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Dr. Mehmet Oz Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1833-P 7500 Security Boulevard Baltimore, MD 21244-1850

Re: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2026 Rates; Requirements for Quality Programs; and Other Policy Changes (CMS-1833-P)

Dear Administrator Oz,

The Association of American Medical Colleges (AAMC or the association) welcomes this opportunity to comment on the proposed rule entitled "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2026 Rates; Requirements for Quality Programs; and Other Policy Changes," 90 *Fed. Reg.* 18002 (April 30, 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, health care, biomedical research, and community collaborations. Its members are 160 U.S. medical schools accredited by the Liaison Committee on Medical Education; 12 accredited 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 graduate medical education payments, hospital payment, quality proposals, and requests for information (RFIs) in the Fiscal Year (FY) 2026 Inpatient Prospective Payment System (IPPS) Proposed Rule.

- *Graduate Medical Education Provisions*. The AAMC thanks CMS for restating and clarifying FTE determinations for cost reporting periods other than twelve months.
- *Market Basket Update*. Increase the market basket update to account for increased costs, particularly the effect of tariffs on hospital supply costs.

- Disproportionate Share Hospital and Uncompensated Care Payments. Increase transparency related to the calculation of the "other" factor in the Factor 1 calculation. Account for the potential of higher rates of uninsured individuals in Factor 2.
- *Labor Related Share:* Ensure accuracy and transparency in the methodology and data used to calculate the labor-related share of the IPPS base payment.
- Low Wage Index Policy: Evaluate factors negatively affecting wages at low wage index hospitals and establish policies to support these hospitals without harming high wage index hospitals.
- *CAR-T:* Further refine policies to ensure payment for CAR T-Cell therapies are adequate by considering both standardized drug costs and diagnostic codes to correctly identify CAR T-Cell therapy clinical trial cases.
- Cross-Cutting Revision to Quality Program Extraordinary Circumstances Policies: Adopt an intermediate form of relief for hospitals experiencing extraordinary circumstances that temporarily affect their ability to submit timely data.
- *Transition to Digital Quality Measures RFI*: Share information on hospital testing and feasibility to report FHIR-based measures and ensure a sufficient timeline for all hospitals to successfully transition to FHIR-based measures.
- Hospital Readmissions Reduction Program: Do not introduce unfair measurement and payment bias into the program by adding Medicare Advantage patients and payment data into performance measurement and fee-for-service penalty calculations.
- *Inpatient Quality Reporting Program*: Finalize the removal of measures from the program, modify hybrid measure EHR-derived data reporting threshold requirements, and consider further delay of the mandatory reporting period for hybrid EHR reporting based on analysis of hospital experience with the July 2024 June 2025 voluntary reporting period.
- Transforming Episode Accountability Model: Use the Community Deprivation Index for beneficiary-level economic risk adjustment, ensure adequate risk adjustment by extending the hierarchical condition categories lookback period, establish a low-volume threshold with no downside financial risk, implement a consistent, well-tested set of quality metrics for the duration of the model, and refine the primary care services referral requirement to improve patient access to care and outcomes.

GRADUATE MEDICAL EDUCATION PROVISIONS

The AAMC thanks CMS for restating and clarifying its longstanding policies used to determine FTE counts and caps for Direct Graduate Medical Education (DGME) and Indirect Medical Education (IME) reimbursements in cost reporting periods other than twelve months. Because no resident may be counted as more than 1.0 full-time equivalent (FTE) in a twelve-month period, certain adjustments to the standard twelve-month FTE determination must be made in cost reporting periods other than twelve months. While CMS is not proposing a new policy for determining FTE counts or caps in nonstandard cost reporting periods, the transparency and public evaluation of the current policies is welcomed by the academic medicine community. Also, CMS's commitment to listen to stakeholders is helpful to refine the overall efficacy of these policies. If stakeholders raise legitimate concerns about this or other policies, CMS should thoughtfully consider their feedback and remain responsive to their input.

PAYMENT PROPOSALS

PROPOSED MARKET BASKET UPDATE

Increase the Market Basket Update for FY 2026 to Accurately Incorporate Expected Growth in Hospital Input Costs

CMS is proposing an increase to the standardized amount of 2.4 percent, reflecting a market basket update of positive 3.2 percent and a total factor productivity adjustment of negative 0.8 percentage points for FY 2026. We are concerned that the data used to calculate the FY 2026 market basket update are not representative of the significantly higher growth in labor and supply costs hospitals continue to experience and which are expected to rise in FY 2026 due to the widespread effect of tariffs on the supply chain. Due to the timing of the projections that the CMS Office of the Actuary used, which was made in December 2024, the effects of tariffs on hospital costs are not accounted for in this market basket projection. The inadequate proposed FY 2026 update, coupled with market basket updates in preceding years that fell short of the actual pace of inflation, necessitate a course correction from CMS to ensure Medicare payments are accurately updated to reflect hospital input costs.

The data used to calculate the market basket update do not accurately reflect the dramatic increase in labor and supply costs that hospitals and health systems have experienced since FY 2022. Hospitals continue to experience substantial annual increases in their expenses, with year-over-year labor expense increases at 6 percent and 9 percent for non-labor expenses.² 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 2022.³ 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 2022.⁴ We do not see these cost trends lessening in FY 2026 or the foreseeable future. On the contrary, in the face of continued economic and supply chain uncertainty stemming from tariffs and other external pressures, we expect these conditions to worsen in 2026. In recognition of the unabating cost increases hospitals face, MedPAC recommended that to ensure beneficiary access to care and hospital access to capital, Congress should direct CMS to provide a payment update 1 percent above the market basket update.⁵ This is the third year in a row that MedPAC has called for an update above the market basket update.

The insufficiency of the FY 2026 proposed market basket update is compounded by underestimates by CMS in FYs 2022 through 2024 of actual cost increases. As shown below in Figure 1, in comparing forecast data CMS uses at the time of the final rule with updated market basket data, it is clear that CMS has consistently underestimated market basket updates in recent years, with a staggering three percentage point underestimate in FY 2022.

¹ Hospitals that successfully report quality measures and are meaningful users of electronic health records are eligible for the full payment update.

² Kaufman Hall March 2025 National Hospital Flash Report. May 7, 2025. https://www.kaufmanhall.com/sites/default/files/2025-05/KH-NHFR-Report Mar 2025 Metrics.pdf

³ MedPAC March 2025 Report to Congress. Chapter 3.

⁴ 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.

⁵ MedPAC March 2025 Report to Congress. Chapter 3.

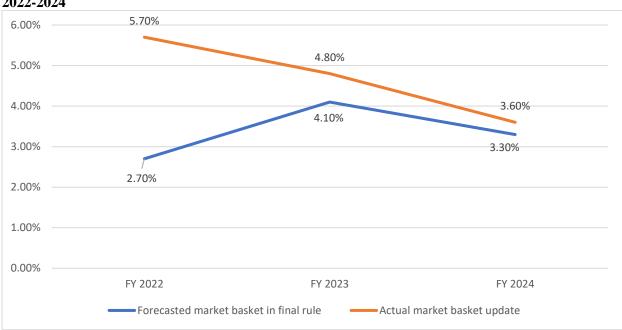


Figure 1: Forecasted Regulation Market Basket Updates vs. Actual Market Basket Updates, FYs 2022-2024

Source: Forecasted market basket updates are from the respective fiscal year IPPS final rule. Actual market basket updates are from CMS published 2024Q4 forecast with historical data through 2024Q3 (Summary Web Table_2024Q4 available at https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-data).

The gap between forecasted and actual market data underscores that CMS continues to underestimate actual cost increases and thus does not accurately account for true increases in hospital input costs. For example, in FY 2022, hospitals experienced record high inflation and significant increases in the costs of labor, drugs, and equipment, yet CMS's market basket update was wholly inadequate in accounting for these costs. CMS calculates the market basket based on forecasts rather than actual labor and supply cost increases, thus failing to incorporate the challenging circumstances brought on by unprecedented labor, supply, and drug cost increases. Therefore, using the current methodology to calculate the payment update inaccurately estimates the financial strain hospitals have experienced and will continue to experience in FY 2026 and is insufficient to address these cost increases. Furthermore, the effect of underestimating the market basket is amplified due to the compounding nature of payment updates, with each year's payment update building on the previous year's. We recommend CMS look to alternative data sources that better reflect true labor and input cost increases in a more timely manner. At a minimum, CMS must provide additional publicly available data on the assumptions and inputs that go into developing a market basket update.

With the imposition of tariffs, hospitals will inevitably experience significant price increases in FY 2026 on items such as pharmaceuticals, medical supplies, medical devices, and building materials used in capital projects.⁶ Routine supplies such as enteral syringes, which come exclusively from China, are

⁶ Healthcare Dive. Tariffs send healthcare industry into 'unchartered waters'. April 4, 2025. https://www.healthcaredive.com/news/tariffs-aha-med-tech-brace-for-impact/744496/.

subject to a 245 percent tariff. Other common supplies and personal protective equipment, such as gowns, gloves, and masks, are also subject to tariffs and are routinely imported. 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. While pharmaceuticals are exempt from reciprocal tariffs, the administration has begun exploring imposing tariffs on pharmaceuticals and pharmaceutical ingredients, 10 with President Trump indicating pharmaceuticals could soon lose their exemption. 11 CMS must ensure that in its final market basket update for FY 2026, it appropriately includes the cost increases attributable to tariffs. In addition to the inadequate market basket update of 3.2 percent, CMS includes a higher-than usual total productivity adjustment of negative 0.8 percentage points, which reduces the net payment update to 2.4 percent. The proposed productivity adjustment is the largest CMS has used since FY 2019 and is the second largest in the 15 years for which CMS has published data.

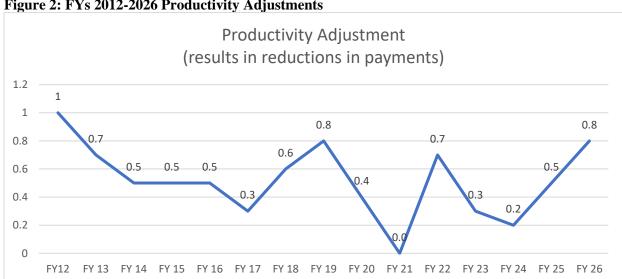


Figure 2: FYs 2012-2026 Productivity Adjustments

Source: 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.

Productivity adjustments are based on a 10-year rolling average of data CMS acquires from the Bureau of Labor Statistics. Because the productivity adjustment has increased significantly, CMS should evaluate how the rolling average experienced such a significant increase when compared with the productivity adjustments ranging from 0.2 to 0.5 percentage points in the last three years.

⁷ Premier. Potential Impacts of Tariffs on Healthcare. Apil 28, 2025. https://premierinc.com/newsroom/policy/update-premier-supply-chain-special-report-tariffs

⁸ Axios. Hospitals Begin to Grapple with Tariff Fallout. May 1, 2025. https://www.axios.com/2025/05/01/hospitalsstruggle-tariff-impacts

https://www.beckershospitalreview.com/supply-chain/hospital-finance-supply-leaders-predict-15-increase-intariff-related-costs/

¹⁰ Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients, 90 FR 15951 (April 16, 2025).

¹¹ https://www.fiercepharma.com/pharma/short-reprieve-pharma-commerce-secretary-lutnick-says-drug-tariffscome-next-month-or-two

Given the low payment update proposed for FY 2026, coupled with persistent increases in hospitals costs that are expected to worsen as tariffs take effect, we call on CMS to utilize its "exceptions and adjustments" authority to make a one-time adjustment to the FY 2026 hospital update for forecast error in the FYs 2022 and 2023 hospital market baskets. Just as CMS has done in recent years for skilled nursing facilities (SNFs) and the capital IPPS update to adjust for discrepancies between the projected and actual market basket updates, CMS should make an adjustment for IPPS operating costs. Because CMS has not traditionally applied a forecast error adjustment in the IPPS, we emphasize this would be a one-time adjustment to correct for significant underestimates of the market basket update amidst historical hospital input cost growth. For the FY 2025 SNF update, CMS finalized a policy to increase the market basket update of 3 percent by an additional 1.7 percentage points. For the FY 2024 SNF update, CMS finalized an increase in the market basket update of 3.0 percent by an additional 3.6 percentage points for forecast error in application of the FY 2022 update. These adjustments indicate CMS' acknowledgement of the insufficiency of previous years' market basket updates.

In both payment systems, CMS applied the forecast error adjustment based on previously established policy if the difference between the update and the actual rate of inflation using after-the-fact data differs by more than a threshold amount (0.5 percentage points for the SNF update and 0.25 percentage points for the capital IPPS update). While CMS has not developed an analogous policy for the IPPS operating update, we believe such a forecast error adjustment to the FY 2026 IPPS operating update could be adopted under CMS' rulemaking authority.

MEDICARE DISPROPORTIONATE SHARE HOSPITAL (DSH) AND UNCOMPENSATED CARE PAYMENTS

Medicare DSH payments are a vital source of support for academic health systems and teaching hospitals, which provide a disproportionate amount of uncompensated care (UC) compared with all hospitals nationally. While representing only 5 percent of all short-term general acute care hospitals nationally, AAMC member hospitals provide 29 percent of all UC as measured by costs. ¹⁵ The DSH payments these hospitals receive enable them to continue to provide care to their low-income patients and offset their high levels of uncompensated care.

Since the Affordable Care Act's (ACA's) revised DSH methodology went into effect in 2014, CMS makes DSH payments to hospitals in two forms: as empirically justified DSH payments and as UC-based DSH payments. A hospital's empirically justified DSH payment amount is 25 percent of the DSH add-on payment it would have received using the traditional DSH formula. The UC-based DSH payment is calculated as the product of three factors: Factor 1, which represents 75 percent of aggregate projected traditional DSH payments across all eligible hospitals; Factor 2, which is equal to one minus the change in the uninsured rate from 2013 (the year before the ACA's coverage expansions took effect) to the fiscal year in question; and Factor 3, which represents each DSH hospital's UC costs as a proportion of all DSH hospitals' UC costs. By multiplying factors 1 and 2, CMS arrives at the total pool of UC-based DSH payments. Multiplying this pool by each hospital's factor 3 results in the hospital's individual UC-based DSH payment. Each of these factors is dependent on the data sources and assumptions CMS uses to calculate them and can vary significantly if those sources or assumptions change.

¹² Section 1886(d)(5)(I) of the Social Security Act

¹³ 89 FR 64048, at 64054 (Aug. 6, 2024).

¹⁴ 89 FR 53200, at 53205 (Aug. 7, 2023).

¹⁵ Source: AAMC analysis of a special tabulation of the FY2023 American Hospital Association (AHA) data. AAMC membership data, December 2024.

For FY 2026, CMS estimates Factor 1 (the total pool of DSH funds before it is reduced to reflect the change in the uninsured rate) to be \$11.843 billion (p.18468). We note that the proposed rule and the Medicare DSH supplemental file published by CMS contain a discrepancy in the published Factor 1, with the preamble to the proposed rule including a Factor 1 of \$11.761 billion (18256). We assume that the \$11.843 billion is the correct figure but ask that CMS confirm the correct number and ensure it addresses the underlying calculation error when it calculates Factor 1 in the final rule. After Factor 2 is applied to reflect the changes in the uninsured rate, CMS calculates a total UC-based payment pool of \$7.19 billion. In comparison to the previous years' UC-based payment pool, this marks an uptick in the amount of funds available for distribution to DSH hospitals. Final Prior to FY 2026, the UC-based payment amounts available each year steadily decreased from FYs 2020 to 2025, with a dramatic decline between FY 2021 and FY 2022. This has raised concerns around the transparency of data used and the inability to validate the accuracy of CMS' overall DSH projections without having full visibility into the inputs that determine DSH payments. For example, the effects of the COVID-19 PHE on Medicare discharges, case mix, Medicaid enrollment and subsequent disenrollment through determinations, all have an effect on CMS' estimates.

These reductions in DSH payments have proved problematic for hospitals as they continue to incur significant amounts of uncompensated care, face unprecedented cost and workforce pressures, and brace for coverage losses and associated increases in uncompensated care resulting from regulatory and legislative changes. Going forward, CMS must ensure robust, accurate, and transparent calculations of DSH payments so that they remain a sustainable source of funding for hospitals treating low-income patients and are protected from large swings attributable to fluctuations in the uninsured rate or inaccuracies in CMS' projections.

Provide Greater Transparency Around "Other" Factors Used to Determine Factor 1

CMS utilized the Office of the Actuary's (OACT's) January 2025 Medicare DSH estimates that were based on the December 2024 Hospital Cost Report Information System (HCRIS) update and the FY 2025 IPPS/LTCH PPS final rule impact file to estimate Factor 1 (p.18256). CMS bases these estimates on OACT's Part A benefits projection model which creates a baseline for Factor 1 and is then updated using a number of additional factors including annual Medicare payment updates, discharges, case mix, and "other" factors (p. 18257). For FY 2026, CMS notes some of the "other" factors applied to Factor 1 include payment rate adjustments that are not reflected elsewhere in the applied factors but does not specify what these entail. CMS is not comprehensive in its explanation of the "other" factors and does not detail what data is utilized for this or how it is applied (p.18257). CMS also references changed Medicaid enrollment as being included in the "other" factor but does not give adequate information to assess the impact.

The AAMC does not believe that CMS is providing sufficient transparency around the data sources or calculations used in the application of these "other" factors. In other words, not all the factors considered as "other" are known or understood by stakeholders to appropriately replicate CMS' calculations. The lack of transparency in the calculations of Factor 1 is further underscored by the discrepancy in the Factor 1 values CMS published in the proposed rule preamble and the DSH supplemental file, which stems from different "other" values that CMS uses in calculating estimated FY 2023 DSH payments, which it then

¹⁶ However, we note that in recent years, when CMS has updated its Factor 1 and Factor 2 calculations, the UC pool has decreased from the proposed to final rule.

trends forward to 2026. This highlights the need for CMS to be transparent in its assumptions and calculations so that stakeholders can replicate CMS' Medicare DSH projections.

As mentioned in our FY 2022 IPPS comment letter, we continue to echo our concerns that the information being used in the "other" factor is not accurately accounting for the effects of the COVID-19 PHE. Additionally, it is unclear how this "other" factor takes into account changes in Medicaid coverage resulting from Medicaid policy changes. The AAMC strongly urges CMS to provide greater transparency on how OACT determines the "other" factor—including both the calculation and individual numbers included in the estimate—so that stakeholders can adequately understand and assess the appropriateness of the Factor 1 amount and the impact of external factors on the Factor 1 calculation in FY 2026. While CMS does provide some examples of the types of data that is included in the "other" factor such as Medicaid enrollment and various payment adjustments, not enough specific and meaningful information is provided to allow stakeholders to determine how these affect the factor. Since it is unclear how influential each of these are and it is unknown what other unnamed factors are considered, the AAMC cannot be confident in assessing the reasonability or appropriateness of the proposal.

One potential way of addressing this issue would be to disaggregate the "other" factor into the main variables that affect its value. CMS could show the impact of each of these named factors and its weight in the "other" factor with a residual for all other items that have less of an impact on the final value.

Account for Expected Higher Rates of Uninsured Individuals Due to Policy Changes Leading to Coverage Losses in the Calculation of Factor 2

Factor 2 of the uncompensated care methodology determines the total available UC-based payment pool. This is determined annually by a percentage amount that represents the percent change in the rate of uninsured individuals in FY 2013 and the estimated percent of uninsured in the most recent year where data is available. OACT determines Factor 2 based on data from the National Health Expenditures Accounts (NHEA). CMS is proposing to continue to use the same methodology to calculate Factor 2 as the agency has in previous years. To calculate the uninsured rate in FY 2026, CMS uses a weighted average of the projected uninsured rates in calendar years 2025 and 2026.

We do not feel that the current proposal for Factor 2 takes into account the magnitude of the dramatic increase in uninsured rates that will occur in FY 2026 due to various policy changes that will result in coverage losses. For example, the enhanced premium tax credits for enrollees in the Affordable Care Act health insurance marketplaces are set to expire under current law at the end of 2025, which in 2026 would result in loss of coverage for four million individuals. An additional 1.8 million individuals are expected to lose coverage due to changes that CMS proposed in its Marketplace Integrity and Affordability rule, which was codified in the reconciliation bill that the House of Representatives passed on May 22. In previous years, CMS underestimated the impact of disenrollments, such as the effect of Medicaid redeterminations on the uninsured rate. With this in mind, we urge CMS to consider alternative data sources or calculations that more accurately account for the expected increase in the uninsured rate for FY

¹⁷ AAMC, Comments to CMS on the FY 2022 IPPS Proposed Rule (June 2021).

¹⁸ Congressional Budget Office Baseline Projections. The Premium Tax Credit and Related Spending. July 2024. https://www.cbo.gov/system/files/2024-07/60523-2024-07-premium-tax-credit.pdf

¹⁹ 90 FR 12942 (March 19, 2025).

²⁰ One Big Beautiful Bill Act. H.R. 1. 119th Cong.

2026. We are concerned that the current data from the NHEA that CMS is proposing to utilize for Factor 2 is not up to date. If CMS chooses to continue with its proposal of utilizing the NHEA data, which do not appear to be accurately accounting for coverage losses, then CMS must ensure that its estimates are accurate and up to date.

LABOR RELATED SHARE UPDATES

To calculate the payment that hospitals receive under the Medicare IPPS, a portion of the base payment is adjusted by a hospital's wage index. The portion that is adjusted is known as the labor-related share. This share is equal to either the standardized share of 62 percent or CMS' estimated national labor-related share, whichever results in a higher payment. Hospitals with a wage index less than 1.000 will receive a labor-related share of 62 percent, while those with a wage index of greater than 1.000 will receive CMS' estimated national labor-related share. CMS updates the estimate of the national labor-related share every four years, and the estimate is due for an update in FY 2026. Currently in FY 2025, CMS' estimate is based on the 2018-based IPPS market basket for discharges after October 1, 2021, resulting in an estimated national labor-related share of 67.6 percent. CMS is proposing to recalculate the estimated national labor-related share using the proposed 2023-based IPPS market basket cost category weights for discharges occurring after October 1, 2025. This would reduce the labor related share from 67.6 percent to 66 percent, reducing the portion of the IPPS base payment rate subject to the wage index. (P.18236). This would disproportionally negatively impact hospitals with a wage index greater than 1.000.

Ensure Accuracy and Transparency in Payment Methodologies and Data Used to Calculate the Labor-Related Share

Included in the proposed rule are the cost category weights CMS utilizes for the labor-related share. Of these, all but the labor-related professional fees remained the same or were reduced from the 2018-based IPPS market basket cost weights to the new proposal based on 2023-based IPPS market basket data. (P.18246). However, in an analysis from KFF and Peterson Center that evaluated changes in hospital employment data, including wage data, from February 2020 at the start of the COVID-19 pandemic through early 2024, wages were found to have increased. These findings are puzzling when compared to what we observed in CMS' proposed cost weights. This analysis found that the average weekly earnings for healthcare employees had gone up 20.8 percent from \$1,038 to \$1,254 weekly in January 2024. Even more specific to IPPS, the report found that hospital workers wages saw a 20.3% increase between February 2020 to January 2024, going from \$1,269 to \$1,527 per week. CMS also observed this shift in wages in the agency's analysis of audited wage data for FY 2020 to 2021 in the FY 2025 IPPS proposed rule, which saw larger increases in average hourly wages and wage indexes than compared to years prior. Given these findings, we believe that CMS' methodology may not be accurately or fully capturing hospital labor expenses reflected in these trends.

To verify the validity of the agency's proposed changes, the AAMC and other stakeholders often replicate CMS' calculations and estimates to verify the accuracy of proposed changes impacting hospital payment. Through this exercise, we were not able to replicate the proposed 66.0 percent labor-related share as CMS has not issued enough information on the intermediate steps used to determine the rebasing to allow

²¹ Section 1886(d)(3)(E) of the Social Security Act

²² "What are the recent trends in health sector employment?" Peterson-KFF Health System Tracker, March 27, 2024.

^{23 89} FR 36151

stakeholders to fully replicate the agency's calculations with certainty and verify CMS' estimate. We understand the need for rebasing the labor share but request that CMS release additional information on how it arrived at its proposed estimate for the national labor-related share for FY 2026. In our attempt to replicate this year's proposed labor-related share in conjunction with Watson Policy Analysis, we calculated a higher labor related share than the 66.0 percent proposed by CMS. However, without additional information, it is impossible to tell if this calculation is a result of an error on our part, CMS' part, or just a difference in methodology or rounding. To accurately replicate and verify the labor related share, we request CMS publish a table of their intermediate steps reflective of the numerators and denominators utilized in each cost category and calculation step. To that end, it would be helpful to also include the dollar values used to calculate the percentage of each cost category. Without this information and transparency, there are gaps in understanding that add challenges to interpreting how CMS calculates the proposed values used to establish the labor-related share. Lastly, this creates more challenges in providing valuable feedback without adequate understanding of how CMS has arrived at these proposed values for the labor-related share.

MEDICARE WAGE INDEX - LOW WAGE INDEX POLICY

In the fiscal year (FY) 2020 IPPS final rule, CMS first implemented the low wage index policy to address disparities between high and low wage index hospitals in the current wage index calculation.²⁴ The finalized low wage index policy directly raised the wage index of the lowest quartile wage index hospitals by half the difference between the 25th percentile wage index value and the hospital's individual wage index. The goal of this policy was to provide an opportunity for these low wage index hospitals to increase employee compensation, which would then be permanently reflected in future wage index data. However, while this policy raised the wage index values of the bottom quartile hospitals, it did so at the expense of all hospitals nationwide due to a budget neutrality adjustment.

CMS implemented this policy for four years from FY 2020 until the end of FY 2023 to allow low wage index hospitals to raise wages, but due to the impact of the COVID-19 public health emergency, the agency extended this policy, once in FY 2024 and then again in the FY 2025 IPPS final rule for an additional three years. During this time, the low wage index policy and associated budget neutrality adjustment faced multiple legal challenges. Prior to the release of the FY 2025 IPPS final rule, the U.S. Court of Appeals for the D.C. Circuit ruled that CMS did not have the authority to implement the low wage index policy or the associated budget neutrality adjustment. Based on the court's July 23, 2024, decision in *Bridgeport Hospital v. Becerra* CMS reversed the continuation of the low wage index policy and associated budget neutrality adjustment for FY 2025 in the FY 2025 IPPS Interim Final Action (IFC). To continue CMS' compliance with the courts orders, CMS is proposing in the FY 2026 IPPS proposed rule to discontinue the low wage index policy and the associated budget neutrality adjustment in FY 2026 and beyond. (P. 18233). The AAMC appreciates CMS' efforts to correct these wage index policies as ordered by the U.S. Court of Appeals.

²⁴ 84 FR 42044

²⁵Bridgeport Hosp. v. Becerra, 589 F. Supp. 3d 1 (D.D.C. 2022)

²⁶ Kaweah Delta Health Care Dist. v. Becerra, 1:21-cv-01422 AWI SKO (E.D. Cal. Sep. 22, 2021)

²⁷ Bridgeport Hosp. v. Becerra, No. 22-5249 (D.C. Cir. Jul. 23, 2024)

²⁸ Id.

²⁹ 89 FR 80405

Ensure the Reversal of the Low Wage Index Policy Has Minimal Harm For All Hospitals

In addition to removing the low wage index policy and associated budget neutrality, CMS is proposing a narrow transitional payment exception for low wage index hospitals significantly impacted by the removal of the low wage index policy in FY 2026. This is similar to the transitional policy included in the FY 2025 IPPS IFC.³⁰ CMS defines significantly impacted hospitals as those that have a proposed FY 2026 wage index decreasing by more than 9.75 percent from their FY 2024 wage index. These impacted hospitals would receive 90.25 percent of their FY 2024 wage index for FY 2026. The policy allows impacted hospitals to receive a slightly higher wage index calculation than if only the cap on wage index reduction was included, which would result in hospitals receiving only 90 percent of their FY 2024 wage index. However, this policy would be budget neutral, which differs from the transitional policy included in the FY 2025 IPPS IFC. CMS cited the timing of the IFC as their reason why they did not originally include a budget neutrality adjustment, but the agency feels this proposed rule allows more notice for stakeholders to respond and comment, making it appropriate to include the budget neutral adjustment in this proposal. (p. 18234).

The AAMC appreciates CMS ensuring there is support for impacted low wage index hospitals by proposing a transitional policy. However, we remain concerned with the inclusion of an associated budget neutrality adjustment that harms higher wage index hospitals for policies to remedy negative impacts on low wage index hospitals. The AAMC supports CMS' underlying goal of addressing financial difficulties faced by low wage index hospitals, but we urge the agency to do so without hindering the payment or wage index of the non-eligible hospitals. Including a budget neutrality adjustment for this policy perpetuates the same issues that arose with the original low wage index policy, which improved the standing of low wage index hospitals at the expense of higher wage index hospitals. This very practice was found by the courts to have exceeded the agency's authority and is the basis for why a transitional policy is now needed. Further, the AAMC does not believe that the agency having more time to issue notice and comment changes requirements for use of a budget neutrality adjustment is a valid reason for making this adjustment. If the agency was able to implement this policy in the FY 2025 IFC without inclusion of a budget neutrality adjustment, it should also be able to do so here. This is especially true given that the scope and magnitude of the proposed FY 2026 transitional policy is even more minimal than the FY 2025 IFC transitional policy. The impact to payment in FY 2026 is \$10 million dollars less than FY 2025. (p. 18235). Therefore, we urge the agency to move forward with the transitional policy but ask the agency not to finalize the proposed budget neutrality adjustment associated with the transitional policy.

Identify Factors and Policies to Support Low Wage Index Hospitals Without Impacting High Wage Index Hospitals Through Budget Neutrality

As described in our response to the FY 2025 IPPS IFC, the AAMC supports CMS' removal of the budget neutrality adjustment associated with the low wage index policy as we have historically been critical of implementing policies to support low wage index hospitals at the expense of higher wage hospitals.³¹ Despite this, we still support CMS' goal to address the difficulties faced by low wage index hospitals resulting in wage disparities and urge the agency to consider alternative policies that improve the standing and ensure adequate reimbursement to low wage index hospitals without negatively impacting payment to

³⁰ 89 FR 80405

³¹ AAMC, Comments to CMS on the FY 2025 IPPS IFC (Nov. 2024)

other hospitals. We also emphasize our prior comments on the low wage index policy in the FY 2025 IPPS proposed rule and years prior to encourage CMS to further investigate the specific factors causing these wage disparities.³² This will allow the agency to evaluate how the wage index has been impacted following the original implementation of the low wage index policy, the disruptions from the COVID-19 public health emergency, and what other factors may be contributing to the disparities in wage index values. Gaining this understanding will make way for CMS to implement more effective and impactful wage index policies.

Re-Align the Wage Index Calculations for Hospital Inpatient and Outpatient Settings

Finally, in the calendar year (CY) 2025 Outpatient Prospective Payment System (OPPS) final rule, CMS departed from its historical practice of utilizing the same wage index calculations in the inpatient setting as the outpatient setting. For CY 2025 under OPPS, CMS continued to utilize the FY 2025 IPPS final rule (not the interim final rule) wage index values that were inclusive of the low wage-index policy and the associated budget neutrality adjustment. ³³ The AAMC shared our concerns with this misalignment in our response to the FY 2025 IPPS IFC, and we remain concerned that a continuation of this misalignment in 2026 will create confusion and uncertainty in hospitals' expected payment. ³⁴ Continuing this misalignment would be a significant departure from the agency's historical practice and could have significant impacts to payment polices in the future that create discrepancies between the two payment systems. Further, continuing to allow for the use of the low wage index policy and associated budget neutrality adjustment in the OPPS context calls CMS' statutory authority into question given the decision in *Bridgeport Hospital v. Becerra.* ³⁵ **Due to this, the AAMC urges the agency to restore its historical precedent of aligning wage index values in IPPS and OPPS in FY and CY 2026.**

While CMS believes that the agency may still apply the low wage index policy and associated budget neutrality adjustment in the OPPS context³⁶, the AAMC disagrees. Given the interconnectedness between IPPS and OPPS, we do not believe that just because the OPPS statute is slightly less prescriptive on how the agency can calculate the wage index values, that the agency can still apply a policy in OPPS that was found to exceed statutory authority under IPPS. This is especially true as CMS has aligned the wage index calculations for both settings since the establishment of the OPPS due to the inseparable, subordinate status of the Hospital Outpatient Department (HOPD) within the hospital overall, meaning there is no significant variability in the geographic makeup of the HOPD and the hospital overall that would require a separate wage index calculation for these two settings.

CHIMERIC ANTIGEN RECEPTOR (CAR) T-CELL THERAPY

Teaching health-systems and hospitals serve as key institutions for patients to receive innovative cutting-edge treatment such as CAR T-cell therapy. These therapies are provided at designated treatment centers, which are almost exclusively within academic health systems as these are the institutions best positioned to provide cutting edge care and manage complications (often life threatening) that are encountered as the patient goes through this course of care. They remain committed to advancing treatment options through medical knowledge of new therapies and technologies to prevent and treat disease. CAR T-cell therapy is

³² AAMC, Comments to CMS on the FY 2025 IPPS Proposed Rule (June 2024)

³³ 89 FR 93912

³⁴ AAMC, Comments to CMS on the FY 2025 IPPS IFC (Nov. 2024)

³⁵ Bridgeport Hosp. v. Becerra, No. 22-5249 (D.C. Cir. Jul. 23, 2024)

³⁶ 89 FR 93975

just one example of these cutting-edge therapies predominantly furnished at teaching health-systems and hospitals. New technologies often come with high price tags and CAR T-cell therapy is no exception as has been discussed extensively through rulemaking in recent years. Ensuring accurate and sufficient payment of these therapies is essential to guarantee patient access. Without proper reimbursement, providers may be unable to provide services and support to the patients who need it most as they pursue these treatment options. As we anticipate additional cutting-edge therapies entering the market, especially in the cell and gene therapy space, we look forward to working with CMS to guarantee reimbursement to hospitals is adequate and reflects the condition of the patient being treated.

Finalize Policies to Ensure CAR T-Cell Therapy Clinical Trial Cases are Correctly Identified

We remain supportive of CMS' policies to exclude CAR T-cell clinical trial cases from the calculation of the relative weight for MS-DRG 018.37 Removing the clinical trial cases allows CMS to evaluate the true costs of CAR T-cell cases given that many of the clinical trial CAR T-cell cases do not include the cost of the CAR T-cell therapy. Including these cases would skew the calculation of the relative weight for MS-DRG 018 given the high cost of the therapy and would not accurately account for the cost to hospitals for these treatments if cases for which the hospital obtains the treatment at zero cost are included. Building on this policy, CMS is proposing for FY 2026 to continue its current methodology to exclude claims in MS-DRG 018 with the presence of condition code "90" or ICD-10-CM diagnosis code Z00.6 without payeronly code "ZC" that group to MS-DRG 018 as well as a new proposal. Condition code "90" is used to identify claims where a service was provided under expanded access approval, meaning that the service was provided to a patient under special FDA approval outside of a clinical trial. Meanwhile, ICD-10-CM diagnosis code Z00.6 describes an encounter in a clinical research program, while the condition code "ZC" indicates that the payment adjustment factor for clinical trials should not be applied to the case. The cases that use condition code "ZC" are typically those where the product was purchased in the usual manner, but the case involves the clinical trial of a different product. In the new proposal, CMS would also exclude claims with standardized drug charges below the median standardized drug charge of clinical trial cases in MS-DRG 018. The agency would apply this policy for two years until the claims data reflects the condition code for immunotherapy products not purchased in the usual manner, such as those purchased at no cost to the provider. (p. 18079).

We agree with CMS' proposal to exclude claims with standardized drug charges below the median standardized drug charge of clinical trial cases in MS-DRG 018. This proposal would include an additional layer of review to ensure there are no cases that are mislabeled. Over the years CMS has refined its methodology to identify clinical trials, and we have previously shared concerns that strictly identifying a clinical trial case by Z00.6 without also looking at the drug costs, could exclude cases that include the full cost of the CAR T-cell therapy. While CMS has made improvements in its methodologies to avoid this scenario, the AAMC still believes the most accurate method would include evaluating standardized drug charges. As the agency continues to tweak and expand its guidance for coding, claims may be wrongly coded or misidentified by condition codes or ICD-10 codes for a clinical trial that reflects the use of a CAR T-cell therapy. Such an occurrence could result in underpayment by excluding a case despite it having the full cost for the product and underpaying hospitals across the board for the treatment. A clinical trial adjuster would also be applied to cases marked as clinical trials or expanded access, lowering payment for the specific case that is not truly a CAR-T clinical trial. **Due to**

^{37 88} FR 58640

³⁸ AAMC, Comments to CMS on the FY 2021 IPPS Proposed Rule (July 2020)

this, the AAMC urges CMS to finalize its proposal and consider further refining its methodology to consider both standardized drug charges and diagnostic codes to correctly identify CAR T-Cell Therapy clinical trial cases. This will ensure that CMS has the most accurate methodology so that hospitals are adequately reimbursed for clinical trials and full cost CAR T-cell therapy as well as clinical trial cases for other treatments, but also include CAR T-cell therapy. This is essential to guarantee patient access, which without proper reimbursement may be at risk.

HOSPITAL QUALITY PROGRAMS

CROSS-CUTTING PROPOSALS AND REQUEST FOR INFORMATION

Ensure Extensions Under Revised Extraordinary Circumstances Exception (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 Readmissions Reduction Program, Value-Based Purchased Program, Hospital-Acquired Condition Reduction Program, and Hospital Inpatient 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. 18289, 18301, 18303, and 18344, respectively). **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 that CMS 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.

RFI: Transition to Digital Quality Measures (dQMs)

The AAMC supports a long-term goal of implementing a digital and interoperable quality measurement enterprise. Such an enterprise has great promise to improve patient outcomes and experience while also lessening quality measurement burdens for both health systems and the federal government. We also support the use of Fast Healthcare Interoperability Resources (FHIR), as this standard is internationally supported and easier to implement and more fluid than many other available frameworks. However, prior to adopting FHIR-based dQMs, we recommend CMS prioritize the adoption of data modernization guidance to ensure public and private infrastructure are well-equipped to support this shift in interoperable data reporting pathways necessary for successful FHIR-based reporting.

Each Measure Under Consideration for Transition to FHIR-based Measurement Should be Evaluated for Potential Benefits and Security Risks and Costs Prior to Proposing the Transition for Use in CMS Programs

The AAMC supports CMS dQM initiative's initiative to adopt self-contained measure specifications and code packages that can be transmitted electronically via interoperable systems. Though dQMs may be helpful for some quality measures to better assess public health and outcomes data, transitioning to dQMs for all measures may not warrant the risk and burden. Given that dQMs require additional considerations for compliance due to the specificity of information, we request the creation of regulatory frameworks to protect patient safety and privacy. In choosing which quality measures to move to dQM, CMS should formally evaluate the potential difference in performance and benefit that could be achieved and

weigh it against the security risk and cost. If the impact of conversion to DQM does not outweigh the burden for a given quality measure, we believe that conversion to FHIR-eCQMs may be sufficient.

Publicly Share Information on Progress to Re-specify eCQMs to FHIR-based Measurement, Including Testing and Feasibility

CMS discusses efforts it is taking to convert current eCQMs to FHIR-based eCQMs using Quality Improvement-Core (QI-Core) Implementation Guides. This includes efforts undertaken through HL7 Connectathons and integrated systems testing. The AAMC asks CMS to publicly share more on this effort, including information on real-world testing and feasibility of the FHIR-based eCQMs. We are concerned that only the most sophisticated health systems can engage with FHIR testing activities and may not be able to provide a comprehensive or representative sample of issues hospitals might face with implementing FHIR-based measurement. During the conversion from QRDA to FHIR, we underscore the importance of data validation to mitigate data gaps and inconsistencies, given that the outputs using QRDA and FHIR can differ even when using the same quality measure definition. Additionally, FHIR-based specifications for eCQMs should go through the measure endorsement process by a Consensus-Based Entity prior to their proposed adoption in CMS programs to ensure the measures, as re-specified, are valid, reliable, and feasible to report.

Ensure a Sufficient Timeline, Greater than 24 Months, for Hospitals to Transition to FHIR-based eCQM Reporting

Specific to timing, CMS asks whether a minimum of 24 months from the effective adoption of FHIRbased eCQM reporting option through ONC Health IT Certification Program criteria is sufficient time for hospital implementation. Similarly, CMS asks if a two-year reporting options window is sufficient prior to mandating eCQMs be reported using FHIR-based methods. (p. 18326) The AAMC believe a longer timeframe will be necessary to support successful transition to FHIR-based eCQM reporting. Changes to ONC Health IT Certification Program criteria often take time to realize on the ground within the EHR and challenges with implementation are only compounded when these changes are needed to meet reporting requirements tied to Medicare funding. For example, CMS initially revised the specifications for the hospital-wide measures in the IQR to become hybrid EHR-based measures, without any direct tie to a CEHRT criteria change, with a two-year voluntary reporting period before transitioning to mandatory status. That voluntary reporting period had to be extended due to the challenges faced by those hospitals able to invest in voluntary reporting, and in this rule CMS proposes further reducing thresholds for reporting EHR-based data to ensure hospitals will be able to successfully report. (p. 18343) Based on this experience, we urge CMS to consider implementation and reporting requirement transitions greater than 24 months to ensure all hospitals have sufficient time to successfully report FHIR-based measurement. We also advocate for flexibility in allowing health systems to choose whether or not to use the FHIR server for data extraction and calculations during this transition period.

HOSPITAL READMISSIONS REDUCTION PROGRAM (HRRP)

Do Not Add Medicare Advantage (MA) Patients and Payment Data to HRRP Measures

CMS proposes to modify all measures in the HRRP to integrate MA patients into each measure and reduce the applicable performance period by one year to a two-year period. (p. 18283) CMS states that integrating MA patients into the measure would ensure that the readmissions measures capture the

outcomes across all Medicare patients, and that with the observed and projected growth of the MA-covered population, failure to include MA patients in the measures would exclude a large segment of the Medicare population for quality measurement. (p. 18284) The AAMC recognizes the growth of MA and agrees that it is critical to ensure quality of care across the entire Medicare population. However, where quality measurement is tied to payment penalties in fee-for-service (FFS) Medicare, we strongly believe that measurement must directly tie to quality outcomes for similarly situated FFS patients and for performance within the hospital's control. The AAMC strongly urges CMS not to finalize this policy in recognition that the addition of MA patients will unfairly penalize hospitals for MA plan behavior rather than hospital quality performance and introduce bias into HRRP.

MA Benefit Design Limiting Access to Appropriate Post-Acute Care is Incongruous with Fair Measurement of Hospital Performance in the HRRP

Patients who receive their Medicare benefit through a MA plan accept different benefit design than that of patients who choose traditional FFS Medicare, including provider network restrictions, referral requirements, and prior authorization of services like post-acute care. A Congressional investigation has highlighted how MA plans deny MA patients access to medically necessary post-acute care. ^{39, 40} This is significant when measuring readmissions, as readmissions are influenced largely by access to appropriate post-discharge care. ⁴¹ Thus, by including MA patients in performance measurement, hospitals are likely to be held accountable for MA plan behavior that restricts access to care that is not present when measuring only FFS patients.

Use of Hospital Shadow Claims Data to Determine Aggregate Excess Readmissions Payments is Biased Against Teaching Hospitals and Safety Net Hospitals

In addition to including MA patients in performance measurement, CMS proposes to use payment data for MA patients to calculate the aggregate payments for excess readmissions, by using MedPAR data from hospital submitted information-only claims for inpatient stays for MA patients. (p. 18287) As noted in analysis prepared for CMS, information-only claims from hospitals are the only source of MA payment information and hospitals that receive medical education and disproportionate-share hospital payments are *required* to submit information-only claims for MA patients with inpatient stays in order to calculate those payments. All hospitals receive those add-on payments, so not all hospitals report complete MA payment information to CMS on the information-only claims they submit, thus CMS will introduce bias in the calculation of aggregate payments for excess readmissions against teaching and safety net hospitals that are required to submit such information. The AAMC strongly believes that payment penalty calculations in the FFS-penalty HRRP must be based upon payment data that is fair and consistently reported and available across all hospitals in the program.

³⁹ U.S. Senate Permanent Subcommittee on Investigations, <u>Refusal of Recovery: How Medicare Advantage Insurers</u> Have Denied Patients Access to Post-Acute Care (October 17, 2024).

⁴⁰ E. Cahan, <u>Medicare Advantage Has Become Notorious for Prior Authorization – CMS and Lawmakers Are Taking Action</u>, JAMA (August 30, 2024).

⁴¹ JS Dhaliwal and AK Dang, <u>Reducing Hospital Readmissions</u>, StatPearls (June 7, 2024).

⁴² Yale New Have Health Services Corporation – Center for Outcomes Research and Evaluation, <u>2024 Conditionand Procedure-Specific Readmission Measures Supplemental Methodology Report</u> (March 2024).

VALUE-BASED PURCHASING (VBP) PROGRAM

Adopting Measure Modifications to the THA/TKA Complications Measure

CMS proposes to modify the Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) to include MA patients and reduce the performance period by one year to two years beginning with FY 2033 program year, after a period of use of the modified measure in the Hospital Inpatient Quality Reporting (IQR) Program. (p. 18290) The AAMC asks CMS to release data on the modified measure with the inclusion of MA patients to enable assessment of whether the expanded population improves measure reliability without skewing performance based on MA benefit design outside of hospital control. We agree that measuring across all Medicare patients facially could improve reliability, as the measure focuses on the lower volume of higher-risk patients having elective THA and TKA procedures in the inpatient setting. However, without data to assess, we remain concerned that MA benefit design, notably the use of prior authorization of services, could influence post-discharge complications in a manner that is incongruous with measuring only FFS patients. Additionally, we ask CMS to confirm that there is no intention to use hospital-submitted MA payment information to influence payment bonuses or penalties under the VBP, unlike the addition of MA patients for the readmission measures. Finally, we support providing hospitals with time to understand measure performance with the modified patient population during the transition period for the measure in the IQR, and if performance is skewed by the inclusion of MA patients due to MA benefit design, CMS should limit the expanded measure population to the pay-for-reporting IQR Program.

INPATIENT QUALITY REPORTING (IQR) PROGRAM

Measure Removals

Finalize Removal of Four Measures from the IQR with CY 2024 Reporting

CMS proposes to remove four measures on the basis that benefits of the measures is outweighed by the burdens of measurement: (1) Hospital Commitment to Health Equity structural measure, (2) COVID-19 Vaccination Coverage Among Healthcare Personnel measure, (3) Screening for Social Drivers of Health (SDOH) measure, and (4) Screen Positive Rate for SDOH. All removals are proposed effective with CY 2024 reporting. (pp. 18336-7) The AAMC supports these measure removals to reduce burden for providers.

Reduce Burden by Replacing the Sepsis Bundle Measure with a Measure of Sepsis Outcomes

Currently, the sepsis bundle measure (SEP-1) is required by hospitals in the IQR since 2015 reporting and the VBP beginning with 2024 reporting. ^{43, 44} Hospitals have spent considerable effort — and achieved significant results — in mitigating the incidence and severity of sepsis, saving lives in the process.

⁴³ 79 FR 50241 (August 22, 2014)

^{44 88} FR 59081 (August 28, 2023)

Unfortunately, research has demonstrated that the sepsis bundle measure has not led to better outcomes yet entails an enormous administrative burden as a chart-abstracted measure.⁴⁵ **The AAMC encourages CMS to work with clinical leaders to develop and adopt a valid, reliable, feasible outcomes measure to inform and improve effective and timely sepsis care.**

IQR Reporting Requirements

Modify Hybrid EHR Measure EHR-Derived Data Thresholds for Reporting and Consider Further Delay of Mandatory Reporting Period Based on Analysis of the July 2024 – June 2025 Voluntary Reporting Period

CMS proposes to decrease the submission thresholds for hospitals reporting hybrid measure core clinical data elements (CCDEs) and linking variables beginning with the July 2025 – June 2026 mandatory reporting period impacting FY 2028 payment determinations. Specifically, CMS proposes to reduce thresholds to 70 percent of discharges, instead of the current 90 and 95 percent thresholds for CCDEs and linking variables, respectively. Additionally, CMS proposes to allow hospitals up to two missing lab values and up to two missing vital signs when reporting CCDEs. (p. 18343) The AAMC appreciates the agency's attention to the challenges hospitals have faced in voluntarily reporting data derived from EHRs. We support these policies to ease burden on hospitals while maintaining statistical validity and progressing the transition to incorporating more granular clinical data into quality measurement. We urge CMS to consider extending voluntary reporting for an additional period, based on analysis of the final voluntary reporting period that ends June 2025, should it find that a significant portion of hospitals voluntarily reporting continue to struggle with CCDEs and linking variables. We remain concerned that hospitals with the least resources have not been able to invest in voluntary reporting may not be able to meet these reduced thresholds for the July 2025 to June 2026 mandatory reporting period and will lose 25 percent of the annual payment update in FY 2028. Any relief on mandatory reporting would come after these hospitals will have needed to commit to reporting, allowing CMS to ensure that it maintains momentum towards reporting by all hospitals in the IQR for the reporting period.

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

New IQR Measures Should be Valid, Reliable, and Meaningfully Connected to Inpatient Care

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 acute care hospitals for the inpatient setting when considered for use in the IQR). In the case of new measures for well-being and nutrition in the IQR, we believe that the metrics must be meaningfully connected to the delivery of high-quality inpatient acute hospital care. Some measure concepts, while critically important to improving population health, may not be valid and reliable for the

⁴⁵ C. Rhee, et al, <u>Complex Sepsis Presentations</u>, <u>SEP-1 Bundle Compliance</u>, and <u>Outcomes</u>, JAMA Network Open (March 19, 2025), finding that complex clinical presentations were more common among patients whose treatment was noncompliant with SEP-1, which may confound the association between SEP-1 compliance and mortality.

inpatient care setting, and instead be better used in health plan or public health department quality measurement and improvement.⁴⁶

Consider Measures that Encourage Providers to Gain Insights on Factors that Influence Individual Well-Being Outside of Health Care

Much of what influences an individual's overall health and well-being is outside the health care delivery system. Nonmedical drivers of health, such as safe environments, access to nutritious food and physical activity, greatly impact well-being. We recommend CMS consider measures for health care providers to drive improvements in well-being that encourage providers to gain greater insights into the nonmedical factors that are influencing their patients' and community's health.

PROMOTING INTEROPERABILITY (PI) PROGRAM

CMS Should Reconsider Inclusion of the Security Risk Analysis Measure in the PI Program as Duplicative with HIPAA Security Rule Compliance

CMS proposes to modify the Security Risk Analysis measure currently included in the PI Program. (p. 18357) The AAMC strongly supports policies that promote cybersecurity best practices, but we question whether this measure does so, given that it is based directly on the Health Insurance Portability and Accountability Act of 1996 (HIPAA) requirements implemented in the HIPAA Security Rule already imposed on hospitals. We urge CMS to reconsider the continued inclusion of this measure in the program as an opportunity to reduce burden of reporting and refocus PI Program measurement to drive improved interoperability and data sharing.

RFI Regarding the Query of Prescription Drug Monitoring Program (PDMP) Measure

Changing the Query of PDMP Measure from an Attestation-Based Measure to a Performance-Based Measure in the Future in Line with ONC Adoption of Certification Criterion to Better Support PDMP Interoperability

CMS is seeking information on whether to change the Query of PDMP measure to a performance-based measure to further promote the utilization of PDMPs and support appropriate prescribing practices. (p. 18373) The AAMC supports improved interoperability measure concepts to improve patient care and ensure legitimate prescribing of controlled substances. One barrier to a performance-based Query of PDMP measure is ensuring all CEHRT products adopt and use the "PDMP Databases – Query, receive, validate, parse, and filter" certification criterion proposed (but not yet finalized) by ONC.⁴⁷ If finalized by ONC as a certification criterion, we believe it will greatly improve hospitals' ability to report a performance-based PDMP query measure, though we must note that it would likely be several years before all certified EHRs would be ready to deploy the criterion and then require a period of transition for

⁴⁶ 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 health plans and integrated delivery systems.

⁴⁷ ASTP/ONC, Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2 Proposed Rule), 89 FR 63498, at 63547 (August 5, 2024).

hospitals to adapt to performance-based measure. Additionally, there is ongoing work to establish a national PDMP to more effectively support data collection and analysis towards the Drug Enforcement Administration's anti-diversion efforts for controlled substances. CMS should consider the government's timeframe for implementing a national PDMP,⁴⁸ and align it with the implementation timeframe to change the Query of PDMP measure to a performance-based measure.

Evaluate Future Modification of the Query of PDMP Measure to Include All Schedule II Drugs in Line with State PDMP Capabilities and Broader Policy Goals of Adopting a Nationwide PDMP

CMS is seeking information on whether to revise the measure to include all Schedule II Drugs, rather than only focusing on Schedule II opioids. (p. 18374) The AAMC supports further investigation of an expanded PDMP measure. As CMS notes, most states (but not all) collect data on Schedules II, III, and IV drugs that are prescribed. (p. 18374) Hospitals in states that do not collect expanded data across all drug Schedules will likely need more time to develop capacity and readiness for expanded PDMP checks once supported in their state. CMS should ensure all states are able to collect data on all Schedule II drugs before expanding the measure in the PI Program. As previously noted, there is ongoing work to establish a national PDMP. ⁴⁹ CMS should consider the government's timeframe for implementing a national PDMP, and whether that timeframe might be best aligned with a modification of the Query of PDMP measure to include all Schedule II drugs. That extra time to implement could align with the time necessary to evaluate the potential unintended consequences of measure expansion, including creating barriers for patients appropriately prescribed Schedule II non-opioid drugs, such as central nervous stimulants to treat ADHD.

RFI: Performance-Based Measures

Leverage Standards for Health IT Modules to Better Support Public Health Data Exchange and Improve Investments in Public Health Agency Capabilities Prior to Transitioning Hospitals to Performance-Based Measures in the Public Health and Clinical Data Exchange Objective of the PI Program

The AAMC strongly supports efforts to modernize public health through advancing data science capabilities. Improving public health interoperability is key not only for the health of individual patients but also for the wellbeing of entire communities. The ability to exchange public health data efficiently between hospitals, health systems, and state/local public health entities is vital for addressing large-scale health challenges, such as pandemics, vaccination programs, and tracking public health trends. Improved public health data and data sharing directly influences the collective health and safety of communities and the nation. We urge CMS and ASTP/ONC to continue to collaborate with the Centers for Disease Prevention and Control (CDC) on efforts to improve public health interoperability, including efforts to understand limitations with underfunded state and local public health departments and their underlying public health technology infrastructure to ensure that our public health agencies have the capabilities needed to work with providers to improve public health interoperability through updated health IT module certification requirements. These standards and public health

⁴⁸ Drug Enforcement Administration, Special Registrations for Telemedicine and Limited State Telemedicine Registrations, 90 FR 6541, at 6543 (January 17, 2025), describing a proposed nationwide PDMP check that would be delayed in effective for three years, based on development of such a nationwide PDMP capability.

⁴⁹ *Id.*

agency capabilities are critically important steps that must be successfully taken prior to holding hospitals accountable for performance-based measures on exchanging clinical data with public health agencies as part of the PI Program.

Rather than transition all measures in the Public Health and Clinical Data Exchange Objective to performance-based measures, we recommend that CMS focus on one or two measures as test cases, potentially the antimicrobial use and resistance (AUR) Surveillance Reporting measure. Current infectious disease public health reporting measures for AUR are largely focused on surveillance, tracking the rates of prioritized infections, antimicrobial use, and antimicrobial resistance in hospitals. While this information is relevant, these measures often do not drive meaningful change in the quality-of-care that patients with infections receive. We suggest the development of a new performance-based quality measure that catalyzes improvement in antimicrobial stewardship efforts.

The data modernization efforts at the CDC, including the Data Modernization Initiative (DMI) and Public Health Data Strategy (PDHS), are critical to reducing AMR. While the PDHS lays out important strategic steps, DMI serves as the vehicle for innovation and improvement in data collection. Since 2019, some progress has been made to accelerate modernization through federal policies, data standards, and system interoperability. CDC modernization efforts must continue to be prioritized in tandem with quality measure restructuring to lower administrative and hospital burden. These efforts will allow for the development of report cards for hospitals to benchmark progress against national averages, driving improved care.

RFI: Data Quality

Commit Resources to Addressing Semantic Differences Across Health Systems to Improve Data Ouality and Interoperability

ASTP/ONC has worked diligently in the last several years to improve interoperability through the implementation of (and updates to) the United States Core Data for Interoperability (USCDI) standards. The AAMC supports policies to improve the widespread adoption of updates to the USCDI, and we recommend that CMS and the ASTP/ONC commit resources to addressing semantic differences across health systems when implementing data standards under the updates to the USCDI. Data standardization is critical for interoperability, and we believe that the USCDI is a key to such standardization. However, we have heard from members that data standardization alone has not yet moved the needle for improving interoperability of health information to improve care delivery due to semantic differences by health systems when implementing data standards. As an example, the AAMC leads Project CORE: Coordinating Optimal Referral Experiences through implementation of electronic consultations through tools built into the EHR. Our experience working with member academic health systems through Project CORE has highlighted significant interoperability issues across systems, even in cases where they are operating within the same platform or using the same EHR tools developed by the same EHR vendor. For example, a call at one institution for the value of a white blood count lab may return the value but using the same vendor platform (or a FHIR application programming interface) to call at another institution might not result in a returned value due to semantic inconsistency. Currently, there are no feedback loops to address such inconsistencies in the implementation of normative standards across the nation. ASTP/ONC could support broader semantic standardization through the development of national and regional user groups that provide feedback loops on semantic differences, helping to serve as a mechanism for truly normalizing national data standards into clinical practice. Additionally,

ASTP/ONC support for broader adoption and implementation of standard ontologies with quality assurance processes (i.e., LOINC, RxNorm, SNOMED, etc.) may help improve semantic differences between health systems.

TRANSFORMING EPISODE ACCOUNTABILITY MODEL (TEAM)

PRICING METHODOLOGY

Apply a Beneficiary Economic Risk Adjustment Factor Based on the Community Deprivation Index (CDI) Using State-Level CDI Rankings and Dual-Eligibility Status

CMS proposes to replace the use of the Area Deprivation Index (ADI) with the Community Deprivation Index (CDI) for purposes of constructing a beneficiary-level economic risk adjustment factor, where the CDI score would be ranked relative to the nation, and would trigger the binary yes/no factor where CDI meets an 80th percentile threshold. (p. 18393) **The AAMC supports replacing the ADI with the CDI, as we previously commented on concerns that the ADI overweighted home values and thus was unable to meaningfully measure deprivation in some high cost of living urban areas.**⁵⁰ CMS also requests feedback on whether to continue to include dual eligibility status as a variable for the economic risk adjustment factor. (p. 18393) **The AAMC continues to support the inclusion of dual eligibility status for the TEAM economic risk adjustment factor methodology**. While dual eligibility is an imperfect proxy of economic need and vulnerability, it remains an accessible, consistent data element that CMS can use and that hospitals understand.

Increase the Hierarchical Condition Categories (HCCs) Lookback Period for Risk Adjustment to a Full Year

CMS proposes to increase the lookback period to capture beneficiary-level HCCs for risk adjustment to 180 days, double the 90 days finalized in the FY 2025 IPPS final rule. (p. 18394) The AAMC appreciates the proposal to recognize the need for a longer period to sufficiently capture beneficiary acuity and better reflect the level of spending outside of the hospital's control. We recommend CMS increase the lookback period to a full year, matching the policy of the prior mandatory episode payment model, Comprehensive Joint Replacement (CJR).⁵¹ A one year lookback period would allow CMS to more accurately capture HCCs for a TEAM patient, as Medicare patients are encouraged to see their primary care physicians on an annual basis.⁵²

Ensure Adequate Risk Adjustment for Pricing Non-Elective Major Bowel Procedures

In analysis of the DRGs included for major bowel procedures, DataGen, Inc. has found a significant difference in the average episode costs of elective vs non-elective procedures, with non-elective

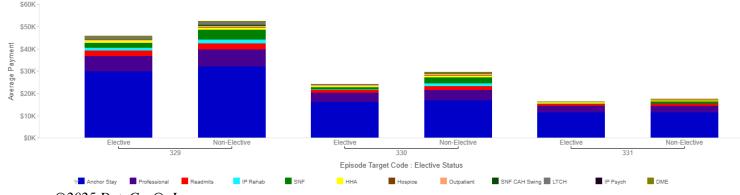
⁵⁰ AAMC, <u>Comment Letter to CMS on the FY 2024 Inpatient Prospective Payment System Proposed Rule</u>, pp. 13-14, 16-18 (June 8, 2023).

⁵¹ 42 CFR §510(a)(2)

⁵² 42 CFR §410.15, describing Medicare coverage of annual wellness visits.

procedures more costly (by 14.0% for MS-DRG 329, 20.9% for MS-DRG 330, and 7.7% for MS-DRG 331), likely due to higher risks for complications, infections, and readmissions.⁵³

The visualization below represents the average Medicare episode spend (in standard/normalized dollars) for Major Bowel Procedure episodes with an anchor admission discharge date during Calendar Year 2023. The average Medicare episode spend is stratified by the trigger code of the inpatient admission and elective/non-elective status. Elective/non-elective status was defined using the admit type code on the anchor admission claim. The stacked vertical bars indicate the average Medicare episode spend by the types of claims/services utilized during the episode period.



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Failure to adequately stratify non-elective episode spending presents the potential for targets that are artificially low for teaching hospitals who care for patients with the most complex conditions and for trauma cases. The AAMC urges CMS to ensure that there is appropriate risk adjustment to capture the spending differences by elective status to ensure that pricing targets are more equitable for hospitals more likely to provide non-elective major bowel procedures.

Establish a Low Volume Threshold by Episode Category with No Downside Financial Risk

CMS requests feedback on potential policies to address concerns about low volume providers participating in TEAM. CMS notes that for BPCI Advanced, a hospital must meet a low volume threshold of at least 31 episodes in a given baseline period for a given episode category and that hospitals are not held accountable for performance year spending if the low volume threshold is not met. (p. 18397) The AAMC recommends CMS continue the BPCI Advanced low volume threshold policy and create a low-volume threshold in TEAM of a minimum of 31 episodes in the three-year baseline for each clinical episode category. Where the low-volume threshold is not met, we recommend that CMS remove downside financial risk for that clinical episode category to hold the hospital harmless for spending over the reconciliation target price. In these instances, exceeding the target may be a product of pricing volatility due to limited episodes and the inability to spread financial risk across enough episodes.

⁵³ DataGen, Inc. simulated Transforming Episode Accountability Model episodes of care according to the specifications detailed in the FY 2025 IPPS Final Rule using the national Medicare Standard Analytic File Limited Data Sets. The source data contains 100% of the claims for institutional settings of care (inpatient hospital, outpatient hospital, skilled nursing, home health, and hospice) and non-institutional claims (carrier and durable medical equipment) for a 5% statistical sample of Medicare FFS beneficiaries. Carrier and durable medical equipment expenditures for beneficiaries not included in the 5% statistical sample are extrapolated by episode parameters (i.e., anchor episode MS-DRG or HCPCS code, first setting of post-acute care, beneficiary age group, beneficiary dual eligibility status, region, and claim setting).

Additionally, the AAMC recommends that CMS maintain data sharing with the hospital for that performance period so that the hospital may continue to invest in care transformation redesign and data analysis capabilities in advance of future performance periods where the hospital may exceed the low volume threshold for that episode category.

QUALITY MEASUREMENT

Implement a Consistent, Well-Tested Set of Quality Metrics for the Duration of the Model

The AAMC strongly recommends against using untested quality metrics in mandatory models. We also recommend keeping a consistent set of quality metrics for supporting continuity and evaluating the model.

Alignment of the Hybrid Hospital-Wide Readmissions Measure to the IQR

CMS previously adopted the Hybrid Hospital-Wide Readmissions (HWR) Measure in the Hospital Inpatient Quality Reporting (IQR) Program and now proposes to recognize changes to the measure in the IQR and align the measure changes for use in TEAM. Specifically, CMS proposes to use the July 1, 2025 – June 30, 2026 first mandatory reporting period under the IQR as the baseline performance period for TEAM for PY 1 (2026) and otherwise include the revised submission requirements proposed under the IQR. (p. 18383).

The AAMC has several concerns with using the first mandatory reporting period for TEAM. First, using the first mandatory reporting period means that TEAM participant hospitals will not have any insight into national measure performance until January 2027, due to the measure reporting timeframe⁵⁴ and public reporting policies of the IQR.⁵⁵ Second, using the first mandatory reporting period as the baseline for model performance comparisons means part of the PY 1 performance period is also part of the baseline. With this overlap, it is unclear how hospital performance will reasonably influence TEAM Composite Quality Scores (CQS). Third, CMS does not discuss in this proposal how it will measure performance on a calendar year performance period relative to a measure that spans multiple performance years as a July – June measure. And finally, the AAMC remains concerned that hospitals may struggle to sufficiently report data derived from the EHR for this measure and may need more time with voluntary reporting status until a majority of hospitals demonstrate measure reporting capabilities.⁵⁶ Holding TEAM participant hospitals to performance-based scoring on a measure that a majority of hospitals have yet to successfully report places undue burden on TEAM participants and CMS should reconsider use of the Hybrid HWR measure in TEAM. As an alternative, CMS could use the claims-based

⁵⁴ CMS, CY 2025 Outpatient Prospective Payment System Final Rule, 89 FR 93912, at 94496 (November 27, 2024), reiterating Oct 1 as the deadline for reporting data to CMS following a July-June reporting period.

⁵⁵ CMS, FY 2012 Inpatient Prospective Payment System Final Rule, 72 FR 51476, at 51608 (August 18, 2011), noting that the IQR public reporting policy is to report measure performance publicly following a 30-day preview period for hospitals. In the case of the Hybrid HWR, with reporting due October 1 following the July - June reporting period, the earliest possible public reporting period for the July 2025 – June 2026 performance period would by the January 2027 refresh to *Care Compare*, which generally would be available to hospitals the fourth Wednesday of January.

⁵⁶ Please refer to page 18 of these comments in response to the proposed modifications to the measure proposed in this year's rule for the IQR.

elements of the measure for performance measurement, as hospitals have long had access to publicly reported performance on the claims-only version of the Hybrid HWR measure.

Adopting the Information Transfer Patient Reported Outcomes-Performance Measure (PRO-PM) from the OQR Beginning with PY 3 (2028)

CMS proposes adopting the Information Transfer PRO-PM for PY 3 (2028) of the model, following the adoption of the measure in the Hospital Outpatient Quality Reporting (OQR) Program. (p. 18384) The AAMC supports the use of patient-reported measures, where the measures are appropriately tested and understood by hospitals prior to use in this mandatory model. That is not the case with the Information Transfer PRO-PM, which is new to the OOR with mandatory reporting beginning with CY 2027 reporting, ⁵⁷ and for which hospitals will not have any insight on national performance trends until measure performance is publicly reported at the earliest in late July 2028.⁵⁸ If the measure is adopted in TEAM for PY 3 it will create a scenario where the majority of hospitals not participating in the model will report the measure under the pay-for-reporting structure of the OQR and the minority of hospitals participating in TEAM will have their Medicare payment influenced by performance on the measure as part of the TEAM Composite Quality Score at best more than halfway through the 2028 performance period. This is problematic as the payment to hospitals participating in TEAM will be impacted without these hospitals having any ability to understand their performance relative to other hospitals across the nation. To remedy this information void, CMS could modify the proposal to adopt the measure beginning with PY 4 (2029), though the AAMC is concerned that adding a measure for the last two years of the model would result in inconsistent metrics across the model test and could impact overall model evaluation for impact on quality of care. Given the inequitable measure use for PY 3 and challenges with later year model changes impact on model evaluation, AAMC strongly encourages CMS not to add the Information Transfer PRO-PM measure to TEAM.

REFERRAL TO PRIMARY CARE SERVICES

Amend Primary Care Referral Requirement to Apply Only Where TEAM Patients Affirm That They Do Not Have a Primary Care Practitioner

CMS seeks feedback on potential modifications to the existing requirement that TEAM participants refer TEAM patients to primary care services prior to discharge from the inpatient stay or hospital outpatient department. Specifically, CMS describes three alternatives to the existing policy: (1) requiring TEAM participants to identify the patient's established relationship for primary care services through a 2-year claims lookback period to refer patients to their existing practitioners; (2) limiting the requirement only to patients without an established practitioner based upon a 2-year claims lookback for prior primary care services; and (3) requiring documentation of a patient's preference where the TEAM participant refers the patient to a practitioner other than the patient's existing primary care clinician. CMS notes that each

⁵⁷ Supra, note 54 [CY25 OPPS] at 94406 and 94420 (November 27, 2024), finalizing adoption of the measure and establishing a Jan 1 – May 15 reporting period following the CY measure performance period.

⁵⁸ CMS, CY 2017 Outpatient Prospective Payment System Final Rule, 81 FR 79562, at 79791 (November 14, 2016), establishing a policy of public display as soon as possible after measure data have been submitted, with a 30-day hospital preview period. In the case of the Information Transfer PRO-PM, with reporting due May 15 following the CY reporting period, the earliest possible public reporting period for the CY 2027 performance period would by the July 2028 refresh to *Care Compare*, which generally would be available to hospitals the fourth Wednesday of July.

option would increase the burden on TEAM participants to identify information through claims data and increased documentation. (p. 18402-3)

The AAMC agrees that there is value in maintaining a modified requirement in TEAM for referrals to primary care. To reduce the burden on TEAM participants, we recommend CMS amend the policy to require a primary care services referral for any TEAM patient who affirms to the TEAM participant that they do not have an existing relationship with a primary care practitioner. This modification to the requirement would be less burdensome. Allowing TEAM participants to make referrals directly in response to the patient's preference to share information about their primary care practitioner (or lack thereof) would ease the burden and make this requirement more feasible to implement. TEAM participants do not generally have access to two years of claims data for all patients at the time of the anchor hospitalization or procedure to evaluate for existing primary care relationships. Only TEAM participants who participate in accountable care organizations (ACOs) are likely to have any historical claims information on ACO-aligned patients to be able to do any sort of claims analysis on established primary care relationships, and due to ACO-alignment, are likely aware of the patient's existing relationship with an ACO primary care practitioner. Were CMS to consider providing past claims information to TEAM participants for all patients who are eligible to trigger TEAM episodes, we are concerned that only those hospitals with ACO or other population-based alternative payment models would have existing analytics capabilities to rely on to meet a claims-based primary care referral requirement.

It is already a best practice for hospitals to incorporate follow-up appointments into their post-discharge procedures, including appointments with a patient's primary care practitioner where appropriate.⁵⁹ This is especially true for academic health systems receiving patients outside of their local geographic area as these systems must plan the post-operative transition of care back to the patient's regular care providers in their local communities. Thus, tailoring the requirement to those patients who do not have an existing care relationship with a primary care practitioner would allow hospitals to focus referrals on improving access to primary care and assisting with the establishment of longitudinal care relationships for those patients who need it most.

Amend Primary Care Referral Requirement to Any Time During the 30-Day Episode

Currently, CMS requires that the referral for primary care services happen prior to discharge from the hospital or hospital outpatient department. CMS seeks feedback on whether to extend the referral timeframe to require the referral any time before the end of the 30-day episode. (p. 18402). The AAMC supports amending the timeframe for the referral requirement to support more tailored transitions from short-term post-operative care back to providers with longitudinal care relationships to support care coordination and better outcomes.

⁵⁹ See, for example, AHRQ's IDEAL Discharge Planning.

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 – 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 programs and Transforming Episode Accountability Model proposals.

Sincerely,

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Chief Health Care Officer

Association for American Medical Colleges

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

Appendix – AAMC Response to Medicare Deregulation RFI
Appendix – AAMC Response to Request for Information on Unleashing Prosperity Through Deregulation of the Medicare Program

Submitted electronically via <u>Medicare Regulatory Relief / CMS</u>

The Association of American Medical Colleges (AAMC) appreciates the opportunity to respond to the Centers for Medicare and Medicaid Services (CMS) request for information on potential approaches and opportunities to streamline regulations and reduce administrative burdens on providers, suppliers, beneficiaries, and other stakeholders participating in the Medicare program.

We appreciate the Trump Administration's emphasis on regulatory reform in the health care system that reduces burden on health care providers, simplifies the health care system, and ensures patients receive optimal care. The increasing amount of administrative responsibility forced upon health care providers is unsustainable, diverts time and focus away from patient care and leads to burn out for providers. Reducing providers' administrative burden in the health care delivery system will improve quality of care, decrease costs, and enable better access to care.

A meaningful and lasting regulatory review must be deliberate, transparent, and grounded in dialogue between federal agencies and the regulated community. Over the years, the AAMC has identified numerous federal regulations that create disproportionate burden without yielding clear benefits. The recommendations that follow reflect specific federal regulations we believe should be revisited, revised, or harmonized to reduce unnecessary burden, lessen financial strain on providers, and eliminate duplication, while protecting the health and safety of Medicare beneficiaries, and promoting high quality care.

STREAMLINE REGULATORY REQUIREMENTS

<u>Recommendations for regulatory requirements that could be waived, modified, or streamlined to reduce burden without compromising patient safety or integrity of the Medicare program</u>

- Remove Respiratory Illness Reporting Requirement from Conditions of Participation
 Beginning November 1, 2024, CMS added mandatory respiratory illness reporting under the
 infection prevention and control and antibiotic stewardship programs condition of participation,
 requiring all Medicare and Medicaid participating hospitals and critical access hospitals to
 electronically submit certain COVID-19, influenza and respiratory syncytial virus data to the
 Centers for Disease Control and Prevention on a weekly basis. (QSO-25-05-Hospitals/CAHs; 42
 C.F.R. §§ 482.42(e), 485.640(d)) Failure to report this information may lead to termination of a
 hospital's participation in the Medicare and Medicaid programs. The AAMC understands the
 potential value of selected data on acute respiratory illnesses to inform public health initiatives.
 However, the use of CoPs to compel hospitals to share data with the federal government is
 inconsistent with the intent of the CoPs. The AAMC urges CMS, HHS and CDC to invest in the
 infrastructure needs to make voluntary sharing of this data on infectious diseases less burdensome
 and more meaningful.
- Re-Evaluate New Obstetrical Service Standards Conditions of Participation and Other Maternal Health CoP Changes

We ask the agency to consider re-evaluating the new Obstetric Service Standards conditions of participation (CoP) as well changes to the Emergency Services and Discharge Planning CoPs to address maternal health for efficacies in these requirements to ensure hospitals can meet these standards without undue burden. (42 C.F.R. §§ 482.59, 482.55, 482.43 - established by 89 FR 93912, November 27, 2024) The new CoP requires Medicare and Medicaid participating hospitals and critical access hospitals that offer Obstetrical services to implement several changes related to service organization, staffing, delivery of services, and training. This CoP also requires hospitals

to use findings from their QAPI programs, to assess and improve health outcomes and disparities among obstetrical patients on an ongoing basis including updating training requirements for staff. While the AAMC supports efforts to improve maternal healthcare outcomes and agrees this is a critical issue facing the United States that must be addressed, the AAMC does not support the use of CoPs to drive these improvements. Further, since the new CoP is considered to be optional, this means that only hospitals that elect to offer this service must comply with requirements. Additionally, the changes to existing CoPs apply to all hospitals participating in Medicare and Medicaid and place varying levels of burden onto hospitals and CAHs depending on their capacity to meet these new standards. Failure to meet CoP requirements may result in sanctions on hospitals including corrective action plans, monetary sanctions, increased reporting requirements, and even termination from the Medicare program. If hospitals feel they are not adequately equipped to meet these standards or that additional investments must be made to meet these requirements, providers struggling to operate these services may ultimately make the decision to eliminate these services to avoid significant penalties for failure to meet CoP requirements.

Ensure Alignment in Care Management Services and Remote Mental Health Services by Allowing Hospital Staff to Provide Care Management Services Remotely Under the Outpatient Prospective Payment System (OPPS) regulations at 42 CFR § 410.27(a)(1)(iii), mental health services provided to beneficiaries in their home are excepted from the requirement that incident to services be provided in the hospital or critical access hospital (CAH) or in a department of the hospital or CAH. However, CMS requires hospital staff providing care management services to be present in the hospital even when the patient is no longer there. In the last 10 years, CMS has developed codes and payment for care management services that are helpful to primary care physicians that treat patients with one or more chronic care conditions. While CMS can pay for these services under the OPPS under general supervision (meaning the physician does not need to be immediately available while the services are taking place), CMS' regulations continue to require the hospital staff (who may be furnishing the services through a contractor "under arrangements") to be present in the hospital even though the patient is no longer there. To ensure parity between remote mental health services and care management services provided remotely, CMS can revise 42 CFR § 410.27(a)(1)(iii) to add the following language after the words "communication technology:" "and care management services when the patient is not physically present in the hospital."

Recommendations regarding Medicare administrative processes or quality and data reporting requirements that create significant burdens for providers and those that could be simplified

• Reform Hospital Quality Performance and Reporting Programs

The AAMC is concerned with the considerable burden in hospital quality measurement and recommends CMS remove chart abstracted measures and structural measures from hospital quality programs to better maximize health care system resources for measurement that can drive meaningful quality improvements. Instead of chart abstracted measures and structural measures, CMS should focus on outcomes measurement. Chart-abstracted and structural measures require significant clerical effort, requiring hospitals to divert resources away from clinical care. Currently, the SEP-1 measure is the only non-electronically chart-abstracted measure included in the Hospital Inpatient Quality Reporting (IQR) Program and was added to the Hospital Value-Based Purchasing (VBP) Program beginning with FY 2026 payment determinations. (88 FR 58640, at 59081, August 28, 2023) The IQR Program currently has three structural measures in place or set to take effect in the coming years: Maternal Morbidity, Patient Safety, and Age-Friendly Hospital. (See Table X.C.2, 90 FR 18002, at 18338, April 30, 2025). While these

measures reflect important quality measurement topics, they do not directly measure outcomes or safety events. Instead, they require hospitals to manually abstract data from patient charts or attest to statements across multiple domains and better reflect a hospital's resources and interpretation of attested-to structures and documented activities. Removing these measures and instead prioritizing outcomes measurement would more effectively use resources to drive quality improvement and performance.

• Remove Duplicative Measurement in Hospital Quality Performance Programs

The AAMC is concerned with the considerable burden in hospital quality measurement and recommends simplification by removing duplicative measurement across performance programs to better maximize health care system resources for measurement that can drive meaningful quality improvements. CMS should remove duplication across performance programs, notably by removing the Safety Domain from the Hospital VBP as it is duplicative with the measures in the Hospital-Acquired Condition Reduction Program (HACRP). Previously, CMS proposed, but did not finalize, the removal of duplicative safety and condition-specific cost measures from the VBP program to better align measurement priorities across inpatient quality reporting and performance programs and reduce provider burden (83 FR 20163, at 20411, May 7, 2018). The AAMC has long recommended that CMS eliminate the measure overlap between the VBP and the HACRP to reduce the likelihood of mixed signals on performance due to the different versions of the measures in use and different scoring approaches across the two programs. In removing the Safety Domain from the VBP, CMS could double the weight of the Clinical Outcomes Domain, ensuring hospitals are incentivized to improve and maintain high performance on the overall effectiveness of the care they deliver.

• Reform the Quality Payment Program (QPP)

The AAMC continues to hear from its members that the Merit-based Incentive Payment System (MIPS) under the QPP should be less administratively burdensome and more clinically relevant. Additionally, there is a growing concern with the budget-neutral design of MIPS under which the amount of funds available to reward superior performance cannot exceed the payment penalties imposed on clinicians for poor performance. This model design should be replaced with payment adjustments that are based on the Medicare Economic Index to account for inflation. The current program is too costly, requires reporting that is unnecessary, and diverts time away from patient care. In the 2025 PFS final rule, CMS estimated the total burden on the U.S. health care system due to the MIPS reporting requirements finalized for CY 2025 would be 586,877 hours and \$70,166,672 (89 FR 97710, at 98470). Below are a few specific recommendations.

- CMS should retain MVP reporting as a voluntary MIPS reporting option and retain traditional MIPS as the agency works to develop the comprehensive, meaningful measures needed to advance MVP adoption and ensure that rules for subgroup reporting allow practices who opt to report MVPs can best represent the clinical context of care delivered within their practice
- All cost measures used in the MIPS program should be appropriately adjusted to account for clinical complexity and economic risk factors.
- CMS should utilize the authority granted to the Secretary through HITECH Act to permit reporting Promoting Interoperability (PI, previously referred to as "meaningful use") through yes/no attestations. Each "yes" would be worth a certain amount of points. In addition to relieving the reporting burden, an attestation-based approach would help facilitate EHR development to be more responsive to real-world patient and physician needs, rather than designed simply to measure, track, and report PI objectives, and could help prioritize both existing and future gaps in health IT functionality.

• Reform and Reduce Reporting Burdens for Accountable Care Organizations (ACOs) in the Medicare Shared Savings Program (SSP)

The AAMC recommends CMS make the following changes to the regulations for ACOs participating in the SSP to relieve burden and ensure continued participation in the largest value-based care model for Medicare providers.

- CMS should modify quality measurement policies to support ACO participation and reduce burden by providing time to ramp up reporting new electronic clinical quality measures under the QPP's Alternative Payment Model (APM) Performance Pathway (APP) Plus measure set (42 C.F.R. § 425.510(b)(2)) and reverse the policy to require ACOs report QPP PI data, regardless of their Qualified APM Participant (QP) status (42 C.F.R. § 425.507).
- CMS should delay the sunsetting of the Web Interface and MIPS CQM reporting options until at least 2028 and assure ACOs that the Medicare CQM option will remain available for the foreseeable future until digital quality measure reporting is feasible and successful.
- CMS should expand the significant, anomalous, and highly suspect billing activity policy to allow ACOs to report suspected fraudulent Medicare billing to CMS to expedite investigations and allow ACOs to partner with the agency on combatting fraud, waste, and abuse in the Medicare program. (42 C.F.R. § 425.672)

OPPORTUNITIES TO REDUCE ADMINISTRATIVE BURDEN OF REPORTING AND DOCUMENTATION

<u>Recommendations for changes to simplify/ease Medicare reporting and documentation requirements without affecting program integrity</u>

Withdraw Prior Authorization Requirement for Hospital Outpatient Prospective Payment System (OPPS) Services

We urge CMS to withdraw the regulations establishing the use of prior authorization for OPPS services, due to its tenuous statutory authority and the clinical and access repercussions. (42 CFR § 419.80 - 419.83, established by 84 FR 61142, November 12, 2019) In 2020, CMS began requiring prior authorization for five categories of OPPS services, subsequently adding three categories of services in additional rulemaking for a total of eight services. This marked the first time CMS required prior authorization for hospital outpatient department services in Medicare fee-for-service. The use of prior authorization as a utilization management tool by payers often causes delays in patients' ability to receive timely, medically necessary care, imposes additional administrative burden on providers, and can result in increased costs for providers and patients. Furthermore, prior authorization in the Medicare FFS outpatient hospital context is not explicitly authorized by the Medicare statute. While the Medicare statute does clearly allow CMS to implement prior authorization for durable medical equipment, which CMS has done, the statute has no such reference to prior authorization in the OPPS.

• Prohibit Restrictive Uses of Prior Authorization by Medicare Advantage Plans That Depart from Traditional Medicare Fee-for-Service

The use of prior authorization by MA plans continues to impact patient access to timely care. In contract year (CY) 2024, the agency adopted regulations explicitly requiring plans to adhere to original Medicare coverage criteria and limiting plans from adopting their own coverage policies unless Medicare policies were not fully established. Providers strive to deliver quality health care in an efficient manner. However, the frequent phone calls, faxes, electronic health record (EHR) connectivity with payer systems, and different forms that physicians and their staff must complete to obtain prior authorizations hinder efficient care. Rules and criteria for prior authorization must be transparent and available to the physician at the point of care. In addition, if a service or

medication is denied in any event, both the patient and the physician should be given a specific reason for the denial, information about rights to appeal the decision, and other alternatives that may be covered (e.g., different medications). Medically necessary care should not be denied because a physician and/or patient cannot jump through complicated, opaque hoops.

According to Kaiser Family Foundation, in 2021, more than 35 million prior authorization requests were submitted to MAOs on behalf of MA beneficiaries. Of these, more than 2 million prior authorization requests were fully or partially denied. Just 11 percent of prior authorization denials were appealed, but of those a whopping 82 percent resulted in the initial prior authorization denial being fully or partially overturned. The burden to respond to these denials rests squarely on providers and contributes significantly to burnout. If the beneficiary is required to follow-up on the denial, they often forego care due to the complexities of filing an appeal. We support changes to reduce the number and burden of prior authorizations in MA. To meaningfully exact change to reduce the number of prior authorization requests, we encourage CMS to put in place a system that requires MA Organizations to submit to CMS the number of prior authorization requests and results (e.g., approval / denial) to allow CMS to accurately track the number of prior authorization requests and denials and identify abuse of utilization management tools.

Further, timely decisions are needed for prior authorization requests to ensure patients receive access to care in a prompt manner to address healthcare needs. As it currently stands, CMS requires MAOs, state Medicaid and CHIP FFS programs, Medicaid managed care plans, and CHIP managed care entities to provide notice of prior authorization decisions no later than 72 hours after receiving a request for "expedited" decisions, and no later than 7 calendar days after receiving a request for "standard" decisions. These standards still create burden for providers needing to offer expedited care and could jeopardize a patient's access to necessary medical care. Faster response times to prior authorization for impacted payers would erode these barriers to care. We urge CMS to consider more timely requirements of 24 hours of receipt of a request for urgent items or services and 48 hours for non-urgent care decisions.

Ensure prior-authorization requirements do not limit patients' access to care by streamlining processes and coverage criteria

Hospitals and health systems have numerous contracts with different insurance plans. Each of these plans include different clinical criteria for coverage, rules and processes regarding how to communicate requests for prior authorization and associated documentation requirements. To improve patients' access to care and reduce provider burden, these rules and processes should be streamlined. CMS has taken significant steps by finalizing rules (89 Fed. Reg 8758 (Feb. 8, 2024), scheduled to go in effect in 2026 and 2027, that set forth requirements for standardized electronic prior authorization processes that will improve the exchange of information. We urge the Administration to ensure timely implementation and enforcement of these rules, and to continue ongoing discussions with providers and patients to ensure prior authorization does not hinder access to care.

Under the No Surprises Act Good Faith Estimates, Eliminate the Requirement that the Convening Provider Obtain Information About Charges from Other Providers as it is Not Feasible to Operationalize

Provisions of the No Surprises Act and CMS regulations, effective Jan. 1, 2022, require, among other things, that all licensed healthcare providers must give "good-faith estimates" (GFEs) to uninsured/self-pay patients upon scheduling any service at least three days in advance, or upon

request. (45 CFR § 149.610; Requirements Related to Surprise Billing; Part II, 86 FR 55980 [October 7, 2021]). The GFE requirements are in place now for uninsured/self-pay patients, with requirements for commercially insured patients on hold until further industry development of standards and additional CMS rulemaking. For uninsured and self-pay patients, the rule requires that the convening provider or facility contact all applicable co-providers and co-facilities no later than 1 business day after the request for the GFE is received or after the primary item or service is scheduled and the patient requests submission of expected charges for the items or services. Creating GFEs that include services providing by convening providers and other co-providers and co-facilities is challenging as providers and facilities need to establish systems and procedures for providing and receiving the required information from other providers and facilities. AAMC members report that it is difficult and costly to operationalize this process for the uninsured and self-pay patients. To create these GFEs, providers are having to implement new workflows (often manual) and communication channels to exchange information between providers in addition to having to purchase costly technology updates to support these processes.

To promote greater price transparency and give patients a reasonable expectation of the costs of planned treatment, the No Surprises Act requires health plans to deliver an Advanced EOB to patients prior to care delivery. (Public Health Service Act section 2799B-6, as added by section 112 of title 1 of Division BB of the Consolidated Appropriations Act [December 27, 2020]). The AEOB is created by insurers using good faith estimates (GFE) from providers in advance. We support this type of meaningful price transparency that aims to provide patients with reliable, personalized estimates of their out-of-pocket costs. We appreciate, however, that CMS has delayed enforcement of these provisions until a standard industry process for such information exchange can be adopted via regulation to ensure that these estimates can be created as efficiently and accurately as possible. When CMS moves forward with implementation in the future, we urge CMS to allow each billing provider to submit a GFE to the health plan for items and services that they will be directly billing to the health plan for the patient and not require the convening provider to obtain information about charges from other providers. The responsibility for combining the GFEs into one Advanced EOB should rest with the insurers. Since insurers already receive and process claims from distinct providers, it is unnecessary to require the convening provider to obtain the information about charges from other providers. Accurate Advanced EOBs could be best established by leveraging existing provider and health plan workflows and standards and technologies for claims submission and adjudication.

IDENTIFICATION OF DUPLICATIVE REQUIREMENTS

Recommendations to eliminate duplicative Medicare requirements or processes within the program itself or other health care programs

• Eliminate Duplicative "Look Back" Validation Surveys of Accrediting Organizations and Permanently Adopt Concurrent Validation Surveys

Currently, CMS regulations include duplicative "look back" validation surveys of accrediting organizations (AOs) at 42 CFR § 488.9. As part of its oversight process, CMS conducts a full resurvey of hospital compliance with Medicare Conditions of Participation on a representative sample of hospitals each year, comparing each hospital's results with the most recent accreditation surveys. Instead of fulfilling CMS' goal of assessing AO performance, the validation surveys result in rework and disruption for hospitals and health systems. CMS should instead permanently adopt concurrent validation surveys that would allow the agency to directly observe AO performance.

Withdraw Information Blocking Disincentives Rule

We respectfully ask the agencies to withdraw the policy finalized in 2024 to impose Medicare payment disincentives on certain health care providers found to have committed information blocking. (89 FR 54662, July 1, 2024). CMS should withdraw the rule to support the critical real-world educational effort necessary to ensure that health care providers have a fair opportunity to self-correct and ensure their information sharing practices comply. Additionally, we call on CMS to work with the HHS Office of the Inspector General (OIG) to ensure that the investigative process and the right of appeal is fair and consistent across all actors regulated under the information blocking rules. Regarding the disincentives through CMS programs, we urge the CMS and OIG to adopt alternative approaches to reduce the significant financial impact and the outsized variance across different types of health care providers, where some providers will be penalized for the actions of another while others will see no reduction in Medicare reimbursement regardless of their conduct. An overly punitive approach could critically impact care delivery and reinvestment in value-based health care delivery for health systems. This would ultimately negatively affect patients and their families.

<u>Recommendations on how Medicare can better align its requirements with best practices and industry standards without imposing additional regulatory requirements</u>

• Expand Medicare Coverage of Telehealth and Communication Technology-based Services by Removing Outdated Restrictions

Unless Congress acts, starting October 1, 2025, CMS will begin to apply geographic limitations and limitations on the site of service Medicare patients may receive telehealth services due to statutory language (Section 1834(m)(4)(C) of the Social Security Act; regulations at 42 CFR 10.78(b)(3) and (4)). While the AAMC understands that CMS may not have the authority to waive these statutory limitations on telehealth services, we strongly support making permanent the waivers and regulatory changes established by CMS in response to the COVID-19 public health emergency that have facilitated the widespread use of telehealth and other communication technology-based services that have improved access to health care. Specifically, we recommend the following: remove geographic site restrictions on telehealth; remove originating site restrictions to enable patients to receive telehealth in their homes; remove the in-person visit requirements for behavioral health telehealth (Sec. 1834 (m)(7) of Social Security Act and 42 CFR section 4180.78(b)(3(xiv)).

Additionally, the AAMC urges CMS to permanently change its regulations to permit practitioners to use their enrolled practice location instead of their home address when providing telehealth services from their home through CY 2025. (89 Fed. Reg. 97710, at 97762). Requiring reporting of practitioner's home addresses for enrollment is likely to discourage practitioner's from providing telehealth services from their home, limiting access to care. Additionally, practitioners have expressed privacy and safety concerns associated with enrolling their home address.

• Permanently Allow Direct Supervision Through Virtual Supervision

The AAMC strongly supports CMS defining direct supervision to permit the presence and "immediate availability" of the supervising practitioner using audio-video technology on a permanent basis. (42 C.F.R. §§ 410.26, 410.32) This policy would enable expanded access to health care services while reducing risk of exposure to all infectious diseases (e.g., coronavirus, seasonal flu, and others). Our members have found virtual supervision of clinical staff to be safe and effective, and improved access to care.

• Allow Virtual Supervision of Residents for Both Telehealth and In-person Services

The AAMC strongly supports revising the regulations to allow virtual supervision of residents for both in-person and telehealth services in all residency training locations permanently for services that may be furnished safely and effectively. (42 C.F.R. § 415.172) At a minimum, CMS should allow virtual supervision of residents for both in-person and telehealth services in underserved areas, as well as in non-metropolitan statistical areas. Allowing residents to provide these services while being supervised virtually is safe and effective, further expands access and promotes training opportunities.

• Address Barriers to Uptake & of Interprofessional Consults

In 2019, CMS finalized payment for six CPT® codes to recognize interprofessional consultations (99446, 99447, 99448, 99449, 99451, 99452). (83 FR 59452, at 59491, November 23, 2018) The AAMC and its member health systems have found interprofessional consultations utilizing provider-to-provider modalities and peer-mentored care as an effective way to improve access to care. Patients benefit from more timely access to the specialist's guidance and payers benefit from a less costly service by avoiding the new patient visit with a specialist.

CMS requires that providers collect coinsurance from their patients when billing for CPT® codes 99451 and 99452. While the AAMC understands that CMS may not have the authority to waive coinsurance for these codes under the Medicare fee-for-service program, we remain concerned that the coinsurance requirement is a barrier to providing these important services for several reasons. First, given the structure of two distinct codes, patients are responsible for two coinsurance payments for a single completed interprofessional consultation, which predictably induces confusion. Interprofessional consultations are often used for patients with new problems who are not established within the consulting specialty's practice and therefore do not have an existing relationship with the consultant. A coinsurance bill for a service delivered from a provider that is unknown to the beneficiary could cause the patient to believe a billing error has occurred. Another barrier is guidance for CPT® code 99452 that clarifies that it should be reported by the treating physician/QHP for 16-30 minutes in a service day preparing the referral and/or communicating with the consultant. We recommend the guidance be changed so that the time for these codes should include all the activities associated with the interprofessional exchange between the treating provider and consulting physician, including follow-through on the consultant's recommendations. This clarification would help to expand the use of these valuable services in the future and ensure from a program integrity standpoint that patients and payers are realizing the intended value of this service.

ADDITIONAL RECOMMENDATIONS

• Work with Model Participants to Improve the Mandatory Transforming Episode Accountability Model (TEAM)

TEAM, as a mandatory model, will require over 700 acute care hospitals to assume financial responsibility for post-procedural care through bundled payments for five types of surgical episodes, irrespective of whether it is feasible for the hospitals to implement the bundles. The model particularly targets hospitals with low levels of existing experience with voluntary episodic payment models, increasing the risk that participating in such a model could financially destabilize them, threatening access to care for everyone in the community. We encourage CMS to work with participating hospitals to improve model design to mitigate this risk, including by revising the pricing methodology, implementing a consistent, well-tested set of quality metrics for the duration of the model, and amending the primary care referral requirement to reduce burden

on participating hospitals. Specific to the pricing methodology, we encourage CMS to ensure adequate risk adjustment for differences in costs between elective and non-elective procedures, to increase the lookback period for hierarchical condition categories, establish a low-volume threshold with no downside risk for hospitals that do not have sufficient volume to meet the threshold, and to use the Community Deprivation Index in addition to dual-eligibility status to apply a beneficiary economic risk adjustment factor.

• Modify Stark Law and Anti-kickback Statute Regulations that Restrict Hospital and Health System Activity that is Beneficial to Patients and Communities

The Stark Law and associated regulations as well as the anti-kickback statute can impede arrangements that improve care delivery for patients. Historically, these laws impeded value-based arrangements involving care coordination, and we appreciated the steps taken by the Trump Administration as part of the "Regulatory Sprint to Coordinated Care" to encourage these value-based care arrangements through modifications to Stark. Even with these reforms, challenges still remain for hospitals and health systems that wish to undertake certain arrangements, preventing beneficial arrangements. We urge CMS to consider additional feedback from stakeholders on regulatory revisions that would help remove or mitigate obstacles.