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September 15, 2021

Ms. Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
ATTN: CMS-1753-P  
P.O. Box 8013  
Baltimore, MD 21244-1850

***Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals (CMS-1753-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 “Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs,” 86 *Fed. Reg.* 42018 (August 4, 2021), issued by the Centers for Medicare & Medicaid Services (CMS or the Agency).

The AAMC is a nonprofit association dedicated to transforming health through medical education, health care, medical research, and community collaborations. Its members are all 155 accredited U.S. and 17 accredited Canadian medical schools; approximately 400 teaching hospitals and health systems, 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 and teaching hospitals and the millions of individuals employed across academic medicine, including more than 186,000 full-time faculty members, 94,000 medical students, 145,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

The AAMC thanks CMS for this opportunity to comment on these proposals and has detailed its feedback on these issues in the sections that follow.

#### **PAYMENT PROVISIONS**

- ***Data Sources for Ratesetting.*** CMS should finalize its proposal to use data sources from Calendar Year (CY) 2019, or CY 2018 where applicable, for CY 2022 Outpatient Prospective Payment System (OPPS) ratesetting.

- **340B Drug Pricing Program.** CMS should not continue the reimbursement reductions for 340B-acquired drugs. The AAMC asks that the Agency provide greater transparency in how it calculates and implements the budget neutrality adjustment.
- **Inpatient Only (IPO) List.** The Association supports CMS's proposal to halt the elimination of the IPO list, which the Agency should finalize.
- **Site-Neutral Payment Policy.** CMS should not continue the reimbursement reductions for outpatient clinic visits (HCPCS code G0463) at excepted off-campus provider-based departments (PBDs) in CY 2022 and beyond.
- **Hospital Price Transparency.** CMS should not finalize new civil monetary penalties (CMPs) for hospitals viewed as noncompliant with price transparency requirements.
- **Medicare Wage Index.** CMS should finalize its continuation of the low wage index policy for the CY 2022 OPSS wage index. However, the Agency should also extend the five-percent transitional cap in CY 2022 to *all* hospitals given the unique impact the COVID-19 public health emergency (PHE) continues to have on both hospital finances and area wages.
- **Ambulatory Surgical Center Covered Procedures List (ASC-CPL).** CMS should finalize its proposals to both reinstate the general standards and exclusion criteria in place prior to CY 2021 for adding procedures to the ASC-CPL and remove 258 of the 267 procedures added to the list in CY 2021. Further, the Agency should finalize its proposal to adopt a nomination process through which stakeholders may nominate procedures to be added to the ASC-CPL.
- **Payment for COVID-19 Specimen Collection.** CMS should make payment for COVID-19 specimen collection under the OPSS permanent.
- **Direct Supervision by Interactive Communications Technology.** CMS should permanently allow hospitals to meet direct supervision through interactive telecommunications technology for select rehabilitation services. The AAMC supports requiring a service-level modifier to identify the extent that hospitals leverage this flexibility, assuming the flexibility is made permanent.
- **Mental Health Services Furnished Remotely by Hospital Staff.** CMS should make permanent the flexibilities that permit hospital staff to remotely provide mental health services furnished to beneficiaries in their homes.

## QUALITY PROVISIONS

- **Adoption of New Measures and Modifying Existing Measures for the Outpatient Quality Reporting (OQR) Program.** CMS should consider impacts of the COVID-19 pandemic on measures proposed for adoption or modification, including whether performance may be substantially affected by the public health emergency. Regarding the COVID-19 vaccination among health care personnel measure, CMS should address outstanding questions that directly impact the design and feasibility of the measure in advance of the measure's inclusion in the OQR.

- ***Potential Efforts to Address Health Equity in the Hospital OQR Program.*** CMS should take a thoughtful and considered approach working with stakeholders to improve data collection in order to better measure and analyze disparities in a manner that builds an evidence-based, valid, and reliable framework towards provider accountability for health equity.
- ***Future Stratification of Quality Measures by Race and Ethnicity.*** CMS should invest in data collection improvements that standardize and use data already collected by hospitals. The Agency also should encourage the reporting and use of actionable data on health-related social needs instead of using indirect estimates of race and ethnicity to stratify measure reporting. Race and ethnicity themselves are not risk factors and reliance on immutable characteristics alone is not informative for intervention.
- ***Improving Demographic Data Collection for Quality Measurement.*** CMS should pursue a policy supporting the collection of standardized multi-sector risk information that will aid improved stratification and risk adjustment beyond individual-level demographic data elements. Data collection and systems for capturing unmet social need at the individual and community levels should be used in conjunction to best identify disparities in quality and equity to guide interventions for improvement.
- ***Advancing Digital Quality Measurement.*** CMS should refine its definition of digital quality measures to focus first on currently available valid and reliable digital data sources, set clear and specific parameters for what the agency hopes to achieve, and make clear what it expects of hospitals as it aims to transition to digital quality measurement by 2025.

## **RADIATION ONCOLOGY (RO) MODEL**

- ***RO Model Design.*** CMS should finalize the proposal to align each RO Model Performance Year with a calendar year, reduce the CMS discount to 2.5 percent, and finalize the addition of the extreme and uncontrollable circumstances policy.
- ***Cancer and Treatment Inclusions and Exclusions.*** CMS should finalize its proposal to exclude liver cancer, remove brachytherapy from the list of included modalities, and retain the current policy of limiting the RO model to radiation therapy that impacts multiple cancers.
- ***RO Payment Methodology.*** CMS should finalize its proposal to establish a fixed baseline period from 2017-2019, as well as its proposed methodology to calculate the trend factor and to include 2020 data in the case mix adjustment. CMS should also finalize its proposal to expand the definition of incomplete episodes to include a beneficiary who switches from traditional Medicare to Medicare Advantage (MA), and expand the stop-loss policy to apply to all model participants.
- ***RO Participant Exclusions.*** CMS should finalize the proposal to include eligible rural Pennsylvania hospitals that are not current Pennsylvania Rural Health Model (PAHRM) participants, as well as the proposal to align Community Health Access and Rural Transformation (CHART) ACO track participant eligibility with Medicare Shared Savings

Program (MSSP) participant rules. The Agency should also finalize the proposal to exclude CHART community transformation track participants.

- **Quality Payment Program.** CMS should finalize the proposal to create Track 1 and Track 2 status to allow the RO Model to qualify as an Advanced Alternative Payment Model (AAPM), reduce payment penalties if Qualified APM Participants (QP) status is retroactively revoked due to participant noncompliance, and allow RO Participants to update and certify the accuracy of their individual practitioner list once per year.
- **RO Quality Measurement and Reporting Requirements.** The Agency should retain two of the finalized quality measures but consider revising the full list to more tightly focus on the work of radiation oncologists with Medicare patients. CMS should also finalize the proposal to administer the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Cancer Care Survey for Radiation Therapy on behalf of RO participants, and should not collect clinical data elements (CDEs) unless used to measure quality and/or set appropriate payment rates. CMS should also revise the finalized list of monitoring requirements from the 2020 RO Final Rule.
- **Technical Adjustments Under the RO Program.** The Agency should finalize its proposed definitions of the legacy CMS Certification Number (CCN) and Tax Identification Number (TIN), and also to not to require RO participants to report new business relationships that do not constitute a change to the CCN or TIN. Additionally, CMS should finalize the proposals to apply technical updates to align with new timelines.

## **PAYMENT PROPOSALS**

### **DATA SOURCE FOR CY 2022 OPPTS RATESETTING**

#### ***Finalize the Proposal to Use CY 2019 Data for CY 2022 OPPTS Ratesetting***

The AAMC appreciates CMS's acknowledgement and support of the financial impact that hospitals continue to face as a result of the COVID-19 PHE. Ambulatory settings saw dramatic decreases in volume at the outset of the PHE. In April 2020, the number of visits to ambulatory care providers had declined by nearly 60 percent.<sup>1</sup> Although the volume of visits returned to near baseline levels toward the end of 2020, providers struggled to balance treating patients with non-COVID-19-related illnesses and keeping staff safe, resulting in less appointments being scheduled.

**The AAMC supports using CY 2019 data sources, or CY 2018 where applicable, for CY 2022 OPPTS ratesetting.** As CMS notes in the proposed rule, there was a 20 percent overall decrease in outpatient hospital claims during 2020, which would be used in ratesetting. The reason for this may have been patients deferring elective care during the pandemic. (p. 42188). We agree with CMS that the CY 2019 data are a better approximation of expected CY 2022 hospital outpatient services. (p. 42189).

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<sup>1</sup> The Commonwealth Fund, "The Impact of COVID-19 on Outpatient Visits in 2020: Visits Remained Stable, Despite a Late Surge in Cases," Feb. 22, 2021. Available at: <https://www.commonwealthfund.org/publications/2021/feb/impact-covid-19-outpatient-visits-2020-visits-stable-despite-late-surge>.

### **340B DRUG PRICING PROGRAM**

Congress created the 340B Drug Pricing Program (340B Program) in 1992 under the Public Health Service Act to support certain safety-net hospitals and other providers that serve low-income, vulnerable patients. At no cost to taxpayers, the program allows these “covered entities” to purchase outpatient drugs at a discount from drug manufacturers to help “stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.

For CY 2022, CMS is proposing to pay for separately payable drugs paid under the OPSS and acquired through the 340B Program at average sales price (ASP) minus 22.5 percent. (p. 42136). We continue to believe CMS has wrongly targeted the 340B Program as the driver of high drug prices, rather than other factors such as prices imposed by pharmaceutical manufacturers. The proposals to continue the payment cuts to 340B hospitals undermine this important program and are counterproductive in addressing access to affordable medication and other programs that 340B has enabled hospitals to undertake for their communities. It is the AAMC’s belief and position that CMS made drastic cuts without legal authority.

#### ***CMS Must Revisit the Budget Neutrality Adjustment and Provide Methodology Used to Determine the Adjustment***

CMS first proposed payment reductions for certain outpatient drugs acquired under the 340B Program in the CY 2018 OPSS proposed rule. Lacking acquisition cost data, CMS nonetheless made drastic cuts to reimbursements for covered drugs based on a figure in a Medicare Payment Advisory Commission report<sup>2</sup> that made various assumptions and estimated the average minimum discount received by 340B hospitals. As stated above, the AAMC strongly believes that the cuts made by CMS were done without legal authority.

In the CY 2018 OPSS final rule CMS acknowledged that “provider behavior” and “overall market changes would likely lower the impact of the payment reduction” and noted that CMS “may need to make an adjustment in future years to revise the conversion factor once we have received more accurate data on drugs purchased with a 340B discount with the OPSS.”<sup>3</sup> This statement suggested that, as has been done for other payments, CMS would revisit its initial budget neutrality adjustment to determine whether it was set correctly. Yet, CMS has not revisited the initial budget neutrality adjustment nor has the Agency provided information about the methodology used for modeling it. The AAMC continues to believe that these drastic cuts made by CMS were done without legal authority. However, if such reductions continue, CMS must ensure that the budget neutrality adjustment is based on the most current data which is now available because hospitals must identify 340B drugs through the use of the JG modifier. We are concerned that over the past several years, and continuing in CY 2022 and beyond, CMS’s failure to make changes in the budget neutrality adjustment results in significant underpayments to hospitals.

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<sup>2</sup> Medicare Payment Advisory Commission. Report to Congress. Overview of the 340B Drug Pricing Program. May 2015. Available at: <http://www.medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0>.

<sup>3</sup> 82 FR 52623.

## **INPATIENT ONLY (IPO) LIST**

In the CY 2021 OPSS final rule, CMS finalized its proposal to eliminate the IPO list over three years, beginning January 1, 2021, with the removal of 298 procedures.<sup>4</sup> In the CY 2022 proposed rule CMS notes its reasoning behind the elimination of the IPO list was that the Agency “no longer saw the need to restrict payment for certain procedures by maintaining the IPO list to identify services that required inpatient care.” (p. 42156). CMS is now proposing to halt the elimination of the IPO list and return all 298 services to the IPO list that were removed in last year’s final rule beginning in CY 2022. CMS states that it does not believe that the removed services meet the established criteria for removal from the IPO list. (p. 42160). Many of the procedures that were removed are invasive and may require post-procedure monitoring, making the inpatient setting a better place to care for individuals undergoing these procedures. **We urge the Agency to finalize the proposal to halt the elimination of the IPO list.**

### ***Identify Procedures that Can be Performed in the Outpatient Setting Based on Considerations of Patient Safety and Quality of Care***

As the proposed rule discusses, procedures removed from the IPO list have historically been assessed using long-standing criteria. The 298 musculoskeletal procedures that CMS is proposing to return to the IPO list were not assessed against the criteria. (p. 42158). We support CMS’s proposal to return these procedures to the IPO list and continue to use the existing criteria to determine whether the removal of any procedures is appropriate. Procedures being considered for removal from the IPO list should be evaluated to determine whether the procedure is appropriate to be performed in the hospital outpatient setting, including patient safety considerations. Procedures are performed in the inpatient setting due to factors that include the complex nature of the procedure, the overall medical condition of the patient, and the need for significant clinical monitoring post procedure. As technology advances and standards of care change, there will be more procedures that can safely and successfully be performed in the outpatient setting. Although a procedure may technically be able to be performed in an outpatient setting a patient’s condition may not tolerate the short follow up and care associated with ambulatory procedures. In addition, a physician is often keenly aware of the skills and technological capabilities of an ambulatory setting and thus, we feel that deference to physician choice on site of service should always be considered. **The Association suggests that CMS work with stakeholders as part of a continuous evaluation process to determine which procedures and treatments are shown to be safely and successfully performed in the outpatient setting.**

### ***Continue Site-of-Service Review Exemptions for Procedures Removed from the IPO List***

Under current policy, Medicare Part A will pay for inpatient surgical procedures, diagnostic tests, and other treatments when the physician expects the patient to require an inpatient stay that crosses at least 2 midnights and admits the patient based on this expectation or the physician determines the patient requires inpatient care. Physician documentation in the medical record must support that the patient will require hospital care spanning at least 2 midnights, or the physician’s determination that

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<sup>4</sup> 85 FR 86084.

the patient requires inpatient care. Services on the IPO list are not subject to the 2-midnight policy and are paid under Medicare Part A regardless of the expected length of stay. CMS is proposing that if the Agency finalizes the proposal to halt the elimination of the IPO list and returns the 298 procedures that were removed, it would also reinstate the 2-year exemption from site-of-service reviews by the Beneficiary Family Centered Care-Quality Improvement Organizations for procedures removed from the IPO list under the OPPI on January 1, 2021, or later. (p. 42179). **The AAMC supports CMS's proposal to continue the 2-year exemption from site-of-service reviews for procedures removed from the IPO list.**

#### **SITE-NEUTRAL PAYMENT POLICY**

CMS is proposing to continue the payment reductions for clinic visits (HCPCS code G0463) when furnished in excepted off-campus PBDs in CY 2022 and beyond. (p. 42148). **The AAMC strongly opposes the reduction in payments.** As we have commented previously, an increase in outpatient volume can occur for myriad reasons and is not indicative of an unnecessary increase in services. The increase in volume of items and services furnished in the outpatient setting is caused by many appropriate factors, including services transitioning from the inpatient to the outpatient setting as advances in medical technology and patient safety permits, and the Agency's regulatory changes, among others. The AAMC continues to believe that reducing reimbursement for items and services furnished in excepted off-campus PBDs in CY 2022 is detrimental to the important care provided at these settings to vulnerable Medicare beneficiaries, which include the right care in the right setting. For these reasons, we reiterate our comments from previous years in opposition to this policy and urge CMS not to continue these reimbursement reductions in CY 2022 and beyond.

#### ***Do Not Continue Site-Neutral Payment Reductions***

The AAMC continues to assert that the shift of services from physician offices to hospital outpatient departments (HOPDs) is not "unnecessary" and can be explained by several factors unrelated to reimbursement rates, including the growth of the Medicare population and increased referrals to HOPDs. Additionally, patients seen at HOPDs often are substantially different and more medically complex than those treated in physicians' offices. We reiterate previous comments on this policy taking issue with a host of CMS's factual assumptions and legal conclusions, specifically that CMS lacks the statutory authority to implement the payment reduction, and that the reduction was not required to be implemented in a budget-neutral manner. We previously commented that Congress has established a clear structure for CMS to make annual changes to payments for covered hospital outpatient services under Medicare, and changes to payments that target only specific items or services must be budget neutral. In addition, by subjecting excepted and nonexcepted PBDs to the exact same payment system and payment rate, the Agency inappropriately abolished the statutory distinction between those two entities. **The AAMC recognizes that the Federal courts have ruled on the site neutral payment reductions, but we believe that CMS should not be imposing these cuts. Further, we continue to object to and believe that the non-budget neutral payment cut for clinic visits furnished by excepted off-campus PBDs causes undue harm to hospitals and**

**the communities they serve. CMS should not continue its site-neutral payment reductions in CY 2022.**

**HOSPITAL PRICE TRANSPARENCY**

Beginning January 1, 2021, hospitals are required to publicly post in a machine-readable format a list of their standard charges<sup>5</sup> for the items and services they provide and to annually update this information. Hospitals are also required to post at least 300 shoppable services in a consumer-friendly manner. CMS may assess civil monetary penalties on hospitals that do not comply with the price transparency requirements. The Agency has been monitoring hospitals' compliance and notes its concern that there is a "high rate of hospital noncompliance" with the price transparency requirements. Therefore, CMS is proposing to increase CMPs for hospitals' noncompliance based on the hospital's bed count, as documented on the hospital's cost report. (p. 42313). Additionally, CMS notes in the proposed rule that it considered "additional scaling factors for assessing CMPs...[f]or example, application of a lesser penalty that takes into account extreme and uncontrollable circumstances." To this end, the Agency asks commenters whether "there [are] bases for imposing lower CMPs, such as resource limitations or extreme or unusual circumstances." (p. 42316).

The COVID-19 PHE has stretched hospitals to the breaking point. Hospitals are battling multiple waves of COVID infections, increases in hospitalizations from patients who delayed care during the PHE and significant staffing shortages and burnout, and many again have had to divert scarce resources to secure additional staffing, expand capacity, and procure supplies needed to care for patients and keep staff safe. Imposing additional penalties would further negatively impact hospitals that are already challenged financially. **We urge CMS not to finalize the proposal to increase the CMPs.** The PHE represents one of the most extraordinary and uncontrollable circumstances the United States and its healthcare providers have ever faced. In response to CMS's question about imposing lower CMPs for extreme or unusual circumstances, the PHE represents an extraordinary circumstance. The AAMC believes it would be appropriate to delay applying any CMPs until the PHE is over. **If CMS finalizes this proposal, it should delay implementation until the calendar year following the end of the calendar year in which the PHE ends.** For example, this means that if the PHE ended Oct. 1, 2021, the effective date would be Jan. 1, 2023. A delay would provide significant relief to the hospitals during the PHE, and would also allow these hospitals time to acclimate once the PHE ends.

***Noncompliance Should Not be Defined as "All or Nothing"***

It cannot be overstated the enormous effort hospitals must undertake to post the required information, and the level of granularity that must be posted remains significant. Hospitals are required to post machine-readable files by individual payers for each plan for all items and services for which there is an established standard charge. Hospitals have multiple contracts – e.g.,

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<sup>5</sup> Standard charges include gross charges, payer-specific negotiated charges, discounted cash price, de-identified minimum and maximum negotiated charges. (84 FR 65525).



employer-sponsored plans, Exchange plans – with each insurance company which requires the posting of numerous large files for each health insurance company. For example, one hospital file contained more than 65,000 items and services for 19 payers with 54 unique payer-plan-contract combinations. Another hospital had more than 120 payer-plan combinations covering more than 98,000 items and services.<sup>6</sup> We also continue to believe that insurers have the most up-to-date information regarding payment and should be a party to help provide factual, specific information to patients and their families.

The proposed rule notes CMS’s concern about the “high rate of hospital noncompliance” is supported through the use of sampling, reviews, and reports of high rates of noncompliance. (p. 42313). However, CMS does not define “noncompliance” in this context. AAMC members report that they have made good faith efforts to post all required information, despite the resource-intensive nature of the process to compile and post this information in the manner required. We believe the appearance of incomplete files should not lead to the imposition of CMPs. Further, CMS should recognize that there are legitimate reasons that a hospital may appear to be noncompliant. For example, if a hospital does not have a payer-specific negotiated charge for a particular item or service, then “N/A” should be reflected in the corresponding cell of the document. If “N/A” is not indicated for an item or service, then it is assumed that the hospital is choosing not to disclose that information, rather than it not having a negotiated charge with the payer. Hospitals should not be penalized the entire CMP amount if they post files with minor exclusions.

## **MEDICARE WAGE INDEX**

For CY 2022, CMS proposes to adopt the Fiscal Year (FY) 2022 Inpatient Prospective Payment System (IPPS) post-reclassified wage index for the CY 2022 OPSS wage index beginning January 1, 2022, including any adjustments to the wage index reflected in the FY 2022 IPPS final rule. (p. 42051-52). Among several other wage index policies and adjustments adopted in the FY 2022 IPPS final rule that would be applied to the OPSS wage index under the CY 2022 proposal, CMS continued its FY 2020 policy to address disparities between high and low wage index hospitals present in the wage index system.<sup>7</sup> In FY 2020, the Agency agreed with the AAMC and other stakeholders to eschew a targeted decrease to the top quartile of wage indexes and instead maintain budget neutrality through a uniform adjustment to the standardized amount.<sup>8</sup> Further, in the FY 2022 IPPS final rule CMS continued its application of the extensive core-based statistical area (CBSA) delineations outlined in the Office of Management and Budget (OMB) Bulletin No. 18-04, extended the transitional five-percent cap on wage index reductions in FY 2022 to hospitals that qualified for the cap in FY 2021, and continued its policy to exclude reclassified urban-to-rural hospitals in its calculation of the rural floor. Finally, CMS finalized the reinstatement and

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<sup>6</sup> Low compliance from big hospitals on CMS’s hospital price transparency rule. Health Affairs. March 16, 2021. Available at: <https://www.healthaffairs.org/doi/10.1377/hblog20210311.899634/full/>.

<sup>7</sup> 86 FR 44778.

<sup>8</sup> 84 FR 42331.

implementation of the imputed floor wage index policy, as required under section 9831 of the American Rescue Plan Act of 2021.<sup>9</sup>

The AAMC appreciates the changes CMS made to the finalized FY 2020 policy to raise the bottom quartile of wage indexes, which addressed several concerns outlined in our comments on the FY 2020 IPPS proposed rule. **The Association reaffirms its support for CMS’s continuation of this policy as it applies to the CY 2022 OPSS wage index.** However, the AAMC reiterates its position below that the transitional cap should be extended to all hospitals, given the unique impact the COVID-19 PHE continues to have on both hospital finances and area wages.

***Extend the Transitional Cap for All Changes to Hospitals’ Wage Indexes***

In FY 2020, CMS finalized a one-year, five-percent transitional cap on reductions to hospitals’ wage indexes between FY 2019 and FY 2020. The cap limited reductions to a hospital’s wage index to no more than five percent between the two years to mitigate the impact of the finalized wage index policies and allow hospitals to prepare for payment reductions. In the following year, CMS adopted the labor market delineation updates described in OMB Bulletin No. 18-04 for both the IPPS and OPSS 2021 wage indexes. Both CMS and commenters recognized that these changes had significant impacts on the wage indexes of hospitals in several areas, and CMS again finalized a five-percent cap on all reductions to hospitals’ wage indexes between FY 2020 and FY 2021 to mitigate the effects of the revised CBSA delineations.

In the FY 2022 IPPS proposed rule, CMS solicited comments on “whether it would be appropriate to continue to apply a transition to the FY 2022 wage index for hospitals negatively impacted by [the Agency’s] adoption of the updates in OMB Bulletin 18-04” given the unprecedented nature of the COVID-19 PHE.<sup>10</sup> Ultimately, CMS finalized an extended five-percent transitional cap to the FY 2022 wage index, but only “for hospitals that received the transition in FY 2021,”<sup>11</sup> which, as proposed, would also be applied to the CY 2022 OPSS wage index. (p. 42051-52). **The AAMC appreciates CMS’s proposal to continue the transitional cap for hospitals that received the cap in 2021, but we reiterate our request<sup>12</sup> that the five-percent cap be applied to all wage index policy changes for all hospitals for CY 2022, regardless of whether the reduction resulted from the new CBSA delineations or other factors.**

While some hospitals are beginning to recover from the impacts of the PHE, many continue to financially struggle. The AAMC believes that the extended transition period aligns with past CMS policy and will more appropriately enable hospitals that are negatively affected to address significant reductions. Additionally, the Association notes that as recently as FY 2015 CMS provided a three-year transition policy for hospitals negatively impacted by CMS’s adoption of

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<sup>9</sup> The American Rescue Plan Act of 2021 (ARPA; P.L. 117-2). Available at: <https://www.congress.gov/bill/117th-congress/house-bill/1319/text>.

<sup>10</sup> 86 FR 45164.

<sup>11</sup> *Id.*

<sup>12</sup> See “AAMC Comments: FY 2022 IPPS Proposed Rule,” Jun. 28, 2021. Available at: <https://www.aamc.org/media/55156/download>.

OMB's delineations based on the 2010 decennial census.<sup>13</sup> **Given the severity and continuing impact of changes related to the OMB updates, the low wage index policy, and the financial burden caused by the COVID-19 PHE, the AAMC believes that it would be appropriate to continue the five-percent transitional cap policy for CY 2022 wage index changes for all hospitals.**

#### **AMBULATORY SURGICAL CENTER COVERED PROCEDURES LIST (ASC-CPL)**

The ASC-CPL identifies separately paid surgical procedures that are appropriately performed on an inpatient basis in a hospital, but can also be safely performed in an ASC, a critical access hospital (CAH), or an HOPD. (p. 42206). Until CY 2020, CMS's exclusion criteria prohibited the addition of surgical procedures that are prolonged, high risk, or directly involved major blood vessels, among several other enumerated concerns. Further, procedures were also required to meet general standards that any procedure added to the list would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. (p. 42208). However, in CY 2021, CMS finalized significant changes to the ASC-CPL that removed the Agency's existing general standards and exclusion criteria, instead turning these standards and criteria into suggested safety factors that physicians should consider in relation to a specific beneficiary when determining whether to perform a covered surgical procedure. (p. 42207). Additionally, under this revised policy, CMS added 267 surgical procedures to the ASC-CPL in CY 2021. (p. 42207).

In CY 2022, CMS is now proposing to reinstate the general standards and exclusion criteria in place prior to CY 2021 that were used to add covered surgical procedures to the ASC-CPL. (p. 42208). Relatedly, CMS is also proposing to remove 258 of the 267 procedures added to the ASC-CPL in CY 2021 that the Agency believes *do not meet* the ASC-CPL criteria proposed to be reinstated. (p. 42209). Finally, the Agency is proposing to revise the current notification process for adding procedures to the ASC-CPL to a *nomination process* through which stakeholders could nominate procedures to be added to the list. (p. 42209). These proposals are a welcome response to the patient safety and quality concerns that the AAMC and other stakeholders cited in response to the CY 2021 ASC-CPL changes. **The AAMC appreciates CMS's consideration of stakeholder feedback and urges CMS to finalize its proposals to both reinstate the general standards and exclusion criteria in place prior to CY 2021 for adding procedures to the ASC-CPL, and remove 258 of the 267 procedures added to the list in CY 2021. We believe that this action strongly supports the primary concern for patient safety. Further, the Association strongly supports the Agency's proposal to adopt a nomination process through which stakeholders may nominate procedures to be added to the ASC-CPL after review.**

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<sup>13</sup> 79 FR 49957.

***Reinstate the General Standards and Exclusion Criteria for Adding Procedures to the ASC-CPL***

In CY 2021, the Agency’s decision to remove existing safety criteria and standards for adding procedures to the ASC-CPL raised a bevy of safety and quality concerns addressed in the AAMC’s and other stakeholders’ comments. The AAMC’s comments on the CY 2021 proposed rule explained that, compared to HOPDs, ASCs generally would not be equipped to perform complex surgical procedures, furnish advanced treatments to a wide variety of patients, or provide overnight post-procedure monitoring when needed.<sup>14</sup> We asked CMS to consider not only an ASC’s ability to perform the procedure, but its capacity for post-operative monitoring based on the procedure and the patient’s age and comorbidities. Further, we provided an overview of deficiencies present in the quality and safety reporting required through the ASC Quality Reporting (ASCQR) Program, as well as the significantly less stringent regulation and oversight of ASCs, including the fact that ASCs are not subject to the Physician Self-Referral Law’s<sup>15</sup> prohibition on physician self-referrals. Given these extensive and varied concerns over patient safety and quality of care at ASCs, the AAMC urged CMS not to finalize its proposal in CY 2021.

In the CY 2022 proposed rule, CMS echoes the AAMC’s concerns that the changes adopted in CY 2021 for adding procedures to the ASC-CPL “do not include safety criteria other than ensuring that the procedure was not on the IPO list as of CY 2020.” (p. 42208). As such, CMS is proposing to revise the CY 2021 changes and reinstate the existing CY 2020 general standards and exclusion criteria. The AAMC appreciates CMS’s thoughtful consideration of the points that we and other stakeholders expressed in our CY 2021 OPPTS proposed rule comments. In particular, we appreciate that CMS notes that the “HOPD setting has additional capabilities, resources, and certifications that are not required for the ASC setting,” and that these features represent material differences between the two sites of care. (p. 42208). Further, we agree with the Agency’s assertion that “a procedure that can be furnished in the HOPD setting is not necessarily safe and appropriate to perform in an ASC setting simply because [CMS] make[s] payment for the procedure when it is furnished in the HOPD setting.” (p. 42209). The AAMC reiterates the positions detailed in its comments on the CY 2021 proposed rule, and remains committed to ensuring that access to care does not come at the expense of either patient safety or quality of care. **For these reasons, the AAMC expresses its firm support for CMS’s proposal to revise the existing requirements for adding a covered surgical procedure to the ASC-CPL and reinstate both the general standards and exclusion criteria in place in CY 2020. We also support CMS’s proposal to remove 258 of the 267 procedures added to the ASC-CPL in CY 2021 that would not meet the criteria and standards that would be reinstated in the proposed rule.**

***Adopt the Nomination Process and Prioritize Nominations Based on Patient-Related Indicators***

CMS also proposes to change the current notification process for adding surgical procedures to the ASC-CPL to “a formal nomination process” conducted through annual notice and comment rulemaking. (p. 42209). Under the current process, CMS unilaterally reviews HCPCS codes paid

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<sup>14</sup> See “AAMC Comments: CY 2021 OPPTS Proposed Rule,” Oct. 5, 2020. Available at: <https://www.aamc.org/media/48576/download>.

<sup>15</sup> 42 U.S. Code § 1395nn.

under the OPPS but not included on the ASC-CPL, and identifies procedure codes that may be appropriately added to the ASC-CPL.<sup>16</sup> The proposed nomination process would permit external parties, such as medical specialty societies or other stakeholders, to formally nominate procedures to be added to the ASC-CPL that would then be addressed in OPPS rulemaking. Specifically, stakeholder-nominated surgical procedures that meet the general standards and exclusion criteria would be proposed to be added to the ASC-CPL in the next available annual proposed rulemaking. CMS proposes that it would consider comments on each procedure submitted during the public comment period and indicate whether or not it would add the procedure after careful review to ASC-CPL in the final rule. (p. 42209). CMS further proposes that the nomination process would begin for CY 2023, and notes that stakeholders would need to send nominations by March 1, 2022 to be considered for the CY 2023 rulemaking cycle and potentially have their nomination effective by January 1, 2023. (p. 42209).

**The AAMC reiterates support for CMS’s proposal to establish a stakeholder nomination process for adding procedures to the ASC-CPL beginning CY 2023.** CMS notes in the proposed rule that it believes certain stakeholders “have a deep understanding of the complexities involved in providing certain procedures, would be able to provide valuable suggestions as to which additional procedures may reasonably and safely be performed in an ASC.” (p. 42209). During the CY 2021 OPPS rulemaking, the AAMC expressed support for a stakeholder nomination process to add surgical procedures to the ASC-CPL.<sup>17</sup> We agree with CMS that the stakeholder nomination process provides a unique and beneficial perspective on the appropriateness of performing certain surgical procedures in the ASC setting. Further, the AAMC believes that the nomination process affords the public a reasonable opportunity to review, assess, and provide input on procedures nominated for inclusion on the list.

As part of its proposal to establish a stakeholder nomination process, CMS seeks comments on how the Agency might “prioritize [its] review of nominated procedures, in the event [CMS] receive[s] an unexpectedly or extraordinarily large volume of nominations for which CMS has insufficient resources to address in the annual rulemaking.” (p. 42209). The Agency suggests that it could potentially prioritize “nominations that have codes nominated by multiple organizations or individuals, codes recently removed from the IPO list, [or] codes accompanied by evidence that other payers are paying for the service on an outpatient basis or in an ASC setting,” among other factors. (p. 42209).

**While the AAMC supports CMS’s proposal to establish a stakeholder nomination process, we strongly urge CMS *not* to prioritize nominations based solely on the number of nominations a procedure code receives.** The AAMC believes that a prioritization approach that values only the raw volume of nominations for a specific code would not necessarily indicate that a nominated procedure could be safely performed in an ASC. **Instead, the AAMC urges CMS to prioritize services that have been shown to be safely and successfully performed on Medicare**

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<sup>16</sup> 85 FR 48958.

<sup>17</sup> See “AAMC Comments: CY 2021 OPPS Proposed Rule,” Oct. 5, 2020. Available at: <https://www.aamc.org/media/48576/download>.

**beneficiaries in the hospital outpatient setting.** Relying on patient-related indicators rather than the volume of nominations would more meaningfully show that a nominated procedure would be appropriate to be performed in an ASC and would have a higher likelihood of meeting the reinstated ASC-CPL criteria. Further, any codes that are nominated should be accompanied by strong clinical evidence that substantiates that the procedure has been safely and reliably performed in the hospital outpatient setting when supporting its addition to the ASC-CPL. We believe that requiring sufficient clinical evidence that procedures can be safely performed in the ASC would also more closely align with the Agency’s reinstated standard.<sup>18</sup>

#### **PAYMENT FOR COVID-19 SPECIMEN COLLECTION**

In 2020, CMS created HCPCS code C9803 (Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), and specimen source) and assigned the code to APC 5371 (Level 1 Minor Procedures) with status indicator “Q1” through the second interim final rule with comment period (IFC).<sup>19</sup> In the CY 2022, OPSS proposed rule, CMS is soliciting comments on whether HCPCS code C9803 should be retired at the end of the PHE, or payment for COVID-19 specimen collection under the OPSS should be made permanent. (p. 42188). CMS intends to retire the code at the end of the PHE. (p. 42187).

**The AAMC urges CMS to make payment for COVID-19 specimen collection under the OPSS permanent.** As CMS notes in the proposed rule, the code was created to “facilitate widespread testing for COVID-19” at HOPDs during the PHE. (p. 42187). The AAMC reiterates its past comments that testing remains critical in tracking and containing the spread of COVID-19 in the United States, as well as for monitoring purposes to ensure that essential workers across numerous professional fields can safely provide critical services during the PHE. At the outset of the PHE, AAMC members increased testing capacity by setting up testing centers and/or staffing community testing centers to meet the needs of their communities. Permanent payment for specimen collection under the OPSS would best enable HOPDs to quickly address testing needs for both current and future COVID variants in the communities they serve, without requiring additional action by CMS. **For these reasons, we strongly urge CMS to finalize the proposal to make payment for COVID-19 specimen collection under the OPSS permanent.**

#### **DIRECT SUPERVISION BY INTERACTIVE COMMUNICATIONS TECHNOLOGY FOR SELECT REHABILITATION SERVICES**

In response to the ongoing PHE, CMS provided a variety of temporary regulatory flexibilities to hospitals through its IFC titled “Policy and Regulatory Provisions in Response to the COVID-19 Public Health Emergency,” including several changes to the supervision requirements for the

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<sup>18</sup> See 42 CFR § 416.166(b)(2)(ii)(A), “Covered surgical procedures.” Available at:

<https://ecfr.federalregister.gov/current/title-42/chapter-IV/subchapter-B/part-416/subpart-F/section-416.166>.

<sup>19</sup> 85 FR 27550, 27604.

provision of certain services.<sup>20</sup> Among these changes, CMS modified the direct supervision requirement for cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation services provided in hospitals and critical access hospitals. Generally, direct supervision for these services requires that “the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure.”<sup>21</sup> However, through both the IFC and the CY 2021 OPSS final rule, CMS permits hospitals to meet direct supervision “through virtual presence using audio/video real-time communications technology (excluding audio-only) subject to the clinical judgment of the supervising practitioner” until the later of either December 31, 2021, or the end of the PHE. (p. 42187).

In the CY 2022 OPSS proposed rule, CMS is soliciting comments on whether it “should continue to allow direct supervision for these services to include presence of the supervising practitioner via two-way, audio/video communication technology permanently, or for some period of time after the conclusion of the PHE or beyond December 31, 2021, to facilitate a gradual sunset of the policy.” (p. 42187). Additionally, CMS seeks comments on “whether a service-level modifier should be required to identify when the requirements for direct supervision for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services were met using audio/video real-time communications technology.” (p. 42187). The AAMC believes that permanently allowing hospitals to meet direct supervision for the select rehabilitation services using interactive real-time audio/video communications technology would help ensure that patients can continue to safely receive these services, provide continuity of care to existing patients, and offer welcome relief to hospitals and physicians that administer these services.

***Make Permanent the Flexibility Allowing Direct Supervision to Be Met Through Audio/Visual Telecommunications Technology for Select Rehabilitation Services***

The AAMC strongly supports making permanent CMS’s temporary flexibility permitting direct supervision to be met for these select rehabilitation services using interactive real-time audio/video communications technology when performed in the hospital or HOPD. The Association reiterates its previous comments on this issue, noting that the COVID-19 PHE has ushered in an era of unprecedented use of telecommunications technology in medicine, allowing teaching hospitals and their affiliated physicians the ability to provide expanded and uninterrupted medical care to patients. CMS notes in the proposed rule that during the PHE “practice patterns may have shifted to support expanded virtual services,” which aligns with the AAMC’s conversations with its member teaching hospitals (p. 42187). We believe that permanently allowing direct supervision to be met using virtual supervision for the select rehabilitation services would prioritize the safety of certain beneficiaries, and would represent an important step in recognizing and providing hospitals with opportunities to leverage existing telecommunication resources, while also improving beneficiary access to care during and beyond the PHE. The AAMC has heard from members that the flexibility has allowed them to safely and efficaciously continue to deliver these rehabilitation services to patients in their homes and in their communities during the ongoing PHE.

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<sup>20</sup> 85 FR 19230, 19245 and 19266.

<sup>21</sup> 85 FR 48936.

CMS seeks comments on the extent that these flexibilities have been used during the PHE. It is our understanding that AAMC member teaching hospitals consistently use and appreciate the virtual supervision flexibility and continue to exhaust all avenues available to them in order to safely and continuously provide high-quality rehabilitation services. **Consistent with our previous comments on the IFC,<sup>22</sup> the AAMC believes that it would be appropriate for CMS to permanently allow hospitals to meet direct supervision through interactive telecommunications technology for these select rehabilitation services.** Making this flexibility permanent advances a set of equally important and intertwined goals: to reduce in-person interaction during the PHE and enable hospitals to best address the medical needs of patients. This will offer flexibility for providers beyond the PHE and recognizes the significant practice changes that are occurring through the integration of telecommunications.

In the event the flexibility were made permanent, CMS also seeks comments on whether a service-level modifier should be required to identify the extent to which hospitals meet direct supervision for these rehabilitation services using audio/video real-time communications technology. **The AAMC supports requiring a service-level modifier to identify the extent that hospitals leverage this flexibility, assuming the flexibility is made permanent.** The AAMC believes the use of a service-level modifier would provide both concrete data regarding hospitals' use of this flexibility, and, more generally, evidence of the value of policies that allow and encourage the use of various telecommunications technologies in practice. The AAMC hopes that making this flexibility permanent represents the first steps in the broader trend to permit providers to leverage technologies in the provision of care to improve access, decrease burden, and advance medical practice into the modern age.

#### **MENTAL HEALTH SERVICES FURNISHED REMOTELY BY HOSPITAL STAFF TO BENEFICIARIES IN THEIR HOMES**

In response to the COVID-19 PHE, CMS provided a group of related flexibilities for the duration of the PHE, including the removal of geographic and site-of-service originating site restrictions and permitting additional types of practitioners to furnish telehealth services.<sup>23</sup> Under the current flexibilities and waivers, hospitals can bill Medicare under the OPPS for hospital outpatient mental health services, education, and training services provided remotely by hospital clinical staff members who cannot bill Medicare independently for their professional service. In the CY 2022 OPPS proposed rule, CMS seeks comments on “the extent to which hospitals have been billing for mental health services provided to beneficiaries in their homes through communications technology during the PHE,” and “whether [hospitals] would anticipate continuing demand for this model of care following the conclusion of the PHE.” (p. 42187). The AAMC thanks CMS for these flexibilities and strongly supports making them permanent to ensure these services can continue to be safely provided to beneficiaries. Further, these provisions assist hospitals in leveraging existing telecommunications technology to promote access and continuity of care for beneficiaries.

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<sup>22</sup> See “AAMC Comments on IFC-1,” p. 6, Jun. 1, 2020. Available at: <https://www.aamc.org/system/files/2020-06/ocomm-hca-AAMC%20Comment%20Letter%20First%20COVID%20IFC%206.1.2020.pdf>.

<sup>23</sup> 82 FR 53006.



***Make Permanent the Flexibilities Permitting Hospitals to Bill for Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes***

**The AAMC urges CMS to make permanent the flexibilities that enable hospitals to bill for mental health services provided by hospital staff to beneficiaries in their homes through certain telecommunications technology.** The Agency is concerned that once the PHE ends, beneficiaries that may currently be receiving mental health services from a hospital clinical staff member that cannot bill Medicare independently for their professional service would need to physically travel to the hospital to continue receiving the services post-PHE. (p. 42186).

**The AAMC shares the Agency’s concern that the removal of these flexibilities at the end of the PHE would negatively impact beneficiaries currently receiving remote mental health services.** It is the AAMC’s understanding that these flexibilities permitting hospitals to provide remote mental health services are widely used by AAMC member teaching hospitals, which have exhausted all available means to provide these and other critical services during the PHE. Further, we believe the advantages observed at the institution noted in the proposed rule – increased access to care, greater ease of scheduling, decreased stigma associated seeking treatment and greater adherence to keeping appointments – reflect the prevailing attitude toward these flexibilities across AAMC member teaching hospitals. (p. 42185). If these flexibilities ended with the PHE, patients would be required to return to in-person visits, which, as CMS noted, may deter beneficiaries from continuing to receive care. To ensure patients continue to receive and have access to mental health services, these flexibilities should continue beyond the end of the PHE.

***Mental Health Services Furnished via Telehealth Should be Permitted Without Restrictions by Geographic Location, In-person Visit or Audio-only Limitations***

**The AAMC strongly supports coverage and payment of telehealth for mental health services.** During the PHE, the removal of Medicare’s geographic and site of service limitations for services furnished via telehealth significantly increased access to care, particularly for behavioral telehealth services. In April 2020, at the height of the PHE, telehealth visits for psychiatry and psychology surpassed fifty percent of the total services. According to data from faculty practices included in the Clinical Practice Solutions Center (CPSC),<sup>24</sup> the use of telehealth for mental health services remained high throughout the remainder of 2020 and continues into 2021, at roughly fifty percent. In addition, there has also been a reduction in missed appointments for behavioral health services because telehealth expansion has made it easier for patients to access care. This is particularly important in mental health because there is a shortage of providers.

**The AAMC believes mental health services should be furnished via telehealth without limiting audio-only communication technology to instances where the beneficiary is unable to use, does not wish to use, or does not have access to two-way, audio/video technology.** Coverage of these audio-only services is particularly important for Medicare beneficiaries who may not have access to, or may not feel comfortable with, interactive audio/video technologies. Initial reports suggest that lack of audio-only services particularly affects vulnerable populations, including the elderly, those with low socioeconomic status, and certain races and ethnicities. Additionally, providers have found that when treating certain mental health conditions, such as post-traumatic stress disorder

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<sup>24</sup> The CPSC, developed by the Association of American Medical Colleges (AAMC) and Vizient, is the result of a partnership that works with member practice plans to collect data on provider practice patterns and performance.

(PTSD), patients often benefit from obtaining services without visual contact with their provider. Audio-only technology allows patients to communicate with providers while maintaining a sense of privacy. Hospital mental health professionals are responsible for the quality of care delivered to their patients, and to effectively treat a patient these professionals need discretion to make clinical decisions based on the needs of the patient. Limiting audio-only technology to instances where the beneficiary is unable to use, does not wish to use, or does not have access to two-way, audio/video technology will ultimately prevent patients from receiving the care that they need. **If these flexibilities that enable beneficiaries to receive remote mental health services are made permanent, we urge CMS to ensure that these services are not restricted by geographic location, in-person visit, or audio-only limitations.**

## **QUALITY PROPOSALS**

### **OUTPATIENT QUALITY REPORTING (OQR) PROGRAM**

#### ***CMS Should Consider the Broader Impacts of the COVID-19 Pandemic on Measures Proposed for Adoption in the OQR***

CMS proposes to adopt three new quality measures. Comments specific to each measure follow.

##### *COVID-19 Vaccination Among Health Care Personnel Measure*

To address the ongoing COVID-19 PHE, CMS proposes to adopt a new COVID-19 vaccination among health care personnel (HCP) measure that calculates the percentage of HCP eligible to work in the hospital for at least one day during the reporting period who received a complete vaccination course. The measure would exclude persons with medical contraindications to the COVID-19 vaccination as described by the Centers for Disease Control and Prevention (CDC), but otherwise all personnel—including licensed independent practitioners affiliated with but not directly employed by the hospital, students, trainees, and volunteers—are included in the denominator, regardless of clinical responsibility or patient contact. The measure would be reported using CDC's National Healthcare Safety Network (NHSN) Healthcare Personnel Safety Component submission framework. CMS proposes to require hospitals report the measure a minimum of one week each month to CDC, beginning with January 2022.

**The AAMC strongly supports COVID-19 vaccinations of both our members' HCPs and the communities they serve and generally supports a measure of HCP vaccination rates.**<sup>25</sup> Recent surges in COVID-19 cases have emphasized the critical need to continue to get individuals vaccinated. We have partnered<sup>26</sup> with the CDC to build confidence in vaccines in part by engaging member medical schools and teaching hospitals in outreach efforts to communicate transparently

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<sup>25</sup> See AAMC Press Release, "[AAMC Statement on COVID-19 Vaccine Requirements for Medical School and Teaching Hospital Employees](#)," (July 16, 2021).

<sup>26</sup> See AAMC Press Release, "[AAMC Receives CDC Award to Build Confidence in COVID-19 Vaccines and Move the Nation Forward](#)," (March 19, 2021).

and dispel myths, with the goal of increasing vaccination rates. Still, several outstanding questions remain, including:

- What is the period of immunity conferred and whether (and how frequently) booster shots may be required?
- And if boosters are required, must the booster be made by the same manufacturer as the original vaccine received?
- Critically, will vaccine supply remain sufficient to ensure HCPs can receive boosters if necessary?
- Additionally, CMS recently finalized the adoption of this same measure for the Inpatient Quality Reporting (IQR) Program beginning with October 2021 reporting<sup>27</sup>, and the measure as specified includes reporting for all departments within a hospital's CCN, including outpatient departments. Will reporting under the IQR satisfy OQR reporting requirements so long as the hospital outpatient department operates under the same CCN for reporting? Or will the hospital be required to report duplicative data to satisfy requirement under each program?

In response to the last question, the AAMC asks that CMS confirm that reporting for the IQR program requirements will satisfy OQR reporting requirements, and that the Agency will not mandate duplicative reporting. **These questions directly impact the design and feasibility of a vaccination measure. Thus, we believe CMS should address these questions to ensure that the measure is valid, reliable, and not overly burdensome to report well in advance of implementation of the measure in the OQR.**

#### *Breast Screening Recall Rates Measure*

CMS proposes to adopt a Medicare fee-for-service claims-based process measure that tracks the percentage of patients who are recalled after traditional mammography or digital breast tomosynthesis (DBT) screening for additional outpatient imaging on the same day or within 45 days of the index image. Measurement is proposed to begin with CY 2023 payment determinations, based on 12-month measurement period running from July 1, 2020 to June 30, 2021. CMS notes that if the measure is adopted, the Agency would provide education and outreach materials, including the measure's use of a range representing ideal performance (which CMS believes should fall between 5 and 12 percent, based on current clinical literature).

**The AAMC supports the adoption of this measure, recognizing that the prior removal of OP-9: Mammography Follow Up Rates has left a measurement gap.** We do raise one concern for continued monitoring by CMS related to the timing of the measure adoption. The first measurement period is in the early stages of the ongoing COVID-19 PHE, during a time when providers saw a significant reduction in patient volume as the healthcare system struggled to keep patients and staff safe, especially for non-urgent care such as cancer screenings.<sup>28</sup> While screenings appear to have

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<sup>27</sup> 86 FR 44774, at 45382.

<sup>28</sup> See National Cancer Institute, "[For Cancer Screening, COVID-19 Pandemic Creates Obstacles, Opportunities.](#)" (March 10, 2021).

rebounded, the AAMC asks CMS to monitor the effects of the declines and delayed screenings on measure performance, including impacts on ideal performance and potential inequities in rebounding screening rates.<sup>29</sup>

*ST-Segment Elevation Myocardial Infarction (STEMI) Electronic Clinical Quality Measure (eCQM)*

CMS proposes to adopt a new facility-level electronic process measure to track the percentage of Emergency Department (ED) patients with a diagnosis of ST-Segment Elevation Myocardial Infarction, who received timely delivery, absent contraindications, of guideline-based reperfusion therapies appropriate for the care setting. CMS believes that this measure more comprehensively captures the population of heart attack patients receiving timely therapy, regardless of ED transfer, than the two current measures in the program, OP-2 and OP-3, which CMS proposes for removal in conjunction with this proposed measure adoption. CMS proposes to begin requiring reporting of the STEMI eCQM with CY 2024 reporting, after a year of voluntary reporting in CY 2023. Notably, this measure would represent the first eCQM adopted in the OQR, and so CMS also proposed additional related policies regarding eCQM reporting in the program. **The AAMC agrees that this is an important area of measurement and supports adoption of the measure as proposed.**

*CMS Should Finalize the Proposed Removal of Two Measures from the OQR*

CMS reviewed the current portfolio of measures in the OQR and proposes to remove two measures: OP-2: Fibrinolytic Therapy Received within 30 Minutes of ED Arrival and OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention. Removal of these chart-abstracted measures is responsive to the proposed adoption of the STEMI eCQM. **The AAMC appreciates CMS's efforts to continuously review measures and supports the proposed removal of both measures.**

*CMS Should Consider the Impacts of the COVID-19 Pandemic Prior to Finalizing Proposed Modifications to Existing OQR Measures*

CMS proposes to modify policies regarding two existing quality measures. Comments specific to each measure follow.

*OP-31: Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery*

CMS proposes to require reporting of OP-31, following several years of voluntary reporting of the measure in the OQR program. The Agency notes that the measure addresses a high-impact condition that is not otherwise adequately measured in the program and that concerns with the survey instruments and operational burden of reporting the measure have been ameliorated in the time that the measure has been voluntary. CMS proposes to begin requiring the measure with CY 2023 reporting. The AAMC is supportive of measurement based on patient-reported data and agrees

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<sup>29</sup> See Labaki et al., [Recovery of cancer screening tests and possible associated disparities after the first peak of the COVID-19 pandemic](#), Cancer Cell, Vol. 39, Issue 8 (June 30, 2021), finding apparent racial disparities between rebound of screening procedures in late 2020, notably in patients undergoing mammography.

that this measure is responsive to an important condition in the Medicare patient population. However, prior to re-implementing the measure as a requirement for OQR reporting, we ask CMS to provide education and outreach on the survey instruments available for use with this measure and best practices based on the experiences of those facilities that have consistently reported the measure while it has been voluntary.

*OP-37a-e Outpatient Ambulatory Surgery Consumer Assessment of Health Care Providers and Systems (OAS CAHPS)*

Similar to the OP-31, CMS proposes to move ahead with now requiring the reporting of the Outpatient Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) patient experience survey, which rolls up into several sub measures under OP-37, beginning with CY 2024 reporting. The OAS CAHPS patient experience survey has been under a national voluntary reporting program that began in 2016 and was delayed for mandatory reporting in the OQR until CMS accrued more information on hospitals' operational experience with the survey. After reviewing the voluntary program, CMS has determined that patients are able to successfully respond to the survey and that such responses are reliable. In addition to mandating the OAS CAHPS measures, CMS is proposing to add two web-based data collection modes with either mail or telephone follow-up of non-respondents under the belief that this may result in greater patient response rates and reduce costs burdens associated with mail-based survey administration. These two web-based modes are in addition to the existing three modes: mail-only, telephone-only, and mixed – mail with telephone follow-up. **The AAMC supports the integration of patient-collected feedback to the OQR. We encourage CMS to continue to monitor patient response rates over time, particularly regarding the two new web-based survey modes.**

*CMS Should Not Reduce Hospital Response Time to OQR Program Data Validation Requests*

CMS proposes to reduce the amount of time hospitals have to respond to quarterly requests for medical documentation for OQR validation to 30 days, 15 calendar days fewer than the current 45-day response window. CMS states that the intent is to reduce the time needed to complete validation and provide hospitals with feedback on their abstraction accuracy in a timelier manner. The AAMC has heard from members regarding delayed feedback from CMS's Clinical Data Abstraction Center (CDAC) Contractor for CY 2020 validation, notably that hospitals did not receive validation results for Q1 submissions until just before Q4 submissions were due. **We urge CMS to evaluate the ability of its CDAC Contractor to provide timely feedback to hospitals.** In the case of CY 2020 validation, had the proposed reduced response period been in effect, it would likely have resulted in hospitals submitting all four quarters of documentation without any feedback whatsoever. **The AAMC does not support reducing hospital response times to validation requests without assurance from CMS that hospitals will receive timely feedback as a result.**

***CMS Should Carefully Evaluate Potential Specification of a Potential Future Measure of Patient Reported Outcomes (PRO) Measure Following Elective Total Hip/Knee Arthroplasty for the OQR***

CMS is considering future inclusion of a Patient Reported Outcomes (PRO) measure following elective total hip and/or total knee arthroplasty (THA/TKA) procedures in the outpatient setting as the first measure to address shifting sites of care. **The AAMC is supportive of exploring the role of PRO measures in hospital quality measurement.** Regarding measuring care across sites of service, the AAMC agrees that it is reasonable to begin with elective procedures that have moved off of the Inpatient Only List. However, **we believe the CMS should carefully evaluate the future specification of this particular PRO to the outpatient setting for inclusion in the OQR due to several concerns.**

First, the THA/TKA PRO has been included in the Comprehensive Joint Replacement (CJR) payment model as a voluntarily reported measure since 2016, and recently CMS has issued increased reporting threshold requirements for measurement. We have heard from members that most are not reporting PRO data in the model due to the 80 percent reporting threshold, which hospitals have been unable to meet. CMS should further analyze survey response rates, especially since this measure requires pre-and post-procedure responses and consider how it can support hospitals in efforts to increase responsiveness, and whether there are potential differences in responsiveness due to site of care. Additionally, CMS should consider whether a lower rate of response is sufficient for measuring performance. Regardless, CMS should cite specific reasons for whatever response thresholds it requires if the measure is adopted in the OQR.

Second, CMS notes that measure developers have implemented a risk adjustment approach in part to address response bias. Such an approach must be critically evaluated to ensure that it addresses such bias in responses, particularly considering language and other socioeconomic barriers that may affect survey completion and response. A recent study<sup>30</sup> noted broader equity challenges with the CJR model. The AAMC urges CMS to consider such broader payment policy incentives for these procedures on equity and disparities when considering inclusion of this measure.

***Request for Comment on Potential Future Efforts to Address Health Equity in the Hospital OQR Program***

CMS requests feedback on making the reporting of health disparities based on social risk factors more comprehensive and actionable for hospitals, clinicians, and patients. The AAMC applauds CMS for its efforts to inform future proposals to address inequities in outcomes in its hospital quality programs. As noted elsewhere in this letter, the COVID-19 pandemic laid bare the realities of longstanding inequities in our communities that must be addressed. This work is critical to building a healthier future for all, and the AAMC strongly supports efforts to move the needle and ultimately eliminate inequity. To this end, the AAMC recently launched a 10-point strategic plan<sup>31</sup>

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<sup>30</sup> See Thirukumar, et al., Journal of the American Medical Association Open Network, "[Association of the Comprehensive Care for Joint Replacement Model with Disparities in the Use of Total Hip and Total Knee Replacement.](#)" (May 28, 2021).

<sup>31</sup> See [A Healthier Future for All: The AAMC Strategic Plan.](#)

to drive systemic change, including the creation of a new AAMC Center for Health Justice and an action plan dedicated to improving access to health care for all. The AAMC is helping to build academic medicine's capacity to contribute to advancing community health systems and to strengthen our sector's commitment to partnerships and policies that promote health equity and health justice.

A critical aspect of this work is the need for clarity on the role of health care quality and measurement in promoting health equity and community health. The AAMC believes that there is valuable overlap in these aims, but also that there are important distinctions that must be made when using quality measurement as a tool for improving equity. Health equity rightfully includes health care but must also evaluate and address broader community resources and needs. More and more evidence show that health care and genetics play a limited role in an individual's health compared to behavioral, social, and environmental risk factors.<sup>32</sup> Improving quality of care is only one aspect of the broader health equity aim which should have the goal of evaluating and driving improvement in care delivery for all patient populations. Health equity data is more meaningful when it considers the community-level, and not just a single hospital.

To this end, when measuring equity, we must measure and shine light on the broad mix of factors at play in order to find appropriate solutions, including the role of measurement. Quality measurement of health care must account for factors which are in the control of providers and not include the health-related social needs that must be addressed by more than just the health care delivery system.<sup>33</sup> The role of improved risk adjustment that addresses clinical risk, unmet social needs, and functional status is crucial for ensuring accurate and fair assessment and ensuring that the safety net is not financially penalized by losing the very resources it needs. When paired with stratification, we can and should ensure that adjustment does not mask inequities, but rather highlights them in a way that points to appropriate intervention and guides investments needed to drive improvement. We believe that CMS can and should drive toward broader health equity in part through its value-based payment programs. CMS could use reporting of stratified measures to incent progress and demonstrate improvement in local care gaps over time. However, joining health care quality and equity with validated health equity measurement<sup>34</sup> must be tested as a means of driving improvement prior to adoption in the Agency's hospital quality programs. In addition, we strongly oppose the use of health care quality metrics to rank hospitals on health equity. Addressing inequities in health requires collaboration and not competition. Rankings and tiers create divisions, rather than rewarding coalitions and sharing successful interventions.

**The AAMC supports the Agency in its efforts to address health equity in part through its quality programs. We agree that this is critical work, and that CMS should pursue a thoughtful and considered approach to improve data collection in order to better measure and analyze disparities in a manner that builds an evidence-based, valid, and reliable framework**

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<sup>32</sup> See National Quality Forum, [Social Risk Trial Final Draft Report](#) at 5 (April 19, 2021).

<sup>33</sup> See [National Quality Forum Issues Quality Roadmap for Reducing Healthcare Disparities](#).

<sup>34</sup> See US Department of Health and Human Services Assistant Secretary for Planning and Evaluation, "[Developing Health Equity Measures](#)" (May 20, 2021).

**towards provider accountability for health equity. This analysis must be able to differentiate those actions that can be targeted for improvement by the health care institution and those that need a more robust community development response. Efforts should be routinely evaluated to ensure they are meeting intended goals.**

*Introduction and Expansion of the CMS Disparity Methods to Hospital OQR Program Setting*

CMS requests comment on expanding the Agency’s inpatient hospital confidential reporting of certain quality measures based on CMS Disparity Methods to the OQR. In particular, CMS has identified six current outpatient measures as candidates for stratified reporting based on dual eligibility status as a proxy for social risk. Those six measures are: OP-8: MRI Lumbar Spine for Low Back Pain; OP-10: Abdomen CT – Use of Contrast Material; OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low Risk Surgery; OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy; OP-35: Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy; and OP-36: Hospital Visits after Hospital Outpatient Surgery. CMS also seeks feedback on whether to publicly report stratified performance results on the *Care Compare* website in the future.

**The AAMC supports the expansion of *confidential* hospital disparities reporting using dual eligibility for the identified outpatient quality measures in an effort to help expose potential inequities in care delivery.** Confidential reporting is a tool that supports a different analysis of quality performance that could inform quality improvement activities, though it is only one data point for identifying potential health care inequities. **The AAMC strongly opposes future public reporting of such stratified results using both dual eligibility or indirectly estimated race and ethnicity data (we discuss our reservations to use this information in more detail in the next section of these comments), as neither has been vetted as a valid or reliable measure of care inequities.** Publishing a potentially invalid or unreliable metric could frustrate the broader intent to improve equity by diverting critical resources to improving performance on metrics that are not supported by evidence of driving improvement. **Simply put, CMS must ensure that public policy measures disparities in a manner that builds an evidence-based, valid, and reliable framework that is actionable for providers to improve health equity.**

*Additional Social Risk Factors*

CMS seeks feedback on considerations for expanding the Agency’s efforts to stratify data by additional social risk factors, including potential future application of an algorithm to indirectly estimate race and ethnicity. CMS is clear that “[s]elf-reported race and ethnicity data are the gold standard for classifying an individual,”<sup>35</sup> but that the Agency does not currently collect such self-reported data and that data accuracy of race and ethnicity data it receives from the Social Security Administration is not accurate or comprehensive enough for such stratification efforts. In response, CMS is exploring the use of indirect estimation methods as a short-term solution to better identify

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<sup>35</sup> 86 FR 42254.



race and ethnicity data while developing sustainable and consistent programs to collect and leverage data on social risk, including self-reported race and ethnicity data.

As CMS describes in the proposed rule, indirect estimation relies on a statistical imputation method that infers a missing variable or improves an imperfect administrative variable using a related set of readily available information.<sup>36</sup> The other data sources that may be predictive of race and ethnicity include language preference, correlation of first and last names to specific national origin groups, and the racial and ethnic composition of surrounding neighborhoods matched with an individual's address. CMS notes that while its efforts to develop indirect estimation efforts can be statistically reliable for calculating population-level results for groups of individuals, a risk remains of unintentionally introducing measurement bias.<sup>37</sup> The potential harm and ethical risks<sup>38</sup> must be more thoroughly evaluated and carefully considered to ensure that use of the indirect estimation method does not unintentionally mislead improvement efforts.

**The AAMC shares the goal to expand data capture and data harmonization in order to ensure providers have actionable information to inform improvement.** However, efforts should be made to incent valid collection of demographic and social risk factor data that will best inform intervention. This also entails an understanding of which social risk factors may be most important to collect, analyze and understand. **Race and ethnicity are not themselves risk factors<sup>39,40</sup> and reliance on immutable characteristics alone is not informative for intervention.** Furthermore, measuring a gap is not the same as measuring equity. Disparities surveillance does not tap into patient populations' perception<sup>41</sup> of (or the reality of) equitable opportunity for optimal care. Stratified quality measurement's ability to reduce inequities is only as good as the stratification factors used. Dual eligibility and race and ethnicity as proxies for actual community social risk factors likely reduces the intended impact. **The AAMC urges CMS not to use indirectly estimated race and ethnicity data in confidential reporting due to our concerns with the accuracy and actionability of such data. Instead, CMS should invest in supporting data**

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<sup>36</sup> *Id.*, citing a 2009 Institute of Medicine 2009 report, "Race, Ethnicity, and Language Data Standardization for Health Care Quality Improvement."

<sup>37</sup> *Id.* at 25559.

<sup>38</sup> Megan Randall, Alena Stern, and Yipeng Su "[Five Ethical Risks to Consider before Filling Missing Race and Ethnicity Data](#)," Urban Institute (March 16, 2021).

<sup>39</sup> Angela King and Kim Shepard, "[Race is not a health risk factor. Racism is.](#)" National Public Radio (July 21, 2020), quoting Dr. Roberto Montenegro "When people look at health inequities, and they focus on differences by race, and they argue that race is a risk factor, it clouds the numerous factors that are really behind what people are intending to capture with race."

<sup>40</sup> Sheets et al, "[Unsupported labeling of race as a risk factor for certain diseases in a widely used medical textbook.](#)" *Journal of Academic Medicine* (October 2011), which found that roughly two-thirds of assertions that different risk factors exist for Black patients found in a widely used pathology textbook could not be supported by the published literature.

<sup>41</sup> For example, refer to the Minnesota Department of Health's Guild, "[HEDA: Conducting a Health Equity Data Analysis.](#)" Version 2 (February 2018), which recommends that health equity data analysis (HEDA) requires engaging populations that experience health inequities in the assessment process, including a principle for community engagement that stakeholders must learn about the community's perceptions of those initiating the engagement activities. Additionally, the AAMC's "[Principles of Trustworthiness](#)" project builds on foundational principle that trust is crucial for equitable community partnerships.

**collection improvements, including how to standardize and use the data already collected by hospitals, understand which data may be most helpful to utilize and encourage the reporting and use of actionable social risk factor data, such as a number of social determinants of health (SDOH)-related ICD-10 z codes identified as actionable,<sup>42,43</sup> in quality and payment programs.**

*Improving Demographic Data Collection*

The AAMC supports efforts to improve data collection and agrees that it should begin with the use of improved demographic data that captures gender, race, and ethnicity as an initial step in a larger process to investigate and remove inequities in health. In doing so, CMS must be unambiguous that those factors themselves do not represent an individual's inherent risk. Rather, such demographic factors may be critical proxies for social risk factors until it is feasible to quantify and capture the actual risks of bias and unjust distribution of resources and opportunity that create the social and structural conditions that heighten inequities.

Many AAMC member teaching hospitals and health systems use electronic health records (EHR)-based social risk screening tools in data collection to be better informed about the broader unmet health-related social needs in their communities. Several organizations have developed standard screening tools and core questions,<sup>44</sup> but our members have told us that they often modify the templates to ensure culturally appropriate dialogue with the patients and communities they serve. Addressing inequity in communities requires integrating local perspectives in partnership with health care organizations that have demonstrated trustworthiness. Dialogue and screening about social risk factors must be culturally competent and help to establish trust between patients and the providers. As this field continues to develop, **we believe that CMS should pursue a policy supporting the collection of standardized multi-sector social risk information to support improved stratification and risk adjustment, balanced with allowing hospitals local flexibility to promote community-based innovation and solutions.**

CMS should also explore whether there are ideas and solutions from the data science and research community on how best to standardize a roll-up of granular data for community use into a format for broader evaluation and analysis. This is a massive undertaking led by the GRAVITY Project<sup>45</sup> to advance interoperable social determinants of health data, beginning with three social risk factors: food security, housing stability and quality, and transportation access. CMS could partner on an effort led by the Office of the National Coordinator for Health Information Technology (ONC) to evaluate interoperability standards that roll data collected through screening tools up into SDOH-related ICD-10 z codes to capture social risk factors and provide actionable data to inform

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<sup>42</sup> See CMS Infographic "[Using Z Codes: The Social Determinants of Health \(SDOH\) Data Journey to Better Outcomes](#)," (Revised February 2021).

<sup>43</sup> See also AAMC Washington Highlights, [AAMC Submits Comments to CMS on Additional ICD-10 Codes for Social Determinants of Health](#) (May 2019).

<sup>44</sup> Examples include CMMI's [Accountable Health Communities \(AHC\) Health-Related Social Needs \(HRSN\) Screening Tool](#), The National Association of Community Health Center's [Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences \(PRAPARE\)](#), and the [Health Leads Screening Toolkit](#).

<sup>45</sup> See Social Interventions Research & Evaluations Network (SIREN)'s [The Gravity Project](#).

intervention. From that, it would be possible to evaluate which z-codes are best suited as a minimum set of social risk factor data elements to incorporate into EHR certification.

**While exploring the utility of additional individual demographic and social risk factor data elements, CMS should also evaluate the use and validity of community-based factors for improving data analysis necessary to inform quality and equity improvement activities.** For example, research<sup>46</sup> shows that community-defined social risk factors cause substantial shifts in projected performance on the Readmission Reduction Program's readmission models above and beyond individual level proxies. A clear benefit of community-based analysis compared to individual-level analysis is the reduced risk of compromising individual privacy in addition to ensuring the use of holistic approaches to broad, structural inequities. To this end, the AAMC urges CMS to evaluate the opportunity to partner with public health departments, which may already have robust data that supports neighborhood stratification. **Overall, data collection and systems for social risk factors at both the individual and community level should be used in conjunction to best identify disparities in quality and equity and guide interventions for improvement.**

Finally, CMS should consider a variety of policy levers to improve hospital data collection. Mandating minimum data collection as a requirement may be one solution. We also urge evaluation of incentives for hospitals to improve data collection in part through a commitment to improving risk adjustment models for the inclusion of factors related to unmet social needs and/or for additional stratification in hospital quality programs. **The AAMC believes that patients, payers, and providers will all benefit from partnership to improve health equity. CMS should lead the effort to demonstrate the benefit of better data to inform solutions.**

#### **HOSPITAL INPATIENT QUALITY REPORTING PROGRAM AND MEDICARE PROMOTING INTEROPERABILITY PROGRAM**

##### ***CMS Should Reconsider Mandated Hospital Reporting Safe Use of Opioids – Concurrent Prescribing eCQM Due to Potential Unintended Consequences of the Measure's Use***

CMS seeks feedback on the Safe Use of Opioids – Concurrent Prescribing eCQM currently included in the IQR and Medicare Promoting Interoperability Programs eCQM measure sets, and where the measure will become a required eCQM for hospitals to report beginning in CY 2022 for both Programs. The measure is scheduled to be submitted to the National Quality Forum next year for re-endorsement, and the Agency would like to gather input on potential measure updates and concerns that could potentially inform future rulemaking regarding the use of the measure in its quality programs.

The AAMC supports efforts to reduce the harms caused by the opioid crisis. We previously supported the adoption of the Safe Use of Opioids eCQM as an *optional* eCQM that a hospital may select to report in order to meet eCQM reporting requirements under both programs. We remain

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<sup>46</sup> Baker et al., Health Affairs Vol. 40, No. 4, "[Social Determinants Matter for Hospital Readmission Policy: Insights From New York City](#)," (April 2021).

concerned that mandatory reporting of the measure may have unintended consequences by stifling appropriate opioid use, particularly for patients taking medication for Opioid Use Disorder as they are included in measurement. We understand that CMS does not intend for hospitals to achieve a measure rate of zero. However, coupled with CMS policy to begin publicly reporting eCQM measure performance on the *Care Compare* website, a non-zero rate may be seen as a negative by some hospitals and inadvertently become an incentive to achieve a zero rate. **We urge CMS to reconsider current policy requiring mandatory reporting on the measure until it is able to address the potential unintended consequences of its use in addressing inappropriate opioid use.**

#### **REQUEST FOR INFORMATION – ADVANCING DIGITAL QUALITY MEASUREMENT**

CMS seeks feedback to inform future rulemaking to support the Agency’s goal of transitioning to digital quality measurement in its quality reporting and performance programs by 2025. Comments specific to topics raised in the RFI are as follows.

##### ***Definition of Digital Quality Measures (dQMs)***

The AAMC believes that improved EHR interoperability for the exchange and use of electronic health data has great promise to not only improve quality measurement and patient outcomes, but also to reduce burden on providers. However, **we encourage CMS to refine its definition of dQMs and set clear and specific parameters for what it hopes to achieve and what it expects of hospitals.**

The definition presented in this Request for Information is incredibly broad, and lists data sources including “administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated health data), health information exchanges (HIEs) or registries, and other sources.” Not all of these data sources are ready for “prime time” and inclusion in quality measurement. For example, wearable devices and patient-generated health data hold great promise for the future but have not been vetted as valid and reliable interoperable data sources or as usable for clinical quality improvement and assessment. CMS should more clearly define what it expects the future of dQMs to look like, and how those expectations differ from the current state of quality measurement. The Agency should also outline plans for piloting new data sources for quality measurement, identifying reasonable near-term and longer-term priorities. As we have seen with the transition to eCQMs from chart-based measurement, the goal for a future state might not be as easily met as initially envisioned. Finally, CMS should engage NQF in this work, to ensure that digital measure specifications are appropriately evaluated for utility in improving quality of care. The AAMC and our members are excited to partner with CMS and to collaborate on more specific plans for digital quality measurement for the future.

***AAMC Comments on Potential Actions in Four Areas to Transition to Digital Quality Measures by 2025***

*Leveraging and Advancing Standards for Digital Data and Obtaining All EHR Data Required for Quality Measures via Provider FHIR-based APIs*

The AAMC supports a long-term goal of implementing a digital and interoperable quality enterprise. Such an enterprise has great promise and could have positive and far-reaching effects of patient outcomes and experience. We also support the potential use of FHIR, as this standard is internationally supported and easier to implement and more fluid than many other available frameworks. However, **we encourage CMS to hone its approach to transforming its quality measurement enterprise by more clearly defining the goals and expectations for patients and providers, in particular considering the specific needs and capabilities of providers across settings.**

*Digital Quality Measures as Self-Contained Tools*

CMS seeks feedback on a list of attributes and functionalities that dQMs could and should have. These range from simpler tasks, such as the ability to generate measure score reports, to more complex areas like being “compatible with any data source,” and “having the flexibility to employ current and evolving advanced analytic approaches like natural language processing.” **Considering the breadth of expanded flexibilities and functionality listed, the AAMC urges CMS to engage stakeholder input to determine which attributes can be sequenced and scaled, and to develop a prioritization framework for what realistically may be achievable with the Agency’s goal of transitioning to dQMs by 2025.**

*Potential Future Alignment of Measures Across Reporting Programs, Federal and State Agencies, and the Private Sector*

**The AAMC strongly supports efforts to better align quality measures across federal, state, and private payer programs.** To do so with fully interoperable data is likely to require leadership from HHS, including CMS and the ONC, and a potential rethinking of its health IT certification activities. This is because health IT certification was initially designed to evaluate a product’s ability to meet minimum meaningful use and security requirements, and not necessarily on the quality, exchange and usability of data aligned with requirements for robust quality measurement. To realize the full extent of digital quality measurement requires EHRs that improve the capture, management, and communication of clinical information and better accommodate the needs of providers and their patients. Relatedly, quality measurement development does not always require inclusion of health IT developers to complete robust testing, resulting in insufficient test cases that do not ensure actual ease and accuracy of measure reporting in addition to ensuring that measurement is clinically useful. CMS will need to partner with ONC to prioritize concurrent certification requirements that validate dQMs and improve overall EHR user experience with measure development and implementation policy. Additional opportunity for alignment could relate to the collection and use of standardized social risk factor data collection and use in measurement.

**CMS should investigate potential incentives for encouraging alignment with providers and other payers.**

**RADIATION ONCOLOGY MODEL**

CMS released updated RO Model proposals as part of the CY 2022 OPPS proposed rule. CMS originally proposed the RO model in 2019 and finalized the model in 2020. However, the RO model's start date was delayed by Congress in December 2020. CMS proposes to start the RO Model on January 1, 2022, with some additional changes to reduce the CMS discount, remove brachytherapy and liver cancer, and apply technical modifications. The AAMC comments in response to the proposed RO Model provisions are described below.

**RO MODEL DESIGN**

**CMS should finalize the proposal to align each RO Model Performance Year with a calendar year.** The AAMC supports CMS's proposal to align each 12-month performance year with the calendar year, starting in 2022, as that will simplify the model for participants. In addition, the AAMC supports the underlying intent of the RO model to promote more equitable and patient-centered care by curtailing hyper-fractionation.

**The Agency should further reduce the CMS discount to 2.5 percent.** The AAMC appreciates the fact that CMS has reduced the proposed discount by 0.25 percentage points relative to the amount finalized previously in 2020. However, we maintain that the currently proposed discounts of 3.5 percent for the professional component and 4.5 percent for the technical component remain too high. These discounts are higher than nearly all other voluntary or mandatory models. We continue to believe that CMS can fulfill the statutory requirement to test models expected to reduce costs and/or improve quality without mandatory CMS discounts of this size. As noted in previous comment letters, we believe a discount of 2.5 percent would be more appropriate, as it would align with the discounts CMS applied to OCM participants in a two-sided risk arrangement.

**CMS should finalize the addition of the extreme and uncontrollable circumstances policy.** The AAMC appreciates CMS's adoption of our previous recommendation in earlier comment letters to add an extreme and uncontrollable circumstances policy. We strongly encourage CMS to deploy these policy options – especially related to quality measure and clinical data reporting – whenever a given state or region faces a relevant emergency that impacts their patients and staff. In the event of a resurgence of the COVID-19 pandemic or another nationwide emergency that leads to large disruptions in medical care, the AAMC believes that CMS should eliminate all downside risk for all participants as was done across models during the COVID-19 PHE in 2020.

## **CANCER AND TREATMENT INCLUSIONS AND EXCLUSIONS**

**CMS should finalize its proposal to exclude liver cancer.** The AAMC supports CMS's removal of liver cancer based on stakeholder feedback and additional literature reviews that indicated liver cancer does not meet the model's inclusion criteria for cancers.

**The Agency should finalize its proposal to remove brachytherapy from the list of included modalities.** The AAMC appreciates the fact that CMS considered stakeholder feedback and the literature, leading to a decision to remove brachytherapy from the model. If CMS finalizes the proposal to remove brachytherapy from RO, then CMS should continue to pay for these services under the fee schedule.

**CMS should retain the current policy of limiting the RO model to radiation therapy that impacts multiple cancers.** The AAMC supports CMS's decision to limit the model to radiation therapy that impacts multiple cancer types, while creating cancer-specific targets. We recommend that CMS not add additional forms of RT that are not used across all cancer types, because this would increase complexity for participants.

## **RO PAYMENT METHODOLOGY**

**CMS should finalize its proposal to establish a fixed baseline period from 2017-2019.** The AAMC supports a fixed baseline period that excludes 2020, as well as CMS's policy to place a heavier weight on the most recent year. We appreciate CMS consideration of our earlier comments to establish a fixed baseline to add predictability for model participants. In addition, excluding 2020 from the baseline because the pandemic depressed healthcare utilization – including essential treatment for conditions such as cancer – in ways that are not representative of best practices outside of a pandemic.

**CMS should finalize its proposed methodology to calculate the trend factor, including the exclusion of 2020 data from the trend calculations.** CMS proposes to calculate the trend factor using 2019 price and utilization data in the denominator throughout the full duration of the model. For the numerator of the trend factor, CMS proposes to use the price for the current calendar year, combined with the most recent complete utilization data. Due to the need for substantial claims runout, the most recent utilization data will be three years delayed relative to the current performance year. The AAMC reiterates our previous comments in support of this methodology, and we further support CMS's proposal to update the methodology to exclude 2020 utilization data from future trend factor calculations. CMS should use the 2019 utilization data as planned for the 2022 performance year. For the 2023 performance year, the AAMC recommends that CMS continue to use 2019 utilization data (excluding 2020 data). In the subsequent 2024 performance year, CMS should use the 2021 utilization data as proposed. This would achieve the goal of removing the artificially low 2020 utilization data from the trend factor, while also supporting CMS's goal of using the most recent year of complete data in the target calculations.

**The Agency should finalize its proposed methodology to include 2020 data in the case mix adjustment.** The AAMC supports CMS's proposal to include 2020 in the case mix adjustment calculation. We agree that this approach is fair to participants since the RO model will be using a rolling three years of data to calculate the case mix adjustment. While many chronic conditions were likely missed in 2020 due to suppressed utilization during the pandemic, these chronic conditions presumably were documented in the other two years of data. In addition, including 2020 in the case mix will capture severe events, including COVID, that occurred during the PHE. Therefore, this approach is designed to capture both chronic conditions and more recent severe events.

**CMS should finalize its proposal to expand the definition of incomplete episodes to include a beneficiary who switches from traditional Medicare to Medicare Advantage.** The AAMC appreciates CMS's adoption of our previous recommendation in earlier comment letters to consider this circumstance to be an incomplete episode. This policy will more accurately pay for services in this circumstance – avoiding either over or underpayments by CMS – and will simplify the model for participants.

**The Agency should expand the stop-loss policy to apply to all model participants.** As proposed, CMS would apply 20 percent stop-loss only for low volume RO participants, defined as organizations with less than 60 episodes during the baseline. The AAMC believes that CMS should expand the stop-loss policy to apply to all model participants. The addition of financial guardrails would protect participants from extensive losses on RT services, increasing their financial viability and thus protecting access to care. In adopting these changes, the RO Model would mirror the model design used in the Comprehensive Care for Joint Replacement (CJR) Model.

## **RO PARTICIPANT EXCLUSIONS**

**CMS should finalize the proposal to include eligible rural Pennsylvania hospitals that are not current Pennsylvania Rural Health Model (PAHRM) participants.** The AAMC supports including eligible rural Pennsylvania hospitals that are not current PARHM participants in RO. Doing so avoids model overlap with PARHM while also applying consistent rules to eligible RO participants.

**CMS should finalize the proposal to align CHART ACO track participant eligibility with MSSP participant rules.** The AAMC supports aligning CHART ACO track eligibility with MSSP participant rules. Doing so provides consistent application of the rules to eligible RO participants, as well as ACO participants.

**The Agency should finalize the proposal to exclude CHART community transformation track participants.** The AAMC supports excluding CHART community transformation track participants from RO in an effort to avoid model overlap and conflicting incentives.



## **QUALITY PAYMENT PROGRAM**

**CMS should finalize the proposal to create Track 1 and Track 2 status to allow the RO Model to qualify as an AAPM.** The AAMC appreciates CMS's adoption of this policy, which will support participants whether or not they are fully compliant with Certified Electronic Health Record Technology (CEHRT). The proposed policy is consistent with other Quality Payment Program (QPP) requirements for AAPM status, and the policy aligns with CJR's approach to participants based on CEHRT status (Track 1 for those that have adopted CEHRT, and Track 2 for those that did not).

**The Agency should reduce payment penalties if QP status is retroactively revoked due to participant noncompliance.** The AAMC supports CMS's proposal to reduce retroactive payment penalties if QP status is retroactively revoked due to a failure, however minor, to comply with model requirements. The AAMC believes that CMS should use its discretion to reduce penalties if it deems that the circumstances merit leniency.

**CMS should finalize the proposal to allow RO Participants to update and certify the accuracy of their individual practitioner list once per year.** The AAMC supports CMS's proposal that all participants must update and certify the accuracy of their practitioner lists prior to the last QPP snapshot date, because this will increase the accuracy of the list and give participants as much time as possible to complete this programmatic requirement.

## **RO QUALITY MEASUREMENT AND REPORTING REQUIREMENTS**

**The Agency should retain two of the finalized quality measures but consider revising the full list to more tightly focus on the work of radiation oncologists with Medicare patients.** The AAMC previously expressed its support for the inclusion of outcome-based quality measures in the RO model. In particular, we supported the use of the Plan of Care for Pain, as well as the development of the new measure, Treatment Summary Communication – Radiation Oncology, which will initially be introduced on a pay-for reporting basis. However, the AAMC previously expressed concerns about two of the measures – Depression Screening and Advanced Care Plans. These measures are outside of the purview of radiation oncologists, and typically are the responsibility of primary care physicians or medical oncologists. In addition, CMS should revise the specifications for all quality measures in the model to include only Medicare patients in the denominator, rather than all the patients (regardless of payer) seen by the radiation oncologists in the model.

**CMS should finalize the proposal to administer the CAHPS Cancer Care Survey for Radiation Therapy on behalf of RO participants.** The AAMC supports CMS's continued commitment to administer the CAHPS Cancer Care Survey for Radiation Therapy on behalf of RO participants. This will serve the important goal of assessing patient experience while also minimizing the administrative burden for RO participants. The AAMC further supports CMS's decision to update the timeline for the administration of this survey, to ensure it captures the experience of patients with completed RO episodes.

**Do not collect CDEs unless the data are used to measure quality and/or set appropriate payment rates.** The AAMC strongly supports the use of CDEs in oncology APMs to accurately measure the quality of patient care and set appropriate payment rates. However, due to the large reporting burden on participants, we believe that CMS should not collect CDEs unless the Agency uses the data for at least one of these purposes. The time and resources associated with unnecessary reporting would be better spent in patient care. Therefore, the AAMC opposes the CDE reporting as currently designed. Our recommendations center on two primary concerns: (1) CMS should not require participants to report CDEs unless they will be used to risk adjust quality performance and payment, and (2) CMS should instead plan to apply both CDE and data on patient's health-related social needs to risk-adjust quality measures and payment rates.

**CMS should revise the finalized list of monitoring requirements from the 2020 RO Final Rule.** The AAMC previously expressed our opposition to the monitoring requirements in the RO model. In response to the first RO proposed rule, the AAMC recommended that CMS eliminate the list of specific electronic medical record (EMR) documentation requirements from the model monitoring requirements. While these clinical elements may be routinely provided, reporting them under this program would be extremely burdensome because they typically are not captured in structured fields. Documenting this information as specified would require building new electronic health record templates in advance of the model start date to ensure that each of these elements are captured in the manner required under the RO Model. In addition, many of the requirements lack clarity from a clinical perspective, such as how "performance status" is defined. Furthermore, it is not clear whether CMS is mandating just the documentation or adherence to specific treatment guidelines within these documentation requirements.

#### **TECHNICAL ADJUSTMENTS UNDER THE RO PROGRAM**

**The Agency should finalize its proposed definitions of the legacy CMS CCN and TIN.** The AAMC supports the policy to consider the legacy CCN/TIN for the purposes of risk adjustment, as this process is both straightforward and fair to the participant.

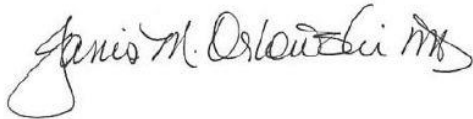
**CMS should finalize its proposal not to require RO participants to report new business relationships that do not constitute a change to the CCN or TIN.** The AAMC strongly supports the proposal not to require other notifications for business relationships that do not constitute a change in CCN/TIN. This policy removes ambiguity from the model requirements, making it easier for RO participants to remain in compliance.

**CMS should finalize the proposals to apply technical updates to align with new timelines.** The AAMC supports CMS's proposed changes to update dates and timelines, refine sequestration language, clarify definitions throughout the rule, simplify language on cancer type inclusions assignment criteria, and simplify logic for identifying RO episodes. The AAMC strongly supports these measures to use clear language, simple processes, and internal consistency.

**CONCLUSION**

Thank you for the opportunity to comment on the CY 2022 OPPS proposed rule. We would be happy to work with CMS on any of the issues discussed above or other topics that involve the academic medical community. If you have questions regarding our comments, please feel free to contact Mary Mullaney at 202.909.2084 or [mmullaney@aamc.org](mailto:mmullaney@aamc.org) or Andrew Amari at 202.828.0554 or [aamari@aamc.org](mailto:aamari@aamc.org) for questions on the payment policy proposals, Phoebe Ramsey at 202.448.6636 or [pramsey@aamc.org](mailto:pramsey@aamc.org) for questions on the quality proposals, and Theresa Dreyer at 202-683-4673 or [tdreyer@aamc.org](mailto:tdreyer@aamc.org) for questions on the RO model proposals.

Sincerely,

A handwritten signature in black ink that reads "Janis M. Orlowski M.D." with a stylized flourish at the end.

Janis M. Orlowski, M.D., M.A.C.P.  
Chief Health Care Officer

cc: Ivy Baer