 603 of the Bipartisan Reform Act of 2015.[43] Specifically, section 603 created two categories of PBDs: 1) those established before November 2, 2015, and 2) those established on or after November 2, 2015. Under section 1833(t) of the Act, excepted off-campus PBDs continue to be paid at OPPS rates.[44] **We believe that CMS does not have the authority to implement the law in a way that eliminates an exception that was established by statute**.

CMS describes increases in the volume of drug administration services provided in off-campus OPDs, as "unnecessary" and cites its authority under section 1833(t)(2)(F) of the to establish a "method for controlling unnecessary increases in the volume of covered OPD services." CMS does not show evidence to support the assertion that the payment differentials are resulting in "unnecessary" increases in volume, let alone any growth in volume. Contrary to CMS' assertion, our analysis demonstrates that drug administration volume is declining even at the current full OPPS payment rate: from 2020 to 2024, the volume for those services at excepted off-campus HOPDs has decreased as a share of HOPD services.[45] Therefore, there is no evidence of recent growth in the types of services that CMS alludes to that would justify reducing payment in the excepted off-campus setting.

Even if CMS asserts that there is an increase in HOPD volume, it must take into account that there may be factors that are outside the control of the hospitals that result in these increases. For example, the increase in volume of services in the HOPD setting could be due to shifts in cases from inpatient to outpatient settings, technological advances, changes in patient demographics, changes in beneficiary needs or availability of care, approval of novel therapies that can be provided exclusively in the HOPD setting, and significant increases in the price of drugs. Additionally, some of the increase in outpatient hospital volume results from independent physicians referring Medicare beneficiaries to a HOPD for essential services that they do not provide in their offices. These services are not the result of an "unnecessary" shifting of services from lower-cost to a higher-cost setting because these services are not available in the physician office. We believe that additional study and analysis, and possibly legislative changes, would be

[43] Pub.L. No. 114-74 section i603, 129 Stat. 584, 597-598.
[44] 42 U.S.C. section 1395l(t)(1)(B)(v)(t)(21)(B)(ii).
[45] Analysis by Watson Policy Analysis (WPA) of 2020-2024 Annual SAF data (quarterly for 2024). HCPCS-level counts of less than 11 are excluded.

necessary before the agency can consider implementing a payment policy to control changes in the volume of drug administration services in HOPDs that are not well-understood, and which may be driven by appropriate clinical or demographic factors, not differential payments.

Additionally, Congress has established a framework for CMS to annually make changes to payments for Medicare covered outpatient hospital services,[46] under which changes to payments that target specific items or services must be budget neutral.[47] Yet, in this rule CMS is targeting a select group of services, drug administration services, for non-budget neutral payment adjustments. According to CMS, the proposed drug administration policy would reduce total hospital payments by $280 million in CY 2026, and $8.150 billion over 10 years, with no offsetting increases in payment for other services. While CMS has authority under section 1833(t)(2)(F) of the Act to develop a method for controlling unnecessary increases in the volume of covered OPD services, when it makes adjustments to payment rates for specific services, it must do so in a budget neutral manner under section 1833(t)(9) of the Act that applies to the entirety of section 1833(t)(2) of the Act.

We recognize that in prior litigation regarding expansion of site-neutral policies to off-campus clinic visits, the D.C. Appeals Court ruled in CMS' favor.[48] CMS indicates that the Circuit Court concluded "a service-specific, non-budget-neutral rate reduction falls comfortably within the plain text of subparagraph (2)(F).[49] However, AAMC disagrees with the Circuit Court's decision and believes if the policy is litigated in a different Circuit, it is likely to be struck down by the Court, particularly under a *Loper Bright* analysis rather than the since reversed *Chevron* framework. At the District Court level, the Court found that:

> the "method" developed by CMS to cut costs is impermissible and violates its obligations under the statute. While the intention of CMS is clear, it would acquire unilateral authority to pick and choose what to pay for OPD services, which clearly was not Congress' intention.

Both the District Court and the Circuit Court did a *Chevron* analysis and the District Court concluded that CMS' site neutral policy failed *Chevron* Step 1 while the Circuit Court concluded CMS was clearly within its statutory authority under *Chevron* Step 1. Neither Court provided CMS with *Chevron* deference under Step 2 but came to opposite conclusions under *Chevron* Step 1. Any future court would not conduct a *Chevron* analysis and would instead use its independent judgment regarding agency actions and interpretations as *Loper Bright* overruled *Chevron*. As indicated by the District Court decision, it is highly possible that a future Court could find CMS' policy to be inconsistent with statute for all the reasons outlined above. If a Court finds CMS' policy to be unlawful, the decision will apply to CMS' clinic visit policy as well as its drug administration policy.

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[46] 42 U.S.C. section 13951(t)(9)(A)
[47] 42 U.S.C. section 13951(t)(9)(B).
[48] 964 F.3d 1230, 1245 (D.C. Cir. 2020)
[49] 964 F.3d 1230, 1245 (D.C. Cir. 2020)

Inconsistency in Estimated Effect of Proposed Changes to Payment for Drug Administration Services

Table 111 (P. 33839) shows the estimated effect of proposed changes to payment for drug administration services when furnished at excepted off-campus providers. CMS estimates that payments would be reduced by $280 million in CY 2026, and in CY 2027, the reduction would be a significantly higher amount, $780 million. CMS appears to be assuming a baseline increase in utilization between 2026 and 2027 of more than 100 percent that would be completely out of line with the increase in any other years. We urge CMS to provide further information regarding how these dollar amounts were calculated, and to make any corrections if there was an error in that calculation. To provide more meaningful comments and better understand the impact, this information is essential.

REQUESTS FOR INFORMATION (RFI): EXPANDING THE METHOD TO CONTROL FOR UNNECESSARY INCREASES IN THE VOLUME OF COVERED OPD SERVICES TO ON-CAMPUS CLINIC VISITS AND ADJUSTING PAYMENT UNDER THE OPPS FOR SERVICES PREDOMINATELY PERFORMED IN THE AMBULATORY SURGICAL CENTER OR PHYSICIAN OFFICE SETTINGS

Expansion of Site Neutral Payment Policies to On-Campus Clinic Visits or For Other Services Provided at On- Or Off-Campus HOPDs Would Reduce Access to Care

In the proposed rule, CMS includes two requests for information on adjusting payments for HOPDs based on purported growth and unnecessary utilization in HOPDs. The first RFI focuses on expanding CMS' clinic visit policy to on-campus clinics and the second RFI more broadly addresses the differences in payment and utilization for services performed in the HOPD as opposed to the ambulatory surgical center (ASC) or physician office setting.

In the first RFI, CMS seeks feedback on expanding its clinic visit policy that went into effect in 2019 to on-campus HOPDs. In the CY 2019 OPPS rule, CMS finalized a policy to pay the PFS-equivalent payment rate for clinic visit services furnished by excepted off-campus HOPDs. CMS is requesting information on whether it would be appropriate to address unnecessary increases in the volume of covered HOPD services by expanding its site neutral policies to on-campus clinic visits. CMS states that the clinic visit is still the most utilized service across the OPPS and over 60 percent of clinic visits furnished under the OPPS are furnished on-campus. CMS seeks feedback on the potential impact of a policy to pay 40 percent of the OPPS rates for clinic visits furnished in on-campus HOPDs. CMS asks whether these clinic visits can be safely performed in other, lower cost settings, and what would be the impact on providers of such a policy, including whether any category of providers would be impacted more than others. CMS also asks about the impact such a policy would have on patients. Additionally, CMS asks whether there would be additional costs associated with on-campus clinic visits.

In the second RFI, CMS seeks feedback for future rulemaking on the development of a more systematic process for identifying ambulatory services at high risk of shifting to the hospital setting based on financial incentives rather than medical necessity and whether to adjust

payments accordingly. Specifically, CMS includes 11 questions, including questions regarding whether they should limit payment based on the site where the service is most performed, the impact of the proposed adjustment on Medicare beneficiaries, whether certain types of services should be exempted from site neutral policies, whether certain hospital types should be exempted from the policy, and if there are other methods other than adjusting payment rates that could be used to control unnecessary increases in the volume of outpatient services.

The AAMC is opposed to the expansion of site neutral policies, whether through application of the clinic visit policy to on-campus HOPDs or through identification of additional services for which payment could be reduced in the on- or off-campus settings. We challenge CMS' premise that there has been unnecessary growth in the volume of services in HOPDs that necessitates a reduction in payment rates. As we explain further below, there are legitimate reasons that could explain different utilization across the various ambulatory settings. **Yet, even if CMS were to focus on utilization and increases in volume, our analysis has shown that over time, the proportion of on-campus clinic visits as a share of all HOPD clinic visits has decreased since 2017 (the year the Section 603 cuts took effect), so there is no evidence to support the assertion that there is unnecessary growth in this setting.**[50]

Site neutral policies stifle access to care for hospitals' complex and vulnerable patients, they undermine and disproportionately affect the academic health systems and teaching hospitals that provide specialized care and innovative procedures in their HOPDs, and they are unlawful under the Medicare statute. Most fundamentally, site neutral policies fail to account for the differences in the types of patients that seek care at HOPDs compared to other ambulatory settings, *even for the same conditions*, and the higher costs that HOPDs incur due to the increased regulatory requirements with which they must comply.

The AAMC has significant concerns with the expansion of site neutral payment policies to on-campus clinic visits or for other services provided at on- or off-campus HOPDs as these significant cuts in payment would reduce access to care, particularly for the sickest and most complex patients that are cared for by AAMC member academic health systems and teaching hospitals. While comprising only seven percent of all OPPS hospitals, AAMC member teaching hospitals would take on 39.4 percent of the payment cut if CMS were to extend its clinic visit policy to on-campus HOPDs. If CMS were to expand site neutral policies to excepted, off-campus PBDs for all services, AAMC member hospitals would receive a staggering 50 percent of the payment reduction.[51]

These disproportionate reductions in payment would come at a time when AAMC-member teaching health systems and hospitals and their affiliated physician practices are already experiencing profound financial challenges that endanger their ability to care for patients and to

[50] Analysis performed by Watson Policy Analysis of final OPPS data for 2015-2023, proposed 2024 data, performed August 2025

[51] AAMC analysis of CY2023 Medicare outpatient claims data, trended forward with CBO's 2024 Medicare baseline. Note: the cumulative effect of multiple proposed cuts may not equal the sum of its parts, due to overlap between proposals.

train the next generation of physicians. According to MedPAC, hospitals' overall fee-for-service Medicare margins dropped to a record low of -13.1% in 2022 and remained at -13% in 2023.[52] The financial outlook for academic health systems is even more grim: AAMC member hospitals' overall Medicare fee-for-service margins were -18.2% in fiscal year 2022. We don't see these trends improving in CY 2026 or the foreseeable future, especially since financial challenges will be further exacerbated by the $1 trillion cut in federal spending on Medicaid and the Health Insurance Marketplace over the next decade as a result of the passage of the OBBBA.[53]

Applying a site neutral policy to HOPD services, including on-campus clinic visits, would be inappropriate as it does not reflect the fundamental differences between the patients receiving care at the HOPD and those receiving care in physician offices, as well as the greater licensing, accreditation, and regulatory requirements for hospitals. Compared to physician offices, patients treated in HOPDs are more clinically and socially complex. Data shows that they have more severe chronic conditions, higher prior utilization of hospital and emergency services, and are more likely to be dually eligible for Medicare and Medicaid, from lower-income areas, and are more likely to be under the age of 65 and disabled.[54]

For safety reasons, physicians often refer sicker patients with higher risk conditions to the outpatient hospital setting for their care since the hospitals have additional resources that enable them to better manage any complications. Additionally, hospitals offer important services such as laboratory, imaging, chemotherapy, surgical and many other services that the patient may need that are not readily available in physician offices. For these patients, the hospital is the best setting to receive their care.

In addition to treating more complex patients, hospitals must comply with a much more comprehensive scope of licensing, accreditation and other regulatory requirements compared to physician offices. Hospitals must adhere to more stringent building codes, life-safety codes, and hospital-level staffing requirements. These requirements make it more costly to provide care in these settings.

Hospitals are the only type of health care provider that delivers emergency care 24 hours a day, 365 days a year to the community, regardless of a patient's insurance coverage or ability to pay. Expanding these site neutral policies to on-campus hospital services or other services would reduce Medicare reimbursement significantly, endangering hospitals' ability to continue to provide 24/7 access to care, capacity for disaster response, and other critical services to the community.

Through their ambulatory networks, AAMC member academic health systems and teaching hospitals expand access to care in their patients' communities—communities that often lack a physician office or ASC. Through these clinics, health systems can provide primary care,

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[52] MedPAC March 2025 Report to Congress. Chapter 3.
[53] H.R. 1 – One Big Beautiful Bill Act. P. Law No. 119-21.
[54] Comparison of Care in Hospital Outpatient Departments and Independent Physician Offices: Updated Findings for 2019-2024. KNG Health Consulting LLC analysis for American Hospital Association. September 2025.

specialty care, cutting-edge imaging, and other key services that keep patients out of the emergency department and the hospital. CMS acknowledges in its question on whether to exempt certain types of services from site neutral payments that there are certain services that are provided exclusively in hospitals, such as trauma care and emergency care. It is therefore imperative that CMS' payment for OPPS services allows health systems to maintain access to care for their patients. Cuts in payment for these services would undermine the very clinics that are keeping these patients healthy.

Finally, CMS lacks the statutory authority to make service-specific adjustments to payment rates for services provided at on-campus HOPDs. Outside of the regular rate setting process, which includes determining weights for Ambulatory Payment Classifications (APCs) based on the resource intensity of the services within that APC, CMS cannot arbitrarily reduce rates under the guise of site neutrality. In enacting Section 603 of the Bipartisan Budget Act of 2015, Congress made a clear distinction that site neutral policies were to apply only to off-campus HOPDs (and specifically, non-excepted HOPDs that were not billing for services furnished before November 2, 2015). Congress chose to specifically reference "off-campus outpatient departments of a provider" and within that category of HOPDs, distinguished between excepted and non-excepted departments. Services furnished at on-campus HOPDs continue to be treated as "covered OPD services" under the OPPS and paid under Section 1833(t)(1)(B)—that is, they are not subject to payment under another applicable payment system under Section 1833(t)(21). Furthermore, CMS' use of the "volume control method" to adjust service-specific rates for purported increases in volume exceeds its statutory authority, as we explain in more depth in our comments above on the proposal to reduce payment for drug administration services.

INPATIENT ONLY LIST

Given The Breadth of Services Included on the IPO List, the AAMC Urges CMS Not to Eliminate the IPO List

The IPO list was established in rulemaking as part of the initial implementation of the OPPS in 2000, pursuant to the Secretary's authority under section 1833(t)(1)(B)(I) of the Act (65 FR 18455). Designation of a service as inpatient only does not preclude the service from being furnished in a hospital outpatient setting, but Medicare will not make payment for the service if it is furnished to a Medicare beneficiary in the hospital outpatient department (65 FR 18443). Currently, the IPO list includes approximately 1,731 services. Services on the IPO list require inpatient care because of the invasive nature of the procedure, the need for at least 24 hours of postoperative recovery time, or the underlying physical condition of the patient requiring surgery. CMS annually reviews the IPO list to identify any services that should be removed from or added to the list based on the most recent data and medical evidence available using criteria specified annually in the OPPS rule.

In the 2021 OPPS/ASC final rule[55], CMS finalized a policy to eliminate the IPO list over three years, beginning January 1, 2021. At that time, AAMC expressed significant concerns with the

[55] 85 Fed Reg 86084 (December 29, 2020).

elimination of the IPO list, which is an important tool to ensure that Medicare beneficiaries receive care in the most clinically appropriate setting. Subsequently, CMS halted the phase-out of the IPO list in the CY 2022 OPPS final rule[56] and restored most of the services that had been removed from the IPO list for CY 2021. In the CY 2026 OPPS rule, CMS again proposes to eliminate the IPO list, beginning in January 2026 with a three-year transition, completing the elimination by January 1, 2029. Because the agency needs time to develop payment rates for services previously not payable under the OPPS, the agency is proposing to eliminate the IPO list in stages beginning with 285 musculoskeletal procedures and 16 non-musculoskeletal procedures. CMS requests comments from stakeholders on whether three years is an appropriate time frame for the transition. The agency also proposes eliminating the criteria for removing procedures from the IPO list as a conforming change.

CMS states in the proposed rule "we have come to believe that, since the IPO list was established, there have been significant developments in the practice of medicine that have allowed numerous services to be provided safely and effectively in the outpatient setting" and "we believe that the IPO list is no longer necessary to identify services that require inpatient care." (p.33667). CMS states that it believes that it is important for the "physician or surgeon and hospital to exercise their professional judgment and assess the risk of the procedure or service to the individual patient, taking into account the site of service and act in that patient's best interest" (page 33665).

Given the breadth of services included on the IPO list, consistent with the position we took in 2021, we urge CMS to maintain the IPO list. There are numerous services on the IPO list that may never be appropriate to furnish in an outpatient setting, such as heart and lung transplants, and coronary artery bypass surgery. Given the complexity and high-risk nature of these procedures and the time frame for postoperative recovery and monitoring before discharge, it would not be safe to perform them in an outpatient setting. Moreover, many of the 285 musculoskeletal procedures listed in Table 69 (p. 33670) for removal in 2026 are invasive, high risk, and require significant post-procedure monitoring. For example, performing facial reconstruction surgery (CPT codes 21145 through 21436), hand replantation surgeries (CPT codes 20808 and 20816) and foot replantation surgeries (CPT code 20838) in an outpatient setting would pose serious risk to patients. Even if CMS' policy would allow payment for these procedures on an outpatient basis, these services will not be performed in outpatient setting – except possibly emergently before an inpatient order is written—making it unnecessary to establish outpatient pricing for these procedures.

CMS acknowledges in the proposed rule the concerns regarding patient safety and quality of care previously voiced by stakeholders if the IPO list were to be eliminated. However, CMS believes that there currently are a variety of safeguards – state and local licensure requirements, accreditation requirements, hospital conditions of participation, medical malpractice laws, and CMS quality and monitoring initiatives – that serve to ensure patient safety even in the absence of the IPO list (page 33667). The AAMC agrees that these safeguards are important, but believes they are insufficient to address the patient safety and quality concerns. **We urge CMS not to eliminate the IPO list. Instead, CMS should continue to solicit stakeholder feedback to**

[56] 86 Fed Reg 63671 (November 16, 2021).

comprehensively evaluate on an annual basis which procedures should remain in the inpatient setting, balancing concerns about beneficiary safety and outcomes and evolving standards of care. If CMS moves forward with its proposal to eliminate the IPO list, we believe that three years is an inadequate time frame to address significant concerns with patient safety and quality.

Enhance the Process to Identify Procedures that Should Not Be Performed in the Outpatient Setting Based on Considerations of Patient Safety and Quality of Care

As described earlier, procedures are performed in the inpatient setting due to factors such as the complex nature of the procedure, the overall medical condition of the patient, and the need for significant clinical monitoring post procedure. In the past, CMS has solicited stakeholder feedback regarding the removal of procedures from the IPO list. As technology changes to allow for more procedures to be performed in the outpatient setting, the IPO list has been modified to accommodate these changes. The AAMC recommends that CMS continue evaluating which procedures and treatments are shown to be safely and successfully performed in the outpatient setting as medical technology advances based on the most recent data and medical evidence available. Additionally, we recommend CMS enhance its criteria for determining which procedures could be safely removed from the IPO list by setting general criteria for procedure selection based upon peer-reviewed evidence, and patient factors, such as age, comorbidities, and social support.

Proposed Exemption of Services that are Removed from the IPO List from Medical Review Activities for Site of Service

Under current policy, Medicare Part A will pay for inpatient surgical procedures, diagnostic tests, and other treatments when the physician expects the patient to require an inpatient stay that crosses at least two midnights and admits the patient based on this expectation or the physician determines the patient requires inpatient care. Physician documentation in the medical record must support that the patient will require hospital care spanning at least two midnights, or the physician's determination that the patient requires inpatient care. Services on the IPO list are not subject to the 2-midnight policy and are paid under Medicare Part A regardless of the expected length of stay. CMS is proposing to exempt procedures that have been removed from the IPO list from certain medical review activities to assess compliance with the 2-midnight rule until the Secretary determines that the service or procedure is more commonly performed in the Medicare population in the outpatient setting (p. 33669) with "commonly performed" defined as 50 percent or of the time. The proposed rule also solicits comments on whether other exemption periods may be warranted.

If CMS finalizes its proposal, we recommend that procedures be exempt from medical reviews for site of service and the 2-midnight requirement for inpatient admission until there is a finding that these services are routinely performed in the outpatient setting as CMS has proposed. We understand that the record must document medical necessity but believe that the medical reviews for site of service should continue to defer to the physician's judgment when the procedure is only appropriate to provide on an inpatient basis.

CMS states in the proposed rule that initial medical review contractors may continue to review claims for procedures previously on the IPO list in order to provide education for practitioners and providers regarding compliance with the 2-midnight rule. Additionally, CMS notes that initial medical review contractors will continue to address any beneficiary quality of care complaints that include concerns about treatment as a hospital inpatient or outpatient, not receiving expected services, early discharge, and discharge planning. If these reviews continue to be performed during the exemption period, as mentioned previously, we believe that CMS should maintain the IPO list and recommend CMS use the information collected from these reviews to determine which procedures should only be performed in the inpatient setting. This information should be made publicly available to stakeholders to better inform patients and providers which surgical procedures are best performed only in the inpatient setting.

Financial Impact of Elimination of IPO List

In addition, we are concerned about the financial and administrative burden of the elimination of the IPO list over such a short period of time, at a time when hospitals are grappling with numerous financial challenges due to historic workforce shortages, supply chain disruptions and insufficient reimbursement from Medicare. When a procedure is removed from the IPO list, the healthier Medicare beneficiaries (who are likelier to have shorter inpatient lengths of stay) are more likely to shift their care to hospital outpatient departments, leaving the sicker and more complex patients as inpatients. Additionally, hospitals will lose any indirect medical education or disproportionate share hospital payment associated with an inpatient procedure being performed in the outpatient setting. Eliminating the entire IPO list over three years will have a significant impact on payments at a time when teaching hospitals are facing profound financial challenges that already seriously endanger their ability to care for patients and train the next generation of physicians.

Furthermore, we are concerned that the elimination of the IPO list may impact provider financial performance in CMS Innovation Center models. AAMC members have been engaged in all the bundled payment models offered through the CMS Innovation Center.

Specifically, CMS' proposal to permit procedures to be reimbursed under OPPS as well as IPPS may significantly alter the composition of the TEAM participant hospitals' patient populations, and thus unfairly hinder hospitals' ability to generate savings under the model. CMS has noted in the past that younger, healthier patients and those with at-home assistance, are more likely to undergo outpatient procedures, meaning a higher proportion of patients receiving inpatient services would be higher-risk and more likely to require additional post-acute care support. As a result, this change in patient mix could increase the average episode payment of the remaining inpatient TEAM cases when compared to current payment levels. Because the episode payments for the remaining inpatient services are reconciled against the baseline target price calculated using both inpatient and outpatient eligible procedures, the remaining inpatient cases would appear high (due to patient mix) relative to the target price. Consequently, hospitals would be more likely to perform worse than the target price and sustain losses in the TEAM model. In the absence of sufficient risk adjustment to modify target prices to reflect CMS' proposed change, some hospitals participating in the TEAM model will be subject to significant financial losses.

Eliminating the IPO list and creating OPPS payment rates for previously IPO services will affect the calculation of episode target prices under TEAM, on an ongoing basis during the first three years of the model. This will introduce unwarranted complexity and financial uncertainty to the model. **CMS should work to ensure that TEAM participants are not negatively impacted with the elimination of the IPO list.**

In addition to the potential impact on participation in CMMI models, we are also concerned that other payers, including Medicare Advantage plans, may use the lack of the IPO list to inappropriately require that patients be treated in the outpatient setting to reduce costs, regardless of the clinical judgement of the physician and needs of the patient.

Quality Measurement and Performance Impact

Eliminating the IPO list without corresponding adjustments to CMS' hospital quality programs will also have unintended consequences for the accuracy of measurement and fairness of performance comparisons. Many of the procedures currently on the IPO list are clinically complex and carry higher risks of complications, readmissions, and mortality. If these cases shift to the outpatient setting, there could be impacts on hospital performance under the Hospital Value-Based Purchasing Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition Reduction Program. Hospitals that serve more medically complex populations may continue to appropriately treat such patients as inpatients, while others shift them to outpatient, likely reducing inpatient measurement validity and reliability in addition to creating inequities in scoring and financial penalties across institutions**.**

At the same time, outpatient hospital departments are not subject to comparable quality reporting requirements for these services, limiting CMS' ability to track outcomes for beneficiaries undergoing complex surgical care. Without addressing these concerns, the elimination of the IPO list would undermine measurement and comparability in hospital quality reporting and performance programs. CMS should not eliminate the IPO list until it conducts a thorough impact analysis and develops a strategy to ensure valid, reliable, appropriate quality performance measurement for both inpatient and outpatient settings of care.

Develop a Mechanism to Determine APC Classifications and Payment Amounts for Services Removed from IPO List

Further, this proposal is premature since CMS does not have the claims, cost and other data that would be necessary to determine the APCs into which procedures removed from the IPO should be classified, and the new payment rates. CMS asks for comments on whether to restructure or create any new APCs or comprehensive APCs (C-APCs) to allow for efficient OPPS payment for services that are removed from the IPO list. Grouping procedures into APCs and creating new APCs for 1731 services would be a huge undertaking, which would most likely not be feasible in three years.

If CMS finalizes its proposal to eliminate the IPO list, the agency will expend significant resources to price services in the outpatient department that have little to no likelihood of being performed on an outpatient basis given current medical technology. For instance, heart

transplantation (CPT code 33945) is currently on the IPO list. There would be no circumstance with existing technology today where a heart transplant could be performed on an outpatient basis; yet CMS' policy to eliminate the IPO list and price all services under the OPPS would unnecessarily require the agency to assign CPT code 33945 to an APC. While a heart transplant may be an extreme, services on the IPO list represent a spectrum and there will be many services less intensive than a heart transplant that are similarly incapable of being performed on an outpatient basis. Alternatively, there may be many services at the opposite end of the spectrum that are less intensive where performance on outpatient basis is more likely for specific patients with existing technology.

Assuming CMS eliminates the IPO list, AAMC recommends that CMS establish a claims processing system edit when a formerly inpatient only procedure is performed in the outpatient department that suspends the claim rather than denying payment or establishing a payment of $0. The claims processing system would then allow for the applicable Medicare Administrative Contractor (MAC) to determine OPPS pricing. This policy would be consistent with CMS' proposal in the CY 2026 outpatient rule to allow MACs to use invoice pricing for Part B drugs furnished in the outpatient department when a drug lacks ASP, WAC, AWP or mean unit cost information to price the drug (see 90 FR 33629). If a contractor can use manual pricing for Part B drugs, a MAC should also have the capability to establish manual pricing when an IPO list procedure is performed on an outpatient basis.

One option the MAC could use is to assign the procedure to a new technology APC or clinical APC based on hospital cost information provided to the MAC as part of the manual pricing process. Once there is sufficient information on hospital costs, CMS could then assign such a procedure to a clinical APC using its normal processes. This process would be parallel to what CMS does currently with new technologies that have insufficient claims to be assigned to a clinical APC and are assigned to a new technology APC based on exogenous cost data. Once CMS has sufficient claims data, CMS could assign the procedure to a clinical APC as it does with all other services.

Given that only a small number of services that are safe to perform would be expected to initially move to the outpatient setting, the burden on the Medicare contractors of manual pricing should be minimal and only be needed the first time a claim is submitted to a given MAC. As utilization grows for a given procedure being performed in the outpatient setting, this process would no longer be needed as CMS' conventional processes using hospitals' costs could be used to assign a procedure to an APC. CMS could further minimize the potential number of claims that would require manual pricing by examining 2021 outpatient utilization during the one year that a large number of musculoskeletal procedures were priced under the OPPS. Costs could be examined for any these procedures with sufficient utilization to make an APC assignment.

AAMC's suggestion would address another issue that has been a perennial problem for hospitals. Under 42 CFR §412.3, an individual is considered an inpatient of a hospital if formally admitted as an inpatient pursuant to an order for inpatient admission by a physician or other qualified practitioner. Under 42 CFR §412.3(c), the physician order must be furnished at or before the time of the inpatient admission. If a patient comes to the ED with an emergency condition, the hospital will treat that condition expeditiously before taking the time to write an inpatient

admission order and formally admit the patient to the hospital as inpatient pursuant to 42 CFR §412.3. Under current policy, this could result in a hospital providing an IPO list procedure before the patient was formally admitted and thus could not be paid. Our suggested policy would allow a hospital to be paid if the hospital provided an emergency medical procedure currently on the IPO list before the patient could be admitted pursuant to an inpatient order by a physician or other qualified practitioner.

This process would reduce the burden on CMS of having to price hundreds of outpatient procedures that do not need immediate outpatient pricing (because these services are highly unlikely to be performed outpatient using existing technology), but still allows a mechanism for the service to be priced on an outpatient basis in the rare event such a procedure is performed in that setting.

AMBULATORY SURGICAL CENTER COVERED PROCEDURES LIST (CPL)

CMS Should Not Eliminate the Current Criteria for Identifying Procedures for the ASC CPL in the Interest of Patient Safety.

CMS proposes significant changes to the ASC-CPL that would modify both the inclusion and exclusion criteria for any surgical procedures considered for the list, removing important guardrails that are currently in place. The ASC-CPL identifies separately payable procedures that can be safely performed in an ASC and would typically not require active medical care or monitoring at midnight following the procedure. The current criteria generally exclude surgical procedures from the list that are prolonged, high risk, or directly involve major blood vessels among several other requirements that protect the patient.

Specifically, CMS proposes to revise its regulatory criteria by removing certain general standard and general exclusion criteria at 42 CFR section 416.166(b) and (c) and moving them to a new section as nonbinding physician considerations for patient safety (page 33717). Specifically, CMS would remove the following two general criteria: 1) that the procedure would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and 2) is one for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. These two criteria would be moved to the physician consideration section. CMS also proposes to remove five current general exclusion criteria at section 416.166(c) and move them to "physician considerations." They include surgical procedures that 1) generally result in extensive blood loss; 2) required major or prolonged invasion of body cavities; 3) directly involve major blood vessels; 4) are generally emergency or life threatening in nature; and 5) commonly require thrombolytic therapy.

Under the revised criteria, CMS proposes to update the ASC CPL (beginning January 2026) by adding 276 potential surgery or surgery-like codes to the list. Additionally, CMS proposes to add 271 surgery or surgery-like codes to the ASC-CPL list that are currently on the IPO list, if CMS finalizes its proposal to remove these services from the IPO list for 2026.

As CMS considers allowing more procedures and treatments to be performed in ASCs, the agency must take into account that not all procedures are suitable to be furnished in the ASC

setting. The AAMC has significant concerns with the proposals to remove the general standard and general exclusion criteria, and we urge CMS not to eliminate these current criteria in the interest of patient safety.

HOPDs Are Better Equipped to Furnish Higher Complexity Services

Patients seeking care at HOPDs, particularly those at teaching hospitals, tend to be sicker and have more chronic and complex conditions compared to patients receiving care in other ambulatory settings. These HOPDs are frequently the sole sources of care for low-income and otherwise underserved populations and are also equipped and staffed to perform complex surgical procedures and furnish advanced treatments to a wide variety of patients. Furthermore, these HOPDs can also provide overnight post-procedure monitoring when needed whereas ASCs are intended only for those patients that do not require ongoing medical monitoring at midnight following the procedure. They are also subject to many regulatory requirements that do not apply to ASCs or physicians' offices. If patients require emergency care, highly trained medical response teams are readily available.

By contrast, ASCs are distinct entities that furnish ambulatory surgical services not requiring an overnight stay in a hospital. The most common ASC procedures are cataract removal with lens insertion, upper gastrointestinal endoscopy, colonoscopy, and nerve procedures.[57] If a patient requires emergency care while undergoing care at an ASC, 9-1-1 must be activated and the patient transferred to a hospital emergency department, potentially delaying life-saving interventions.

The AAMC is concerned that eliminating the current exclusion criteria and general standard criteria and moving them to "physician considerations" as proposed could result in complicated procedures being inappropriately performed in the ASC setting, negatively impacting patient safety and outcomes. We are concerned that there will not be sufficient safeguards to ensure patient safety, thereby increasing safety risks to patients.

We believe that there are numerous procedures listed on Table 80, such as CPT code 37195, administration of a thrombolytic agent intravenously to treat cerebrovascular occlusion, commonly associated with stroke treatment. A stroke is a medical emergency. Patients do not have a stroke treated on a scheduled basis in an ASC. A stroke is a medical emergency that requires treatment in hospital. CPT code 37195 should not be an ASC list procedure. There are several procedure codes for exploration of a penetrating wound (often billed when the patient has a gunshot or a stab wound). There are many other procedures that treat trauma that are not likely to be scheduled and should not be eligible to be done in the ASC. While they do not pose a safety risk when performed in an ASC, the proposed ASC covered procedures list includes several pheresis procedures that are not surgical procedures at all even though an ASC is specifically for surgical procedures. The existence of these procedures on the ASC covered procedures list is indicative that CMS needs to more carefully consider this policy before it proceeds further.

[57] MedPAC, "A Data Book: Health care spending and the Medicare program," July 2020. Available at: http://www.medpac.gov/docs/default-source/data-book/july2020_databook_sec7_sec.pdf?sfvrsn=0.

Unlike HOPDs, ASCs are not equipped to treat complex patients who require significant post-procedure monitoring. Some ASCs require the patient to stay post-procedure in a local hotel and the patient is seen again in the morning. These unusual situations do not provide appropriate post-procedure monitoring for patient safety. In reviewing this list, CMS must consider not only the ability to perform the procedure but the additional need for post-operative monitoring based on the procedure and the patient's age and comorbidities. For these reasons, we urge CMS to not allow complicated procedures to be performed in the ASC until such time as clinical experts determine that these procedures can be performed safely in the ASC setting and that patients are able to be safely discharged to home after the procedure. **Given these safety concerns, the AAMC urges CMS not to remove the general criteria and exclusion criteria as proposed and recommends a comprehensive review of the 276 procedures by clinical experts before adding them to the ASC list.**

ASC Oversight is Severely Limited

We remain concerned that ASCs are also subject to considerably less stringent regulation and oversight. Current safety certification standards for ASCs under the Conditions for Coverage (CfCs) are not as comprehensive as those for the hospital setting, including HOPDs, under the Conditions of Participation. For example, ASCs, while required to maintain an infection control program, they do not have the additional requirement of maintaining an antibiotic stewardship program as required for hospitals.

For these reasons, CMS should <u>not</u> eliminate the current general standards and exclusion criteria. However, if CMS does elect to eliminate the exclusion criteria, the AAMC urges the Agency to establish additional ASC CfCs and other safeguards to ensure patients are adequately informed and protected. As further protection for patients CMS should require physicians to inform patients of the risks of having a procedure in the ASC rather than in an HOPD; in effect, this could become part of the informed consent process. For instance, the physician would need to discuss actions that would be taken in the case of an adverse event or the need for extended post-procedure monitoring which could not be performed in the ASC.

Beneficiary Coinsurance Liabilities are Higher for Procedures Performed in ASCs

Finally, for both proposals (elimination of the IPO list and making the inclusion and exclusion criteria for a procedure to be performed in an ASC considerations rather than requirements), the AAMC reiterates its previous comments[58] that CMS should consider the additional beneficiary cost-sharing in the ASC setting. While Medicare's overall costs may be lower in the ASC for some procedures, beneficiaries are not protected from cost-sharing liabilities in the ASC setting as they are in the HOPD. Currently, a beneficiary's cost-sharing liability is limited to the Part A deductible[59] for a service performed in the HOPD. There is no such protection in the ASC where beneficiary coinsurance for the procedure itself may be less, but beneficiaries pay coinsurance for each separate service. For example, beneficiaries who choose to have a total hip arthroplasty

[58] *See* "AAMC Comments: CY 2020 OPPS Proposed Rule," Sep. 27, 2019. Available at: https://www.aamc.org/system/files/2019-09/ocomm-org-FINALAAMCCY2020OPPSProposedRuleCommentLetter%209_26%20%282%29.pdf.

(THA) in an ASC would have higher cost-sharing than if that same procedure was performed in an HOPD. In adding procedures to the ASC list under either proposal, CMS should carefully consider that beneficiaries are protected from additional cost sharing liability.

MARKET BASKET WEIGHTS FOR THE INPATIENT PROSPECTIVE PAYMENT SYSTEM (IPPS)

CMS Should Not Require Hospitals to Report Median Payer-Specific MA Negotiated Rates on the Cost Report and Should Not Use Those Rates as the Basis for MS-DRG Weights in the Future

In the FY 2021 IPPS final rule, CMS required hospitals to report the median payer-specific charge negotiated by MS-DRG with Medicare Advantage Organizations (MAOs) on their Medicare cost reports effective for cost reporting periods ending on or after January 1, 2021. This information was intended to be used to set the IPPS relative weights beginning in FY 2024. One year later CMS rescinded these policies. In this proposed rule, for cost reporting periods ending on or after January 1, 2026, CMS proposes to reinstate the requirement with some modifications. Specifically, CMS proposes to require hospitals to report on their cost reports the median of the payer-specific negotiated charge by MS-DRG that the hospital negotiated with its MAO, which would be included in the hospital's most recent machine-readable file (MRF) published prior to submission of its cost report. CMS plans to use the information to set IPPS relative weights using a new market-based MS-DRG relative weight methodology, beginning in FY 2029. AAMC urges CMS not to finalize this proposal as we believe it raises statutory concerns, is unnecessarily burdensome on hospitals, and, as CMS itself notes would not involve changes to the MS-DRG relative weights as its research suggests that payer-specific charges negotiated between hospitals and MA organizations are generally well-correlated with Medicare IPPS payment rates.

CMS is Required to Calculate MS-DRG Relative Weights Based on Hospital Resource Costs

Under section 1886(d)(4)(B) of the Act, CMS is required to assign an "appropriate weighting factor" to each MS-DRG, and that weighting factor must reflect the "relative hospital resources" used with respect to discharges classified in that MS-DRG relative to discharges classified in other MS-DRGs. Since 2007, CMS has used a cost-based methodology to determine the relative hospital resources used for each discharge and adjusts the MS-DRG relative weights based on these relative costs. This methodology involves converting hospital charges reflected in the chargemaster to costs using hospital cost-to-charge ratios. This cost-based system for MS-DRG relative weights reflects hospitals relative resource utilization as required by section 1886(d)(4)(B) of the Act.

In the proposed rule, CMS does not provide information that supports how the median payer-specific negotiated rates, as displayed in a hospital's MRF for purposes of the Hospital Price Transparency (HPT) initiative, represents the relative hospital resources used in discharges by MS-DRG. While the AAMC appreciates CMS' interest in moving beyond the hospital chargemaster to set the relative weights, the hospital chargemaster would continue to be required to determine outlier payments. Since CMS is required to use a resource-based weighting system and the hospital chargemaster would continue to be required to determine Medicare payments, AAMC does not see reducing reliance on the hospital chargemaster as sufficient justification for

moving to this new system of determining relative weights. **AAMC requests that CMS not adopt its proposal to adopt median payer-specific MA negotiated rates as the basis for the MS-DRG weights.**

CMS Cannot Require the Submission of Data on Cost Report that Is Unrelated to Payment

The proposed rule suggests that CMS has the authority under 42 U.S.C section 1395 (g)(a) and 1395l (e) to require submission of the median payer-specific negotiated rates through hospital cost reports. While CMS does have the authority to collect certain information through annual cost reports, this authority is for data that is necessary to determine the amount of payment to the provider. Specifically, 1395l (e) bars payment to a provider unless the provider has "furnished such information as may be necessary *in order to determine the amounts due* such provider . . . under this part for the period with respect to which the amounts are being paid or for any prior period." CMS can determine Medicare payment for inpatient hospital services without requiring hospitals to submit median payer-specific negotiated rates through hospital cost reports as it does so currently and has for many years.

Using Hospital MRF Data for The Purpose of Ratesetting Would Result in Distortions and Circularity

AAMC also has concerns about circularity and distortions using the data for the purpose of setting MS-DRG relative weights. Hospital MRF data are limited to charges for items and services and do often do not reflect patient discharges or certain arrangements with payers that are unconnected to the provision of specific items and services (such as capitated or value-based payment arrangements). Therefore, the MRF data is a subset of negotiated rates and does not, and is not intended to, clearly reflect a market-based picture. On top of this, the MA rates displayed in hospital MRFs do not provide any sort of adequate proxy for market-based rates. CMS presumes that MA rates reflect competitive negotiations between hospitals and commercial plans. While this may be the case for some markets and individual hospitals, other factors often contribute to the rates paid by MA plans and private insurers, including whether rates are set based on Medicare fee-for-service or the level of competition (between either hospitals or payors) in the individual hospital's market.

For example, research has shown that, unlike other commercial insurers, MA plans nominally pay only 100-105% of traditional Medicare rates and, in real economic terms, possibly less. Reasons for this include statutory and regulatory provisions that limit out of network payments to traditional Medicare rates, de facto budget constraints of MA plans, and a market equilibrium that permits relatively lower MA rates as long as commercial rates remain well above traditional Medicare rates.[60] As a result, using MA rates that are artificially depressed and based on traditional Medicare rates is both distorting and circular. Given that many MA contracts with hospitals are at a percentage of Medicare's IPPS rate, it seems likely that competitive market forces are limited to the percentage of the IPPS rate being paid (e.g. some percentage above or below the IPPS rate with the MS-DRG being used as a convenience mechanism for determining the distribution of payments among the MA patients the hospitals will treat). This would explain

[60] Why Medicare Advantage Plans Pay Hospitals Traditional Medicare Prices | Health Affairs

CMS' statement that "research suggests that payer-specific charges negotiated between hospitals and MA organizations are generally well-correlated with Medicare IPPS payment rates." [61]

Additionally, in this proposed rule, CMS is proposing to change its policies in the hospital price transparency initiative to require that beginning January 1, 2026, hospitals would be required to report the median dollar allowed amount when a standard charge is based on a percentage or algorithm, which would be defined as the median of the total allowed amount that the hospital has historically received from a third-party payer for an item or service, instead of the previous requirement to calculate an average 'estimated allowed amount.' Under this proposal, hospitals would be required to exclusively use EDI 835 electronic remittance advice (ERA) transaction data to calculate this amount. This is a new methodology for calculating these amounts, and it is unclear whether these dollar amounts will be an accurate reflection of the negotiated rates.

Additionally, as CMS acknowledges in the rule, there are situations where the payment rates agreed upon by MAOs and providers are based on percentages or algorithms and do not lend themselves to an easy calculation of a set dollar amount for each DRG. The payment negotiated between the MAOs and providers may be determined using a methodology that is not based on MS-DRGs, precluding a hospital from directly mapping a dollar amount to an MS-DRG. For example, many third-party payers negotiate rates on a per diem basis, a percentage discount off of charges, or an alternative method. In the rule, CMS acknowledges this challenge and recommends that if there are codes identified that are not MS-DRG codes, or discharges that are not classified to MS-DRGs, the hospitals crosswalk these codes or classify those discharges to MS-DRGs. CMS suggests the use of the CMS GROUPER and its associated definitions manual for this crosswalk. We are concerned that this crosswalk will be difficult, and the variability in provider methodologies for the cross-walking process could skew the data.

Additionally, there are hospital reimbursement methodologies, such as capitation arrangements, value-based reimbursement methodologies, and incentive payment arrangements that would make it difficult to determine a payer-specific negotiated rate for each MS-DRG. It is uncertain how a provider could calculate a payer-specific negotiated rate to be reported on the cost report for these financial arrangements. In the rule, CMS states that it would exclude capitated rates from its calculation. We are concerned that excluding the data from these arrangements could skew the data by excluding hospitals that take on greater levels of risk in their contracts.

It Is Not Possible to Directly Use 'Payer-Specific Negotiated Charges' to Determine Median MS-DRG Amounts

CMS' proposal that hospitals report the "median payer-specific negotiated charges by MS-DRG" is confusing and a misuse of a term used for purposes of the Hospital Price Transparency initiative. Under the Hospital Price Transparency initiative, the term 'payer-specific negotiated charge' (and the resulting median amount which is calculated when the payer-specific negotiated charge can only be expressed as a percentage or algorithm) depends entirely on the specific method (which may or may not be an MS-DRG methodology) that is established by hospitals and payers for reimbursement for specific items and services and service packages. As noted above, not all arrangements between hospitals and payers are displayed in the hospital's MRF,

[61] 90 FR 33807

for example, capitated arrangements and value-based payment arrangements are not represented because such arrangements do not result in data that meets the definition of a 'standard charge'. Additionally, as CMS itself acknowledges, not all payer-specific negotiated charges are established based on the MS-DRG methodology. For example, some hospitals may negotiate rates on a per diem basis and others may negotiate a percentage off each chargemaster rate. Others may negotiate value-based purchasing agreements or capitated rates. As a result, hospitals will have to use their own discretion to crosswalk or otherwise standardize the other methodologies to MS-DRGs which may not always be possible.

The OPPS rule provides a simplified example where a hospital negotiates payments with five different MA organizations and the process whereby a hospital would calculate the median for 12 discharges for a certain MS-DRG. This example grossly oversimplifies the process that most hospitals would have to undertake. For example, a health system operating in numerous states will have multiple contracts for each individual hospital, within each state, and with each payer. This could result in the system needing to array the rates for hundreds of discharges for a given MS-DRG across more than 300 different payor contracts to determine the median.

Additionally, CMS' stepwise guidance in the preamble does not sufficiently explain how to translate the payer-specific negotiated charges (and corresponding codes) for discharges that are referenced in Step 1 to the MS-DRGs that are referenced in Steps 2-4. Specifically, Steps 2-4 require hospitals to identify the number of discharges per MS-DRG, something that cannot functionally be accomplished by using or looking at a set of standard charges. This is because discharges are based on post-claim individual experiences, whereas standard charges, such as the payer-specific negotiated charge for an item or service, are largely pre-claim amounts that apply to a group of people. For example, the 'payer-specific negotiated charge' for 15 minutes of operating room time may be $100. As this would be indicated in the hospital's MRF as a dollar amount, the 'mean payer-specific negotiated charge' for 15 minutes of operating room time would be $100. The hospital, however, may bill and be reimbursed $400 for a patient who needed one hour of operating room time and $500 for another who needed 90 minutes of operating room time. In this example, the amounts associated with each individual's discharge would be different than the amount established as the mean payer-specific negotiated charge. Moreover, it is unclear how the payer-specific negotiated charge associated with 15 minutes of operating room time could be used to establish a median MS-DRG. Instead of providing examples of how hospitals would translate payer-specific negotiated charges into MS-DRGs in cases such as these, the examples given by CMS start with the assumption that all the information has already been neatly packaged into MS-DRGs, thereby sidestepping a significant barrier to using MRF data for the proposed purpose. As a result, we question CMS' use of the term 'payer-specific negotiated charge' and what purpose is served by the awkward and unsuccessful attempt to require use of these data to determine the mean MS-DRG amounts. In fact, throughout the preamble, it appears that CMS is actually proposing that hospitals sort their reimbursement amounts for each 'discharge' into episodes of care that can be defined by an MS-DRG and determine and submit the median of the standardized MS-DRG amount. CMS should be clear about its proposal to calculate and submit median MS-DRG amounts. If CMS chooses to finalize its proposal, we recommend that hospitals be permitted to use actual discharge

information to calculate a median MS-DRG amount rather than require hospitals to artificially derive MS-DRG amounts from 'mean payer-specific negotiated charges'.

HOSPITAL PRICE TRANSPARENCY

CMS Should Review and Streamline the Existing Price Transparency Policies, Rather Than Continuing to Add Requirements as Proposed in This Rule

CMS proposes a number of modifications to its hospital price transparency initiative policies. CMS proposes, beginning January 1, 2026, to require hospitals to disclose the tenth, median and ninetieth percentile allowed amounts in their MRFs when payer-specific negotiated charges are based on algorithms. Hospitals would also be required to include the count of allowed amounts used to determine the percentiles. Additionally, CMS proposes to require hospitals to use electronic data interchange (EDI) 835 electronic remittance advice (ERA) transaction data to calculate and encode allowed amounts in these instances. The agency also proposes to replace the currently required "good faith effort" and affirmation statement in the MRF with a new and expanded attestation, and to encode the name of the hospital chief executive officer, president or senior official designated to oversee the encoding of true, accurate and complete data.

The AAMC supports the goal of increasing health care price transparency and strongly believes patients should have the information that they need to make informed decisions about their health care. We support patient access to consumer-friendly and personalized out-of-pocket cost estimates for shoppable services. Hospitals and health systems have invested considerable time and resources to comply with the HPT Rule and the No Surprises Act. Many hospitals and health systems have embraced new technologies that enable patients to obtain tailored out-of-pocket cost estimates through online tools that can be very effective.

However, we have concerns with the Administration's current approach to price transparency, including the proposals included in this rule. We believe that these price transparency policies are overly burdensome and costly for health systems and hospitals, do not enable patients to understand what they will actually pay for a healthcare service, and have resulted in widespread confusion for patients. Hospitals and health systems and insurers are subject to several different price transparency policies, including:

- **Hospital Price Transparency Rule.** This rule requires hospitals to publicly post via machine-readable files five different "standard charges": gross charges; payer-specific negotiated rates; de-identified minimum and maximum negotiated rates; and discounted cash prices. It also requires hospitals to provide patients with a consumer-friendly display for at least 300 shoppable services, which can be satisfied by offering an online price estimator tool that provides personalized out-of-pocket pricing information.
- **No Surprises Act - Good Faith Estimates.** The No Surprises Act requires hospitals and other providers to share Good Faith Estimates with uninsured/self-pay patients for most scheduled services. "Convening providers" are required to seek and combine information on their price estimates from other unaffiliated providers involved in the patient's care to provide uninsured/self-pay patients with a single, comprehensive Good Faith Estimate of the cost for an episode of care.

- **Advanced Explanation of Benefits.** The No Surprises Act requires insurers to share advanced explanations of benefits with their enrollees. This policy has not been implemented yet due to operational challenges. In the future, hospitals will need to provide Good Faith Estimates to health insurers under this policy.
- **Transparency in Coverage Rules.** These rules, which apply to health insurers and group health plans, require health plans to post three separate MRFs each month that contain: 1) in-network negotiated rates for all covered items and services, 2) out-of-network allowed amounts and billed charges for all covered items and services, and 3) negotiated rates and historical net prices for covered prescription drugs. In addition, insurers must offer their members an internet-based price comparison tool allowing an individual to receive an estimate of their cost-sharing responsibility for a specific item or service from a specific provider or providers (including hospitals), for all items and services.

The amount and complexity of data that hospitals are currently required to provide has resulted in MRFs that are so large that it is extremely difficult for patients to navigate to find "payer-specific negotiated charges" corresponding to their health plan issuer and health plan type. To provide context, many AAMC member-hospitals have contracts with over 100 different plans, often with multiple negotiated rates depending on the type of health plan (e.g. Medicare Advantage, HMOs, individual preferred provider organizations (PPO), self-insured plans), and therefore are required to include tens of thousands of negotiated rates in the MRF. If patients are able to locate this information, they would still be many steps away from deriving a personalized estimate of their out-of-pocket costs due to their health plan's benefit design. In fact, CMS itself has acknowledged that MRFs are not intended for direct patient use as they are not consumer friendly. Specifically, in the CY2024 OPPS final rule, CMS stated: "The MRF format is designed to be used by machines for further processing of the data and is not tailored for direct use by individual patients. In short, MRF formats are not consumer friendly."[62]

Ultimately, the most important and useful information for patients is knowing their financial obligation or out-of-pocket costs for the services they receive, which will be based on a personalized combination of standard charges as well as their insurance coverage. The resulting out-of-pocket costs depend on their plan-specific cost-sharing requirements such as their deductible and co-pay amounts. Where patients are in reaching their deductible and total out-of-pocket spending amounts will impact their payment amount. Additionally, the patients' insurer may cover only a portion of the services and/or bundle some of the services in ways that do not "add up" to the negotiated rates from the provider. All of these specifics make up a health plan product's benefit design, and only the insurer is in a position to make this type of information available to the patient. Therefore, we believe that the information that the insurer is required to provide to the patient under the Transparency in Coverage rules may be much more relevant than any pricing information that providers would be able to deliver to the patient. For patients that are insured, actionable pricing information can be obtained via price comparison tools that insurers are required to make available under the Transparency in Coverage rules.

[62] 88 FR 81540

For patients that are uninsured/self-pay, the No Surprises Act requires hospitals and other providers to furnish the patient with a Good Faith Estimate of their costs for the episode of care. Therefore, much of what is required under the hospital price transparency rule is unnecessarily redundant and burdensome.

We understand that the hospital price transparency rules were established in the absence of the other newer and more targeted authorities under Transparency in Coverage and the No Surprises Act, however, we believe it is past time for CMS to develop a cohesive and streamlined approach to price transparency across these initiatives. Given the patient confusion and regulatory burden resulting from these multiple different price transparency rules, the AAMC urges the Administration, in accordance with the President's Executive Order 14192, to review and streamline the existing price transparency policies, rather than continuing to add requirements as proposed in this rule.

CMS Should Give Hospitals Time to Operationalize the Recent and Significant Adjustments Already Made to The Hospital Transparency Rule Before Adding New Requirements

Notably, CMS recently required hospitals to adopt a new standard format to comply with the MRF requirement, which includes encoding new data elements such as negotiated rate contracting type or methodology, an accuracy and completeness affirmation and (as recently as January 1, 2025) an "estimated allowed amount." CMS has also recently finalized new requirements related to use of .txt files and homepage footers that are designed to allow users of MRFs to find them more easily. These recent policy changes are broad in scope and take time for hospitals to operationalize. While hospitals are making progress on implementing these new requirements, operationalizing such changes is resource-intensive and takes time. Additional changes at this point, such as those proposed in this rule, would threaten to derail progress made to date. Moreover, the proposed January 1, 2026, implementation date does not provide hospitals with enough time to produce their data in a revised CMS template format and to calculate newly proposed data elements (10^{th}, median, and 90^{th} percentile allowed amounts) from EDI 835 remittance advice data. Once an updated CMS template and validator tool are made available, hospitals will need at least 6-12 months to calculate, encode, validate, and display these data. More time will be required if a hospital, as a result of the new requirements, must hire new staff or a vendor that can perform the proposed calculations for the 10^{th}, median, and 90^{th} percentile allowed amounts.

AAMC therefore recommends that CMS take time to assess the impact of CMS' recently implemented requirements and guidance before revising the requirements again so soon. If CMS decides to finalize any of the proposed new requirements, we recommend that CMS provide hospitals with adequate time to implement them by extending the implementation timeline to January 1, 2027. Alternatively, CMS could retain the January 1, 2026, effective date but delay enforcement until January 1, 2027.

The Proposed Attestation Statement is Overly Broad, and We Recommend Retaining the Affirmation Statement in Its Current Form

In this rule, CMS proposes to replace the currently required "good faith effort" and affirmation statement in the MRF with a new and expanded attestation, and to encode the name of the

hospital chief executive officer, president or senior official designated to oversee the encoding of true, accurate and complete data. While we share CMS' goal of making sure that data is accurate and complete, we believe it is important for CMS to recognize that it has made recent and significant adjustments to the Hospital Price Transparency Rule, including changes related to standardization, new data elements, file accessibility, an accuracy and completeness affirmation, as well as changes to CMS' monitoring and enforcement processes.

We support CMS' goal of ensuring that data in the MRF is accurate and complete, and hospitals have invested a significant amount of time and resources to ensure that the data that they provide in the MRF is accurate and complete. It is important to recognize that building files that meet the specifications of the HPT rule, which requires sharing "standardized" negotiated rates, is challenging for AAMC-members, given the realities of hospital billing and reimbursement, and may not be feasible for some hospitals. Often contracts between health plans and providers start with a basic discount off of all gross charges billed on a claim. However, the health plan/provider contract typically has a number of different payment policies that apply to claims that may change the actual reimbursement rate for an individual patient, making it very difficult to accurately identify a single "standard" negotiated charge for a particular service. For example, the insurer may have an algorithm that bundles the reimbursement rate for certain services and results in a payment that varies according to the needs of the individual patient. Providers do not always know how the billed services will be bundled and paid until the claim has been adjudicated by the payer who then transmits the information to the hospital via EDI 835 remittance advice. In addition, the MRFs can become outdated quickly as contracts are frequently updated throughout the year. In fact, some types of charges can change daily based on changes to acquisition costs. All of these factors and others may impact the accuracy and completeness of the HPT MRF files.

AAMC has several specific concerns with the proposed attestation language. Specifically, by removing the phrase "to the best of its knowledge and belief," the proposed revised language no longer leaves room for human error which is necessary when handling (in some cases, manually) millions of datapoints. Additionally, the phrase "has provided all necessary information available to the hospital for the public to be able to derive the dollar amount" is overbroad and lacks specificity; as noted previously, CMS itself has acknowledged that the MRF data is not intended for direct patient use and some contractual algorithms must take into account so many individualized dependencies, they do not lend themselves to being displayed in a single cell in an MRF. Finally, hospitals do not have full control over the accuracy and completeness of EDI 835 ERA data which are developed exclusively by payers. It would therefore be unreasonable to hold hospitals accountable for the accuracy and completeness of data developed by a third party.

For all these reasons, AAMC recommends that CMS retain the affirmation statement in its current form. If CMS decides to finalize a new attestation statement, we recommend, at minimum, that CMS re-instate the phrase "to the best of the hospital's knowledge and belief."

CMS Should Reconsider Its Proposal to Replace the "Estimated Allowed Amount" with a 10th, Median, and 90th Percentile Allowed Amount Using Exclusively EDI 835 Remittance Data

As discussed above, hospitals have recently revised their systems to accommodate the "estimated allowed amount", and hospitals are also required to include the de-identified 'minimum' and

'maximum' negotiated charges in the MRF. CMS does not provide an adequate rationale for its proposal to replace the established min/max and newly-implemented estimated allowed amount with the 10th, median, and 90th percentile allowed amounts or why CMS now believes that the "estimated allowed amount" is less valuable or insufficient to achieve its stated goal of bringing more meaning to hospital standard charges when such charges can only be expressed as an algorithm or percentage. Changing the requirements now would serve only to markedly increase hospital burden without any clear benefit to the public.

CMS also proposes to require hospitals to exclusively use EDI 835 electronic remittance advice data using a one-year lookback period for calculating the 10th, median, and 90th percentile allowed amounts. We have several practical concerns with this proposal. First, as CMS is aware, not all providers receive remittance advice from payers in electronic form.[63] Second, even if CMS were to permit hospitals to use both electronic and paper remittance advice data for calculation of the new data elements, a one-year lookback may not be enough to accumulate an adequate or meaningful count for a payer's plan with which the hospital has recently negotiated or renegotiated a contract. We are specifically concerned about the inclusion of small data sets in this calculation, for example, for services that the hospital provides infrequently. CMS recognizes challenges related to small data sets when it publishes fee-for-service provider utilization and payment data on its own website. [64] As stated in CMS' methodology "To protect the privacy of Medicare beneficiaries, any aggregated records which are derived from 10 or fewer discharges are excluded from the Inpatient dataset." Continuing to permit hospitals to calculate and display an "estimated allowed amount" using all the data available to the hospital sidesteps this problem. Finally, the reimbursement amounts on EDI 835 remittance data may not reflect the true market value of a service package furnished by the hospital because some of the hospital's reimbursement may come in the form of per month supplements or value-based payment distributions. Thus, the calculated 10th, median, and 90th percentile allowed amounts derived exclusively from EDI 835 remittance data is not as meaningful as the "estimated allowed amount" that is currently based on all data available to the hospital.

AAMC therefore recommends that CMS maintain its current requirement for hospitals to calculate and disclose the "estimated allowed amount" using the data available to the hospital. If CMS finalizes its policy as proposed, we recommend that CMS allow hospitals to leave the 10th, median, and 90th percentile allowed amounts blank when the EDI 835 ERA data count is "less than 10" to align with CMS' guidance and best practices for making claims data public. Additionally, if CMS finalizes its policy as proposed, in order to reduce burden, we recommend CMS remove the existing requirement that hospitals include the de-identified minimum and maximum negotiated charges as these do not appear to serve any purpose and can be derived by file users.

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[63] CMS' guidance (Remittance Advice Resources and FAQs) acknowledges that some providers receive remittance advice information on paper.

[64] https://data.cms.gov/sites/default/files/2024-06/MUP_INP_RY24_20240523_Methodology_508.pdf (May 2024)

VIRTUAL SUPERVISION

CMS Should Finalize the Proposal to Make Permanent Virtual Direct Supervision of CR, ICR, PR, and Diagnostic Services

During the COVID-19 PHE, CMS allowed for remote direct supervision of cardiac rehabilitation services (CR), intensive cardiac rehabilitation services (ICR) and pulmonary rehabilitation services (PR) and diagnostic services. This flexibility was extended through December 31, 2024, by the CAA, 2023, and later extended by CMS through December 31, 2025, to allow for the direct supervision of CR, ICR, PR services and diagnostic services via audio-video real-time communications technology (excluding audio-only) under OPPS.[65] Under this year's proposed rule, CMS is proposing to permanently extend remote direct supervision for CR, ICR and PR and diagnostic services under OPPS (excluding audio-only tech) for consistency with the CY 2026 Physician Fee Schedule (PFS) proposed rule (P.33694). **The AAMC is pleased to see the agency propose this extension on a permanent basis and urges the agency to move forward with finalizing.** We refer CMS to more detailed AAMC comments on virtual supervision in our comment letter in response to the proposed CY 2026 PFS proposed rule.[66]

WAGE INDEX

CMS Should Finalize Realignment of the IPPS and OPPS Wage Indexes

In the CY 2025 OPPS final rule, CMS departed from its historical practice of utilizing the same wage index calculations in the inpatient setting as the outpatient setting. This decision had been driven by the agencies decision to discontinue the low wage-index policy and the associated budget neutrality adjustment in FY 2025 for the IPPS, but not the OPPS.[67] As a result, in 2025, there were different wage index calculations for the two payment systems. For CY 2026, CMS is proposing to discontinue the low wage index policy and associated budget neutrality adjustment in the OPPS for 2026 and subsequent years to align with the IPPS wage index. (P.33512). The agency is proposing the same budget-neutral transitional policy from the FY 2026 IPPS rule for hospitals significantly impacted by the removal of this policy. (P.33513).

The AAMC had previously shared our concerns with the misalignment of the IPPS and OPPS wage index in prior comments, [68] and we **urge CMS to finalize the proposal to realign the IPPS and OPPS wage index values.** Lastly, the AAMC highlighted our support of the proposed transitional policy in our FY 2026 IPPS proposed rule comments but urged the agency not to implement in a budget neutral manner.[69] We have the same recommendation regarding the transitional policy in the OPPS.

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[65] 89 FR 93912
[66] AAMC, Comments to CMS On the CY 2026 PFS Proposed Rule (September 2025)
[67] 89 FR 93912
[68] AAMC, Comments to CMS on the FY 2026 IPPS Proposed Rule (June 2025)
[69] AAMC, Comments to CMS on the FY 2026 IPPS Proposed Rule (June 2025)

GRADUATE MEDICAL EDUCATION PROPOSALS

Definition of "Approved Medical Residency Programs"

CMS Should Not Finalize the Proposed Changes to the Definition of Approved Medical Residency Program

The AAMC welcomes the opportunity to comment on the CMS proposal to amend the regulatory text for approved medical residency programs on behalf of the nearly 500 academic health system and teaching hospital member institutions. The AAMC is not an accreditor of graduate medical education programs, but our members provide 70% of residency training in the United States.[70] We believe that any changes to GME policy should be guided by objective research and designed to produce a measurable, positive change to the development of our future physician workforce.

The CMS is proposing to amend the criteria for approved medical residency program accrediting and oversight organizations. By statute, only approved medical residency programs are eligible to receive Medicare direct graduate medical education (DGME) and indirect medical education (IME) reimbursements.[71] Under 42 CFR 413.75(b) for DGME and 412.105(f)(1)(i) for IME, CMS outlines the organizations eligible to approve medical residency programs. The effective date for the proposed amendments is January 1, 2026.

Specifically, CMS proposes that accreditors may not use accreditation criteria that promote or emphasize diversity, equity, inclusion or awareness based on race, color, sex, sexual orientation or identity, national origin, or any other characteristic which serve as a proxy to achieve the same ends.[72] Accrediting organizations have been stewards of program oversight for over 40 years, and have developed standards that incorporate a broad range of clinical safety requirements, account for differing patient populations, and ensure every resident meets similar educational requirements. The added language is an unnecessary deviation from the deference CMS has given to accrediting bodies to establish appropriate standards for GME programs.
The AAMC respectfully disagrees with the Agencies assertion that such language is necessary to "…ensure that accreditors of academic medical institutions are focused on the mission of ensuring excellence in graduate medical education…" and fears that these changes may substantively interfere with patient and resident safety. The amended definitions will likely cause unnecessary confusion among GME stakeholders and uncertainty for hospitals that rely on accrediting organizations for approved medical residency program status. The AAMC urges CMS to not finalize the proposed changes to the definition of approved medical residency program accrediting and oversight organizations.

[70] AAMC analysis of AHA Annual Survey Database FY2023 and NIH Extramural Research Award data. Note: Data reflect all short-term, general, nonfederal hospitals.
[71] 1886(h)(5)(A).
[72] 90 FR 33860-1.

HOSPITAL QUALITY MEASUREMENT PROGRAMS PROPOSALS

CROSS-CUTTING PROPOSALS AND REQUEST FOR INFORMATION

Extraordinary Circumstances Exception (ECE) Policies

Align ECE Request Deadlines with ECE Policies for Inpatient Quality Reporting and Performance Programs

CMS proposes to reduce the timeframe from 90-days to 30-days of the date of the extraordinary circumstance for a hospital to request an ECE under the Hospital Outpatient Quality Reporting (OQR) Program, Rural Emergency Hospital Quality Reporting (REHQR) Program, and the Ambulatory Surgical Center Quality Reporting (ASCQR) Program. (p.33757) **The AAMC does not support this proposal and instead urges CMS to align the reporting timeframe in these programs with the 60-day timeframe for the hospital inpatient quality reporting and performance programs**.[73] In adopting a 60-day request timeframe for the inpatient programs, CMS acknowledged stakeholder concerns with a proposed 30-day timeframe as insufficient time for a hospital to assess the impact on quality data submissions and complete the necessary paperwork following an extraordinary circumstance.[74] The AAMC believes the same consideration should be given to hospitals and facilities participating in the OQR, REHQR, and ASCQR Programs.

Ensure Extensions Under Revised ECE Policy Do Not Become the Default Relief for Hospitals Requesting an ECE

CMS proposes to update the Extraordinary Circumstances Exception (ECE) Policy for the Hospital Outpatient Quality Reporting (OQR) Program, Rural Emergency Hospital Quality Reporting Program, and the Ambulatory Surgical Center Quality Reporting Program to consistently include reporting extensions as a form of relief CMS may grant hospitals in response to a hospital's ECE request across the programs. (p. 33757). **The AAMC supports the proposal to provide an intermediate form of relief for hospitals experiencing extraordinary circumstances that temporarily affect their ability to submit data.** We ask CMS to commit to providing transparency when it grants both forms of relief (and in which circumstances) to ensure that reporting extensions are not disproportionately utilized as the default relief even where a full exception to reporting may be more appropriate relief.

Measure Concepts Under Consideration for Future Years—RFI: Well-Being and Nutrition

New Measures Should be Valid, Reliable, and Meaningfully Connected to the Measured Entity's Care Setting

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[73] 90 FR 36536, at 36942, 36961, 36966, and 37027 (Aug. 4, 2025)
[74] *Id.*

The AAMC supports the agency in its efforts to improve well-being and nutrition in part through its quality measurement programs. In general, we believe that new quality metrics should be endorsed by a Consensus-Based Entity as valid and reliable for the measured entity (i.e., valid and reliable for analysis of performance of ambulatory care in the outpatient setting when considered for use in the OQR, REHQR, or ASCQR). In the case of new measures for well-being and nutrition in the OQR, we believe that the metrics must be meaningfully connected to the delivery of high-quality outpatient ambulatory care. Some measure concepts, while critically important to improving population health, may not be valid and reliable for the outpatient facility care setting, and instead be better used in health plan or public health department quality measurement and improvement.[75]

OUTPATIENT QUALITY REPORTING (OQR) PROGRAM

Consider Modifications to Proposed New Measure on Emergency Care Access & Timeliness to Ensure Measurement Meaningfully Supports Quality Improvement Efforts

CMS proposes to adopt the Emergency Care Access & Timeliness eCQM beginning with voluntary reporting in CY 2027 followed by mandatory reporting beginning CY 2028. CMS believes this new measure would more comprehensively measure the quality and timeliness of care in the ED relative to existing measures in the OQR. (p. 33758) **The AAMC strongly supports quality measurement that can meaningfully help hospitals to improve access to and timeliness of quality ED care.** Such measures must be specified such that they measure that which is within the hospital's control, and not the upstream or downstream influences on the ED boarding crisis in this country.

The proposed measure is comprised of four numerator triggering events, based on ED encounters where the patient experiences: (1) wait time longer than one hour after arrival to the ED to be placed in a treatment room or dedicated area that allows for audiovisual privacy during history-taking and physical examination, (2) patient left the ED without being seen, (3) the patient boarded in the ED for longer than four hours, or (4) the patient had an ED length of stay longer than eight hours. The measure denominator includes all ED encounters of all patients, across all insurance coverage types and payers, during a 12-month period of performance. Encounters are included in the numerator only once, even if the same encounter includes multiple numerator events. ED encounters with ED observation stays are excluded from components (3) and (4), but are included in the denominator. The measure score is calculated first as the proportion of ED encounters where any one of the four outcomes occurred, and then standardized by ED case volume using z-scores to compare performance to the average of a similar-volume ED. ED volume strata are defined in volume bands of 20,000 ED visits. CMS will stratify results into four groups: two by age (18 and older and under 18 years of age) and two by mental health diagnoses (with and without). CMS believes the volume stratification and stratification by age

[75] For example, "Dehydration Admission Rate (PQI 10)" is a well-being measure for a population, assessing data from claims in the acute care facility that analyzes performance at the city/county/national population-level and "Well-Child Visits in the First 15 Months of Life" is a well-being measure of care delivered in the ambulatory care setting that analyzes the performance of health plans and integrated delivery systems.

and mental health diagnosis "is sufficient to account for differences between hospitals without further need for risk adjustment." (p. 33759)

ED throughput is most strongly correlated to hospital inpatient capacity. MedPAC observed hospital occupancy rates nationally around 69 percent, though the Commission acknowledge consideration variation in capacity.[76] Our member teaching hospitals have continued to operate at or above 100 percent capacity since the COVID pandemic. One major cause of operating at (or above) capacity is challenges with discharging patients to post-acute care (PAC) settings, specifically issues with available PAC beds and delays due to onerous prior authorization requirements. While we support CMS efforts to stratify performance to ensure fair "like for like" comparisons between EDs, the AAMC encourages CMS to consider additional or alternative stratification factors such as teaching status and trauma level designation, to better ensure performance comparisons capture similarly situated capacity constraints. We do not believe comparisons based on number of ED encounters, age, and mental health diagnoses alone is sufficient to account for differences between hospitals.

The AAMC is also concerned that this measure, as currently specified, may actually hinder ED throughput quality improvement activities. This is because it combines separate and distinct issues within the course of ED throughput into a combined measure, making it challenging for a hospital to understand where, during an ED encounter, there are *actionable* areas for improvement. It also does not distinguish a hospital's performance on wait times versus boarding times for patients and their families. We strongly urge CMS to consider the Pre-Rulemaking Measure Review Hospital Recommendation Group's feedback to CMS to revise the measure to create separate measure components, rather than a total combined score to ensure performance measurement can support quality improvement activities and meaningfully inform patients.

Finally, specific to the first two numerator events, wait time longer than one hour after arrival to be placed in a treatment room or dedicated area that allows for audiovisual privacy during history-taking and physical examination and left without being seen, we ask CMS to consider revising the qualifier to ensure novel ED triage programs could qualify as appropriate treatment for the encounter and not trigger a measure event. For example, some programs now employ strategies where clinical staff first triage within the waiting room of the ED, based on chief complaint and initial assessment of lower acuity patients, to appropriately redirect patients to timely clinic visits (either urgent care clinics or to primary care clinics). We are concerned that such programs would not be sufficient to not trigger the first numerator event, even if the patient is triaged within an hour of ED arrival. In these instances, if the patient is triaged and appropriately redirected to a clinic within an hour, we are concerned that it could then trigger the second numerator event.

[76] MedPAC, Report to Congress, Chapter 3: Hospital inpatient and outpatient services (Mar. 2025), stating, "In addition, hospitals' occupancy rate remained at about 69 percent, and the median percentage of emergency department patients who left without being seen remained near 2 percent."

Indefinitely Allow Voluntary Reporting of Excess Radiation or Inadequate Image Quality for Diagnostic Computed Tomography eCQM

CMS proposes to continue voluntary reporting of the Excess Radiation or Inadequate Image Quality for Diagnostic Computed Tomography eCQM (Excess Radiation eCQM) indefinitely beginning with the CY 2027 reporting period, when the measure was previously finalized to become a mandatory measure in the OQR, in response to continued feedback on the complex interfaces necessary to develop, maintain, and report the measure, including the financial burden and operational feasibility needed to translate CT radiology data into standardized eCQM-consumable data used by the measure. (p. 33762) **The AAMC supports this modification to reporting and commends CMS for proactively responding to hospital feedback regarding the measure.**

Finalize Measure Removals as Proposed

Measures Proposed for Removal Under Factor 8: Costs Associated with Measure Outweigh the Benefit of the Measure's Continued Use in the Program

CMS proposes the removal of four quality metrics, Hospital Commitment to Health Equity (HCHE), Screening for Social Drivers of Health (SDOH), Screen Positive Rate for SDOH, and COVID-19 Vaccination Rate Among Health Care Personnel, in recognition of the burden on hospitals to collect and report data for these measures. (pp. 33754-33756) CMS estimates that the cumulative reporting time burden on hospitals in the OQR is roughly 2,158 hours of staff time at an average cost of $118,819 annually (p. 33813). The AAMC supports CMS decision to remove these measures and appreciates the agency's efforts to evaluate existing measures and remove those with disproportionate costs relative to observed improvement in patient care**.**

Measures Proposed for Removal Under Factor 4: Availability of a More Broadly Applicable Measure for the Topic

CMS proposes to remove two chart-abstracted measures, Median Time From ED Arrival to ED Departure for Discharged ED Patients and Left Without Being Seen, effective with CY 2028 reporting in relation to the proposed adoption of the new Emergency Care Access & Timeliness eCQM (p. 33761). The AAMC supports this proposal in recognition that the Emergency Care Access and Timeliness measure, if appropriately modified, provides an alternative approach to quality measure used to assess ED throughput.

OVERALL HOSPITAL QUALITY STAR RATING

Ensure Policies to Greater Emphasize Patient Safety in the Star Ratings Best Reflect Patient Priorities and Appropriately Balance Safety with Important Areas Like Patient Experience and Mortality

CMS proposes to modify the Overall Hospital Quality Star Ratings methodology to better emphasize patient safety performance. (p. 33785) Currently, the methodology weighs the Safety of Care measure group equally with Mortality, Patient Experience, and Readmissions. Additionally, hospitals may receive a rating if they have three measure scores in at least three measure groups, so long as one of those measure groups is Safety of Care or Mortality. This means there are hospitals that are included in the ratings without comprehensive assessment of their performance on patient safety measures.

The AAMC has previously supported an approach where an individual user on *Care Compare* could customize the overall group weights and see a different set of ratings in response to those preferences.[77] We continue to believe customizable ratings is the best policy, as it allows individual engagement with the overall ratings to help inform decisions on where to seek care. For a patient who cares most about experience or mortality, they're able to do so without CMS dictating that Safety should be the *de facto* measure group to move the needle. Alternatively, recognizing the complexity to provide variable ratings information, CMS could maintain the methodology as is and apply a unique flag to any hospital in the bottom quartile of performance on Safety and a separate, distinct flag to any hospital without a Safety score to highlight information that might be of interest.

Policy-Based Star Rating Cap (2027 Only)

CMS proposes to apply a maximum rating cap of 4-stars for hospitals that perform in the bottom quartile of performance on the Safety group for one year only. (p. 33786) The AAMC is concerned this policy would do a disservice to patients and communities when choosing a hospital, as their hierarchy of measure groups might not be represented by the ratings. We believe it is an error to assume a patient would prefer a hospital that had no Safety of Care performance but achieves a 5-star rating to a hospital that was reduced to 4-stars due to its Safety of Care measure group performance.

Policy-Based 1-Star Reduction for Poor Performance on Safety of Care (Starting in 2028)

CMS proposes adopting a permanent policy-based adjustment where the agency will reduce the rating of any hospital in the bottom quartile of performance on the Safety of Care measure group, beginning with 2028 ratings. Under this policy, any hospital receiving a rating of 2 stars up to 5 stars would see their rating drop by 1 star based on their bottom quartile performance on the Safety measure group (hospitals with a 1-star rating would remain unchanged). CMS notes this policy would have reduced the rating for 459 of 2,847 hospitals in the July 2024 ratings. (p. 33786) The AAMC is concerned that this is not meaningful and will not drive performance improvement, considering the majority of those 459 hospitals received a 2- or 3-star rating. This suggests that ratings *already* indicate some level of reduced performance relative to top

[77] AAMC, Comments re: Overall Hospital Quality Star Rating on Hospital Compare Public Input Request (Mar. 19, 2019), referencing Friedberg and Gurvey, Personalized Hospital Performance Report Card: Review, Customize, and Compare Hospital Overall Star Ratings, RAND (Aug. 29, 2018).

performers. It is unclear how a star reduction in such cases will drive performance improvement, as every year up to a quarter of all hospitals could be subject to a star reduction.

Conclusion

Thank you for the opportunity to comment on this proposed rule. We would be happy to work with CMS on any of the issues discussed or other topics that involve the academic medicine community. If you have questions regarding our comments, please feel free to contact my colleagues – Gayle Lee (galee@aamc.org), Shahid Zaman (szaman@aamc.org) and Katie Gaynor (kgaynor@aamc.org) on the payment proposals; Bradley Cunningham (bcunningham@aamc.org) on the GME proposals; Phoebe Ramsey (pramsey@aamc.org) on the quality program proposals.

Sincerely,

Jonathan Jaffery, M.D., M.S., M.M.M., F.A.C.P.
Chief Health Care Officer
AAMC

Cc: David J. Skorton, M.D., AAMC President and Chief Executive Officer