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September 8, 2023

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1785-P
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Administrator Brooks-LaSure:

Re: Medicare Program: Calendar Year 2024 Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems Proposed Rule (CMS-1785-P)

The Association of American Medical Colleges (AAMC or the Association) welcomes this opportunity to comment on the proposed rule entitled Calendar Year (CY) 2024 "Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule," 88 *Fed. Reg.* 49552 (June 31, 2023), 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 157 U.S. medical schools accredited by the Liaison Committee on Medical Education; 12 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.

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 market basket update to account for increased labor and supply costs.
- *Partial Hospitalization and Intensive Outpatient Program*: Finalize proposal to establish the Intensive Outpatient Program (IOP) under Medicare Part B effective January 1, 2024.
- *Payment for Intensive Cardiac Rehabilitation Services (ICR) Provided by an Off-Campus, Non-Excepted Provider Based Departments*: Finalize proposal to equalize payment rates for ICR

services at non-exempt Provider Based Departments (PBDs) of a hospital with other sites of service to eliminate payment disparities.

- *Dental Services*: Finalize proposal to expand coverage for certain dental services furnished in hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs).
- *Essential Medicines 'Buffer' Stock*: Finalize separate add-on payment to hospitals to establish and maintain a buffer stock of essential medicines.

Quality Proposals

- *Changes to the Outpatient Quality Reporting (OQR) Program:* CMS should (1) not adopt a new procedural volume indicator, (2) adopt the excess radiation dose/ inadequate image quality eCQM as an optional measure hospitals may choose to report under the OQR, (3) not finalize proposed modifications to the COVID-19 vaccination rate among healthcare personnel until there is greater clarity around booster doses that might support annual reporting similar the influenza vaccination measure, and (4) removed OP-22 from the program.

PAYMENT PROPOSALS

PAYMENT UPDATE

Increase the OPPS Payment Update for CY 2024 to Reflect Higher Growth in Labor and Supply Costs

CMS is proposing a payment update of +2.8 percent for CY 2024. The proposed update is based on the Inpatient Prospective Payment System (IPPS) proposed rule[1] market basket update of +3.0 percent and a total factor productivity adjustment of minus 0.2 percent. (p. 49581). 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 have experienced as a result of the COVID-19 public health emergency. Most hospitals are operating on very thin Medicare margins that make providing care challenging. In the fiscal year (FY) 2024 IPPS final rule[2], CMS finalized a market basket update of 3.3 percent minus a total factor productivity adjustment of negative 0.2 percent which equaled a final update of 3.1 percent. However, even with the IPPS market basket increase, we believe the update does not adequately account for the financial challenges hospitals continue to face. We urge CMS to consider these factors and how they attribute to the increased cost of providing care to Medicare beneficiaries. We strongly encourage CMS to increase the CY 2024 OPPS market basket to reflect these financial challenges and to enable health systems to continue to provide access to essential care to beneficiaries.

PAYMENT FOR PARTIAL HOSPITALIZATION AND INTENSIVE OUTPATIENT SERVICES

Section 4124 of the Consolidated Appropriations Act, 2023[3] established the Intensive Outpatient Program (IOP) under Medicare Part B effective January 1, 2024. The IOP will serve as another option for Medicare beneficiaries to access outpatient behavioral and mental health services. Under the proposal, CMS would establish coverage for IOP services for Medicare beneficiaries to address gaps in behavioral health coverage in Medicare and promote access to behavioral health care. CMS proposes that IOP services may be furnished in hospital outpatient departments, community mental health centers (CMHCs),

[1] 88 FR 26658
[2] 88 FR 586408
[3] Pub. L. 117-328

federally qualified health centers, and rural health clinics. Additionally, the proposed rule states that it is appropriate to align both the IOP and PHP through a consistent list of services as the statutory definitions generally contain the same types of services, but they differ in level of intensity. (p. 49702). The IOP services and benefits would mirror existing PHP services and benefits, but IOP services would not be required in lieu of hospitalization and would only require a minimum of 9 hours of therapeutic services as certified by a physician in a plan of care. (p. 49670).

CMS proposes a list of HCPCS codes (Table 43) that identifies the full range of covered services that a PHP or IOP may provide to Medicare beneficiaries. (p. 49704). Table 44 of the proposed rule provides the Partial Hospitalization and Intensive Outpatient Primary Services list. CMS proposes that a program must provide at least one service from this list to qualify for payment. (p. 49705). The AAMC supports the use of this list of services as part of the PHP and IOP. However, we urge CMS to annually evaluate utilization rates for IOP and PHP services to determine if certain services are still appropriate for these programs. CMS should also review utilization data to determine which services should be required for payment and add or remove services from the Partial Hospitalization and Intensive Outpatient Primary Services list based on this evaluation.

The AAMC supports CMS' efforts to expand access to behavioral and mental health services and create a spectrum of services that allow beneficiaries to access the level of care that is most appropriate for them. We urge CMS to move forward with finalizing the establishment of the IOP under Medicare Part B. In response to the proposals, we offer the following comments regarding the services that would be provided through the IOP and PHP and the payment methodology used for these programs.

Finalize Proposed Payment Rates for the Intensive Outpatient Program and Partial Hospitalization Program under Part B

The Agency included in the proposal a description of their payment methodology for both PHP and IOP for CY 2024. Since there is no Medicare utilization data on the IOP, CMS proposes to utilize the same data and methodology for calculating payment rates for both PHP and IOP. (p. 49708). However, the agency plans to re-evaluate these proposals once IOP utilization data becomes available.

Data Sources and Payment Rates: The proposed rule notes that although the IOP is a new benefit, many of the items and services that will be included in the IOP have been paid for by Medicare, either as part of the PHP benefit or under the OPPS generally. (p. 49708). Because there is no IOP-specific data, CMS proposes to use the broader OPPS data set to calculate payment rates for IOP and PHP, using PHP and non-PHP days that include 3 or more of the same service codes, rather than using PHP specific data only. (p.49707). CMS notes that initially the same payment rates will be used for IOP and PHP since IOP is a new benefit that does not have definitive utilization data. The proposed rule states that CMS will re-evaluate this proposal once utilization data for the IOP program becomes available. The AAMC urges CMS to finalize the proposal to initially align payment between IOP and PHP, and we agree that the utilization of these services should be monitored and evaluated for rate setting as more data becomes available. The utilization data should be used to refine the number of services required for PHP versus IOP and the payment rates for these programs. Lastly, in the CY 2024 OPPS final rule and annually in the OPPS rules thereafter, CMS should provide more clarity on the data and methodology that is used to calculate payment rates in order to provide greater transparency. Moreover, the AAMC asks CMS to annually identify and include the data sets used to calculate these payment rates to allow stakeholders to replicate these payment rates.

Site of Service and Payment Rates: While IOP and PHP will initially be paid the same rate, CMS is seeking comment on two payment rate methodologies to determine how the rate will be established in future years with the main difference being dependent on site of service. Under the first proposal, CMS proposes that payment rates would be based on the costs for three and four services per day and be dependent on the location of the program, specifically, whether the program is hospital-based or based in a CMHC as reflected in Table 45 of the proposed rule. For this method, CMS proposes 8 different APCs. Alternatively, CMS is also considering establishing the same payment rates for both hospital based and CMHC based programs. These payment rates are shown in Table 46 of the proposed rule. (p. 49711).

The AAMC supports the proposal that bases payment rates on site of service (Table 45) to safeguard access to mental and behavioral health services for Medicare beneficiaries. Generally speaking, 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. Additionally, Medicare beneficiaries receiving care in an HOPD were 1.9 times more likely to be dual eligible beneficiaries.[4] Sixty-four percent of dual-eligible Medicare beneficiaries have a mental health diagnosis.[5] Finalizing the payment rate proposal that takes into account these variations between the sites of service and the complexities in the populations they treat, will ensure that hospital-based programs can sustain these services, expand the behavioral and mental health workforce, and maintain greater access for beneficiaries. Ensuring adequate reimbursement rates will incentivize both hospitals and CMHCs to adopt IOP programs, which would expand access for Medicare beneficiaries and improve patient outcomes.

In addition, CMS proposes to utilize the CMHC rates for PHP and IOP services furnished by non-excepted off-campus hospital departments, rather than the hospital-based payment rates. (p. 49723). With this in mind, the AAMC strongly urges CMS to not finalize its proposal to pay less for IOP and PHP services furnished by a non-excepted off-campus hospital outpatient departments than they would for other hospital-based programs. Reducing the payment for these services furnished by a non-excepted off-campus hospital departments could negatively impact beneficiary access to behavioral and mental health services, undermining CMS' goals for establishing this program.

Evaluate Additional Codes Related to Caregiver and Peer Services for the Intensive Outpatient Program and Partial Hospitalization Program

CMS seeks comment on its proposed list of HCPCS codes that would be payable when furnished in a PHP and IOP (shown in Table 43), and asks whether codes should be added, modified, or created to describe specific services. (p. 49705). CMS is particularly interested in caregiver-focused services for the list of recognized services as well as codes related to peer-services. As more Americans find themselves caring for adult loved ones, many of these caregivers are forced to both work and provide caregiving, which adds an additional physical and emotional toll on the caregiver. According to the AARP, 38 million Americans spent 36 billion hours on caregiving for adults with chronic, disabling, or serious health conditions. Family caregivers provide needed day-to-day support and services and manage complex care tasks. The cost of this care is valued at $600 billion.[6] Additionally, there are large out-of-

[4] 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
[5] https://atiadvisory.com/wp-content/uploads/2022/06/A-Profile-of-Medicare-Medicaid-Dual-Beneficiaries.pdf
[6] https://www.aarp.org/content/dam/aarp/ppi/2023/3/valuing-the-invaluable-2023-update.doi.10.26419-2Fppi.00082.006.pdf

pocket costs that caregivers cover on behalf of the individual for whom they provide care. In a 2021 brief, AARP reports that three fourths of family caregivers spent on average $7,242 annually on these out-of-pocket costs related to caregiving with on average one fifth of this spending going directly to payments for health care providers, hospitals, therapists, etc.[7] Providing reimbursement for caregiver services can ease some of the financial burden on both the beneficiary and the caregiver in order to allow the caregiver to be more attentive and provide better assistance.

The AAMC urges CMS to initially include the proposed list of caregiver codes in the list of HCPCS codes that would be payable when furnished as part of a PHP and IOP (shown in Table 43). Further, CMS should continue to evaluate additional codes, such as those related to caregiver and peer services, as the programs expand in order to further bolster the range of behavioral and mental health services as clinically appropriate.

PAYMENT FOR INTENSIVE CARDIAC REHABILITATION SERVICES (ICR) PROVIDED BY AN OFF-CAMPUS, NON-EXCEPTED PROVIDER BASED DEPARTMENT OF A HOSPITAL

Finalize Proposal to Increase Payment Rates for ICR Services Furnished at Non-Excepted Off-Campus PBDs

Under section 603 of the Bipartisan Budget Act of 2015[8], CMS has established physician fee schedule equivalent rates for applicable items and services provided at non-excepted off-campus PBDs. In the OPPS proposed rule for CY 2024, CMS notes that ICR services have been reimbursed 100 percent of the OPPS rate when provided in a physician's office since 2017. However, ICR services provided at non-exempt, off-campus PBDs have been paid at 40 percent of the OPPS rate. (p. 49728). In this proposed rule, CMS acknowledges that this is inconsistent with its implementation of section 603, which is intended to pay an equivalent rate, not less, for services provided in non-excepted off-campus PBDs relative to physician offices. Under current policy, ICR is paid $120.47 in on-campus hospital departments, excepted off-campus PBDs and physician offices, but $48.03 in a non-excepted off-campus PBD in 2023. To address this disparity, CMS is proposing to pay for ICR services provided by non-excepted, off-campus PBDs at 100 percent of the OPPS rate, the same as the PFS rate. As a result, effective January 1, 2024, HCPCS codes G0423 and G0422 would be paid 100 percent of the OPPS rates. (p. 49728).

The AAMC supports this proposal and asks that the agency move ahead with finalizing the proposal. We echo CMS' concerns that if not corrected, these disparities in payment will create significant barriers to access and negatively impact patient care. We also urge the agency to continue to monitor for these disparities in payment rates and act swiftly to correct any discrepancies to ensure and maintain access to services regardless of location.

Additionally, we urge the agency to retroactively review payments made from CY 2017 through CY 2023 for ICR services (HCPCS codes G0422 and G0423) provided by a non-excepted, off campus PBD and prospectively adjust payment rates to reimburse off-campus PBDs the difference between what was paid, 40 percent of the OPPS rate, and what should have been paid,100 percent of the OPPS rate. Doing so will

[7] https://www.aarp.org/content/dam/aarp/research/surveys_statistics/ltc/2021/family-caregivers-cost-survey-2021.doi.10.26419-2Fres.00473.001.pdf
[8] Pub. L. 114-74

ensure that providers negatively affected by this payment discrepancy can continue providing these services moving forward.

DENTAL SERVICES

Finalize Proposal to Expand OPPS Reimbursement for Certain Dental Services

In the CY 2023 Physician Fee Schedule final rule[9] CMS finalized payment for certain dental services performed in the outpatient setting. CMS is proposing to expand the dental services eligible for coverage when furnished in HOPDs and ASCs. Under the proposal, 229 additional dental codes would be assigned to clinical APCs to enable them to be paid for under the OPPS when payment and coverage requirements are met. Dental services that are eligible for coverage under Medicare must be "inextricably linked and substantially related to the clinical success of other covered medical services" and payable under Medicare Part B. (p. 49732). The AAMC supports this proposal and asks CMS to finalize it.

Oral diseases cause pain and disability for millions of people in the United States, and some are linked to other diseases — like diabetes, heart disease, and stroke.[10] Even if people can afford care and have providers available in their area, they may face additional barriers that prevent them from getting the services they need. Addressing the social, behavioral, and environmental determinants of health as part of oral health care offers a new approach to prevention and treatment. These factors can inform new research and technology, which can lead to more personalized medicine and tailored recommendations to better meet the needs of high-risk individuals.[11]

REQUEST FOR INFORMATION: ESSENTIAL MEDICINE "BUFFER STOCK"

Finalize Separate Payment Under IPPS to Establish and Maintain Buffer Stock of Essential Medicines

CMS seeks comment on separate payment under the IPPS for establishing and maintaining access to a buffer stock of essential medicines to foster a more reliable, resilient supply chain of these medicines. The proposed rule notes that more must be done to curtail shortages of essential medicines. (p. 49869). Specifically, it is CMS' goal that these payments would account for any increased resource costs for a hospital to establish and maintain access to a buffer stock of more expensive domestically manufactured essential medicines compared to non-domestically manufactured ones. (p. 49870). The separate IPPS payment would not be budget neutral. An adjustment under the OPPS could be considered in future years. Based on comments, CMS notes it would consider adopting a policy that would be effective as soon as cost reporting periods beginning on or after January 1, 2024.

Under the proposal, costs could include those to hold essential medicines directly at the hospital or contractually with a distributor or wholesaler. A hospital would report these costs in the aggregate on its cost report to CMS. These costs would not include the costs of the essential medicine itself. This information could be used to calculate a Medicare payment to establish and maintain access to a buffer stock of these essential medicines. Payments would be in accordance with reasonable cost principles through a biweekly payment with reconciliation during settlement of the cost report.

The AAMC supports CMS' efforts to ensure hospitals, providers and patients have access to needed medicines. However, we also call upon policymakers to investigate the causes of drug shortages and to

[9] 87 FR 69663
[10] https://www.cdc.gov/oralhealth/about/healthy-people.html
[11] https://health.gov/sites/default/files/2021-09/OH_ExecutiveSummary_2020-06-19_508.pdf

make changes that support the entire supply chain. Drug shortages negatively impact patients by adversely affecting drug therapy and potentially causing delays in medical treatments. While the AAMC supports an add-on payment, the add-on payment should not be limited to domestically produced medications. It could be difficult to identify which products meet the definition of domestically produced under the Berry Amendment, even if manufacturers share all data.

HOSPITAL QUALITY PROPOSALS

OUTPATIENT QUALITY REPORTING PROGRAM

Proposed Measure Adoptions

Volume Data on Select Outpatient Surgical Procedures

CMS proposes to re-adopt a volume indicator measure for the OQR, effective with CY 2026 reporting, impacting CY 2028 payment (following one voluntary reporting period). (p. 49780) Unlike the previous OP-26 measure, which was removed in the CY 2018 final rule, [12] effective for CY 2020 payment determinations, CMS proposes to require hospitals report the top five most frequently performed procedures, as identified by Medicare FFS claims for outpatient hospital services, across eight clinical categories, across all patients and payers. (p. 49782) **The AAMC does not support this measure, as it is unclear how, as specified, it provides a meaningful picture of outpatient procedural volume.** This is in part because the five procedures per category a hospital must report are based upon Medicare FFS frequency, and not frequency across all patients and payers. Considering the growth of the Medicare Advantage program, the frequency of procedures based on Medicare FFS claims is unlikely to accurately reflect the frequency of procedures performed for the entire Medicare population, let alone all patients.

As noted in our comments to last year's request for feedback on a volume indicator, there remains little evidence to support a facility volume indicator as the more meaningful measure for patients and families when considering where to seek care, relative to outcomes measures. We urged CMS to focus on developing measures that are meaningful to patients and clinicians and that are accessible and comprehensible.[13] If volume metrics are found to be more comprehensible and accessible for patients and families than outcomes measures, we urge CMS to then develop an indicator that truly represents that information. In this proposal, we do not see that as the case, as there is a mismatch between the facility volume reported (all patients) for procedures most common to a sub-set of that population (Medicare FFS). CMS should reconsider this proposal and go back to the drawing board to (1) fully understand what information is most helpful for patients when selecting an outpatient facility for a procedure, and (2) design a measure that appropriately specifies the hospital reporting of that information that minimizes administrative burden relative to the value of the information provided.

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[12] "Medicare Program: Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs", 82 Fed. Reg. 52356 (November 13, 2017)

[13] *See* Jha AK. "Back to the Future: Volume as a Quality Metric," JAMA Forum Archive (June 2015), concluding "[W]e still need to work to develop the measures that are meaningful to patients and clinicians and that are readily available in a way that is accessible and comprehensible."

Total Hip Arthroplasty (THA)/ Total Knee Arthroplasty (TKA) Patient-Reported Outcome Performance Measure (PRO-PM) (#3559)

CMS proposes to adopt the THA/TKA PRO-PM measure for the outpatient setting effective with CY 2027 reporting, impacting CY 2030 payment (following two voluntary reporting periods). (p. 49787) The measure is currently adopted in the Inpatient Quality Reporting (IQR) Program and CMS believes the measure should also be included for the outpatient setting, considering the shift in site of service following the removal of both procedures from the Inpatient Only List. (p. 49784) The AAMC supports PRO-PMs that are valid, reliable, and capable of informing performance improvement. As more PRO-PMs are developed and adopted in CMS programs, we ask CMS to monitor and evaluate patient willingness to respond to requests for patient-reported information necessary for meaningful measurement. CMS should report on the landscape of PRO-PMs and assist providers in best practices to improve and maintain patient responsiveness to data collection requests that support quality measurement.

Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computer Tomography (CT) in Adults (Hospital Level – Outpatient) eCQM (#3663e)

CMS proposes to adopt the endorsed Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT measure to better monitor performance of diagnostic CT and discourage unnecessary radiation exposure balanced by preserving image quality. The measure is currently CBE endorsed and reflects clinical guidelines for optimizing CT radiation doses. (p. 49788) The AAMC supports the adoption of the Excess Radiation eCQM as an *optional* measure that hospitals may select to report to meet OQR requirements, similar to the measure's adoption for the IQR and Promoting Interoperability Programs. This is in part because the measure as specified for endorsement is at the facility level and includes imaging for both the inpatient and outpatient care settings.[14] As such, it is unclear how a hospital could report the measure for the outpatient setting without reporting for the inpatient setting, which in turn is a *de facto* regulatory change that would require hospitals to report the measure under the IQR and Promoting Interoperability Programs without formal notice and comment rulemaking.

Proposed Measure Modifications

OP-38: COVID-19 Vaccination Rates Among Healthcare Personnel (HCP) (#3636 – modifications not endorsed)

CMS proposes to modify the existing COVID-19 Vaccination Rate Among Health Care Personnel (HCP) measure effective with CY 2024 hospital reporting to reflect Centers for Disease Control and Prevention (CDC) updates that expressly specify for HCP to receive the primary series and booster vaccine doses in a timely manner. Specifically, CMS would replace the term "complete vaccination course" with "up to date." (p. 49776) The original version of the measure is endorsed, though that version does not include reporting booster doses. The proposed modified version is undergoing endorsement review as part of the Spring 2023 cycle.[15] CMS does not propose modifications to the frequency of data collection and reporting for the measure, though notes that the measure is based upon the annual reported Influenza

[14] *See* CBE ID Number 3663e Excess Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Facility Level), stating in the measure description "All diagnostic CT exams of specified anatomic sites performed in inpatient and hospital outpatient care settings are eligible."
[15] *See* public comments submitted in response to the Spring 2023 measure evaluation cycle, as of July 16, 2023, largely in support for retiring the measure or at least transitioning the measure to annual reporting in light of the end of the COVID-19 Public Health Emergency.

Vaccination Coverage among HCP measure. (p. 49776) **The AAMC strongly supports vaccination as the most effective means to prevent COVID-19. However, we recommend that CMS hold off on measure modifications to the COVID-19 vaccination measure until there is greater clarity regarding seasonal vaccination strategy to support annual reporting.**[16]

We are concerned that CMS significantly underestimated the burden of this proposed measure modification. Health systems would have to make individualized determinations of "up to date," based on a relatively complex set of potential original course and booster dose combinations. For example, one individual might only be up to date if they received two primary series mRNA doses, one primary booster dose, and two bivalent booster doses, whereas another individual might be up to date with only a single primary dose and one bivalent dose. This level of detailed analysis necessary for reporting, when indications suggest we are nearing a recommendation for seasonal vaccination, suggests the burden under the proposed modification is not commensurate with the potential benefits of modified measurement. This is in part due to challenges for patients to truly understand public reporting of the measure, which lags a year behind when a patient might search for such information.[17] We advise CMS to step back this rulemaking cycle and revisit the measure's specifications and reporting cadence next year, when ideally the measure can be modified to reduce burden on health systems and provide beneficial information to patients and public health officials.

OP-31: Cataracts Visual Function

Currently, the OP-31 measure is a voluntary measure that hospitals may choose to report as part of the OQR. Under the measure, hospitals may select a survey instrument of their choice to evaluate improvement in patient's visual function 90 days following cataract surgery. CMS proposes to limit survey instruments to three specified tools effective with the CY 2024 voluntary reporting period. Those tools are the National Eye Institute Visual Function Questionnaire-25, or NEI VFQ-25, the Visual Functioning Patient Questionnaire, or VF-14, and the Visual Function Index Patient Questionnaire, or VF-8R. CMS believes that limiting measurement to three specific instruments standardizes assessment while also providing some administrative flexibility to hospitals on which survey to administer. For example, the NEI VFQ-25 is available in languages other than English, the VF-14 instrument is currently the most used tool, and the VF-8R is the most concise of the three options, while still achieving adequate measure validity and reliability. The AAMC supports this modification to support better measure standardization without sacrificing administrative flexibility. CMS should consider providing additional information to hospitals on any trends it observes on choice of instrument in the coming years.

OP-20: Colonoscopy Follow-Up Interval

CMS proposes to modify the existing OP-20 measure in recognition of 2021 final recommendations by the US Preventive Services Task Force (USPTF) to begin colorectal cancer screenings at 45, instead of aged 50. (p. 49779) Under this proposal, CMS would begin measuring performance on an adult patient population aged 45 to 75 years who receive a screening colonoscopy without biopsy or polypectomy,

[16] M Herper, FDA proposes annual Covid shot matched to current strains, STAT (January 23, 2023), highlighting that seasonal vaccination recommendations may come prior to the end of this calendar year, when CMS proposes incremental burdensome reporting modifications.
[17] For example, current COVID-19 vaccination rates reported on *Care Compare* are for the period April – June 2022.

effective with CY 2024 reporting, impacting CY 2026 payment. The AAMC supports this measure modification considering new recommendations finalized by the USPTF.

Proposed Measure Removal

OP-22 Left Without Being Seen

CMS proposes to remove the OP-22 Left Without Being Seen measure effective with CY2024 reporting on the basis that performance on the measure does not result in better patient outcomes. (p. 49774) CMS notes that routine measure monitoring over the past few years has indicated limited evidence to link to the measure to improved outcomes, that increased rates of left without being seen may reflect poor access to timely clinic-based care rather than an intrinsic systemic issue within the hospital's emergency department, and unintended effects on left without being seen rates caused by other policies, programs, and initiatives may lead to skewed measure performance. (p. 49774) The AAMC agrees and supports this proposed removal.

Quality Measure Topics for Potential Future Consideration

In general, the AAMC strongly believes that any new measure for a CMS quality reporting or performance program must be endorsed as valid and reliable as well as meaningful to patients and providers. Comments specific to areas for future consideration follow.

Safety

The AAMC supports CMS's desire to promote safety through the OQR. We are committed to working with policymakers to ensure access to high quality care for patients and advance the well-being of our nation's health care workforce. The COVID-19 pandemic has posed enormous challenges and placed tremendous stress on our entire health care system – and academic health systems, medical schools, and teaching physicians have mobilized on all fronts to contain and mitigate COVID-19. We believe that there is much that we can learn and share from care delivery during the public health emergency (PHE) to inform CMS and other agency efforts to advance a culture of patient and workforce safety. To this end, we urge CMS to actively engage and collaborate with federal partners on these efforts, including with the Agency for Healthcare Research and Quality, who was recently tasked with leading a new National Action Alliance to advance a culture of safety.[18]

Sepsis Care Measures

The AAMC fully supports the development and adoption of a valid, reliable, feasible outcomes measure to inform and improve effective and timely sepsis care. However, we urge CMS to focus on development of a better measure than the *Severe Sepsis and Septic Shock: Management Bundle (#0500)* measure due to current challenges with the measure in the IQR Program rather than adopting the measure into the OQR**.** The primary challenges with the measure include reconciliation of current specifications with infectious disease expertise on the use of antibiotics and the burden of chart-abstracted measurement. The AAMC is concerned that expanding the measure's inclusion in CMS quality programs amidst clinical disagreement on measure specifications and ongoing abstraction issues will provide no additional benefit to patients, considering the measure's current use in the IQR. Instead, broader use of the measure could frustrate hospital efforts to improve sepsis care by creating greater incentive to potentially overuse

[18] https://www.ahrq.gov/cpi/about/otherwebsites/action-alliance.html

antibiotics against clinical judgment or treat according to clinical judgment and document (and invest in sophisticated data abstractors) to enhance publicly reported performance.

The Infectious Diseases Society of America (IDSA) and five other endorsing societies have called on CMS to address significant concerns that the measure fails to "account for the high rate of sepsis overdiagnosis and encourages aggressive antibiotics for all patients with possible sepsis, regardless of the certainty of diagnosis or severity of illness."[19] To mitigate the potential for antibiotic overuse, the IDSA recommends that CMS modify the measure to focus solely on septic shock, for which there is the greatest evidence supporting the benefits of immediate antibiotics, whereas there is "insufficient data on the necessity of immediate antibiotics to support a mandatory treatment standard for all patients."[20] The AAMC urges CMS to provide greater evidence in response to this critical concern to ensure that the measure is congruent with efforts to combat antibiotic overuse and potential antibiotic resistance and provides actionable information for improvement.

In documentation submitted by the measure developer to the Measure Application Partnership, it was noted that this measure requires data abstractors to review documentation in various formats, including narrative free text, to identify specific information to report the measure and that as currently specified the information cannot be captured electronically in discrete fields. Some of this effort is necessary to ensure documented cases of appropriate clinical judgment against immediate antibiotics are captured to ensure accurate measure scoring. However, this requires significant background expertise identifying and parsing out complex clinical information and time-consuming attention to the abstraction process. The IDSA recommendation to focus the measure on septic shock would simplify data abstraction, in part by limiting measurement to evidence-based elements without greater need to identify and account for more flexible clinical judgment to mitigate unintended consequences of measurement.[21] Furthermore, regarding the burden of manual chart-abstraction, CMS has previously committed to moving Medicare quality measurement into the digital age, as early as 2025.[22] The AAMC asks CMS to provide greater discussion of the benefits of adopting a burdensome chart-abstracted measure for the OQR in contrast to the agency's broader goals for digital measurement. In light of these concerns, we urge CMS to focus energies instead on developing a clinically appropriate, less-burdensome measure of sepsis care for its quality reporting programs.

Workforce Safety Measures

In responding to an RFI earlier this year regarding AHRQ's National Action Alliance,[23] we noted that there is an incredible need for greater coordination across federal Departments that work on patient and workforce safety. We noted the need for coordination between efforts by the Occupational Safety and Health Administration and the Centers for Disease Control and Prevention regarding health care infection control practices and health care workplace safety. This is also true for policy efforts to address workplace violence, especially efforts tailored for the health care setting. Should CMS choose to address

[19] C Rhee et al., Infectious Diseases Society of America Position Paper: Recommended Revisions to the National Severe Sepsis and Septic Shock Early Management Bundle (SEP-1) Sepsis Quality Measure, Clin Infect Dis. (2021).
[20] *Id.*
[21] *Id.*
[22] 86 FR 44774 (August 13, 2021) at 45345, where CMS lays out potential actions in four areas to transition to digital quality measures for quality reporting and value-based purchasing programs by 2025.
[23] AAMC Comments to AHRQ RE: Request for Information on Creating a National Healthcare System Action Alliance to Advance Patient Safety (Jan. 2023).

workforce safety through quality measures, we urge the agency to consider how measures would (or would not) interact with other federal policies and ensure that measurement adds to such efforts, rather than hinders or distracts from them.

Behavioral Health

CMS seeks comment on behavioral health topics under consideration for measure development, including, adoption of the Adult Major Depressive Disorder (MDD): Suicide Risk Assessment measure, availability of and access to services and patient experience of care.

Adult Major Depressive Disorder (MDD): Suicide Risk Assessment (CBE #0104) – Endorsement Removed

CMS asks for feedback on broad adoption of the suicide risk assessment measure as appropriate and feasible for the OQR Program. The measure assesses the number of adult patients with a diagnosis of major depressive disorder with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified. Endorsement of the measure was removed by the consensus-based entity review process in July 2022, apparently due to measure retirement by the measure steward.[24] The removal of measure endorsement is a significant concern, and the AAMC urges CMS to consider whether measure specification changes are warranted, and if so, wait until such modifications allow the measure to regain endorsement as valid and reliable. Until then, the AAMC does not support future adoption of the measure in the OQR.

Quality Measurement Approaches to Improving Access to Behavioral Health Services in Outpatient Settings

There are significant barriers to access to behavioral health services in the US, including availability of providers and affordability and third-party payment for such services. It is unclear how, absent broader policy changes to increase availability and affordability of services, quality measurement approaches could improve access to services. A significant barrier in access to mental health care in the U.S. are the shortages of mental health providers. An AAMC Research and Action Institute Issue Brief found that "less than one-third of the U.S. population (28%) lives in an area where there are enough psychiatrists and other mental health professionals available to meet the needs of the population — in fact, most states have fewer than 40% of the mental health professionals needed."[25] According to data from the Health Resources and Services Administration (HRSA), as of August 2023, 163 million people currently reside in a Mental Health Professional Shortage Area (HPSA) and there are 8,253 fewer practitioners than are needed.[26] Regarding payment and affordability, there are significant barriers to care due to cost and ability to find a provider who accepts insurance.[27] While there are existing state and national mental health parity laws, they do not meaningfully achieve true parity in insurance coverage for behavioral health services, as inadequate insurance coverage of medical-surgical services will similarly inadequately cover mental

[24] Adult Major Depressive Disorder (MDD): Suicide Risk Assessment (#0104)
[25] H Modi, et al., Exploring Barriers to Mental Health Care in the U.S., AAMC Research and Action Institute (Oct. 2022).
[26] HRSA data on health professional shortage areas by discipline
[27] Nicole Rapfogel, The Behavioral Health Care Affordability Problem, CAP Report (May 2022).

health care.[28] To improve access through measurement approaches, we must first adopt policies that prioritize growing the workforce, expanding insurance coverage, increasing reimbursement rates, and enforcing parity laws. The AAMC encourages CMS to work with federal policymakers to address the provider shortages and payment policies that reduce access to care.

Patient Experience of Care Measurement

The AAMC recommends that CMS take a deliberate and careful approach to assessing the appropriateness in the design of the patient experience of care measures for behavioral health and fully evaluate the breadth of potential unintended consequences. To evaluate potential unintended consequences, we must first clearly define behavioral health care services and settings for measurement, assess nuances and characteristics of voluntary and involuntary psychiatric care,[29, 30] and analyze variations in state privacy laws.[31] Together, or individually, these variables could create challenges for developing valid and reliable patient experience measures. At a minimum, we suggest that CMS convene Technical Expert Panels to bring together patient experience, psychiatric providers, and privacy law experts, to better understand potential challenges with patient experience measures for behavioral health care services.

Telehealth

CMS seeks feedback on measuring the quality of telehealth services. The AAMC strongly supports the telehealth waivers and regulatory changes established by CMS in response to the COVID-19 public health emergency that have facilitated the widespread use of telehealth and other communication technology-based services that have improved access to health care. We support efforts to measure telehealth quality, in part to inform broader adoption of telehealth to meet its potential to transform the health care delivery system and access to care.

Measurement Priorities

CMS asks for comment on the highest priority topics for outpatient telehealth-related quality measurement. The AAMC believes measurement focused on understanding patient experiences with telehealth and disparities in utilization should be the top priorities for telehealth quality metrics. Regarding the potential to stratify existing outpatient quality measures by telehealth as the mode of delivery, the AAMC urges such approaches to be evaluated by a consensus-based entity to ensure validity and reliability in the results. Such measures could focus on measuring the potential influence of telehealth on hospital ED visits and readmissions as well as intermediate outcomes such as diabetic A1c and breast cancer screening rates and concordance with treatment plans and prescribed medications.

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[28] Richard G. Frank, Reflection on the Mental Health Parity and Addiction Equity Act After 10 Years, Milbank Quarterly (Dec. 2018), noting the broad differences between meaningful parity in principle in contrast with parity in law.
[29] Jason Craw and Michael T. Compton, MD, MPH, Characteristics associated with involuntary versus voluntary legal status at admission and discharge among psychiatric inpatients, Soc Psychiatry Psychiatr Epidemiol (October 2006).
[30] American Psychiatric Association Position Statement on Involuntary Outpatient Commitment and Related Programs of Assisted Outpatient Treatment (Dec. 2020).
[31] Timothy Stoltzfus Jost, Appendix B Constraints on Sharing Mental Health and Substance-Use Treatment Information Imposed by Federal and State Medical Records Privacy Laws, *Improving the Quality of Health Care for Mental and Substance-Use Conditions: Quality Chasm Series*. The National Academies (2006).

Patient Experience of Care Delivered via Telehealth

The AAMC strongly supports the expansion of patient experience as a critical quality measurement area, and this is especially true for telehealth quality as it can help inform broader telehealth payment and access policy. When developing patient experience of care measures for telehealth, we believe that measurement should focus both on technical delivery aspects (ease of use of a platform, connection issues, etc.) and experience receiving care from the clinician (for example, patient-centeredness of care, timeliness, shared decision making, etc.). Both areas could meaningfully inform care delivery improvements, while also ensuring that challenges with an electronic-based platform or poor internet connection are not co-mingled with the clinical experience of care.

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 Katie Gaynor (kgaynor@aamc.org) and Mary Mullaney (mmullaney@aamc.org) regarding the payment proposals and Phoebe Ramsey (pramsey@aamc.org) regarding the quality proposals.

Sincerely,

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Chief Health Care Officer

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