Submitted electronically via www.regulations.gov

Association of
American Medical Colleges
655 K Street, N.W., Suite 100, Washington, D.C. 20001-2399
T 202 828 0400
www.aamc.org

September 9, 2024

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1809-P
P.O. Box 8010
Baltimore, MD 21244-8010

Re: Medicare Program: Calendar Year 2025 Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems Proposed Rule (CMS-1809-P)

Dear Administrator Brooks-LaSure:

The Association of American Medical Colleges (AAMC or the Association) welcomes this opportunity to comment on the proposed rule entitled Calendar Year (CY) 2025 "Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule," 89 *Fed. Reg.* 59186 (July 22, 2024), 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, medical research, and community collaborations. Its members are all 158 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 accredited Canadian medical schools; approximately 400 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 193,000 full-time faculty members, 96,000 medical students, 153,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened participation in the AAMC by U.S. and international academic health centers.

AAMC member institutions share a common mission to care for the underserved and train the nation's future health care workforce, making life-saving health care services available to all patients, regardless of their ability to pay. Academic health systems provide highly specialized health care services that are often unavailable in other settings, including oncology services, transplant surgery, trauma care, pediatric specialty care, and treatment for rare and complex conditions. Through their expansive ambulatory networks, they bring high-quality, specialized care into their patients' communities. Our recommendations below will ensure the continued stability and viability of academic health systems and their ability to provide these specialized services to their patients. By implementing these recommendations, CMS will ensure our members can navigate these challenges, supporting their ability to maintain, improve, and expand access to care for their patients.

The following summary reflects the AAMC's comments on CMS' proposals in this proposed rule regarding hospital outpatient payments, quality proposals, and requests for information.

Payment Proposals

- *Payment Update*: Increase the OPPS payment update for CY 2025 to account for increased labor and supply costs.
- *Outlier Threshold*: Calculate the outlier threshold for high-cost services using a cost-to-charge ratio adjustment more reflective of recent data.
- *Payment for Cell and Gene Therapies*: Finalize the proposal to exclude cell and gene therapy services from being packaged into comprehensive ambulatory payment classifications (C-APCs) and ensure accurate reimbursement for cell and gene therapies in the OPPS.
- *Telehealth and Remote Services*: CMS should work with Congress to maintain access to telehealth and other remote services including virtual direct supervision of cardiac rehabilitation (CR) services, intensive cardiac rehabilitation (ICR) services, pulmonary rehabilitation (PR) services, and diagnostic services by making permanent or at a minimum providing a two-year extension to existing telehealth flexibilities.
- *Payment for Remote Services Billed on Institutional Claim Forms*: Reimburse for remote services provided by institutional staff that are billed though institutional claims forms and consider adopting new codes to describe these remote services.
- *Obstetrical Service Standards CoP and Other CoP Changes*: Maternal health outcomes are a critical issue that must be addressed, but conditions of participation (CoP) changes are not the appropriate vehicle to address these challenges. CMS could consider alternative policy levers, such as quality reporting and performance programs, to incentivize improvements for maternal health care.
- *Separate Payment for Diagnostic Radiopharmaceuticals*: Allow for separate payment for diagnostic radiopharmaceuticals with a daily cost that exceeds 1.75 times the volume weighted average offset amount.
- *Invoice Pricing for Drugs without ASP Data*: Withdraw the proposal to require hospitals to report invoice prices for drugs with no sales data due to the burden of this approach and consider using wholesale acquisition cost to set payment.
- *Non-Opioid Treatments for Pain Relief*: Finalize the proposal to provide additional payments for non-opioid treatments for pain relief.
- *Payment for HIV PrEP in HOPDs:* Ensure adequate payment and access for HIV PrEP drugs and related services under OPPS.
- *Prior Authorization*: Reconsider the use of prior authorization for OPPS services and further shorten prior authorization timelines to 24 hours for emergency requests and 48 hours for standard requests.
- *'In Custody' Definition for Medicare Eligibility*: Finalize the proposal to narrow Medicare's custody definition to no longer include individuals on bail, parole, probation, and home detention to expand access and promote successful reentry.
- *Continuous Eligibility in Medicaid and CHIP*: Finalize proposal to require continuous eligibility for up to 12 months for children under 19 in Medicaid or Children's Health Insurance Program (CHIP).

- *Medicaid "Four Walls" Exception*: Finalize the proposal to expand exceptions to the Medicaid "four walls" requirement for clinical services. Adopt a broad and inclusive policy of the definition of rural.
- *Cardiac CT Services*: Ensure reimbursement for cardiac CT services accurately reflects the cost of providing these services; issue education and guidance on use of revenue codes for cardiac CT services.
- *Payment for NIOSH-approved N95 masks*: Finalize the proposal to expand the scope of products eligible for add-on payments and ease hospital burden but do not implement the policy in a budget neutral manner.

Quality Proposals

- *Changes to the Outpatient Quality Reporting (OQR) Program*: CMS should adopt proposed measures with modifications and finalized measures as proposed.
- *Changes to the Inpatient Quality Reporting (IQR) Program*: CMS should delay mandatory reporting of core clinical data elements and linking variables for the hybrid EHR-based measures and provide additional technical support to hospitals voluntarily reporting these measures.
- *RFI on Emphasizing Patient Safety in the Overall Hospital Quality Star Ratings*: CMS should ensure any future policies to emphasize patient safety best reflect patient priorities and appropriately balance safety with important areas like patient experience and mortality.

PAYMENT PROPOSALS

PAYMENT UPDATE

Increase the OPPS Payment Update for CY 2025 to Reflect Higher Growth in Labor and Supply Costs

CMS is proposing an OPPS conversion factor update of positive 2.6 percent for CY 2025. The proposed OPPS payment update is based on the fiscal year (FY) 2025 Inpatient Prospective Payment System (IPPS) proposed rule[1] market basket increase of 3.0 percent and a total factor productivity adjustment of minus 0.4 percentage points. (p. 59223) The AAMC is concerned that the proposed OPPS payment update does not adequately account for the significantly higher growth in labor and supply costs health systems continue to experience after the end of the COVID-19 public health emergency (PHE). AAMC member health systems continue to experience financial challenges post pandemic, including workforce shortages, capacity constraints, insufficient reimbursement by payers, supply chain disruptions, and significant growth in expenses such as labor costs. The proposed CY 2025 update, coupled with 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 CMS used to calculate the inpatient market basket update, which are also used to calculate the OPPS conversion factor update, do not accurately reflect the dramatic increase in labor and supply costs that hospitals and health systems have experienced since 2022. In the FY 2025 IPPS final rule,[2] CMS finalized a market basket update of 3.4 percent minus a total factor productivity adjustment of 0.5

[1] 89 FR 35934 (May 2, 2024).
[2] 89 FR 68986 (Aug. 28, 2024).

percentage points, which equaled a final update of 2.9 percent. However, even with the final FY 2025 IPPS market basket increase, which we anticipate CMS will adopt in the OPPS final rule, we believe the update does not adequately account for the financial challenges hospitals continue to face. One report found that labor expenses in 2023 were a staggering 20 percent higher than 2020, with no signs that this trend will abate.[3] More recent data demonstrate that these cost pressures continue into 2024—year-to-date expenses for hospitals are six percent higher in 2024 than 2023.[4] Most hospitals are operating on negative Medicare margins, which makes providing care challenging. In its March 2024 report, the Medicare Payment Advisory Commission (MedPAC) found Medicare margins of negative 8.1 percent in 2021 and a record-low negative 12.7 percent in 2022.[5] Citing concerns about hospital financial sustainability in 2025, MedPAC recommended a Medicare payment update of 1.5 percent above the market basket update—the second year in a row for which MedPAC has called for an increase above the market basket update.[6] The financial outlook for academic health systems specifically is even more grim—AAMC member hospital overall Medicare margins were negative 17.5 percent in 2021.[7] Whereas we may have thought this trend would have reversed after the pandemic, we do not see these cost trends lessening in 2025 or the foreseeable future. We urge CMS to consider these factors and how they contribute to the increased cost of providing care to Medicare beneficiaries. We strongly encourage CMS to increase the CY 2025 OPPS market basket to reflect these financial challenges and to enable health systems to continue to provide access to essential care to beneficiaries. While CMS has used inpatient market basket data to set the outpatient update, CMS has leeway under the statute to use other data for the OPPS conversion factor update. Specifically, under section 1833(t)(3)(C)(iv) of the Social Security Act, CMS can "substitute[e] for the market basket percentage increase an annual percentage increase that is computed and applied with respect to covered OPD services furnished in a year in the same manner as the market basket percentage increase is determined and applied to inpatient hospital services for discharges occurring in a fiscal year." Therefore, CMS has flexibility to deviate from the IPPS market basket update to provide for a higher OPPS conversion factor update that is more reflective of actual inflation and increases in hospital input costs.

HOSPITAL OUTPATIENT OUTLIER PAYMENTS

Calculate the Outlier Threshold for High-Cost Services Using a Cost-to-Charge Ratio Adjustment More Reflective of Recent Data

The AAMC urges CMS to evaluate the factors affecting the calculation of the fixed-dollar amount to ensure accuracy in operating outlier payments and that hospitals are adequately reimbursed for high-cost services. Outlier payments are intended to cover a portion of the expenses associated with extraordinarily high-cost services. CMS sets a target for total outlier payments at 1 percent of aggregate OPPS payments. A hospital qualifies for an outlier payment for a given service if the costs of the service exceed the ambulatory payment classification (APC) payment multiplier threshold and the APC payment amount plus the fixed-dollar amount threshold. For CY 2025, CMS proposes an APC payment multiplier threshold of 1.75 times the APC payment amount and a fixed-dollar amount threshold of $8,000. An

[3] Kaufman Hall January 2024 National Hospital Flash Report. Jan. 30, 2024.
[4] Kaufman Hall June 2024 National Hospital Flash Report. Aug. 5, 2024.
[5] MedPAC March 2024 Report to Congress. Chapter 3.
[6] MedPAC March 2024 Report to Congress. Chapter 3; MedPAC March 2023 Report to Congress. Chapter 3.
[7] Note: AAMC margin data for 2022 are not yet available for comparison to MedPAC's 2022 all-IPPS hospital Medicare margins. Source: AAMC analysis of FY 2021 hospital cost reports from the Hospital Cost Reporting Information System (HCRIS) September 30, 2023, update obtained from CMS.

increase in the fixed-dollar threshold results in fewer OPPS services being eligible for high-cost outlier payments.

To calculate the fixed-dollar threshold, CMS uses charges from historical claims data (CY 2023 for the CY 2025 proposed rule) and updates the charges with a charge inflation factor. CMS converts these charges to costs using hospital-specific cost-to-charge ratios (CCRs), which are adjusted for expected year-over -year changes in CCRs using a CCR adjustment factor. In the OPPS proposed rule, CMS uses the same CCR adjustment factor and charge inflation factors as CMS uses in the IPPS rule. As the AAMC explained in more detailed comments on the FY 2025 IPPS proposed rule, we believe the CCR adjustment factor used overstates the effect of cost increases that took place from 2022 to 2023.[8] Since at least FY 2014, the CCR adjustment factor CMS used in each IPPS final rule (and thus the OPPS final rule, which uses the same CCR adjustment factor) has been under 1, meaning CCRs have been expected to decrease year-over-year. For the first time in recent memory, as CMS did in the FY 2025 IPPS proposed rule, CMS is proposing to use a CCR adjustment factor greater than 1.0, specifically 1.03331, which is an over four percent increase compared with the CY 2024 finalized CCR adjustment factor (and the highest year-over-year increase registered as far back as 2014). A CCR adjustment factor over 1.0 ultimately results in a higher estimate of the fixed-dollar threshold, which sets a higher threshold for qualifying for outlier payments. We believe more recent data on 2023 CCRs will verify that CCRs began to trend downward in 2023. In fact, this point was borne out in the FY 2025 IPPS final rule, in which the CCR adjustment factor decreased to 1.015123.[9] While this finalized CCR adjustment, which we anticipate CMS will adopt in the OPPS final rule, indicates this trend, we expect actual CCRs will ultimately be even lower.

Due to the anomalous increase in CCRs from 2022 to 2023, and the incompleteness of the data used to calculate the CCR adjustment factor, CMS should revise its CCR adjustment factor. CMS could, for example, use the previous year's CCR adjustment factor or cap the CCR adjustment for use in calculating the CY 2025 fixed-dollar threshold at 1. CMS should substitute a different CCR adjustment factor that will be more aligned with actual year-over-year changes in CCRs and will be borne out as more recent data become available.

PAYMENT FOR CELL AND GENE THERAPIES

Finalize the Proposal to Exclude Cell and Gene Therapy Services from Being Packaged into C-APCs and Ensure Accurate Reimbursement for Cell and Gene Therapies in the OPPS

For CY 2025 only, CMS proposes to exclude HCPCS codes for nine cell and gene therapies from being packaged under its C-APC policy. (p. 59203) Under its C-APC packaging policy, CMS pays a single payment amount for the primary service or procedure (denoted by status indicator "J1" or "J2") and all services that appear on the claim that are considered integral, ancillary, supportive, or adjunctive to the primary procedure. The primary procedures are typically major, high-cost services or procedures. While high-cost cell and gene therapies have separate APC payment rates under the OPPS, in certain instances when a code for a cell or gene therapy service appears on a claim with a primary C-APC service, the payment for the cell or gene therapy is made as part of the single primary C-APC payment.

We are encouraged by CMS' acknowledgment that these high-cost cell and gene therapies should not be packaged both due to the detrimental effect on hospital reimbursement, as well as because these

[8] AAMC Comment Letter on FY 2025 IPPS Proposed Rule.
[9] 89 FR at 69959.

treatments are independent services that are not considered secondary or adjunctive to other services. Innovative gene and cell therapies, such as chimeric antigen receptor T-cell therapy (CAR T-cell therapy) are revolutionizing the treatment landscape, offering potential cures for previously untreatable diseases. However, these treatments can be extremely expensive and complex. **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 deal with the complications (often life threatening) that are encountered as the patient goes through this course of care.** Failing to adequately reimburse providers for the cost of providing these therapies will threaten beneficiary access to these services. While CAR T-cell therapy is mostly provided in the inpatient setting, its use in the outpatient setting is increasing.[10] Other therapies on the list of codes that CMS proposes to exclude from packaging are primarily outpatient therapies, such as the administration of Luxturna for retinal disorders.[11] To preserve access to these services and ensure hospitals are adequately reimbursed for their costs, CMS should finalize its policy to unpackage cell and gene therapies from C-APCs and expand the list of codes to include all cell and gene therapies. Furthermore, we urge CMS to make this policy permanent, as there is no rationale for packaging these services, which are performed independent of other procedures.

CMS should continue to evaluate payment for cell and gene therapies, including by ensuring that it is accurately paying for them and that it is covering all costs of the therapy itself as well as related services. CMS seeks feedback on creating cell and gene therapy C-APCs. We caution CMS against creating C-APCs for cell and gene therapies. Inadequate Medicare reimbursement to hospitals has the potential to jeopardize beneficiary access to CAR T-cell therapy and other high-cost therapies as institutions weigh reimbursement challenges with their ability to provide this costly care. These therapies involve highly specialized procedures, intensive monitoring, and multidisciplinary care teams, all of which contribute to their substantial costs. Administration of cell and gene therapies are multi-step processes that include cell collection, lab processing of the cells, dose preparation, and administration of the treatment.[12] From beginning to end, this entire process can take weeks if not months and entail multiple services that would not appear on the same claim. CMS must ensure that it is reimbursing hospitals for the full range of costs that go into cell and gene therapies by reimbursing separately for the therapies and for the various distinct services provided as part of the overall treatment.

Taking the example of CAR T-cell therapy treatment, CMS does not currently account for the full range of services that are provided in relation to a course of treatment. Notably, CMS does not reimburse separately under the OPPS for the cell collection, cell processing, and dose preparation that occur before the administration of the CAR T biologic. While there are three category III Current Procedural Terminology (CPT) codes that currently describe these services, CMS has not assigned payment to these CPT codes because of its belief that costs are incorporated into the payment for the CAR T-cell product

[10] Hansen, DK, et al. The Impact of Outpatient versus Inpatient Administration of CAR-T Therapies on Clinical, Economic, and Humanistic Outcomes in Patients with Hematological Cancer: A Systematic Literature Review. Cancers (Basel). December 2023, 15(24):5746.
[11] About Luxturna Administration.
[12] Alexander, M. et al. Chimeric Antigen Receptor T Cell Therapy: A Comprehensive Review of Clinical Efficacy, Toxicity, and Best Practices for Outpatient Administration. Transplantation and Cellular Therapy Volume 27, Issue 7, 2021.

itself.[13] The CPT editorial panel approved three category I CPT codes that will replace these three codes beginning on January 1, 2025: 3X018, 3X019, and 3X020.[14] However, CMS has assigned status indicator B ("codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x)") to these three codes, which means no payment for these services would be made under the OPPS when the respective CPT codes appear on the claim.

CMS has an opportunity to appropriately reimburse for CAR T-cell therapy by ensuring these services, which are an essential part of the course of the CAR T-cell therapy treatment, have a payable status indicator. **Specifically, we recommend that CMS assign status indicator S, which is assigned to procedures or services paid separately and not subject to the multiple procedure reduction. In addition to assigning status indicator S, CMS should ensure these services are assigned to the appropriate APC reflecting the costs of providing the services.** Cell collection and processing occur before the cells are sent to the drug manufacturer to genetically engineer the patient's T-cells with the appropriate chimeric antigen receptors. Once the modified cells are prepared, the manufacturer sends the cells back to the hospital, which will then prepare the dose, prior to administering the treatment to the patient. The cell collection, processing, and dose preparation are currently not reimbursed and not included in the average sales price (ASP) based payment for the CAR T-cell therapy biologic itself, leaving hospitals unreimbursed for significant costs associated with the procedure. Furthermore, there are instances where a patient dies before being able to receive treatment, the manufacturer is unable to engineer the specific treatment, or the patient's prognosis improves, no longer necessitating the administration of the biologic. In these cases, hospitals receive no ASP based payment for the biologic or any payment for the services involved in anticipation of administration of the drug. By allowing hospitals to bill and be paid for these services, CMS would be ensuring payment adequacy and preserving beneficiary access to CAR-T and other lifesaving gene and cell therapies.

REMOTE SERVICES

Work With Congress to Maintain Access to Remote Services and Ensure Adequate Reimbursement Rates for Remote Services

During the COVID-19 PHE, institutional staff in hospital outpatient departments could provide services billed on institutional claims forms virtually via communications technology to a patient while registered as an outpatient, and the home was considered an "expansion site" under the Hospitals Without Walls program (HWOW).[39] Specifically, CMS allowed for outpatient therapy services (e.g., physical therapy (PT), occupational therapy (OT), and speech-language pathology (SLP)), diabetes self-management training (DSMT), and medical nutrition therapy (MNT) to be provided via audio-visual technology to beneficiaries in their homes. Bills for these services could be submitted and paid when the services were provided by institutional staff and billed for by institutions (such as HOPDs, SNFs and HHAs). The Consolidated Appropriations Act (CAA) of 2023 extended flexibilities for Medicare telehealth services beyond the COVID-19 PHE until December 31, 2024, and CMS extended its policy allowing payment for outpatient therapy, DSMT, and MNT services to be furnished via audio-video technology by hospital-employed staff of hospital outpatient departments and billed on institutional claim forms through CY 2024. While these flexibilities are set to expire at the end of 2024, CMS is expecting if the flexibilities are

[13] CY 2019 OPPS final rule, 83 FR 58818 (Nov. 21, 2018). CY 2020 OPPS final rule, 84 FR 61142, 61232 (Nov. 12, 2019). "CMS does not believe that separate or packaged payment under the OPPS is necessary for the procedures described by CPT codes 0537T, 0538T, and 0539T for CY2020."
[14] CPT Editorial Summary of Panel Actions May 2023. https://www.ama-assn.org/system/files/cpt-summary-panel-actions-may-2023.pdf

extended by Congress, to align payment policies for outpatient therapy, DSMT, and MNT services furnished remotely by hospital staff to beneficiaries in their homes with policies for Medicare telehealth services under the Physician Fee Schedule (PFS). (p. 59389)

The AAMC supports CMS' continued efforts to allow the use of audio-video technology to provide medical services to beneficiaries and we urge the agency to continue working with Congress to maintain beneficiary access to remote services by making permanent, or at a minimum, by providing a two-year extension, to existing telehealth flexibilities**.** Patients have come to rely on receiving these services virtually, while providers have demonstrated that they can provide these services safely and effectively through audio-video technology. **We urge CMS to permanently pay for these remote services provided by institutional staff and billed by the hospital to promote continuity of care. One approach would be for CMS to adopt new codes describing these remote services that are similar to the C codes used to pay for mental health services furnished via remote technology by institutional staff employed by hospitals to beneficiaries in their homes.**[15] This is especially essential for beneficiaries in rural and underserved areas, to increase access to specialized care[16] and mental and behavioral health services.[17] Telehealth and remote services provide an additional delivery modality for medical care that allows for patients to access care more broadly. Continuing beneficiary access to remote services by maintaining existing telehealth flexibilities ensures that patients can continue to receive the necessary care they need. Additionally, for remote services to remain successful, reimbursement for these services must be commensurate with the costs of providing care through video visits.

Additionally, in the 2023 OPPS final rule, CMS adopted a policy to allow OPPS payment of remote mental health services when a hospital outpatient is receiving these services in their home. Under this policy, CMS requires an in-person visit within 6 months prior to or within 12 months after the initial remote mental health service. However, CMS delayed this requirement for CY 2024 until December 31, 2024, to align with the CAA of 2023. For FY 2025, CMS expects to align its applicable policies with hospitals through rulemaking if the requirement is delayed further by statute under the telehealth benefit. (p. 59390) The AAMC continues to urge CMS to not require an in-person visit for coverage of mental health services furnished via audio-video technology. We refer CMS to more detailed AAMC comments on the in-person visit requirements in our comment letter to the proposed CY 2023 OPPS proposed rule.[18]

Maintain Virtual Direct Supervision of CR/ICR/PR and Diagnostic Services

CMS also allowed for remote direct supervision of CR, ICR, PR services, and diagnostic services during the COVID-19 PHE. This flexibility was extended through December 31, 2024, by the CAA, 2023. For CY 2025, CMS is proposing to further extend this flexibility until December 31, 2025, to allow for the direct supervision of CR, ICR, PR services and diagnostic services via audio-video real-time communications technology (excluding audio-only) under OPPS. (p. 59391) The AAMC supports this proposal and urges the agency to finalize it. Additionally, we urge the agency to consider making this policy permanent.

---

[15] 2024 Hospital Outpatient Prospective Payment System, 88 FR 81540 at 81870
[16] Marcin, J., Shaikh, U. & Steinhorn, R. Addressing health disparities in rural communities using telehealth. *Pediatr Res* 79, 169–176 (2016).
[17] Ward MM, Ullrich F, Bhagianadh D, Nelson EL, Marcin JP, Carter KD, Law KB, McCord C, Neufeld J, Merchant KAS. Telehealth and In-Person Behavioral Health Services in Rural Communities Before and During the COVID-19 Pandemic: Multisite Prospective Cohort Study. JMIR Ment Health. 2023 Sep 18
[18] *Id.*

OBSTETRICAL SERVICE STANDARDS COP AND OTHER COP REVISIONS

Building off the request for information included in the FY 2025 IPPS proposed rule focused on maternal health, the agency included a proposal to establish a new optional service CoP for obstetrical service standards and to revise two existing CoPs. The new obstetrical service standards CoP includes requirements for service organization, staffing, delivery of services, and training. Through this CoP, hospitals would also be required to utilize their Quality Assessment and Performance Improvement (QAPI) programs to assess and improve health outcomes and disparities among obstetric patients on an ongoing basis. (p. 59490) **While the AAMC supports the agency's interest in improving 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.**

AAMC-member medical schools, teaching health systems and hospitals, and faculty physicians play a critical role in the maternal health care delivery system, offering highly specialized services that are often unavailable in other settings. As compared to only 12 percent of hospitals nationwide, 73 percent of AAMC-member health systems and hospitals provide level III obstetrics and gynecology services, which includes the management and treatment of complex maternal medical conditions, obstetric complications, and fetal abnormalities.[19] This level of care offered by our members establishes them as key players in addressing maternal health outcomes. Our members are committed to improving maternal health outcomes through investing in several factors affecting maternity care, including workforce, clinical care, research, and fostering relationships with patients, families, and communities.[20] Maintaining services offered by hospitals and health-systems across all levels of care ensures access and can drive improvements to maternal health outcomes.

CMS Should Not Finalize New CoP Requirements for Obstetrical Services or Changes to Existing CoPs

As of 2019, 1,775 counties in the United States were devoid of hospitals or birthing centers.[21] Additional CoPs increase cost, burden, and potential risk to hospitals that offer obstetrical care services. As an optional CoP requirement, meaning that only hospitals offering obstetrical services will be subject to these requirements, the AAMC remains concerned that this proposal carries the unintended consequence of exacerbating maternal care deserts. 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. Due to the punitive nature of Medicare CoPs, hospitals that are uncertain of their ability to meet these requirements or cover the additional costs associated with implementation may ultimately forgo offering obstetrical services. For example, in the past five years over 100 rural hospitals have shuttered their labor and delivery services.[22] In 2022-2023, nearly 40 percent of rural hospitals continuing to offer labor and delivery services lost money on patient services overall, leaving remaining rural hospitals at risk.[23] Reduced labor and delivery services also impacts access and health outcomes in urban areas with one of three women residing in metropolitan or urban

[19] AAMC Analysis of American Hospital Association (AHA) Annual Survey Database, FY2021. Hospital counts reflect total number of hospitals in the database and excludes federal hospitals, long-term care hospitals, and specialty hospitals. Reflects AAMC membership as of January 2024.
[20] AAMC, Medical Schools' and Teaching Hospitals' Efforts to Address the Maternal Health Crisis (June 2021)
[21] U.S. Health Resources and Services Administration (HRSA), Area Resources Files, 2021; American Association of Birth Centers, 2022.
[22] Center for Healthcare Quality & Payment Reform. Addressing the Crisis in Rural Maternity Care (July 2024)
[23] *Id.*

areas living in an obstetrical care desert.[24] Additionally, these closures disproportionately impact communities of color and exacerbate already high health risks for birthing women of color.[25] 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.

As an alternative, the AAMC encourages CMS to explore policy options that incentivize and bolster providers' ability to meet standards rather than penalizing them. Additional investment provides the opportunity to alleviate pressure on hospitals that may already be struggling to operate obstetrical services. Within the proposal CMS includes requirements for hospitals to utilize their QAPI programs to assess and improve health outcomes and disparities among obstetric patients on an ongoing basis. (p. 59494) As noted in our response to the request for information (RFI) in the FY 2025 IPPS proposed rule,[26] CMS could utilize alternative policy levers, such as quality reporting and performance programs, to incentivize improvements for maternal health care. However, the QAPI program requirements are still tied to CoPs, which still pose an additional risk for hospitals that may not have the resources to enhance their QAPI programs to meet these new proposed standards. While some hospitals may already have well-established QAPI programs with administrative and clinical support, other facilities will struggle to establish these programs due to limitations in work force, data reporting, and interoperability. This proposal would also be CMS' most extensive quality requirements under a CoP and requires investment and a well-defined timeline for implementation that facilities may use as a guide ramp for coming into compliance. The AAMC does appreciate the flexibility CMS built into these requirements to allow hospitals to tailor to their needs, but we remain concerned that some facilities may face significant barriers to establishing these programs.

CMS Should Delay Consideration of Requirements Related to Race and Ethnicity Data Collections Until After HHS Completes its Action Plan on Race and Ethnicity Data for the OMB's Revised Standards

As a part of the QAPI program requirements, hospitals would need to analyze data and quality indicators within the program by diverse subpopulations. (p.59495) The AAMC is aligned with CMS on the importance of data collection by diverse subpopulations to support health equity and clinical delivery improvements.[27] Within the proposal, CMS does not specify exactly what it means by "diverse subpopulations," but if CMS intends for this to include collecting demographic data, we urge the agency to take into account the following considerations. Some patients may be less willing to share additional demographic information, which may hinder data collection efforts if hospitals choose to instead honor patient choices. This should be considered by the agency when evaluating potential demographic reporting requirements. Additionally, data collection standards for race and ethnicity data continues to evolve as seen in the Office of Management and Budget (OMB) revisions of the Statistical Policy Directive No. 15 on Standards for Maintaining, Collecting, and Presenting Federal Data on Race and

[24] Hostetter M, Klein S. "Restoring Access to Maternity Care in Rural America," *Transforming Care* (newsletter), Commonwealth Fund, September 30, 2021. https://doi.org/10.26099/CYCC-FF50
[25] McGregor AJ, Hung P, Garman D, Amutah-Onukagha N, Cooper JA. Obstetrical unit closures and racial and ethnic differences in severe maternal morbidity in the state of New Jersey. *Am J Obstet Gynecol MFM*. 2021
[26] AAMC Comment Letter on the FY 2025 IPPS Proposed Rule (June 2024).
[27] See, AAMC, Comments to the Interagency Technical Working Group on Race and Ethnicity Standards (April 2023), specifically referencing the challenges during the COVID-19 pandemic with federal data to best identify and address health inequities experienced by racial and ethnic minorities and the importance of improved national standards to accurately capture race and ethnicity data.

Ethnicity (SPD No. 15).[28] These new standards were recently put into effect for all new record keeping and reporting requirements that include race and ethnicity data, and require agencies to submit no later than September 29, 2025, to OMB a publicly available Action Plan on Race and Ethnicity Data describing how the agency intends to bring their collections and publications into compliance with the new standards by March 28, 2029.[29] **Due to this, we urge CMS to not require reporting of race and ethnicity under the requirements within a CoP, and instead focus on contributions to a whole HHS approach to devising its Action Plan on Race and Ethnicity Data due in September 2025.**

CMS has a vital role in working across HHS to ensure that policy change is consistent across the Department, considering its interactions with the CDC, Food & Drug Administration, and the Office of the National Coordinator for Health Information Technology (ONC). Hospitals' systems for collecting and reporting race and ethnicity are simply not yet configured to the new standards and will rely on the agencies across HHS to provide clear guidance and technical assistance to adopt these changes on the ground. The AAMC believes that implementing the OMB's changes to race and ethnicity data collection will meaningfully improve the data that agencies, healthcare providers, and communities all rely on to impact change and reduce health inequities. The OMB's changes to federal race and ethnicity data collection are significant and will require significant policy changes to fully implement. In the meantime, we ask CMS to withhold any new race and ethnicity data collection policies and instead focus on ensuring a seamless implementation of the revised standards that set healthcare delivery up for real success.

Delay the Implementation Timeline, Provide Adequate Time for Hospitals to Come into Compliance

Beyond our concerns around exacerbating maternal care deserts, the AAMC is apprehensive about the implementation timeline for hospitals to come into compliance with the proposed Medicare CoP changes. Within the proposed rule, the agency does not outline a specific implementation date or timeline, which leads us to assume hospitals will need to be compliant with any CoP changes finalized in the final rule by January 1, 2025. CMS does allot flexibility to meet these new standards; however, this flexibility still leaves questions for hospitals around some aspects of implementation that likely will require additional guidance from the agency. Even with this flexibility, these questions will need to be addressed for facilities to come into compliance. Without clarification, it is unreasonable to expect hospitals to be able to meet these new requirements by January 1. In addition to further clarification, these changes involve several moving parts that require investment from hospitals and collaboration between clinicians and hospital leadership and administration. For some hospitals, especially those most at risk for eliminating labor and delivery services, the added pressure to meet such a quick deadline that involves additional resources and staffing may prove to be too much to continue offering these services. If CMS chooses to finalize these new COP requirements, **the AAMC urges CMS to delay the implementation timeline and include a phased in approach.** This will allow hospitals to stretch their resources and meet new requirements gradually over time, minimizing administrative burden and financial strain.

Invest in Hospitals' Ability to Provide Obstetrical Services Rather than Increase Costs

CMS estimates it will cost approximately $4.27 billion over 10 years to implement the changes to CoPs, which averages $70,671 per year for each hospital affected by these changes. (p. 59542) The AAMC is concerned that the estimates the CMS has put forth do not accurately represent potential costs for hospitals, especially given the variations between facilities and the levels of care offered. For example, in

[28] 89 FR 22182 (March 29, 2024).
[29] Id., at 22196.

several of the estimates the agency provides there is an expected cost listed for the first year of implementation followed by an estimated cost of zero dollars for each subsequent year, not considering the potential costs of maintaining compliance or upkeep of required equipment under these standards year after year. For example, Table 147 of the proposed rule estimates about $201 million for obstetrical equipment over ten years with all $201 million estimated to take place only in the first year. (P.59562) This estimate neglects the cost of upkeep or replacement that poses additional barriers for hospitals stretching scarce resources.

Beyond this, the AAMC remains concerned with other factors driving hospital costs, such as workforce, that may not be fully recognized within these estimates. Specific to workforce, hospitals saw costs increase by more than $42.5 billion between 2021 and 2023 to a total of $839 billion, accounting for nearly 60% of the average hospital's expenses.[30] This trend is expected to continue increasing for the foreseeable future; however, many of CMS' estimates involving hourly wages and workforce estimates remain stagnant year over year, neglecting to account for this trend in workforce costs. CMS also does not include estimates for attracting and retaining qualified clinicians, which requires significant investment from hospitals and health systems. These costs will vary from facility to facility and are likely to disproportionately impact facilities most at risk for closing labor and delivery services. Specific to the staffing requirements within CMS' proposed CoP, labor and delivery rooms, rooms for operative delivery, and post-partum and recovery rooms would have to be supervised by an experienced registered nurse, certified nurse midwife, nurse practitioner, physician assistant, or a physician. (p. 59491) To meet this requirement hospitals must employ and retain multiple qualified practitioners to maintain this level of supervision, adding additional cost and strain on hospitals ability to recruit and retain clinicians. Due to this, it is imperative that CMS explore policy options that invest in the maternal healthcare system rather than increase costs.

Ensure Adequate Medicare and Medicaid Payment for Hospital and Maternal Health Services

Investment in maternal care must include accurate reimbursement rates for maternal health services, as well as for services overall. Throughout our comments, the AAMC has highlighted the financial challenges hospitals and health-systems continue to face. Within Medicare, the market basket for Medicare base rates over recent years has failed to keep up with increased costs and the rate of inflation as detailed earlier in this letter and in prior AAMC comment letters.[31] The AAMC continues to articulate the need for adequate payments rates for all Medicare services inclusive of accurate market basket updates for hospitals to maintain access to needed services such as obstetrical care. The emergence of "maternity care deserts," defined as counties without a hospital or birth center offering obstetric care, is the direct result of hospital-based maternity ward closures. In 2022, over 2.2 million women of childbearing age lived in a maternity care desert.[32] This challenge is expected to worsen in the coming years due to the profound financial pressures facing health systems, affecting access for all patients, especially for those in rural and historically under-resourced communities. The AAMC detailed the challenges associated with Medicare and Medicaid payment rates on maternal health in our FY 2025 IPPS comment letter in response to CMS' maternal health RFI.[33] Collectively, the ability for hospitals and

[30] AHA, America's Hospitals and Health Systems Continue to Face Escalating Operational Costs and Economic Pressures as They Care for Patients and Communities (May 2024).
[31] AAMC, Comments to CMS on the FY 2025 IPPS Proposed Rule (June 2024).
[32] Brigance, C., Lucas R., Jones, E., Davis, A., Oinuma, M., Mishkin, K. and Henderson, Z. (2022). Nowhere to Go: Maternity Care Deserts Across the U.S. (Report No. 3). March of Dimes.
[33] AAMC Comment Letter on the FY 2025 IPPS Proposed Rule (June 2024).

health systems to participate in Medicare and receive adequate payment for all services including obstetrical and perinatal services, plays a vital role in a hospital's financial viability and ability to continue operating a multitude of service lines.

CMS Should Focus on Perinatal Services to Improve Maternal Health Outcomes

CMS must also acknowledge the broader role of the full range of maternal care providers and services (e.g., physicians, certified nurse midwives, mental health providers) who provide prenatal and postpartum maternal care largely outside of the hospital inpatient setting. CMS' proposal is limited in the fact that the new CoPs and CoP changes only address care within the hospital setting and do not fully encompass the root issues associated with increasing rates of maternal morbidity and mortality. High quality care throughout pregnancy and following delivery are essential elements to achieving positive outcomes for babies and birthing persons. Focusing on access to perinatal services is especially critical as the percentage of mothers receiving prenatal care dropped in the last year.[34] Additional patient monitoring associated with perinatal care can identify potential health issues, such as high blood pressure or postpartum depression, and provide patients with care before causing additional health complications that may lead to serious illness or death. For example, one of the most common complications of pregnancy and childbirth are mental health conditions, which affect 1 in 5 mothers every year in the United States[35] with less than 15 percent of those receiving treatment.[36] Suicide and overdose are the leading causes of death in the first year postpartum, of which many of these deaths are preventable. While hospitals do have a critical role in improving maternal health care equity, especially for labor and delivery outcomes, they cannot be held solely responsible for implementing much needed improvements and solutions.

To address maternal deaths during or within one year of pregnancy, Maternal Mortality Review Committees (MMRC) convene at the state or local level to comprehensively review deaths with the goal of understanding the circumstances surrounding each death and developing recommended actions for prevention moving forward. CMS looks to tap into this information by requiring hospitals to incorporate MMRC data and recommendations into their QAPI programs if the MMRC is in the same state or local jurisdiction as the hospital. (p.59497) The AAMC supports the work that MMRCs do and appreciates CMS for tapping into and leveraging already existing data where applicable. However, MMRC data also may include data and recommendations related to adverse events that take place outside of the hospital and inpatient setting meaning some findings and recommendations from MMRCs may be outside of a hospital's scope. CMS should focus maternal health policy approaches in a way that addresses the full spectrum of perinatal care including care taking place outside of the inpatient setting.

Lastly, without coverage many of CMS' polices to improve maternal health outcomes may still be out of reach. The AAMC appreciates CMS' work to address maternal health outcomes, including extending

---

[34] Martin JA, Hamilton BE, Osterman MJK. Births in the United States, 2023. NCHS Data Brief, no 507. Hyattsville, MD: National Center for Health Statistics. 2024.
[35] Fawcett EJ, Fairbrother N, Cox ML, White IR, Fawcett JM. The Prevalence of Anxiety Disorders During Pregnancy and the Postpartum Period: A Multivariate Bayesian Meta-Analysis. J Clin Psychiatry. 2019 Jul 23;80(4):18r12527. https://pubmed.ncbi.nlm.nih.gov/31347796/.
[36] Puspitasari AJ, Heredia D, Weber E, Betcher HK, Coombes BJ, Brodrick EM, Skinner SM, Tomlinson AL, Salik SS, Allen SV, O'Grady JS, Johnson EK, L'amoureux TM, Moore KM. Perinatal Mood and Anxiety Disorder Management in Multicenter Community Practices: Clinicians' Training, Current Practices and Perceived Strategies to Improve Future Implementation. J Prim Care Community Health.

postpartum coverage.[37] We urge the agency to continue to advance polices that promote universal access to postpartum coverage. Providing this extended coverage allows for increased access to primary care as well as mental health services, which would incorporate an additional focus on perinatal care needs. Additionally, coverage alone does not guarantee access to care for pregnant patients. Barriers imposed by insurers, including administratively burdensome prior authorization requirements, can reduce patients' access to care and place additional strain on providers due to added costs and workforce needs. This is particularly concerning in the context of maternity care, as prior authorization requirements can limit patients' access to time-sensitive diagnostic and treatment procedures, such as genetic testing. To address this challenge, the AAMC continues to urge CMS to prohibit prior authorization for maternal care during the prenatal and one-year postpartum period. To support continuity of care during this critical window, the AAMC recommends requiring payers to honor prior authorization approvals issued by a previous payer during pregnancy and for one-year postpartum. This policy would ensure that pregnant and postpartum patients have continued access to medically necessary care, regardless of whether their source of coverage has changed.

CMS Should Work with Policymakers to Ensure Access to The Full Scope of Obstetrical Care Services including Emergency Services

In addition to a new CoP to address obstetrical service standards, CMS is also proposing revisions to the Emergency Preparedness CoP to include an Emergency Services Readiness standard to set clear expectations for emergency services for pregnant and postpartum individuals regardless of whether a hospital or CAH offers obstetric care. (p. 59497) The AAMC supports CMS' efforts to ensure emergency preparedness, including appropriate training and access to emergency care for obstetrical patients. However, the AAMC remains concerned with the punitive nature of CoPs and the initial investment for certain hospitals to meet these standards. Establishing guidelines for emergency services for pregnant and postpartum individuals is an important step to ensure patient safety, but hospitals may require initial investments and ample time for implementation for these requirements that the punitive nature of the CoPs does not take into account. For example, hospitals may need to establish proper storage, tracking, and protocols related to the requirements including the readily available supplies for emergency services for pregnant and postpartum individuals which will require time, workforce, and investment to ensure hospitals can met these requirements and patient safety needs. Without these elements, the CoP revisions may add additional strain on hospitals and consequently impact their Medicare eligibility.

Further, the AAMC is concerned with barriers to access to clinically appropriate protocols needed for emergency maternal care in certain states due to restrictions on women's health care. State laws that restrict women's health care may negatively impact the ability for health systems and hospitals to adequately provide the emergency services as well as education and care needed for these patients. Since the United States Supreme Court issued a final decision in the *Dobbs v. Jackson Women's Health Organization*[38] case and reversed federal abortion protections, the AAMC has observed a noticeable change in residency applications in states that have issued restrictions on women's health care, affecting

[37] Centers for Medicare and Medicaid. (2021). Improving Maternal Health and Extending Postpartum Coverage in Medicaid and the Children's Health Insurance Program (CHIP) (SHO# 21-007).
[38] Dobbs v. Jackson Women's Health Organization, 597 U.S. ___ (2022)

where physicians plan to practice regardless of whether the specialty is focused on treatment of pregnant patients or not.[39]

In the long term, this shift has the potential to further exacerbate provider shortages in states with restrictive practice environments and negatively impact access to care and maternal health outcomes. In Idaho following the passage of restrictions on women's health care, this trend is already being observed. From August 2022 to November 2023, the state lost twenty-two percent of its practicing obstetricians within a fifteen-month period including fifty five percent of its Maternal Fetal Medicine doctors who treat high risk patients.[40] Related to emergency services, under the Emergency Medical Treatment and Labor Act (EMTALA) hospitals receiving Medicare funding must provide treatment necessary to stabilize patients in emergencies. On rare occasions, providers may be required to carry out the termination of a pregnancy to stabilize a patient's emergency condition. The question of whether EMTALA preempts state laws that prohibit abortions is still being contested within the courts. Specifically, in *Moyle v. United States*, the United States Supreme Court remanded the case back to the lower courts to decide whether Idaho's state law that criminalizes providing an abortion, except in a few narrow circumstances, is preempted by EMTALA.[41] Without EMTALA protections, patients may be faced with longer travel, greater barriers to access pregnancy-related care, and increased risk for negative maternal health outcomes especially for historically under-resourced patients.[42] Without EMTALA and protections for patients' access to necessary medical treatment certain nationally recognized standards of care may be unobtainable for millions of women within the US, even if these new CoP requirements are finalized. **The AAMC urges CMS to work with relevant policymakers and stakeholders to maintain current EMTALA protections and protect access to all women's health services.**

Ensure Hospitals Have Flexibility Regarding Transfers in Order to Address Patient Needs

Under EMTALA, hospitals are required to provide medical screening examinations when requested for an emergency medical condition as well as stabilize patients within their capacity before they can initiate a transfer to another hospital or medical facility.[43] CMS builds on the standard for transfers outlined under EMTALA by proposing revisions to the Discharge Planning CoP related to patient transfers. Under CMS' proposal, hospitals would be required to have written policies and procedures for transferring patients under their care (e.g., hospital inpatient transfers, hospital-to-hospital transfers) as well as training for staff on the written polices required for transfers. This requirement would be applicable to all hospitals for all transfers. CMS will consider a safe transfer to include risk identification and determination of conditions necessitating consultation, referral, and transfer, mechanisms and procedures for transfer and transport to a higher-level hospital at all times, and reliable, accurate, and comprehensive communication systems between participating hospitals, hospital personnel, and transport teams. (p.59499)

The AAMC appreciates CMS' interest in establishing standards for transfers and agrees these standards would be beneficial to patient care; however, these changes should not be implemented through CoPs due to the significant consequences for failure to comply. Teaching hospitals provide care for a

---

[39] Orgera, Kendal, Grover, Atul. States With Abortion Bans See Continued Decrease in U.S. MD Senior Residency Applicants. AAMC. 2024
[40] The Idaho Physician Well-Being Action Collaborative. A Post Roe Idaho (February 2024)
[41] 603 US _ (2024).
[42] Kidd, Camille, Goodman, Shaina, Robbins, Katherine Goodman. State Abortion Bans Threaten Nearly 7 million Black Women, Exacerbate the Existing Black Maternal Mortality Crisis. National Partnership for Women & Families. 2024.
[43] 42 U.S.C. 1395dd.

disproportionate share of transfer cases including approximately eighty percent of Medicare transfer cases.[44] To ensure patient safety, the AAMC supports utilizing evidence-based guidelines and adequate and appropriate staffing for transfers to ensure a seamless transition in care and to support patient safety. As mentioned throughout our comments, CMS should explore other policy levers outside of CoPs, such as quality metrics, to accomplish the goal of improving service standards while maintaining flexibility for providers and without jeopardizing access to care. To maintain flexibility for providers CMS must ensure standards for transfer account for the expertise and resources available at each hospital. Additionally, CMS should not require hospitals to have a documented partnership with another hospital unless already established. These arrangements create an additional burden on hospitals to establish and if the contract terms are limiting may pose a safety risk for patients that may require care at another facility. **To best ensure patient safety, the AAMC urges CMS to maintain flexibility for hospitals to utilize clinical judgement when determining when and where to transfer patients so they may receive the appropriate level of care.**

PAYMENT FOR DIAGNOSTIC RADIOPHARMACEUTICALS

Allow for Separate Payment for Diagnostic Radiopharmaceuticals with a Daily Cost That Exceeds 1.75 Times the Volume Weighted Average Offset Amount

Since 2008, CMS has "policy packaged" diagnostic radiopharmaceuticals, meaning they are treated as ancillary and supportive to the primary diagnostic procedure, regardless of the per day cost of the diagnostic radiopharmaceutical. To address potentially inadequate payment for certain high-cost diagnostic radiopharmaceuticals that are used in nuclear medicine tests and for which payment is packaged into payment for the nuclear medicine test, CMS proposes to pay separately for diagnostic radiopharmaceuticals that have a per day cost greater than $630.

The AAMC supports CMS' proposal to pay separately for drugs above a certain cost threshold, as this will lead to accurate payment for these drugs and consistency with how CMS pays separately for other drugs, biologics, and therapeutic radiopharmaceuticals. CMS' current policy of packaging diagnostic radiopharmaceuticals into the APC payment for the nuclear medicine service, irrespective of the diagnostic radiopharmaceutical's cost, poses significant challenges, especially for academic health systems. Unlike other drugs, biologics, and therapeutic radiopharmaceuticals that receive separate payment under the OPPS when their costs exceed a per-day cost threshold (currently set at $140), diagnostic radiopharmaceuticals are policy packaged no matter their cost. This rigid policy does not account for the substantial costs associated with many diagnostic radiopharmaceuticals, particularly those newly developed or used in cutting-edge diagnostic procedures. Diagnostic radiopharmaceuticals are an essential part of the nuclear imaging services performed at academic medical centers for diagnosing and monitoring complex conditions such as cancer, neurological disease, and cardiovascular disease. They are integral to both patient care and the research missions of academic health systems, which are at the forefront of developing and using innovative diagnostic imaging procedures. For example, they are used in advanced neurological scans that can detect the risk of developing Alzheimer's disease and track its progression.[45] Due to CMS' packaging policy, many of these critical high-cost radiopharmaceuticals are paid far below cost when they are packaged into the APC for the underlying test, and they do not have a

[44] Kelly B, Iyer P, Xu S. Teaching hospitals are critical providers of care for Medicare hospital transfer patients. AAMC Analysis in Brief. 2019;19(2)
[45] Uzuegbuna, B, et al. PET Radiopharmaceuticals for Alzheimer's Disease and Parkinson's Disease Diagnosis, the Current and Future Landscape. Molecules. 2020 Feb 21;25(4):977

lower-cost alternative. Paying separately for diagnostic radiopharmaceuticals above a daily cost threshold will address this issue, leading to accurate reimbursement and preserving beneficiary access to these cutting-edge diagnostic procedures.

Packaging Threshold

The AAMC recommends that CMS set the threshold for paying separately at 1.75 times the volume weighted average offset amount, instead of two times the volume weighted average. To calculate the volume weighted average offset amount, CMS estimated the percentage of the APC payment that would typically be attributable to diagnostic radiopharmaceuticals within each of the four nuclear medicine APCs. (p. 59215) CMS then calculated a volume weighted average across the four nuclear medicine APCs, yielding $314. CMS multiplied this by 2 and rounded it to $630 to reach its proposed per-day cost threshold of $630. The assumption CMS used was that any diagnostic radiopharmaceutical that is at least two times more expensive than the offset amount (the APC payment amount that is associated with the diagnostic radiopharmaceutical), warrants separate payment. We believe that using a multiplier of 1.75 instead of 2 would be more consistent with other CMS policies, such as outlier payments, which use a threshold of 1.75 times the APC payment amount. Additionally, setting the threshold at 1.75 times the offset amount (which would be $550 in 2025) would result in separate payment for additional diagnostic radiopharmaceuticals that would not be separately paid under the $630 threshold, such as HCPCS code A9597, which is for a radiopharmaceutical used for diagnosing tumors through positron emission tomography (PET) scans.

Separate Payment Amount for Diagnostic Radiopharmaceutical

CMS proposes to establish the payment rate for separately payable diagnostic radiopharmaceuticals using mean unit cost. We urge CMS to instead pay using its ASP methodology for other separately payable drugs, biologics, and therapeutic radiopharmaceuticals. CMS states in the rule that the diagnostic radiopharmaceuticals that exceed the cost threshold would be classified as specified covered outpatient drugs (SCODs), for which payment is established under section 1833(t)(14)(B) of the Social Security Act. The methodology under this section of the statute directs CMS to pay based on ASP, and CMS' current statutory default payment rate for SCODs is ASP plus six percent. CMS notes that ASP data is lacking for many diagnostic radiopharmaceuticals and that paying based on ASP would yield inaccurate payment rates. CMS should work to incentivize manufacturers to report ASP data so it can use these data to set payment rates. We stress the importance of requiring manufacturers to provide accurate, robust ASP payment data that can be used in establishing payment rates, as recommended by MedPAC in the context of its previous Part B drug recommendations.[46] While CMS awaits more complete ASP data, the agency could pay using wholesale acquisition cost (WAC) or average wholesale price (AWP), as the agency does for other drugs that do not yet have ASP data. As CMS notes in the section of the rule setting payment rates for SCODs and other separately payable drugs and biologics, "In the case of a drug or biological during an initial sales period in which data on the prices for sales of the drug or biological are not sufficiently available from the manufacturer, section 1847A(c)(4) of the Act permits the Secretary to make payments that are based on WAC." (p. 59367) It would be consistent with this methodology for payment of SCODs for CMS to set payment rates for diagnostic radiopharmaceuticals based on WAC in the interim.

[46] MedPAC Report to Congress. June 2017.

INVOICE PRICING FOR DRUGS

Withdraw the Proposal to Require Hospitals to Report Invoice Prices for Drugs With No Sales Data Due to the Burden of This Approach and Consider Using Wholesale Acquisition Cost to Set Payment

Beginning in CY 2026, for drugs and biologics that do not yet have sales data, CMS proposes to pay using invoice pricing. Because there is no sales data for these drugs and biologics, CMS says that it cannot calculate ASP, WAC, AWP, or mean unit cost and therefore no payment is made for them under the OPPS currently. Establishing an invoice pricing payment policy would require hospitals to report their invoice prices to CMS, which CMS defines as net acquisition cost minus any rebates, chargebacks, or post-sale concessions. CMS does not yet have this data or a mechanism for hospitals to report invoice prices, so it proposes to work with the National Uniform Billing Committee to create a value code to report invoice prices.

While we understand CMS' intent to establish a method for determining payment in the absence of ASP data, we have significant concerns about the feasibility of the proposed approach and the administrative burden it would impose on hospitals. Due to the varied arrangements that hospitals use to purchase drugs, such as through various contracts, direct negotiations with manufacturers, or through other supply chain intermediaries such as wholesalers and group purchasing organizations, there is significant variability in pricing and discount structures related to invoices. Reporting invoice price would require hospitals to develop new administrative processes to track, document, and submit this information to CMS. Furthermore, due to the variability in invoice prices, there could be inconsistencies in the reported invoice prices. Tracking rebates and netting rebate amounts out of invoice prices reported to CMS can be challenging as rebates are retrospectively made after the sale, often months after the initial drug sale. Instead of putting the onus on hospitals to report their invoice prices, CMS should require manufacturers to report ASP and other pricing data in a timely manner so that CMS can establish payment rates for these drugs. Prior to ASP being available, CMS can use WAC or AWP, as it does for other drugs without ASP data. WAC data is typically available in advance of ASP data and soon after a drug is on the market. As noted in the section of our comment letter on diagnostic radiopharmaceuticals, there is precedent for CMS using WAC-based payment for drugs without ASP data.

NON-OPIOID TREATMENTS FOR PAIN RELIEF

Finalize the Proposal to Provide Additional Payments for Non-Opioid Treatments for Pain Relief

CMS is proposing to codify separate payments of non-opioid treatment for pain relief under OPPS and ASC payment systems for at least three years, through the end of CY 2027, to align with requirements in the CAA of 2023. (p. 59428) Both drugs and devices would be eligible if they meet the criteria outlined in statute to qualify. For CY 2025, CMS has identified six drugs and one device that qualify for separate payment under this proposal. For a non-opioid drug or biologic to qualify, it must have a Food and Drug Administration (FDA) label "to reduce postoperative pain, or produce postsurgical or regional analgesia, without acting upon the body's opioid receptors." For non-opioid devices to qualify for separate payment, they must be ''used to deliver a therapy to reduce postoperative pain, produce post-surgical or regional analgesia," have an FDA approval or clearance or an exemption, and demonstrate the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or quantity through a clinical trial or data published in a peer review journal. (p. 59430)

The AAMC supports CMS' proposal to unpackage and pay separately for non-opioid treatments for pain relief and urges the agency to finalize the proposal. An uptick in opioid related deaths began in the 1990s

and has continued increasing in waves to present day, making it imperative that providers, policymakers, and relevant stakeholders continue to work together to combat the effects of the opioid epidemic. In 2020 through a Medicare Current Beneficiary Survey from the Office of Enterprise Data and Analytics (OEDA) of CMS, 78 percent of Medicare beneficiaries reported experiencing chronic pain.[47] In order to treat chronic pain, adults may turn to opioid treatments to manage their condition, which when used for longer periods of time may present a greater risk for developing opioid use disorder (OUD). While there are certain indicators that a patient may be at greater risk for OUD, developing a dependence on opioids is not exclusive to a single population and increasing access to non-opioid treatment options can aid in reducing the risk of opioid related deaths or OUD.

As part of this proposal, CMS is proposing that drugs and devices that qualify will be paid separately through an additional payment and will not be subject to threshold or C-APC packaging. For qualifying drugs and biologics, the CAA of 2023 sets the payment using the methodology under section 1847A of the Social Security Act, which is generally ASP plus 6 percent. The separate payment amount will then be determined by subtracting the otherwise applicable OPPS payment amount associated with the drug or biologic from the ASP-based reimbursement amount. For qualifying devices payment is set at the charges for the device adjusted to cost and then subtracting the otherwise applicable OPPS payment amount associated with the device. CMS will apply a payment offset to reflect the portion of the non-opioid treatment in the procedure payment rate. However, CMS is proposing to calculate the payment offset as $0 for CY 2025 due to the newness of the drugs and devices affected by this proposal as their costs have not yet been fully reflected in the costs of the procedures in which they are used. (p. 59429) The statute also would require these additional payments to be made in a budget neutral manner. (p. 59428) Additionally, qualifying treatments would be subject to a payment threshold of 18% of the estimated average of the OPPS/ASC amount of the services that the treatment is furnished with.

The AAMC agrees with CMS' proposal to utilize a payment offset of $0 for CY 2025 and urges the agency to finalize this policy for CY 2025 and consider maintaining the $0 payment offset until CMS has accurate data related to the cost of the non-opioid treatment with the procedure. Disrupting the current payment rates without fully understanding how the costs of these treatments are reflected in the costs of the procedures using non-opioid treatment options could hinder the goals of this policy. Further, while the agency must provide these payments in a budget neutral manner for the three years required under statute until January 1, 2028, CMS should work with policy makers to ensure any extension is implemented in a non-budget neutral manner. Maintaining payment for other services will ensure providers have the resources to support a wider range of services and treatment options including those for non-opioid pain relief.

Additionally, CMS should explore expanding access to non-opioid treatment options for pain relief by considering additional eligibility beyond pharmacologic therapies. AAMC member teaching health systems lead and have embraced opioid-free pain management programs that include non-drug pain management techniques such as acupuncture, mindful breathing, auriculotherapy, and among other services to provide relief for patients without reliance on potentially addicting medications.[48] Further, a survey from the OEDA found that 36 percent of Medicare beneficiaries that reported chronic pain also

[47] Office of Enterprise Data and Analytics (OEDA) of the Centers for Medicare & Medicaid Services (CMS), Chronic Pain in the Medicare Population Survey. June 2020.
[48] https://www.upmc.com/services/center-for-perioperative-care/resources/opioid-free-surgical-pain-management-program

use at least one non-medication pain management technique.[49] As providers adopt additional non-opioid treatment options for pain relief, CMS should evaluate these services and treatments for coverage and payment to ensure access. Without coverage from Medicare, Medicaid, or other third-party insurers patients may find these treatment options inaccessible due to cost. Physical therapy may also serve as a useful and necessary non-drug pain management technique. In addition, we urge the agency to ensure access and adequate reimbursement for these services.

Lastly, we would be remiss to not mention access to mental health services and substance use disorder (SUD) treatment when discussing the use of opioids and options to improve access to non-opioid treatment options for pain relief. In a recently published study from the journal PAIN, 43.2 percent of adults sampled with chronic pain reported also having a mental health need, while only 17.4 percent of individuals sampled without pain reported a mental health need.[50] The AAMC has long supported efforts to increase access to behavioral and mental health services, specifically supporting expanding and extending the behavioral health workforce, promoting the use of integrated behavioral health models, and ensuring access to behavioral health care.[51] We urge the agency to continue to promote policy options that address beneficiaries needs and increase access to mental and behavioral health services, including SUD treatment.

PAYMENT FOR HIV PrEP IN HOPDS

Ensure Adequate Payment and Access for HIV PrEP Drugs and Related Services Under OPPS

CMS previously proposed to cover PrEP for HIV prevention under Medicare Part B as an additional preventive service without Part B cost sharing. Currently, these drugs are covered under Medicare Part D with cost sharing. While the final national coverage determination (NCD) associated with this proposal has yet to be released, CMS included in its OPPS proposals payment for HIV PrEP drugs and related services under OPPS if covered in the final NCD. (p.59399) In anticipation of the final NCD, the agency proposes payment for seven HCPCS codes and believes the resource costs for these codes would be similar between HOPDs and physicians' offices. Therefore, the agency is proposing similar payment for these services under PFS and OPPS. (p.59400)

The AAMC supports CMS' effort to reduce cost sharing for beneficiaries in need of HIV PrEP drugs and related services. However, we remain concerned about the potential for unintended consequences affecting access by moving coverage from Medicare Part D to Part B and urge the agency to do its due diligence in identifying and removing potential barriers to access associated with this shift. For example, while HIV PrEP drugs and related services would be covered under Part B for preventive services, there remain other indications for which HIV PrEP drugs would remain covered under Medicare Part D, such as for treatment rather than prevention. This would subsequently require a process to identify and determine whether drugs should be billed to Medicare Part B or Part D, similar to prior authorization, that may be administratively burdensome for providers and delay patient care. The shift from Part D to Part B

---

[49] Chronic Pain in the Medicare Population Survey. Office of Enterprise Data and Analytics (OEDA) of the Centers for Medicare & Medicaid Services (CMS). June 2020. https://www.norc.org/content/dam/norc-org/pdfs/2018MCBSCPQInfographic.pdf

[50] De La Rosa, Jennifer S.a,b,*; Brady, Benjamin R.a,c; Herder, Katherine E.a,d; Wallace, Jessica S.a,b; Ibrahim, Mohab M.a,e; Allen, Alicia M.a,b; Meyerson, Beth E.a,b; Suhr, Kyle A.a,f; Vanderah, Todd W.a,g. The unmet mental health needs of U.S. adults living with chronic pain. PAIN ():10.1097/j.pain.0000000000003340, July 2024.

[51] AAMC. Focusing on Mental and Behavioral Health Care. https://www.aamc.org/media/61651/download?attachment

may also impact certain providers' ability to prescribe and administer these drugs, such as pharmacists operating within a health system, due to legal barriers preventing pharmacists from enrolling as prescribers under Medicare Part B. Additionally, to ensure access to HIV PrEP drugs and related services through HOPDs, it is imperative that the agency ensure adequate payment for these services in a way that takes differences in site of service into account. Hospital outpatient departments are more likely to care for patients who are more medically and socially complex. Medicare beneficiaries receiving care in HOPDs have higher rates of ED visits and hospitalizations (2.1x and 2.2x, respectively) than those who received care in a physician's office.[52] Utilizing a payment rate for these services that considers the variations between sites of service and the complexities in the populations they treat, will ensure that hospital-based programs can sustain these services and maintain greater access for beneficiaries.

PRIOR AUTHORIZATION

Reconsider the Use of Prior Authorization for OPPS Services and Further Shorten Prior Authorization Timelines to 24 Hours for Emergency Requests and 48 Hours for Standard Requests.

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: blepharoplasty, rhinoplasty, botulinum toxin injections, panniculectomy, vein ablation, cervical fusion with disc removal, implanted spinal neurostimulators, and facet joint interventions. CMS proposes to shorten prior authorization timeframes for hospital outpatient department services paid under the Medicare fee-for-service (FFS) to align with the shorter timeframes it finalized earlier this year for Medicare Advantage and other payers.[53] (p. 59486) Specifically, for standard (non-urgent) requests, CMS proposes that instead of requiring a decision on the request in 10 business days, it would use the seven calendar days timeline finalized in the interoperability and prior authorization final rule. CMS does not propose to change the timeline for expedited requests, which is currently two business days in OPPS and 72 hours for Medicare Advantage, noting that there are certain scenarios in which the 72 hours timeframe would not result in a quicker decision. (p. 59487) For example, if the prior authorization request is submitted on a weekday, such as Monday, the two business days requirement would result in a shorter turnaround than the 72 hours requirement. Conversely, a prior authorization request submitted on a Friday, or a holiday weekend would be resolved more expeditiously under the 72 hours timeline than the two business days timeline.

As a foundational matter, the AAMC opposes CMS' use of prior authorization and urges CMS to reconsider its use for Medicare FFS outpatient hospital services. At the very least, we urge CMS not to add additional services to the list of services requiring prior authorization. We oppose prior authorization due to concerns that its use as a utilization management tool by payers often causes delays in patients' ability to receive timely, medically necessary care and imposes additional administrative burden on providers. Additionally, there is some literature that suggests prior authorization may negatively impact the treatment of underserved patients.[54] Prior authorization can delay necessary care and treatment, such

---

[52] Koenig, L., Sheriff, J., Nevo, O., Mehmet, S., KNG Health Consulting. Comparison of Medicare Beneficiary Characteristics Between Hospital Outpatient Departments and Other Ambulatory Care Settings, March 2023. https://www.aha.org/system/files/media/file/2023/03/Comparison-of-Medicare-Beneficiary-Characteristics-Between-Hospital-Outpatient-Departments-and-Other-Ambulatory-Care-Settings.pdf

[53] CMS Interoperability and Prior Authorization Final Rule. 89 FR 8758.

[54] Lu et al., "Unintended Impacts of Medicaid Prior Authorization Policy on Access to Medications for Bipolar Illness," Medical Care. Volume 48, Issue 1 (January 2010). Association of Black Cardiologists, Inc. "Identifying How Prior Authorization Impacts Treatment of Underserved and Minority Patients," (Winter 2019). http://abcardio.org/wp-content/uploads/2019/03/AB-20190227- PA-White-Paper-Survey-Results-final.pdf

as in the case of facet joint interventions, which CMS added to the list of prior authorization services in CY 2023. Facet joint injections are a valuable treatment option for chronic pain, including pain caused by osteoarthritis.[55] As first line treatment options are exhausted, coupled with patient and provider reluctance to use prescription pain medications, facet joint injections under image guidance have become a valuable tool in diagnosing and treating chronic pain.[56] As an example, instituting prior authorization for this procedure could limit beneficiaries' access to valuable tool for diagnosing the origins of their chronic pain.

Aside from these concerns about the effects of prior authorization on patients and providers, CMS' imposition of prior authorization requirements 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.[57] CMS has previously cited the provision of the Social Security Act allowing CMS to "develop a method for controlling unnecessary increases in the volume of certain OPD services," as granting the agency authority to implement prior authorization in the OPPS.[58] However, this provision makes no reference to prior authorization as an acceptable method to control for "unnecessary increases" in the volume of outpatient services. Even if prior authorization were considered to be one such acceptable method, CMS would first have to meet the burden of demonstrating that services on the prior authorization list have experienced an unnecessary increase in volume that necessitates the imposition of prior authorization. Therefore, without explicit statutory authority, CMS cannot arbitrarily impose prior authorization requirements on categories of services.

While we oppose prior authorization and urge CMS to reconsider prior authorization in OPPS both due to its tenuous statutory authority and the clinical and access repercussions, if CMS is to continue requiring prior authorization for this list of services, the agency should further shorten prior authorization timelines. Although CMS' proposed new timelines are a step in the right direction, we urge CMS to consider more timely requirements, in line with our prior recommendations for Medicare Advantage and other payers:[59] within 24 hours of receipt of a request for urgent items or services and 48 hours for non-urgent care decisions. The AAMC believes coverage decision timeliness is critical for patient care, and decisions must be made more quickly than current timelines.

'IN CUSTODY' DEFINITION FOR MEDICARE ELIGIBILITY

Finalize Changes to the Definition of 'In Custody' for Medicare Eligibility

As described in the proposed rule, under the "no legal obligation to pay" payment exclusion for Medicare, payment is prohibited under Medicare Part A or Part B for expenses incurred for items or services furnished to an individual identified as having no obligation to pay. Individuals considered to be 'in custody' of the penal authority are included under the "no legal obligation to pay" payment exclusion.

---

[55] Le, Danh T., Alem, N. Facet Joint Injection. https://www.ncbi.nlm.nih.gov/books/NBK572125/; Gellhorn AC, Katz JN, Suri P. Osteoarthritis of the spine: the facet joints. Nat Rev Rheumatol. 2013 Apr;9(4):216-24. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4012322/
[56] Le, Danh T., Alem, N. Facet Joint Injection. https://www.ncbi.nlm.nih.gov/books/NBK572125/.
[57] Section 1834(a)(15) of the Social Security Act expressly authorizes CMS to develop and update a list of services requiring prior authorization under the durable medical equipment, prosthetics, orthotics, and supplies fee schedule.
[58] CY 2020 OPPS final rule. 84 FR 61142.
[59] AAMC Comments on CMS Advancing Interoperability and Improving Authorization Processes [CMS-0057-P]. March 10, 2023.

CMS is proposing to narrow the definition of 'in custody' under the penal authority by removing individuals that are on supervised release or home detention from the definition. This would allow Medicare to pay for health care items and services furnished to an individual while on bail, parole, probation, or home detention. (p. 59503) The agency's current policy assumes that these individuals are receiving covered health care from a correctional institution, other governmental entity, or another organization obligated to pay for their care. However, there are limited circumstances where these individuals can access free or low cost health care and while some individuals may be eligible for Medicaid or other coverage, it is not guaranteed. For these individuals, while being excluded from Medicare coverage, there is no entity with a legal obligation to provide care. This creates significant health care costs for individuals reentering the community as they would need to either pay out-of-pocket or find other insurance, leading to delayed or forgone treatment.[60] **The AAMC supports CMS' proposal to narrow Medicare's custody definition to no longer include individuals on bail, parole, probation, and home detention and urges the agency to finalize its proposal.** The modification to the definition of custody will expand access to coverage and care for older adults and people with disabilities and promote successful reentry and community integration, while aligning with other federal eligibility policies such as those under Medicaid. CMS' proposal also includes revisions to the eligibility criteria for the special enrollment period (SEP) for formerly incarcerated individuals so that people under community supervision can enroll in Medicare. The AAMC supports this proposal as well. Together these proposals eliminate barriers to Medicare enrollment and protect individuals from high medical costs later in life due to delayed enrollment.

CONTINUOUS ELIGIBILITY IN MEDICAID AND CHIP

Finalize Proposal to Require Continuous Eligibility for Up to 12 Months for Children Under 19 in Medicaid or CHIP

In alignment with the CAA of 2023, the agency is proposing to require continuous eligibility (CE) for up to 12 months for children under 19 in Medicaid or CHIP, with limited exceptions. CMS is also proposing to remove the option to disenroll children from separate CHIP coverage for failure to pay required premiums or enrollment fees during a CE period. (p. 59487) The AAMC appreciates CMS' efforts to maintain access to care for children through this proposal and urges the agency to finalize these policies. Lapses in coverage may result in delayed care, fewer preventative services, more emergency department visits, and inconsistencies in prescription medication adherence, negatively impacting effected children's health and subsequently furthering inequities in care.[61] Expanding continuous eligibility in Medicaid and CHIP provides stability and reassurance to families that may experience administrative barriers or temporary changes to income by ensuring continuity in coverage.

MEDICAID CLINICAL SERVICES FOUR WALLS EXCEPTION

In addition to extending continuous eligibility under Medicaid and CHIP, CMS is proposing an expansion to the Medicaid clinical services four walls exception. The four walls exception describes services furnished outside the clinic, by clinic personnel under the direction of a physician, to an eligible individual who is unhoused. Without this exception, providers would not be able to receive

---

[60] Zhao J, Star J, Han X, et al. Incarceration History and Access to and Receipt of Health Care in the US. *JAMA Health Forum.* 2024;5(2):e235318. doi:10.1001/jamahealthforum.2023.5318.

[61] Sugar, S., Peters, C., De Lew, N., Sommers, B. Medicaid Churning and Continuity of Care: Evidence and Policy Considerations Before and After the COVID-19 Pandemic. ASPE Office of Health Policy, (2021). https://aspe.hhs.gov/sites/default/files/private/pdf/265366/medicaid-churning-ib.pdf

reimbursement for clinic services provided outside the four walls of the facility. Currently, the only exception to the four walls requirement applies to Medicaid clinical services offered to individuals who are unhoused. However, there are clinic types that do not have a federal four walls requirement including Medicaid Federally Qualified Health Centers (FQHCs), Rural Health Clinics (RHCs), and certified community behavioral health clinics (CCBHC). CMS is proposing to expand this exception to also apply to Indian Health Service/tribal clinics, behavioral health clinics, and clinics located in rural areas (not including RHCs). For behavioral health and clinics in rural areas, CMS proposes to authorize states to pay facility-based clinic services payment rates when they opt into this exception. (p. 59477) CMS notes it selected these groups for the exception as the agency believes these populations experience similar patient needs and barriers to accessing care as those experienced by individuals who are unhoused. This is based on four criteria which CMS outlines as high rates of behavioral health diagnoses or difficulties accessing behavioral health services, issues accessing services due to lack of transportation, a historical mistrust of the health care system, and high rates of poor health outcomes and mortality. (p. 59478)

Finalize the Proposal to Expand Exceptions to the Medicaid Four Walls Requirement for Clinical Services

The AAMC commends CMS for considering polices to expand access to care and urges the agency to finalize the proposal to expand the four walls exception for the specific populations proposed. CMS' proposal is unique in the fact that it aims to meet patients where they are to eliminate barriers to accessing care. The ability for states to pay providers higher facility-based clinic services payment rates for these services under this exception would enhance providers' ability to maintain access and invest in services for these populations. These exceptions provide flexibility to enable these clinics to be creative in the way services are provided through unconventional methods such as mobile clinics.

In addition to this proposal, the AAMC encourages the agency to explore additional expansion of the exception to ensure consistency in access to care for underserved populations and increase coordination among providers by including policies to promote integrated care so that patients' needs are met across the continuum of care. Specific to behavioral health, the agency notes that the proposed exception would include any clinic service furnished outside the four walls by a behavioral health clinic including non-behavioral clinic services that may be offered in addition such as those for physical health. (p.59480) As indicated by the criteria used to select behavioral health clinics for this exception, individuals in need of behavioral health services tend to have a higher rate of physical comorbidities and a higher rate of poor health outcomes.[62] With this in mind, the AAMC encourages CMS to explore polices that assimilate behavioral and physical health care in order to further increase access to care, reduce stigma surrounding behavioral and mental health care, and promote whole person care.[63] Incorporating both of these types of care addresses the medical, behavioral, and social factors that affect a patient's health and wellbeing by breaking down silos in care and encouraging collaboration among providers to meet patient needs.

Adopt a Broad and Inclusive Policy of The Definition of Rural

While CMS did not include a specific definition of rural in determining eligibility for the Medicaid clinic services four walls exception, the agency did detail four different approaches to identifying a definition that the agency is considering adopting in the final rule. These approaches included using a definition of

[62] Ramanuj P, Ferenchik E, Docherty M, Spaeth-Rublee B, Pincus HA. Evolving models of integrated behavioral health and primary care. Curr Psychiatry Rep. 2019;21(4). https://doi.org/10.1007/s11920-019-0985-4.
[63] AAMC. Focusing on Mental and Behavioral Health Care.
https://www.aamc.org/media/61651/download?attachment

rural adopted by Federal governmental agencies across all states, allowing states to select a definition of rural that is adopted and used by a Federal governmental agency for programmatic purposes, allowing states to select a definition of rural that is used by a state governmental agency with a role in setting state rural health policy, or not adopting a definition of rural and allowing states to determine themselves. The agency seeks feedback on these four options. (p.59483)

The AAMC appreciates the opportunity to comment on what definition of rural should be used for the Medicaid clinic services four walls exception. As CMS highlights within the proposed rule, there are many, often conflicting definitions of rurality, across governmental entities, even within the Department of Health and Human Services. For instance, CMS relies on core-based statistical areas (CBSAs) to determine rurality for wage index calculations, while the Health Resources and Services Administration (HRSA) has adopted, in some circumstances, the Federal Office of Rural Health Policies (FORHP), a more expansive definition of rurality. Specifically, HRSA adopted the FORHP definition of rurality due to the fact "that proximity to a Metropolitan area does not mean a county is not rural in character and that shifts in employment and job creation have drawn people to commute to jobs in Metropolitan Statistical Area (MSA) even though they still live in rural areas."[64] HRSA's stance indicates limitations to certain definitions of rurality utilized by federal agencies in determining rural status by potentially excluding areas from eligibility that under a more expansive definition of rurality would qualify. Additionally, in other policies related to the definition of rural CMS has left the determination of rurality to more than one definition, such as hospitals located in an urban area that are seeking rural status. The regulatory text specifically allows for determinations of rurality based on more than one definition of rurality, a policy that could be advantageous to states and beneficiaries by expanding access to a wider array of potentially rural areas. The regulation grants hospital eligibility for reclassification if it is outside of a MSA or "is located in an area designated by any law or regulation of the State in which it is located as a rural area, or the hospital is designated as a rural hospital by State law or regulation."[65]

Within the proposed rule, CMS highlights that the definition of rural can be highly specific to circumstances within the state, which lends itself to the need for varying definitions of rural. (p. 59482). The AAMC agrees with this need for variation and urges CMS to adopt a broad and inclusive policy that accurately captures the breadth of the rural population. CMS should be permissive by allowing clinics to meet the definition of rural based on a range of definitions rather than limiting to one definition selected by the federal agency or state to ensure flexibility and avoid narrow or restrictive definitions of rural.

CARDIAC CT SERVICES

Ensure Reimbursement for Cardiac CT Services Accurately Reflects the Cost of Providing These Services; Issue Education and Guidance on Use of Revenue Codes for Cardiac CT Services

CMS is seeking comments on the appropriate payment rate for three CPT codes for cardiac CTs (75572; 75573; 75574), as well as how hospitals are billing for these services. (p. 59276) CMS has assigned these CPT codes to APC 5571 (Level 1 Imaging with Contrast) but has received feedback that the payment rate for this APC has been decreasing since 2017 and not keeping pace with the cost of providing cardiac CT services. The assignment of the three CPT codes to this APC, as opposed to a higher-paying APC that is more reflective of the costs of providing cardiac CT services, could be driven by the inability of hospitals to include the appropriate revenue codes. Until December 2023, a revenue code edit prevented hospitals

[64] 86 FR 2418.
[65] 42 CFR 412.103.

from reporting the cardiology revenue code (048X) when billing for cardiac CT services. This effectively required hospitals to use the CT scan (035X) or radiology diagnostic (032X) revenue codes on their claims for cardiac CT services. CMS made a change in December 2023 that allows hospitals to use the 048X revenue code where appropriate.[66] The use of the revenue code affects the cost center that CMS uses in calculating the cost of these services and setting payment for these services. Due to the higher costs of the cardiology cost center, a higher payment rate would result for these CPT codes if hospitals were using the cardiology revenue code.

To calculate the geometric mean cost and determine the appropriate APC assignment for cardiac CT services, CMS is requesting feedback on the extent to which hospitals have begun to use the 048X revenue code when billing for cardiac CT services. Because CMS made the change in December 2023 that allowed for the use of the 048X revenue code, there is insufficient 2024 claims data to date to determine how hospital billing practices have shifted. CMS also seeks comment on which department in the hospital cardiac CT services are being provided in and what factors determine the revenue code assignment. **We encourage CMS to analyze the claims data to which it has access to determine the scope of the use of the 048X revenue and to continue to evaluate claims data as they become more complete. Regardless of which revenue code is predominantly being used, we urge CMS to continue to analyze costs and assign these services to an APC that most accurately covers the costs of providing cardiac CT services.**

Specific to the issue of revenue code use, we believe there could be some issues that are affecting hospitals' ability to use the 048X revenue code. It has come to our attention that although CMS has changed its guidance on the use of the revenue code, various clearinghouses, as well as other payers, are not yet accepting the 048X revenue code and continue to return claims to providers for resubmission. It is also likely that the widespread disruptions caused by the Change Healthcare ransomware attack could have affected the ability of clearinghouses to update their systems to accept claims with the cardiology revenue code. **To this end, CMS should engage in additional outreach and education with involved stakeholders to ensure their systems are up to date and they allow hospitals to bill using the appropriate revenue code.**

PAYMENT ADJUSTMENTS UNDER THE IPPS AND OPPS FOR DOMESTIC PERSONAL PROTECTIVE EQUIPMENT

Finalize the Proposal to Expand the Scope of Products Eligible for Add-on Payments and Ease Hospital Reporting Burden but do not Implement the Policy in a Budget Neutral Manner

In the CY 2023 OPPS final rule, CMS established payment adjustments under the OPPS and IPPS for hospitals that purchase domestically produced NIOSH-approved and FDA-certified surgical N95 respirators. These adjustments are intended to cover the marginal costs associated with higher acquisition costs of domestically produced surgical N95 respirators. The adjustments are non-budget neutral in the IPPS and budget neutral in the OPPS. To qualify for a payment adjustment under CMS' current policy, a hospital must provide a written statement from the manufacturer of the surgical N95 respirator, certifying that it is domestically produced, and must report additional cost information on the Medicare cost report. This supplemental cost report information is then used to calculate the payment adjustment at the hospital level.

[66] CMS Transmittal 12421, Change Request 13488, Dec. 21, 2023. https://www.cms.gov/files/document/mm13488-hospital-outpatient-prospective-payment-system-january-2024-update.pdf.

CMS requests comment on expanding the types of respirators and other personal protective equipment (PPE) that would be eligible for the payment adjustment, changing the payment methodology, and reducing reporting burden on hospitals. (p. 59396) The AAMC appreciates the Agency identifying ways to increase the purchase of domestically produced N95s and other PPE in a way that would also reduce burden on hospitals. We provide additional comments on the topics in the request for information below.

Ensuring a Robust Domestic Supply Chain

The COVID-19 PHE showed the fragility and weaknesses of the global supply chain. The goal of the payment adjustments is to sustain a level of supply resilience for surgical N95 respirators that is critical during a PHE. We agree that more needs to be done to ensure a stable health care supply chain, and while the payment adjustments alone are not enough to build up the domestic supply chain, the steps CMS seeks comments on would increase demand for domestically produced N95s, thereby stimulating domestic production. We continue to stress the need to strengthen current supply chains, specifically the need for more than one supply chain to ensure adequate product supply. CMS should work with other agencies that play a critical role in developing and maintaining the domestic supply chain, including the Administration for Strategic Preparedness and Response and the Department of Defense, as well as with private sector stakeholders, to develop a cohesive national strategy for addressing the impact future PHEs may have on the nation's health care supply chain.

Budget Neutrality

As the Association has recommended to CMS in previous comments,[67] we urge the Agency not to apply this payment adjustment under the OPPS in a budget neutral manner. Rather, we urge CMS to find an alternative authority for subsidizing the purchase of domestically made N95 surgical masks that does not require an offsetting reduction in OPPS payments. As CMS looks to expand the scope of the adjustments, the budgetary impact and corresponding offsets will increase, so it is imperative that payment for hospitals for other OPPS services not be decreased through a budget neutrality adjustment.

Payment Adjustment Methodology

Under CMS' current approach for calculating the payment adjustment, it provides biweekly interim payments based on the estimated unit cost differential between domestic and non-domestic surgical N95 respirators. After a hospital submits supplemental cost report information for the year in question related to the costs of purchasing domestic N95 respirators, CMS will settle payments for each hospital at cost report reconciliation. This approach requires hospitals to report detailed information on a supplemental cost report form related to the quantity and costs of domestic and non-domestic respirators, as well as IPPS and OPPS payments to the hospital for domestic respirators. CMS is seeking comments on whether to modify this methodology to instead pay based on a national standard unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators. The AAMC supports this approach, which would reduce burden on hospitals and avoid the need for retrospective reconciliation of payment adjustment amounts. By shifting to a national standard unit cost differential, CMS would not need to collect information from hospitals through additional information on the Medicare cost report.

[67] AAMC Comments to CMS on CY 2023 OPPS Proposed Rule.

Notably, the Medicare Payment Advisory Commission, noting the burden associated with the hospital-specific approach, recommended that CMS consider using a national cost differential.[68]

Payment Adjustment Eligibility

CMS seeks comments on difficulties with its current requirement that hospitals rely on a written attestation from the manufacturer that a certain NIOSH-approved surgical N95 respirator is domestically produced. Among the areas for feedback, CMS asks whether having a publicly available list of eligible products and not requiring hospitals to obtain a written statement from the manufacturer would incentivize more hospitals to utilize the payment adjustment. The AAMC encourages CMS to work with the relevant government agency, such as NIOSH, to create a publicly available list of domestically produced eligible respirators. This approach would remove from the hospital the burden of determining whether an N95 respirator is domestically produced and allow it to cross-reference the list prior to making decisions on which products to purchase. Furthermore, removing the requirement to obtain a written statement from the manufacturer would streamline the process of purchasing eligible respirators and could encourage uptake of the payment adjustment.

Types of N95 Respirators and Other PPE

CMS' current payment adjustment applies specifically to NIOSH-approved domestically produced *surgical* N95 respirators—that is, those respirators that also have the added protection that surgical masks provide from fluid penetration and are appropriate for use in settings such as the intensive care unit, emergency department, or the operating room. CMS is evaluating whether to expand the payment adjustment to all domestic NIOSH-approved N95 respirators, both surgical and non-surgical. CMS also seeks comment on expanding payment adjustments to other PPE, such as nitrile gloves. The AAMC supports the expansion of the payment adjustment to cover all NIOSH-approved N95 respirators, as well as other categories of PPE, and urges CMS to modify the payment adjustment accordingly. As was evident during the COVID-19 PHE, in times of supply shortages and dire need, hospitals turned to whichever respirators were more easily available to them, including non-surgical N95 respirators. This is particularly relevant in settings where the added protection of a surgical N95 is not as necessary, such as in non-surgical settings. To the extent that hospitals are purchasing these non-surgical N95 respirators, expanding the payment adjustment would encourage purchase of more domestically produced respirators. Hospitals should be reimbursed for the additional cost that they are incurring by purchasing domestically made products while supply and demand balance out and costs of domestic products mitigate. The Association also supports reimbursement for purchasing nitrile gloves, which are another type of PPE that is vital both during and outside of a PHE for the protection of both healthcare workers and their patients.

[68] MedPAC Letter to CMS on CY 2023 OPPS Proposed Rule. https://www.medpac.gov/wp-content/uploads/2022/09/09122022_OPPS_FY2023_MedPAC_COMMENT_v2_SEC.pdf.

HOSPITAL QUALITY PROPOSALS

OUTPATIENT QUALITY REPORTING PROGRAM

Consider Modifications to Proposed Measure Adoptions

To advance health equity and improve outcomes, CMS has proposed the introduction of three new quality metrics concerned with health equity, Hospital Commitment to Health Equity, Screening for Social Drivers of Health, and Screen Positive for Social Drivers of Health.

Hospital Commitment to Health Equity (HCHE)

CMS proposes to adopt the Hospital Commitment to Health Equity measure in the Outpatient Prospective Payment Program, starting in CY 2025, as hospital leadership is a key component to a commitment to closing disparities (p. 59439). The AAMC supports the use of this measure but believes that it is duplicative, as the same requirement exists for the Inpatient Quality Reporting (IQR) Program. Given that the hospital leadership and infrastructure is the same across inpatient and outpatient units of the same hospital, making the requirement is repetitive and will add undue burden. **CMS should utilize the Hospital Commitment to Health Equity measure for IQR in the OQR program, rather than introducing a duplicative requirement for OQR.**

Screening for Social Drivers of Health (SDOH)

CMS proposes to introduce the Screening for Social Drivers of Health measure, starting in CY 2026, as a mechanism for identifying and addressing patient needs for underserved patient populations. (p. 59443) As the measure is currently utilized in the IQR Program, CMS proposes to allow the HOPD to confirm the current status of any previously reported health-related social needs in another care setting in lieu of re-screening the patient within the same reporting period. (p. 59447) The AAMC supports policies that encourage screening for SDOH, as it allows providers to gain a better understanding of the broader social context affecting a patient's health and opportunity to identify resources for mitigating these issues. We appreciate CMS' decision to allow inpatient screenings in the same reporting period to also be considered for measuring screening rates in the outpatient setting. Screening the same patient multiple times is not only burdensome on providers but can also be difficult for patients, who may have shared their personal situation with multiple providers. Additionally, multiple screenings may create distrust between patients and the health system if a patient feels that continuing to provide sensitive social information does not result in any meaningful change in their care. There is one point of clarification we seek from CMS on the measure. As proposed, it is unclear whether non-office/ procedural/ emergency department visits, such as services specific to imaging or labs in the outpatient department, would be considered "admissions" to an HOPD subject to screening in the measure calculation. (p. 59447) Screening in such services might not be appropriate, as the patient often does not see a provider in a traditional consultative manner. CMS should clarify that screening in the outpatient setting should be limited to office, procedural, and ED visits where patients have a direct treatment service with their clinician.

Screen Positive Rate for SDOH

Coupled with the screening rate measure, CMS also proposes a separate measure of the positive screening rates for each of the five health-related social needs (HRSNs), also beginning with CY 2026 reporting, following a year of voluntary reporting (p. 59448). This measure would be reported as five separate rates, one for each HRSN, as the number of patients who screened positive for the HRSN out of the overall number of patients screened. (p. 59449)

The AAMC agrees that the results of screening could be an additional data point that can help inform hospital collaboration with community partners and community investment, as well as for use by local, state, and federal policymakers in their efforts to improve health equity. **The AAMC urges CMS to commit to evaluating the interaction between positive rates for these five HRSNs and performance on quality measures, and to consider how positive rates of HRSNs could be appropriately incorporated into identifying underserved patients for purposes of CMS' Rewarding Excellence for Underserved Populations approach to promote equity in quality and value programs, rather than relying on proxies for social risk.**[69]

Additionally, we remain concerned about the use of this measure to inform patients and communities about a facility's quality of care. Simply put, it is unclear how this measure data might be interpreted or what it says about a hospital. Is a hospital high quality if it has fewer patients who screen positive for health-related social needs? Or do measure rates say more about the resources of the communities it serves? CMS should monitor use of the measure performance data to evaluate whether there are unintended uses of the data that might misinform or inhibit the measure's value.

Patient Understanding of Key Information-Related to Recover After a Facility-based Outpatient Procedure or Surgery Patient Reported Outcome-based Performance Measure (Information Transfer PRO-PM)

CMS has proposed the introduction of a new patient reported outcome measure, concerned with information sharing, that outlines questions on daily activity, medications, and personalized information received by a patient to determine the clarity of discharge instructions. CMS proposes to introduce the Information Transfer PRO-PM, with voluntary reporting in CY2026 and mandatory reporting starting in CY2027. This measure includes nine questions on three domains, including personalized health information, medications, and daily activity. CMS has stated that they intend to introduce this measure as a means of determining the clarity of care information provided at discharge. (p. 59452)

Given this measure's purpose, CMS should consider adding additional questions to ensure proper measurement regarding the completeness of discharge information. Specifically, the medication question category should be expanded to account for a patient's understanding of the care plan in general. CMS should also consider the timing of the Information Transfer measure to ensure it does not overlap with the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey. Currently, CMS proposes that the Information Transfer measure will be collected between 2 and 7 days post-discharge and outpatient HCAHPS is collected between 2 and 42 days post-discharge. **CMS should monitor to ensure that the administration of two surveys simultaneously does not lead to survey fatigue and a subsequent lack of responses from patients.**

Specific to timing of adoption, the AAMC is concerned that a single voluntary reporting period is insufficient, given the challenges hospitals have faced when reporting measures that utilize clinical data elements from the electronic health record (EHR) and the agency's proposal in this rule to add a voluntary reporting period for the hybrid measures in the Inpatient Quality Reporting Program. **CMS should allow a minimum of two voluntary reporting periods and commit to providing technical assistance necessary to support successful reporting.**

[69] D. Jacobs, et. al, The CMS Strategy to Promote Equity in Quality and Value Programs, JAMA Viewpoint (Oct. 20, 2023), where CMS presents its Rewarding Excellent for Underserved Populations (REUP) policy framework, which in part relies on identifying underserved populations a provider treats.

Proposed Measure Removals

CMS proposes the removal of two quality metrics, MRI Lumbar Spine for Low Back Pain Measure and the Cardiac Imaging for Perioperative Risk Assessment for Non-Cardiac Low-Risk Surgery, as these measures were determined to not improve patient outcomes (pp. 59454 - 59455). The AAMC supports CMS decision to remove these measures and appreciates the agency's efforts to evaluate existing measures and remove those that do not lead to improved quality or outcomes**.**

Additional Proposed Provisions

Reconsider Policy to Public Reporting of ED Throughput Measure Stratified for Psychiatric/ Mental Health Patients

CMS has previously publicly reported the Time from ED Arrival to ED Departure for Discharged ED Patients measure, stratified by four different categories. Currently, only three of the four strata have been publicly reported on the *Care Compare* website (as opposed to all four strata being included in publicly available data files) and CMS proposes to include the fourth strata, Psychiatric/Mental Health Patients, on *Care Compare* (p. 59459), starting in CY2025. While the AAMC supports CMS' decision to promote transparency and increase a patient's engagement with care, we are concerned about potential unintended consequences. ED throughput times, while an important metric, are often influenced by factors outside of the hospital's control, including community access to primary care and urgent care services more broadly. We are concerned that providing wait times stratified by patients seeking mental health services could ultimately prevent patients from accessing critical, lifesaving care. **CMS should reconsider this policy for potential unintended consequences, and if finalized, commit to monitoring impacts of this policy on patient patterns to seek emergency care.**

Provide Greater Detail for Hospitals to Report PRO-PMs Through the Hospital Quality Reporting System

CMS proposes to require all patient reported outcome measures to be reported through the Hospital Quality Reporting system, consistent with policies established for reporting the Total Knee and Total Hip Arthroplasty PRO-PM. (p. 59459) The AAMC supports the use of the Hospital Quality Reporting system for patient reported outcome measures, however, a date was not provided for when this change would go into effect. **CMS should provide additional details on this proposal, including the effective date of this change, as well as the potential impact this change could have on hospitals.**

INPATIENT QUALITY REPORTING PROGRAM

Delay Mandatory Reporting of Core Clinical Data Elements (CCDEs) and Linking Variables for the Hybrid EHR-based Measures and Provide Additional Technical Support to Hospitals Voluntarily Reporting These Measures

CMS proposes to extend an additional year of voluntary reporting of CCDEs and linking variable data for the two hybrid hospital-wide measures in the IQR. (p. 59501) CMS notes that three-quarters of hospitals that have voluntarily reported these measures would not have met the reporting thresholds for the CCDEs and linking variables if the reporting requirement had been mandatory, and that those hospitals that participated in voluntary reporting tended to be large, non-rural, non-critical access, and non-safety net. (p. 59502) Considering this, CMS believes the reporting failure rate would have been even higher if all IPPS hospitals participated, potentially leading to a vast majority of hospitals failing to earn the 25 percent of the annual inpatient market basket update tied to successful IQR reporting.

The AAMC strongly supports this proposal and commends CMS for acknowledging that hospitals have made good faith efforts to report these novel measures and need more time to implement digital measures. Hospitals choosing to invest resources in voluntary reporting are struggling with CCDE and linking variable collection timing and clinical workflows and the achievability of the data submission requirement thresholds (currently set at 90 percent for CCDEs and 95 percent of linking variables). We ask CMS to commit greater resources to technical assistance to hospitals with this additional voluntary reporting period, and to provide more timely feedback and support to hospitals in advance of measure reporting requirements becoming mandatory.

Additionally, we ask CMS to provide hospitals public notice of the agency's intent to exercise scoring discretion for these measures for the FY 2026 payment determination. This is because current IQR program rules require reporting of the July 2023 – June 2024 performance period by October 1, 2025, which falls before the anticipated final CY 2025 OPPS rule. We thank CMS for referencing this proposal in its final FY 2025 IPPS rule,[70] but are concerned there is no note of scoring discretion related to this proposal. Without this, hospitals will feel they must report the CCDEs and linking variables by the reporting deadline and simply hope this policy is finalized as proposed in the event they have not successfully remedied data collection and reporting activities.

OVERALL HOSPITAL QUALITY STAR RATING

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

CMS seeks feedback on potential future options to greater emphasize patient safety in the Overall Hospital Quality Star Rating, in response to the federal government's inter-Agency recommitment to improve safety. (p. 59513) Currently, the methodology weights the Safety of Care measure group equally with Mortality, Patient Experience, and Readmissions. In general, CMS notes that hospitals that perform well in Safety of Care tend to also receive a high overall rating. (p. 59511) However, the methodology does allow for some hospitals to perform poorly on safety measures and still receive a 5-star rating. CMS seeks feedback on three potential future options to better emphasize patient safety in the ratings. The AAMC provides comments on each option below.

Reweight the Safety of Care Measure Group

CMS has explored the potential to increase the weight of the Safety of Care measure group from the current 22 percent to 30 percent, while proportionally reducing the weights of the other four measure groups. CMS acknowledges that this approach would "slightly reduce the influence of the other measure groups" on the ratings. (p. 59514) The AAMC shares that concern, as we believe it sends an inconsistent message to decrease the influence of Patient Experience, in particular, on a hospital's rating when CMS has previously stated a goal of more broadly incorporating the patient's voice in quality measurement.[71] Additionally, as Safety of Care is not a required measure group for obtaining a rating, we believe this creates a conflicting prioritization, where hospitals that do not have any measures within the Safety group would see even greater differential in the group weights for scoring in comparison to hospitals with sufficient safety measure scores (and those with fewer than 3 measures would see at least 30% of their

[70] 89 FR 68986, at 69561-69562 (August 28, 2024).
[71] In the 2024 update to its National Quality Strategy, CMS gave equal weight to Engagement as it did Safety, noting a key action is to "expand the use of person-reported outcomes and experience measures."

overall score based on one or two measures). CMS should consider a flag for such hospitals to note that Safety of Care has not factored into (or few safety measures factored into) such a hospital's overall rating.

Policy-Based 1-Star Reduction for Poor Performance on Safety of Care

CMS has explored the adoption of a post-hoc policy-based adjustment where it would reduce the rating of any hospital in the bottom quartile of performance on the Safety measure group. (p. 59514) Under this policy, any hospital receiving a rating of 2 stars up to 5 stars would see their rating drop by 1 star based on their bottom quartile performance on the Safety measure group (hospitals with a 1-star rating would remain unchanged). CMS notes this policy would have reduced the rating for 530 hospitals in the July 2023 ratings. The AAMC is concerned that this has an overreaching impact for hospitals, considering 414 of those 530 hospitals received a 2- or 3-star rating. This suggests that ratings already indicate some level of reduced performance relative to top performers, and it is unclear how a star reduction in such cases will motivate performance improvement.

Reweighting the Safety of Care Measure Group Combined With a Policy-Based Star Rating Cap

A third option CMS has explored is to combine the reweighting approach of the first option with a policy to apply a cap on the maximum 4-star rating a hospital could receive should it perform in the bottom quartile of performance on the Safety group. (p. 59514) Rather than impacting 530 hospitals, this would be felt by just 3 hospitals, after accounting for the effects of reweighting, in the July 2023 ratings. However, we feel this policy would do a disservice to patients and communities when choosing a hospital, as their hierarchy of measure groups might not be represented by the ratings.

The AAMC has previously supported consideration for an approach where an individual user on Care Compare could customize the overall group weights and see a different set of ratings in response to those preferences.[72] We continue to believe that would be the best policy going forward, as it allows individual engagement with the overall ratings to help inform decisions on where to seek care. For a patient who cares most about experience or mortality, they're able to do so without CMS dictating that Safety should be the *de facto* measure group to move the needle. Alternatively, recognizing the complexity to provide variable ratings information, CMS could maintain the methodology as is and apply a unique flag to any hospital in the bottom quartile of performance on Safety and a separate, distinct flag to any hospital without a Safety score to highlight information that might be of interest.

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

CONCLUSION

Thank you for the opportunity to comment on this proposed rule. We would be happy to work with CMS on any of the issues discussed or other topics that involve the academic 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) regarding the payment proposals. For questions related to the quality proposals, please contact Phoebe Ramsey (pramsey@aamc.org) and Erin Hahn (ehahn@aamc.org).

Sincerely,

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

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