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June 16, 2022

Ms. Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services U.S. Department of Health and Human Services Attention: CMS-1771-P P. O. Box 8013 Baltimore, MD 21244-1850

RE: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment Systems and Proposed Changes and Fiscal Year 2023 Rates Proposed Rule (CMS-1771-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 Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2023 Rates," 87 *Fed. Reg.* 28108 (May 10, 2022), issued by the Centers for Medicare & Medicaid Services (CMS or the Agency).

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members comprise all 155 accredited U.S. and 16 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 191,000 full-time faculty members, 95,000 medical students, 149,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. In 2022, the Association of Academic Health Centers and the Association of Academic Health Centers International merged into the AAMC, broadening the AAMC's U.S. membership and expanding its reach to international academic health centers.

The following summary reflects the AAMC's comments on CMS' proposals regarding graduate medical education payments, hospital payment, quality proposals, and requests for information (RFIs) in the Fiscal Year (FY) 2023 Inpatient Prospective Payment System (IPPS) Proposed Rule.

- *Graduate Medical Education*. Finalize both graduate medical education proposals. Engage in future rulemaking to allow rural track programs to enter into affiliation agreement following the conclusion of the cap-building period.
- *Market Basket Update and Ratesetting*. Increase the market basket update under the "exceptions and adjustments" authority to account for increased labor and supply costs. Finalize the proposal to blend COVID-19 and non-COVID-19 cases for FY 2023 ratesetting.
- *Outlier Fixed-Loss Threshold*. Consider removing COVID-19 cases from the fixed-loss outlier threshold calculation.
- *Disproportionate Share Hospital and Uncompensated Care Payments*. Account for the potential of high rates of uninsurance when the public health emergency ends in Factor 2.
- *Medicaid Fraction*. Include all Medicaid beneficiaries covered under an 1115 demonstration waiver in the Medicaid fraction.
- *Wage Index*. Consider the impact of the COVID-19 public health emergency on the wage index.
- *COVID-19 and Seasonal Influenza Reporting*. Do not finalize the proposal to require continued COVID-19 and seasonal influenza reporting as a hospital condition of participation.
- Payment Adjustment for N95 Masks. Continue stakeholder engagement to ensure that
 Medicare is the proper program to incentivize the purchase of wholly domestically made N95
 masks.
- Social Determinants of Health Diagnosis Codes (Z-codes). Explore tying the Z59.0 (Homelessness) code to payment by reclassifying it to a complication or comorbidity (CC) code for purposes of MS-DRG grouping and encourage involvement of stakeholders to determine the best way to proceed.
- *Climate Change Impacts on Health Equity*. Commit more broadly to a collaborative approach to developing innovative solutions to address the health care sector's role in climate change.
- *Measuring Disparities*. (1) Focus on development of the Within Hospital Method to measure inequities; (2) Prioritize process and access measures; (3) Carefully evaluate the precise health-related social needs (HRSNs) and social risk factors to evaluate inequities, and (4) Focus primarily on how to use inequities measurement to inform providers and interventions.
- Measure Suppressions and Technical Changes to Address Impacts of COVID-19 in the Pay-for-Performance Quality Programs. Finalize measure suppressions as proposed for FY 2023 and consider additional changes to proposed risk adjustment changes based upon history of COVID-19.
- Adoption of New Measures for the Inpatient Quality Reporting (IQR) Program. Consider the burden of adopting ten new measures in the Program in a single year and prioritize those measures that are most meaningful to hospitals and patients.
- **Promoting Interoperability (PI) Program.** Balance increasing emphasis on public health reporting through proposed scoring changes with the need for greater investment in public health departments to better support improvements to electronic health record (EHR) reporting and data exchange.

GRADUATE MEDICAL EDUCATION PROPOSALS

Payment for Direct Graduate Medical Education Costs: Milton S. Hershey Medical Center et al. v. Becerra Litigation

The direct graduate medical education (DGME) payment calculation considers the number of weighted full-time equivalent (FTE) residents that train at a hospital. Statutorily, each resident is counted as a 1.0 full-time equivalent (FTE) trainee while they train within their initial residency period (IRP), not to exceed five years, and 0.5 FTE for additional training in an approved post graduate training program. Prior to 1996, hospitals used the total weighted FTE count to calculate the DGME payment. In response to Congress capping the number of residents for which a hospital can be reimbursed, CMS developed a "proportional reduction methodology" to ensure that a hospital's adjusted weighted FTE count did not exceed their 1996 cap. In May 2021, the United States District Court for the District of Columbia held that the proportional reduction method inappropriately reduced the statutorily mandated weighting factors for hospitals that had a weighted FTE count higher than their 1996 cap, and trained residents beyond their IRP. In effect, the proportional reduction method reduced the statutorily mandated weighting factors to less than their required weights under the law.

In response to the District Courts holding, CMS has proposed a new methodology to arrive at an adjusted weighted FTE count that would have only one consideration: whether the hospital's weighted FTE count exceeds the hospital's 1996 cap. Where a hospital's weighted FTE count is greater than the 1996 cap, a hospital would adjust the weighted FTE count to their 1996 cap. Hospitals that have a weighted FTE count that does not exceed the 1996 cap would use their weighted FTE count. CMS has also proposed making the change effective for hospitals with open or openable cost reports as of October 1, 2001. The AAMC appreciates the proposed changes to the adjusted weighted FTE count calculation and agrees with the American Hospital Association's comments regarding retroactive rulemaking.

The proposed methodology preserves the statutorily mandated weighting factors and is equitable to teaching hospitals. Under the proposed change, hospitals that train residents in excess of their 1996 caps would no longer experience a reduction in their FTE count, if the excess is because they train residents beyond their IRP. The AAMC supports CMS's proposed changes to the calculation for the adjusted weighted DGME count, and thanks CMS for its thoughtful proposal.

Proposal to Allow Medicare GME Affiliation Agreements Within Certain Rural Track FTE Limitations

For the first time, CMS is proposing to allow hospitals that established an ACGME separately accredited 1-2 family medicine program prior to October 1, 2022, to create Rural Track Medicare GME Affiliation Agreements. Once hospitals participating in a 1-2 family medicine program have finished their cap-building period, these affiliation agreements would allow them

¹ Milton S. Hershey Medical Center v. Becerra, 2021 WL 1966572(D.D.C. May 17, 2021).

to share FTE caps for agreed upon-academic years while providing flexibility to match resident rotation schedules where needed. This would allow training experiences for residents that may be required but not available in certain areas. The AAMC supports this proposal and encourages CMS to engage in future rulemaking that will allow rural track programs that were established under §127 of the Consolidated Appropriations Act, 2021 to also engage in affiliation agreements to strengthen the training of residents following the conclusion of the cap-building period.

PAYMENT PROPOSALS

MARKET BASKET, OUTLIER FIXED-LOSS THRESHOLD

Increase the Market Basket Update for FY 2023 to Reflect Higher Growth in Labor and Supply Costs

CMS is proposing an increase to the standardized amount of 2.7 percent reflecting a market basket update of +3.1 percent and a total factor productivity adjustment of minus 0.4 percent for FY 2023.² We are concerned that the data used to calculate the FY 2023 market basket update are not representative of the significantly higher growth in labor and supply costs hospitals have experienced as a result of the public health emergency (PHE).

The data used to calculate the market basket update does not accurately reflect the dramatic increase in labor and supply costs that hospitals and health systems have experienced in FY 2021 and FY 2022. We do not see this cost trend lessening in FY 2023 or the foreseeable future. Recent reporting indicates that labor costs are 11 percent higher than May 2021 and 26 percent higher than May 2020. CMS calculates the market basket based on forecasts rather than actual historical labor and supply cost increases; it does not incorporate the challenging circumstances brought on by the pandemic. Therefore, using the current methodology to calculate the payment update inaccurately estimates the financial strain hospitals have experienced and will continue to experience in FY 2023 and is insufficient to address these cost increases. Given the exceptional times we are in, the increase in labor costs that are expected to remain and the continuing financial struggles of hospitals as they try to maintain access to services, we call on CMS to utilize its "exceptions and adjustments4" authority to use hospital data that shows larger increases in costs than is being recognized by the Bureau of Labor Statistics and other forecasts thus basing the payment update for FY 2023 on more accurate and timely hospital data.

Finalize the Proposal to Blend COVID-19 and Non-COVID-19 Cases for FY 2023 Ratesetting

CMS is proposing to modify the historical methodology for FY 2023 rate setting. The proposal reflects CMS' belief that there will be a decline in COVID-19 hospitalizations in FY 2023 as

² Hospitals that successfully report quality measures and are meaningful users of electronic health records are eligible for the full payment update.

³ https://www.kaufmanhall.com/sites/default/files/2022-05/KH-NHFR-05-2022-Mav.pdf

⁴ Section 1886(d)(5)(I) of the Social Security Act

compared with FY 2021 based on CDC data. (p. 28124). Under the proposal, two sets of relative weights would be calculated using FY 2021 MedPAR data and FY 2020 HCRIS data. One set would include COVID-19 claims and one would exclude COVID-19 claims. CMS would average the relative weights in two sets of data to determine the relative weights for FY 2023. The AAMC supports this proposal and urges CMS to finalize it. Hospitals are hopeful that COVID-19 cases will decline and the cases that require inpatient care will be less severe than those cases during the baseline period. This proposal would more accurately account for the anticipated change in case mix as COVID-19 cases decline.

Consider Removing COVID-19 Cases from the Fixed-Loss Outlier Threshold Calculation

CMS proposes to adopt a fixed-loss outlier threshold for FY 2023 of \$43,214. This is a \$12,266, (39.5 percent) increase from the FY 2022 amount. (p. 28669). CMS projects that the proposed outlier threshold for FY 2023 would result in outlier payments equal to 5.1 percent of operating MS-DRG payments. We are concerned that the threshold for FY 2023 is significantly higher that it would otherwise be because of a concentration of high-cost COVID-19-related cases used in the baseline calculation. We, therefore, ask CMS to recalculate the outlier threshold by removing high-cost cases in MS-DRGs identified as COVID-19 related. As mentioned in the proposed rule, CMS anticipates that COVID-19 cases will decrease in FY 2023. Removing these high-cost cases from the outlier threshold would be a better predictor of the anticipated case mix in FY 2023. Also, including COVID-19 cases could cause CMS to fall short of its target of outlier payments equal to 5.1 percent of operating DRG payments. The proposed threshold is intended to be as close as possible to the 5.1 percent targeted based on the assumption that the distribution of high-cost cases will follow a trend from the baseline year. However, if the number of high-cost COVID-19 cases declines in FY 2023 relative to the baseline year FY 2021, as CMS has referenced, the proposed threshold risks generating less than 5.1 percent of operating MS-DRG payments in FY 2023.

CMS should consider using a different baseline for its calculation such as a blend of 2019 and 2020 data to reflect an expected decrease in COVID-19 cases in FY 2023 similar to the proposal to determine ratesetting. In this alternative, COVID-19 cases should also be removed to determine the threshold to acknowledge that COVID-19 cases will have a continued effect in FY 2023, but the impact will likely be lessened as compared with previous years.

Finalize the Proposal to Place a 10 Percent Cap on Decreases to MS-DRG Relative Weights

CMS is proposing a permanent cap on year-over-year decreases of MS-DRG relative values. If finalized, there would be a cap on MS-DRG relative weight decreases of more than 10 percent for a fiscal year as compared to the previous fiscal year. The AAMC supports this proposal and urges CMS to finalize it. The proposed rule acknowledges stakeholders' concerns about significant decreases in the relative weights, particularly for some low-volume MS-DRGs.

Based on AAMC's analysis of the data in Table 5⁵ included with the proposed rule and AAMC membership data as of April 2022, many of these low-volume MS-DRGs are specialty services that are predominantly furnished at AAMC-member academic institutions. For example, MS-DRG 927, Extensive Burns or Full Thickness Burns with MV >90 hours with Skin Graft, is one of the MS-DRGs that would be impacted. As AAMC member hospitals account for 67 percent of all burn unit beds, they are likely to benefit from the proposal. Other complex procedures such as heart transplants and the implantation of cardiac mechanical assistive devices – MS-DRG 002, Heart Transplant or Implant of Heart Assist System – are almost exclusively performed at AAMC member teaching hospitals. This proposal would help to sustain these critically important tertiary and quaternary services. AAMC supports this proposal to ensure Medicare beneficiaries have access to these life-saving treatments. The positive impact that this proposal will have on many AAMC member hospitals underscores the importance of these institutions in providing complex services to their communities.

MEDICARE DISPROPORTIONATE SHARE HOSPITAL AND UNCOMPENSATED CARE PAYMENTS

Account for the Potential of High Rates of Uninsurance When the Public Health Emergency Ends in the Calculation of Factor 2

CMS calculates Factor 2 of the uncompensated care payment methodology to determine the total available uncompensated care payment pool. Factor 2 is an annually determined percentage amount that represents the percent change in the rate of uninsured individuals in FY 2013 and the estimated percent of uninsured in the most recent year where data is available. The CMS Office of the Actuary determines Factor 2 based on data from the National Health Expenditures Accounts. CMS is proposing to calculate Factor 2 for FY 2023 as it has for previous years.

The COVID-19 PHE upended insurance coverage for many individuals and families resulting in a significant increase in the uninsured.⁶ Some of those impacted were eligible for enrollment in Medicaid. Enhanced subsidies authorized under the American Rescue Plan (Pub.L. 117-2) allowed others to afford COBRA or purchase coverage through the Marketplace. However, when the PHE ends, many of these individuals could find themselves uninsured again due to the expiration of these expanded coverage options.

We are concerned that the proposed Factor 2 calculation does not account for the potential dramatic increase in uninsured individuals due in large part to the requirement for states to begin redeterminations on all individuals currently enrolled in Medicaid at the end of the PHE. Moreover, some premium tax credits and cost-sharing subsidies for individuals enrolled in Marketplace insurance plans could expire, leaving these individuals without affordable coverage. Given these scenarios, we urge the Agency to recalculate Factor 2 to account for the potential for more uninsured individuals than is currently included in the proposed calculation of Factor 2.

⁵ https://www.cms.gov/medicare/acute-inpatient-pps/fy-2023-ipps-proposed-rule-home-page#Tables

⁶ https://sanford.duke.edu/story/new-study-health-insurance-coverage-declined-during-pandemic/

<u>Medicaid Unwinding</u>. Medicaid and the Children's Health Insurance Program (CHIP) enrollment increased during the COVID-19 PHE due to pandemic-related job losses. The Families First Coronavirus Response Act (FFCRA, Pub.L. 116-127) provided states with enhanced Medicaid funding if states maintain continuous coverage for Medicaid beneficiaries during the PHE. States claiming the temporary federal medical assistance percentage (FMAP) increase must maintain beneficiary enrollment and coverage of all Medicaid beneficiaries through the end of the month in which the COVID-19 PHE ends. According to CMS, Medicaid and CHIP enrollment has grown to nearly 85 million individuals due, in large part, to the continuous enrollment condition.⁷

However, due to disruptions of state operations during the COVID-19 PHE and the continuous coverage requirements of FFCRA, it is expected that states will face a large number of eligibility and enrollment actions which they will need to complete once the PHE ends. Renewal processes will likely rely heavily on state Medicaid agencies communicating with enrollees by mail if the agency is unable to redetermine eligibility based on available data sources. Because many changes have occurred relating to enrollees' income, residence and family composition, the potential for loss of coverage among eligible individuals as states address the backlog of pending eligibility and enrollment actions is very high.

Expiration of Marketplace Subsidies. The American Rescue Plan expanded premium and cost-sharing subsidies to individuals purchasing Marketplace insurance coverage. According to CMS, 5.8 million people were able to gain coverage because of the expanded subsidies. However, these enhanced subsidies are set to expire at the end of 2022. Without an extension of these subsidies, some individuals will no longer be able to afford insurance coverage through the Marketplace and more families could become uninsured. Moreover, these individuals are likely not eligible for Medicaid. Therefore, FY 2023 Factor 2 calculations should account for the possibility of a larger pool of uninsured individuals.

MEDICAID FRACTION

Continue to Include in the Medicaid Fraction Individuals Receiving Benefits Under an 1115 Demonstration Waiver

The Medicaid fraction is used to calculate a hospital's disproportionate share hospital payment adjustment. Some states provide medical benefits under a section 1115 demonstration waiver to individuals who are otherwise not eligible for medical assistance under the Medicaid state plan. CMS states in the proposed rule that for certain individuals receiving medical benefits under an 1115 waiver that are similar to benefits provided to traditional Medicaid beneficiaries, including inpatient hospital days, could be included as patient days in the calculation of the Medicaid fraction.

⁷ https://www.medicaid.gov/federal-policy-guidance/downloads/sho22001.pdf

⁸ https://www.cms.gov/files/document/american-rescue-plan-fast-facts-cms.pdf

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CMS is proposing to revise the regulation to explicitly state its interpretation of the statute's reference to "regarded as" eligible for Medicaid with respect to expansion populations under a section 1115 waiver. Under this proposal, only patients who receive health insurance provided by an 1115 demonstration waiver where state expenditures to provide the insurance may be matched with funds from Title XIX (Medicaid) would be "regarded" as eligible. Only the days of those patients who receive hospital health insurance that provides essential health benefits, and if bought with premium assistance, for which the premium assistance is equal to at least 90 percent (i.e., "all or substantially all") of the cost of the health insurance, would be included in the Medicaid fraction of the DSH calculation, as long as the patient is not also entitled to Medicare Part A. (p. 28400 - 28401).

Individuals eligible to receive medical assistance under 1115 waivers are low income and often eligible for a limited set of benefits under the Medicaid program. Many of these individuals are working adults who do not qualify for medical assistance under the traditional Medicaid program due to income. If a state expands coverage for specific services through an 1115 waiver, the individuals in these expansion populations are still considered to be Medicaid beneficiaries. Therefore, we believe individuals covered under 1115 waivers are indeed Medicaid beneficiaries and their inpatient hospital days must continue to be counted in the Medicaid fraction. Further, as noted in the proposed rule, many court cases have supported the interpretation that these individuals be included in the Medicaid DSH calculation.

Accordingly, the AAMC does not support this change and urges CMS to not finalize the proposal. The purpose of DSH is to compensate hospitals that serve a disproportionate share of low-income patients. Even if an 1115 waiver does not include premium assistance for insurance coverage with EHBs or does not provide inpatient benefits to the expansion population, the individuals who qualify under the waiver are low-income Medicaid beneficiaries and should be counted in the numerator. Removing the ability for hospitals to include these individuals in the Medicaid fraction will financially disadvantage hospitals' that serve a high volume of low-income individuals. For many AAMC members the impact of this change could be dramatic. In 2020, AAMC teaching hospitals accounted for 27 percent of all Medicaid inpatient days.⁹

MEDICARE WAGE INDEX

In FY 2020, CMS finalized several policies to address disparities between high and low wage index hospitals present in the wage index system including a policy to increase low wage index hospitals' wage indexes to provide an opportunity for these hospitals to increase employee compensation, which could be permanently reflected in future wage index data. The policy directly raised wage indexes of the lowest quartile wage index hospitals by half the difference between the 25th percentile wage index value and the hospital's individual wage index. At the

⁹ Source: AAMC analysis of American Hospital Association Annual Survey Database FY 2020 and National Institutes of Health Extramural Research Award Data. Note: Data reflect all short-term, general, nonfederal hospitals.

time this policy was finalized, CMS intended to apply it for a minimum of four years, citing the four-year lag between increasing wages and the wage index data reflecting those increases. CMS initially proposed to make the policy budget neutral through an equivalent reduction to the wage indexes of hospitals in the top quartile of wage index values. While the AAMC supported the Agency's proposal to raise low wage hospitals' wage indexes, it opposed doing so through the targeted reduction to high wage index hospitals. The AAMC commented and remains concerned that the targeted reduction did not reflect the relative hospital wage levels in their geographic areas and was therefore contrary to the purpose of the wage index.

The proposed rule notes that although the policy is the subject of pending litigation, CMS is proposing to continue this low wage index policy in FY 2023 but depending on stakeholders' comments and developments in the court proceedings, may not finalize the policy as proposed. (p. 28370). CMS would continue to apply a budget neutral adjustment to standardized amounts to offset the increase in IPPS payments to hospitals with low wage index value for FY 2023 and subsequent years.

Consider the Impact of the COVID-19 PHE on Area Wage Indexes and Evaluate the Low Wage Index Policy

The pandemic's impact on wages remains uncertain and CMS needs to collect more data in this area. As a result, wage data collected during the COVID-19 PHE stands to drastically impact the hospital wage index adjustment for areas heavily impacted by COVID0-19 once used to determine area wage indexes. The COVID-19 PHE could also affect CMS' review of its lowwage index policy.

Additionally, CMS originally stated that it intends to "revisit the issue of the duration of the [low wage index] policy in future rulemaking" – presumably as the four-year lag of wage data becomes available. (84 FR 19395). The AAMC also recommends that CMS exclude the use of 2020 and other years of data significantly impacted by the COVID-19 PHE as it deliberates how it will appropriately evaluate the effectiveness of its policy to raise low wage hospitals' wage indexes in the near future.

CONDITIONS OF PARTICIPATION REQUIREMENTS FOR HOSPITALS TO REPORT DATA ELEMENTS TO ADDRESS ANY FUTURE PANDEMICS AND EPIDEMICS

COVID-19 and Seasonal Influenza Reporting Requirements Should Not be Part of the Hospital Conditions of Participation (CoPs)

The Medicare CoPs set minimum health and safety standards for hospitals participating in Medicare. Compliance with CoPs allows hospitals to maintain their CMS certification and continue to receive reimbursement for services furnished to Medicare and Medicaid beneficiaries. CMS has the authority to terminate a hospital's certification if it deems a hospital is noncompliant with the CoPs.

Traditionally, CMS has used the threat of non-compliance with CoPs and potential hospital decertification from the Medicare and Medicaid programs as a mechanism to address significant breeches of quality and safety that may threaten patient care. The AAMC is concerned that CMS has begun to use decertification as its main threat of compliance and that this misuse could have significant impacts on the nation's health care system. For example, during the PHE CMS used decertification as a means to increase compliance with <u>DAILY</u> coronavirus reporting, at a time when the hospital systems were most stretched. Nevertheless, CMS maintained that hospitals must use their scarce resources to count supplies rather than care for patients or face decertification, even though daily reporting was unlikely a critical data factor in understanding the pandemic's effect and despite the majority of hospitals were already voluntarily compliant with this request. We urge CMS to utilize the consequences of decertification for only the most dire concerns of patient safety and quality.

The AAMC and its members appreciate CMS relaxing some of the CoPs during the COVID-19 PHE to allow hospitals and health systems to meet the extraordinary demands of the PHE. In this proposed rule, CMS would continue to tie COVID-19 and seasonal influenza reporting to compliance with hospital CoPs. If hospitals do not comply with reporting requirements, they will be in violation of CoPs and could be subject to termination from Medicare and Medicaid. We believe that tying reporting to CoPs that involve removal from the Medicare and Medicaid programs as a potential consequence is inappropriate. Throughout much of the PHE, hospitals reported these data elements voluntarily and worked with federal and state governments to assist with surveillance. Requiring data collection, some of which is duplicative and redundant, does not improve the data collection; it just adds to the burden of those required to report it.

Do Not Extend Data Reporting Beyond the End of the COVID-19 PHE

Although hospitals voluntarily reported data at the beginning of the COVID-19 PHE, CMS tied mandatory reporting of COVID-19 data and subsequently seasonal influenza data to the CoPs. Throughout the PHE, hospitals have continued to report COVID-19 data on a daily basis. The AAMC and its members continue to oppose tying this reporting to the CoPs. CMS has included in this proposed rule a proposal to extend the current hospital reporting of COVID-19 data and seasonal influenza data requirements. Beginning at the conclusion of the current COVID-19 PHE declaration and continuing until April 30, 2024, a hospital would have to electronically report information about COVID-19 and seasonal influenza.

The AAMC recognizes the value of data reporting but does not believe that the CoPs are the appropriate mechanism for doing so. Moreover, the Association does not support extending the reporting requirements beyond the end of the PHE. Despite a myriad of other challenges faced during the COVID-19 PHE, hospitals continued to report daily the required data elements and redirecting scarce resources from other settings to comply with the reporting. It remains unclear, however, how federal agencies are utilizing this mountain of information. We urge CMS to end the data reporting requirements at the end of the COVID-19 PHE declaration. CMS and other

¹⁰ CMS-3401-IFC

federal agencies should provide hospitals with a detailed analysis of the data collected, how it was used during the PHE, and solicit stakeholder input as to the value of continuing to collect this data, as well as identifying best reporting practices for future pandemics.

Do Not Finalize New CoP Reporting Requirements for COVID-19 and Seasonal Influenza

To be better prepared for future pandemics or epidemics, CMS and other federal partners are considering ways to ensure a more flexible regulatory framework to ensure a "nimble and informed response" to the next pandemic or epidemic. (p. 28619). To this end, the Agency is proposing to establish new reporting requirements under the hospital infection prevention and control and antibiotic stewardship programs CoPs. (p. 28619 – 28620). Specifically, if the HHS Secretary declares a PHE, hospitals would be required to report specific data elements to the Centers for Disease Control and Prevention's (CDC's) National Health Safety Network (NHSN) or other CDC-supported surveillance systems. The proposed requirements would apply to local, state, and national PHEs as declared by the HHS Secretary.

The Association appreciates the need for data to understand the impact of public health emergencies; however, during the pandemic, hospitals submitted an enormous amount of data without knowing how, or whether, it was used by the federal government. Data reporting, particularly when it does not have a targeted purpose, is very burdensome, forcing hospitals to redirect scarce resources in order to comply with reporting requirements. While CMS expects that at some point in the future reporting will become more automated, ongoing reporting will continue to demand high resource consumption. (p. 28622). Hospitals will struggle to maintain staff and systems to be prepared to respond to any future PHEs. Once automated data is available, we urge CMS to work with stakeholders to determine the type of reporting that would be valuable.

The proposed rule notes that CMS considered data elements that provided informative and actionable over the course of the COVID-19 PHE. (p. 28621). Further, while the proposed rule states that it "aims to minimize reporting burden" we believe CMS could meet this goal by addressing the points below prior to finalizing any new COVID-19 or seasonal influenza reporting requirements. (p. 28622).

Increase transparency of data. Hospitals agree with the need for transparency in COVID-19 data reporting. However, despite multiple inquiries as to the purpose and use of COVID-19 and seasonal influenza data collection, it is still unclear how this data is being used to guide the federal government's response to the pandemic. Throughout the PHE, hospitals have provided an overwhelming amount of information, but the government has not been transparent regarding its usefulness. We call on the Administration to be explicit about the reasons for collecting the current extensive amount of information, inform hospitals about how the data are being used, and discuss future plans for use of the data before adding additional data reporting requirements. In addition, this data must be available under proper HIPAA controls to be analyzed and studied to make important recommendations for future data collection, use of data and appropriateness of the types of data which were or can be most useful

Currently, state and local public health agencies have limited access to certain National Healthcare Safety Network (NHSN) data via their NHSN accounts. (p. 28622). However, providing more access to the data will allow stakeholders to better understand how the PHE impacts them and their communities and allow for more detailed feedback on how the federal government can collect data that is informative and actionable.

Reduce data submission redundancy; simplify data elements; make definitions consistent. CMS should ensure that data reporting is streamlined, including making definitions consistent across federal, state, and local reporting platforms. Federal reporting requirements are often in addition to reporting hospitals are required to do at the state and local levels. Increased reporting combined with inconsistent requirements adds to the confusion on what and to whom to report. These inconsistencies are burdensome and have resulted in hospitals reporting the same or similar information to state and local governments and the federal government to ensure compliance.

For example, the CDC collects, compiles, and analyzes information on influenza activity year-round in the U.S. FluView¹¹ is a weekly influenza report that tracks seasonal influenza activity in the U.S. The Influenza Hospitalization Surveillance Network4 (FluSurv-NET) collects laboratory-confirmed influenza-associated hospitalizations among children and adults from a network of acute care hospitals to track influenza infections. Therefore, requiring hospitals to also report this information as part of hospital CoP data requirements is unnecessary.

<u>Report only confirmed cases</u>. CMS proposes that hospitals would continue to report suspected cases of COVID-19 and seasonal influenza. Hospitals test patients for COVID-19 upon admission so it will be easier and more accurate to capture confirmed cases. Additionally, many of these patients are asymptomatic and suspected cases would likely be under reported. Also, it is being reported that the CDC has plans to end the reporting of suspected cases. ¹²

REQUEST FOR FEEDBACK ON PAYMENT ADJUSTMENT FOR WHOLLY DOMESTICALLY MADE NIOSH-APPROVED SURGICAL N95 RESPIRATORS

The COVID-19 PHE showed the fragility and weaknesses of the global supply chain. Hospitals and health care settings realized that just-in-time and Lean inventory management strategies were not sufficient to meet the extraordinary demands for supplies that the PHE demanded. CMS requests feedback on the appropriateness of a payment adjustment to acquire NIOSH-approved surgical N95 respirators that are wholly domestically made. The goal of this adjustment is to sustain a level of supply resilience for surgical N95 respirators that is critical during a public health emergency. We agree with the Administration that more needs to be done to ensure a stable health care supply chain. While we support the CMS goal, we question whether using the Medicare hospital payment system is the right avenue to meet this goal.

¹¹ https://www.cdc.gov/flu/weekly/overview.htm

¹² https://www.bloomberg.com/news/articles/2022-05-26/cdc-plans-to-stop-reporting-suspected-covid-cases-to-ease-burden

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Ensuring a sufficient supply of critical medical supplies seems to be outside the scope of the Medicare program.

The unprecedented demand for health care supplies both globally and nationally during the PHE led to an imbalance in supply versus demand. This supply chain imbalance revealed that more than one source of goods and materials needs to be maintained in order to ensure a robust supply chain. It is critical to establish relationships with dependable onshore and offshore suppliers and invest in companies that can fill the needs during peak surges. Separate supply chains should be required to meet the same standards.

The Association supports incentivizing U.S.-based manufacturing, but we stress the need for more than one supply chain to ensure adequate product supply. We saw the devastating impact Hurricane Maria caused when intravenous fluids quickly were in short supply because the hurricane put Puerto Rican manufacturers offline. Health care facilities scrambled to find IV fluids in order to continue needed care such as surgical procedures and outpatient infusions. Having more than one manufacturing option could have lessened the impact of the shortages. The health care system must anticipate how it will respond to unprecedented demands in surge for critical medical supplies and drugs in the event of another PHE. We look to the Administration to work with stakeholders to develop a cohesive national strategy for addressing the impact future PHEs may have on the nation's health care supply chain.

CMS seeks comments on how to structure a payment adjustment to incentivize hospitals to purchase wholly, domestically made, NIOSH-approved N95 surgical masks. Hospitals are even more cost conscious considering the financial strain they continue to face due to postponement of elective services, staffing shortages and supply costs. While hospitals would not oppose purchasing domestically made N95 masks, they should not be penalized if they choose to purchase an imported mask that meets standards at a lower cost. Having more options for purchase also should increase competition and reduce costs. Due to financial considerations and storage capacity, it is unlikely that even with a financial incentive, hospitals will substantially change the amount of supplies they have on hand and will continue to utilize just in time supply which further underscores the need for a cohesive national strategy.

If CMS decides to move forward with this proposal, the AAMC supports the biweekly interim lump-sum payment proposal. Under this proposal, a hospital would separately report on its cost report the aggregate cost and total quantity of NIOSH-approved surgical N95 respirators it purchased that were wholly domestically made and those that were not, for cost reporting period beginning on or after January 1, 2023. Payments would be reconciled at Medicare cost report settlement. (p. 28624). We do not support a budget neutral implementation under the Outpatient Prospective Payment System. Identifying that N95 masks meeting the criteria to be wholly, domestically made should rest with NIOSH or another federal agency. NIOSH or another federal agency would certify whether a mask meets the criteria based on information submitted by the manufacturer and issue an identifier that hospitals would use on the Medicare cost report. The obligation to determine whether a mask meets the requirements should not rest with the hospital; that is between the manufacturer and NIOSH or another federal agency.

REQUEST FOR INFORMATION – SOCIAL DETERMINANTS OF HEALTH DIAGNOSIS (SDOH) CODES

CMS seeks additional information on how reporting ICD-10-CM diagnosis Z codes in categories Z55-Z65 (Persons with potential health hazards related to socioeconomic and psychosocial circumstances) may improve the ability to recognize the severity of illness, complexity of illness, and utilization of resources under MS-DRGs. CMS believes better reporting of these Z codes through inpatient claims could enhance coordination within hospitals across their clinical care and discharge planning teams, including with post-acute care providers.

The AAMC has previously supported the expansion of Z codes and consideration of policies to better encourage providers to include Z codes on claims. We believe that Z codes can provide better data to providers and payers alike on the health-related social needs (HRSNs) of patients that influence health care outcomes and utilization of services. CMS notes that Z codes are rarely included on Medicare inpatient claims, and we believe this is in part because they are not directly tied to provider payment. We support CMS's exploration of tying the Z59.0 (Homelessness) code to payment by reclassifying it to a Complication or comorbidity (CC) code for purposes of MS-DRG grouping and encourage involvement of stakeholders to determine the best way to proceed.

CMS also seeks information on which Z codes may improve the ability to recognize severity and complexity of illness and utilization of resources under MS-DRGs and potential burdens of documenting and reporting Z codes. The AAMC recommends that CMS seek alignment between payment and quality measurement by prioritizing CC consideration of Z codes related to the five HRSNs proposed under a new quality measure for the Inpatient Quality Reporting Program. That measure would assess hospitals rates of screening adult inpatients for:

- housing instability (Z59.0, Z59.1 Inadequate housing, and Z59.81 Housing instability, housed),
- food insecurity (Z59.4 Lack of adequate food),
- transportation needs (Z59.5 Extreme poverty, Z59.6 Low income, and Z59.7 Insufficient social insurance and welfare support),
- utility difficulties (Z59.5 and Z59.6), and
- interpersonal safety (Z62.81 Personal history of abuse in childhood, Z63.0 Problems in relationship with spouse or partner, and Z63.1 Problems in relationship with in-laws).

Alignment with the quality measure and the allowance for any member of the care team to collect and document Z codes in the medical record together helps to relieve burden on providers. We have heard from AAMC members that one burden limiting the use of Z codes is the limit on the number of diagnoses allowed to be included on Medicare inpatient claims. We urge CMS to evaluate the potential to expand the number of diagnoses providers may submit, or to otherwise allow documentation of Z codes in addition to the current limit of diagnoses codes on Medicare inpatient claims. Additionally, the AAMC encourages CMS to continue its commitment to improving communication and education around the use of Z codes.

¹³ AAMC Comments on Proposal to Expand ICD-10 Codes for Social Determinants of Health (May 2019).

Finally, CMS asks several other related questions. One is whether CMS should mandate the reporting of Z codes. The AAMC believes that CMS should continue to evaluate provider use of Z codes before mandating their reporting. This is critical considering points above regarding alignment with the screening quality measure and potential challenges of inclusion due to limits on the number of codes CMS accepts on inpatient claims. CMS should test reimbursement of Z codes and publicize impacts of those tests before mandating their use. Another is whether there are other criteria CMS should consider when promoting other CCs. The AAMC urges CMS to monitor emerging research on which Z codes correlate to specific outcomes and resource use to help inform future criteria for promoting CCs.

HOSPITAL QUALITY PROVISIONS

RFI - CLIMATE CHANGE IMPACTS ON OUTCOMES, CARE, AND HEALTH EQUITY

CMS requests feedback on hospital responses to climate change and how CMS and HHS can support health care providers in their efforts to prepare for both catastrophic events and chronic impacts of climate change on operations and the health of patients and communities.

The AAMC appreciates CMS's interest in addressing climate change, its impacts on patients, and the health sector's carbon footprint. We look forward to continuing to work with the Agency on this important issue. As an organization representing the medical education, patient care, medical research, and community collaboration missions of academic medicine, our organizational support for efforts to address climate change also extend beyond the teaching hospitals where patient care occurs. For more information specific to the AAMC's efforts, both independently and through partnership with other national organizations, to address the impacts of climate change on the health sector as well as decarbonization efforts across the sector, we direct you to our responses to a recent request for information from the U.S. House of Representatives Committee on Ways and Means. ¹⁴

Our members recognize that climate change has been and continues to be a growing health threat for their patients and acknowledge their own carbon contributions exacerbating the threat. Teaching hospitals and health systems are partnering on issues of environmental justice within their communities, focusing on those economically and socially disadvantaged groups that face the greatest risks from climate change. Many are investing in system-wide efforts to help mitigate their institutions' impact on climate change and are undertaking efforts to better understand their climate footprints. This includes identifying potential mechanisms to reduce the impacts of patient care and research practices on the environment, including decreasing energy utilization in the operating room, expanding use of renewable energy, designing green buildings, and supporting green community design, evaluating sustainable procurement and supply chains, etc. We continue to engage with our members to understand and support their efforts.

¹⁴ AAMC Comments to Ways and Means Committee Chairman Richard E. Neal (May 2022).

As we take the time to better understand the many facets of climate change and its varied impact on the delivery of care, health of patients and communities, and the role of the U.S. health care system on the nation's carbon footprint, we urge CMS and HHS more broadly to commit to a collaborative approach with stakeholders to developing innovative solutions. To this end, we appreciate the efforts for a voluntary Health Care Sector Commitment to Emissions Reduction and Resilience¹⁵ and an Office of Environmental Justice. The former includes a pledge for organizations to lower greenhouse gas emissions and build more climate resilient infrastructure. A number of AAMC members have committed to this effort. The latter is a new office within the Department to coordinate and provide expertise to support efforts to protect the health of disadvantaged communities and vulnerable populations on the frontlines of pollution and environmental hazards. Dr. Balbus, who heads the office, recently spoke to a meeting of the CEOs of AAMC member hospitals and health systems to discuss his office, its goals, and the special role that teaching hospitals and health systems can play. These sorts of collaborations and supports for hospitals are critical to ensure that providers and policymakers are able to share knowledge and develop solutions collectively.

A critical aspect to addressing climate change is equitable distribution of necessary resources for this work. Not every hospital and health system can quickly shift to invest in this critical work, especially after the financial impact of the pandemic, and we cannot allow some hospitals and the communities they serve to fall behind due to lack of resources. The AAMC asks CMS and HHS to explore ways to increase funding to incentivize and support hospital adoption of effective innovations to address healthcare's carbon footprint and reducing emissions.

Finally, **CMS** and **HHS** should holistically consider broader policies for their potential climate-related impacts. For example, there is a separate dialogue regarding expansive data collection and potentially maintaining exponential amounts of individual health information electronically for increasing periods of time. Even in this proposed rule there is consideration of significant proliferation of the data that quality measures might tap into for digital quality measurement goals. It is unclear whether the potential benefits of unlimited cloud-based health data collection and storage is being evaluated against the real environmental impacts of data storage.¹⁷ Data proliferation should be balanced on the evidence of the benefits of increased data collection and storage is worth the potential climate-related impacts.

¹⁵ See HHS Press Office, <u>HHS Launches Pledge Initiative to Mobilize Health Care Sector to Reduce Emissions</u> (Apr. 22, 2022), where health care entities may voluntarily pledge to reduce emissions by 50% by 2030 and to net zero by 2050 and publicly report progress in addition to developing climate resilience plans for their facilities and communities.

¹⁶ See 87 Fed. Reg. 33174 (Jun. 1 2022), detailing the organization of the new office under the Office of the Assistant Secretary for Health.

¹⁷ See AJ Dellinger, "The environmental impact of data storage is more than you think – and it's only getting worse, Mic.com (June 19, 2019), describing in general the environmental costs of expanded data storage, including citing to a 2015 report that found data centers to be responsible for about 2 percent of global greenhouse gas emissions, similar to that of the aviation industry.

RFI - MEASURING HEALTHCARE QUALITY DISPARITIES ACROSS CMS QUALITY PROGRAMS

CMS seeks feedback to inform future rulemaking to support the Agency's goal of addressing disparities, or inequities, in healthcare outcomes as part of the Agency's broader health equity goals. To do so, CMS presents key principles and approaches for consideration when addressing inequities through quality measurement and stratification. Comments to selected topics raised in the RFI are as follows.

Identifying Goals and Approaches for Measuring Health Care Inequities

The AAMC supports establishing express goals and approaches to measurement as a component of addressing health care inequities. We believe that a critical starting point is to clearly state the role of health care quality and measurement in promoting equity in health care delivered in an acute care setting versus those that are more appropriate to promote health equity and community health. We believe 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 shows that health care and genetics play a limited role in one's health compared to behavioral, social, and environmental risk factors. In Improving quality of care is one of a myriad factors within the broader health equity aim. It is an important aspect for evaluating and driving equitable access to high quality care for all patient populations.

We appreciate that in creating a system for measuring healthcare inequities CMS sets out to establish alignment across CMS programs and provider settings. Consistency across CMS programs ensures that all health care providers can engage in health care equity work and collaborate on solutions.

CMS currently employs two disparity methods as part of confidential reporting that hospitals receive: (1) Within Hospital and (2) Across Hospital. This reporting currently is based on patient dual-eligibility and statistically imputed race and ethnicity data. **CMS should prioritize expansion of inequity reporting based on the Within Hospital method.** The Within Hospital method is a useful metric for hospitals to understand the inequities within their own setting, so long as it is based on additional data points beyond dual eligibility. (We refer CMS to AAMC comments on the use of dual eligibility as a proxy for social risk in further detail on principles for data selection and in response to the request for feedback to including disparities measurement in the Hospital Readmissions Reduction's performance measurement.) Given differences in case mix and community contexts, comparing inequities across hospitals is an incomplete picture and does not inform a hospital's understanding of its own performance as it does not incentivize local progress for health care equity.

¹⁸ See National Quality Forum, Social Risk Trial Final Draft Report at 5 (April 19, 2021).

Guiding Principles for Selecting and Prioritizing Measures for Inequity Reporting

The AAMC believes that measures should be prioritized for inequity reporting that satisfy the following conditions: (1) existing, validated, reliable clinical quality measures that can be feasibly stratified for disparity measurement; (2) evidence supporting inequities exist when measuring for a specific social risk factor, demographic factor, or community-level characteristic for the clinical quality measure; and (3) valid and reliable data to measure such inequities (i.e., there is sufficient data to stratify measure performance to that social risk factor, demographic factor, or community-level characteristic). Regarding the first criterion, we believe that there should be a prioritization of measures for stratification, focusing first on measures of equitable access to care and equitable health care policies. Then, as the measurement program develops CMS should commit to thoughtfully building a strong foundation to support this work for the long term. In that way health care providers can begin to invest in the necessary infrastructure to understand and respond to inequities measurement, including data collection and reporting.

Principles for Social Risk Factor and Demographic Data Selection and Use

The AAMC believes that when measuring inequities, we must measure and shine light on the broad mix of factors at play in order to find appropriate solutions. Quality measurement of health care must measure factors which are in the control of providers and helps shed light onto the social factors that are outside the realm of health care delivery. The role of improved risk adjustment that addresses clinical, social, and functional status risk factors is crucial for ensuring accurate and fair assessment so that safety net providers are not penalized by losing the very resources they need. We agree with the National Academies, that when measurement is 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 are supportive of CMS proposals to use quality measurement as an incentive for provider screening of health-related social needs (HRSNs). We believe this has the potential to improve data collection of individual-level social risk factors that contribute to inequities and highlight potential intervention points. We must start by identifying precisely which HRSNs are key and can inform improvement. However, as we note in our comments to both the request for information on incorporating Z codes into DRG payment and the adoption of new quality measures for the Inpatient Quality Reporting (IQR) Program, CMS should look to align

¹⁹ See National Quality Forum Issues Quality Roadmap for Reducing Healthcare Disparities

²⁰ See the National Quality Forum's framework to develop risk adjustment guidance for CMS, a second report is forthcoming in 2022.

²¹ See National Academies of Sciences, Engineering, and Medicine, <u>Accounting for Social Risk Factors in Medicare Payment</u> (2016) at 71, finding a conceptual framework "that social risk factors may influence health care process as well as outcomes of care among Medicare beneficiaries in many interrelated way....At the same time, there are mechanisms through which the health care system can itself ameliorate the impact of social risk factors on quality, outcomes, and cost."

approaches to data collection and use of HRSNs to mitigate burden on providers, including costs associated with data collection.

Patient self-reported demographic information is noted as the gold standard, and only such demographic data should be used for measuring inequities. CMS should also be clear that demographics themselves are not actionable risk factors. Furthermore, disparities surveillance does not tap into patient populations' perception²² 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. For example, dual eligibility and race and ethnicity as proxies for actual social risk factors likely reduces the intended impact because there is no intervention for "Dually Eligible" or "Asian-American". Finally, we support the use of community-level factors such as the area deprivation index, to ensure that we measure inequities for whole communities, in addition to individual social risks. Addressing health care equity through measuring inequities must give us insight into both individual and community-level factors, but hospitals must only be held accountable for those factors which are hospital specific and that hospitals can address, while still being supportive of community activities that address the broader health-related needs.

Identifying Meaningful Performance Differences

The AAMC believes that we must first focus on building the measurement basics for informing intervention. CMS should prioritize valid and reliable measurement that can support hospital improvement at the outset. Understanding meaningful performance differences is a critical component to measurement. With time, and maturity, national or state benchmarking could become a key tool for helping providers understand and contextualize their own performance in relation to that of their peers. Then, even further down the line, CMS could consider additional approaches, such as ranked ordering and percentiles, or defined thresholds, if there is evidence that such approaches can further support improvement and expand our understanding of measure performance.

Guiding Principles for Reporting Inequity Measures

The goal of inequity measurement is to both inform providers of areas where inequities exist and must be addressed and to eventually shine light on provider performance for patients and communities. Confidential reporting should be prioritized as inequity reporting is expanded in order to meet that first goal of informing providers. Providers and policymakers must agree that they have the data necessary to measure inequities and how measurement informs improvement. Public reporting should not be considered until such agreement is widely accepted. Furthermore, providers should have at least one year of data to

²² For example, refer to the Minnesota Department of Health's Guild, "<u>HEDA: Conducting a Health Equity Data Analysis,</u>" 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 Center for Health Justice's "<u>Principles of Trustworthiness</u>" project builds on foundational principle that trust is crucial for equitable community partnerships.

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understand performance on a given inequity measure before any consideration of public reporting.

The AAMC believes that any publicly reporting of disparity measure performance is premature at this stage. When implemented in the future it must be meaningful and well understood. Patients and communities must trust the information that is presented to them. CMS should thoughtfully examine the potential unintended consequences of public reporting, including understanding how patients and communities interpret inequity measurement. Public reporting should not place a burden on patients and communities to "do their homework" to parse through stratified and non-stratified results to gain a comprehensive understanding of their health care providers.

RFI – FAST HEALTHCARE INTEROPERABILITY RESOURCES (FHIR) IN HOSPITAL QUALITY PROGRAMS

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, with a focus on the use of FHIR-based application programming interfaces to support such efforts.

Definition of Digital Quality Measures (dQMs)

The AAMC believes that improved electronic health record (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 continue 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 other key principle is that the primary purpose of a medical record is for use by the care team to assess, plan for care, and transmit data to other providers. The EHR has been criticized in the past for becoming more of a tool for billing, obfuscating its use to relay critical information to the care team. As CMS looks at the important use of the EHR for dQMs, it must keep in mind that these processes must not interfere, delay, or hinder patient care.

The definition as revised in this Request for Information remains overly broad, and lists data sources including "administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, laboratory systems, prescription drug monitoring programs (PDMPs), instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated health data such as home blood pressure monitor, or patient-reported 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. There is real concern

that letting data from wearable devices or patient-generated health data flow freely into EHRs might obfuscate clinically relevant information rather than enhance it and may require redesigning clinical workflows to reduce provider burden.²³, ²⁴ Beyond the validity and utility of the data generated, wearable devices such as smartwatches and fitness trackers are not universally adopted, with some research suggesting higher uptake by Americans with higher earnings or levels of educational attainment.²⁵ CMS should be cautious about using data from wearable devices to ensure that such data does not invite bias or inequities.

Approaches to Achieve FHIR eCQM Reporting

Last year, the AAMC recommended that CMS should also outline plans for piloting new data sources for quality measurement, identifying reasonable near-term and longer-term priorities. We are encouraged to see CMS respond in this year's RFI with an acknowledgement of an iterative process and a focus on more interoperable eCQM reporting. We believe that as CMS tests FHIR-based conversions for eCQM reporting, it should ensure that hospitals and their vendors are able to implement and optimize interoperable FHIR-based exchange without any unintended setbacks or consequences.

Finally, we continue to recommend that CMS engage the National Quality Forum (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.

RFI – ADVANCING THE TRUSTED EXCHANGE FRAMEWORK AND COMMON AGREEMENT

CMS seeks feedback to inform future rulemaking to support the Agency's approaches to the adoption of the Office of the National Coordinator (ONC) for Health Information Technology (HIT)'s first version of the Trusted Exchange Framework and Common Agreement (TEFCA) as a universal policy and technical floor for interoperability. The AAMC is supportive of TEFCA and recommends that CMS create a collaborative environment for providers to engage with and implement TEFCA capabilities and use-cases. Due to the ongoing COVID-19 PHE, hospitals and health systems have had to divert resources to manage surges and other operational constraints. Time is needed to allow hospitals to evaluate and implement TEFCA standards.

²³ See Jim et al, <u>Innovations in Research and Clinical Care Using Patient-Generated Health Data</u>, CA: A Cancer Journal for Clinicians Vol. 70: 182-199 (2020), finding challenges and solutions for the integration of PGHD into clinical care are presented. The challenges include electronic medical record integration of PROs and biometric data, analysis of large and complex biometric data sets, and potential clinic workflow redesign.

²⁴ See Lavallee et al, mHealth and patient generated health data: stakeholder perspectives on opportunities and barriers for transforming healthcare, mhealth (2020), noting that significant barriers included data validity and actionability, and burden of integrating patient-generated health data into existing care processes.

²⁵ See Emily A. Vogels, <u>About one-in-five Americans use a smart watch or fitness tracker</u>, Pew Research (Jan. 9, 2020) finding device use varies substantially by socioeconomic factors.

HOSPITAL READMISSION REDUCTION PROGRAM (HRRP)

Incorporating a History of COVID-19 into Measure Risk Adjustment

CMS proposes to adopt a technical measure specification update to each of the readmission measures in the HRRP to include a covariate adjustment for COVID-19 beginning with FY 2023. This would adjust for patient history of COVID-19 in the 12 months prior to the admission. The AAMC supports this technical specification update in concept for its recognition of potential lasting effects of COVID-19 that could affect a patient's risk of being readmitted following an index admission for the conditions included in the HRRP but has concerns about some of the proposed technical specifications.

We are concerned that initial data presented after the publication of the proposed rule requires additional review and revision to the proposed technical specification update. Measure Methodology Reports referencing to the QualityNet website in the rule published in May 2022 show that History of COVID-19 is *negatively* correlated to readmissions for four of the five conditions. There are a several factors that could lead to these results: inconsistent documentation of prior history of COVID-19 through the code established in 2021, documentation challenges of diagnosing COVID-19 through home-tests without additional need for care, and interactions with the policy to exclude patients with COVID-19 present on admission. Regardless, these results demonstrate that there is much more we must know about the history of COVID-19 as a covariate adjustment. In response to this initial data, CMS should revise the proposal to include a policy to only include the covariate adjustment for conditions where it is a positive risk variable for the performance period in line with the proposal's intended recognition that history of COVID-19 "could affect a patient's risk factors for being readmitted."

Possible Future Inclusion of Disparities Performance in Readmissions Measurement

CMS requests comment on the benefits and potential risks of incorporating hospital performance for beneficiaries with social risk factors in the HRRP, approaches to linking performance in caring for socially at-risk populations and payment reductions based on readmission outcomes for socially at-risk beneficiaries compared to other hospitals or to performance for other beneficiaries within the hospital, and measures of indices of social risk in addition to dual eligibility that should be used to measure equity performance.

The AAMC shares the goal to reduce inequities in health care quality across beneficiary groups with health-related social needs. The key to improving performance is better data to ensure providers have actionable information to inform improvement. Efforts should be

²⁶ See 87 Fed. Reg. at 28422, which links to https://qualitynet.cms.gov/inpatient/measures/readmission/methodology; the individual measure reports posted show negative coefficients ranging from -.030 to -0.266 for AMI, CABG, HF, and THA/TKA for the FY2023 performance period. For COPD there is a small positive coefficient of 0.037.

²⁷ See CDC, New ICD-10-CM code for the 2019 Novel Coronavirus (COVID-19) (December 3, 2020).

²⁸ 87 Fed. Reg. at 28422.

made to incent valid collection social risk factor data that will best inform intervention. CMS proposes new measures in the Hospital Inpatient Quality Reporting (IQR) Program to encourage screening patients for health-related social needs, which in turn could support the use of actionable social risk factor data, such as ICD-10 Z codes, in quality measurement and information linkages between such social needs and potential referrals and interventions to improve performance. Including current disparity performance based solely on dual eligibility as a beneficiary group is challenging, as it is unclear which particular health-related social needs dual eligible patients have that heighten their likelihood of readmission. Medicaid coverage varies across states, and evidence shows that the range of benefits and health care experiences²⁹ of dual eligible beneficiaries is diverse.

Additionally, **CMS** should consider and explore the use of social risk data at both the individual and community level to best identify inequities and guide interventions for improvement. CMS has expressed interest in the use of broader community-based social determinants for use in inequity reporting.³⁰ There is evidence^{31, 32} that the current use of dual-eligibility alone to stratify penalties in the HRRP is insufficient. Neither dual eligibility nor one's community are sole determinants of an individual's health.³³ Hospitals need insight not only into factors to inform individual patient-level interventions, but also potential community investments as part of its quality improvement efforts. CMS can also glean information about community investments though the Community Health Needs Assessment (CHNA) and Implementation Strategy that the Internal Revenue Service requires of every 501(c)(3) hospital.

We believe that the use of CMS Disparity Methods is not ready for use in performance measurement, considering both the lack of actionable information to drive improvement and specifics as to how CMS would incorporate such performance into overall HRRP measurement and scoring. We appreciate that CMS acknowledges a need to evaluate different approaches to encourage improved performance for socially at-risk populations, and that approaches might have unintended consequences. The most critical risks of unintended consequences are a potential disincentive for hospitals to treat socially at-risk patients or financially penalizing those hospitals that treat larger proportions of patients in under-resourced communities. CMS could consider an alternative path to reduce unintended consequence by establishing a bonus points

²⁹ See Reaves et al., <u>Faces of Dually Eligible Beneficiaries</u>: <u>Profiles of People with Medicare and Medicaid Coverage</u>, KFF (Jul. 2013) illustrating the diverse experiences of dually eligible beneficiaries in obtaining medical care and non-medical, supportive services.

³⁰ See 87 Fed. Reg. at 28425, stating "[m]easures of social risk could also include indices developed for the purpose of identifying socially at-risk populations and measuring the degree of risk."

³¹ See Baker et al., Social Determinants Matter for Hospital Readmission Policy: Insights from New York City, Health Affairs Vol. 40, No. 4 (Apr. 2021) finding that including social determinants of health (SDOH) data constructed with granular geographic data, along with social risk factor variables, substantially affects projected penalties for hospitals treating the highest proportion of patients with high SDOH scores, even after including peergroup stratification in the program's model based on proportion of dual-eligible patients served.

³² See Alberti and Baker, <u>Dual eligible patients are not the same</u>, Medicine (Sep. 18, 2020), evaluating stratification of the pneumonia readmission measure under the HRRP and finding that broad differences in dual-eligible populations could mislead between-hospital comparisons using dual eligibility as a social risk factor.

³³ See Silvestri et al., <u>Factors Associated With Disparities in Hospital Readmission Rates Among US Adults Dually Eligible for Medicare and Medicaid</u>, JAMA Health Forum (Jan. 2022).

system as way to reduce a hospital's penalties under the program based on measurement of inequities performance.

HOSPITAL VALUE-BASED PURCHASING PROGRAM (HVBP)

Application of COVID-19 Measures Suppression Policy to HVBP Program

CMS proposes to suppress measures under three of four domains: Efficiency and Cost Reduction, Person and Community Engagement, and Safety for FY 2023, as a continuation of the policy finalized for FY 2022. Due to this expansive suppression proposal, CMS proposes to apply a neutral payment adjustment for FY 2023, where no hospital will receive a penalty or bonus, and hospitals will not receive a Total Performance Score. CMS also proposes changes to the baseline and performance periods for FY 2025 for Efficiency and Cost Reduction, Person and Community Engagement, and Safety domains to account for downstream effects of measure suppressions proposed for FY 2023. The AAMC appreciates the recognition of the continuing stress of the pandemic on hospitals and supports this approach for addressing the impact of COVID-19 on the HVBP for FY 2023.

Incorporating a History of COVID-19 into Measure Risk Adjustment

CMS proposes to adopt a technical measure specification update to each of the measures in the Clinical Outcomes domain to include a covariate adjustment for COVID-19 beginning with FY 2023. This would adjust for patient history of COVID-19 in the 12 months prior to the admission. The AAMC supports this technical specification update in concept for its recognition of potential lasting effects of COVID-19 that could affect a patient's risks following an index admission for the outcome measures included in the HVBP but believes that some revisions should be made to the proposed technical specification update.

However, we are concerned that initial data presented after the publication of the proposed rule requires additional review and revision to the proposed technical specification update. Measure Methodology Reports referencing to the QualityNet website in the rule published in May 2022 show that History of COVID-19 is *negatively* correlated for outcomes measured for the five conditions in the domain for FY 2023.³⁴ There are several factors that could lead to these results: inconsistent documentation of prior history of COVID-19 through the code established in 2021, ³⁵ documentation challenges of diagnosing COVID-19 through home-tests without additional need for care at the time, and interactions with the policy to exclude patients with COVID-19 present on admission. Regardless, these results demonstrate that there is much more we must know about the history of COVID-19 as a covariate adjustment. **In response to this initial data,**

³⁴ See 87 Fed. Reg. at 28434, which links to https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology; the individual measure reports posted show negative coefficients ranging from -.026 to -0.232 for AMI, CABG, COPD, and HF mortality measures, and THA/TKA complications for the FY2023 performance period.

³⁵ See CDC, New ICD-10-CM code for the 2019 Novel Coronavirus (COVID-19) (December 3, 2020).

CMS should revise the proposal to include a policy to only include the covariate adjustment for measures where it is a positive risk variable for the performance period in line with the proposal's intended recognition that history of COVID-19 "could affect a patient's risk of mortality or complications." ³⁶

HOSPITAL-ACQUIRED CONDITION REDUCTION PROGRAM (HACRP)

Application of COVID-19 Measures Suppression Policy to HACRP Program

CMS proposes to suppress all the measures in the HACRP measures for FY 2023, due to the misalignment of the performance period impacted by COVID-19 with the reference period. Due to this expansive suppression proposal, CMS proposes to not apply penalties for FY 2023 due to the complete suppression of performance measurement. The AAMC supports and applauds this approach for addressing the impact of COVID-19 on the HACRP for FY 2023.

Incorporating COVID-19 into PSI-90 Measure Risk Adjustment

In addition to measure suppressions for FY 2023, CMS proposes to make a technical measure specification to the PSI-90 measure for FY 2024 to include a COVID-19 diagnosis in the measure's risk adjustment. CMS cites analysis finding adjusting for patient-level COVID-19 diagnoses removes incremental risk of adverse patient safety events associated with COVID-19. **The AAMC supports this technical update in recognition of COVID-19 impact.**

INPATIENT QUALITY REPORTING (IQR) PROGRAM

Adoption of New Measures

CMS proposes to adopt ten new quality measures. The AAMC urges CMS to consider the potential burden on providers with such a significant increase in measures for the Program, especially in light of the ongoing COVID-19 PHE. CMS should prioritize the adoption of measures that are most meaningful to hospitals and patients. Comments specific to each measure follow.

Hospital Commitment to Health Equity

CMS proposes to adopt a structural measure that assesses a hospital's commitment to health equity based on a set of equity-focused organizational competencies across five domains, beginning with CY 2023 reporting. The AAMC has previously commented on the value of structural measures as a starting point for addressing health equity through quality

³⁶ 87 Fed. Reg. at 28434.

measurement and appreciates CMS responding to our recommendation.³⁷ Regarding this specific structural measure, we urge CMS to consider additional testing of the measure, possibly through a period of voluntary reporting, to assess whether hospitals are consistently interpreting each of the attestation elements within each domain. This measure has the potential to inform better understanding of correlation between processes and activities with quality performance, and it can only meet that potential if consistently applied across hospitals.

Additionally, we urge CMS to ensure that publicly reporting this measure does not mislead patients and communities. CMS proposes to publicly report a fraction representing the number of complete competency domains to which a hospital attests. For example, a hospital's scoring could be 3/5. Would this be represented as Hospital A is 3/5 committed to health equity? What would that mean to patients? Considering the lack of clarity such public reporting presents, we recommend that CMS consider the alternative public reporting options previously established for measures where "information may not be relevant to or easily understood by beneficiaries" by reporting it as part of a publicly available dataset instead of on the Care Compare website.³⁸

Screening for Social Drivers of Health

CMS proposes to adopt two screening measures assessing a hospital's rate of screening inpatients for five health-related social needs (HRSNs) beginning with CY 2024 reporting (following a voluntary reporting period in CY 2023). The five HRSNs are: food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety, and are based on the five domains screened as part of CMS's Accountable Health Communities (AHC) model. While based on the screening in the AHC model, CMS does not mandate the screening tool hospitals must use to report this measure.

The AAMC supports this measure as a targeted step towards expanding data collection and data harmonization to provide actionable information to inform improvement. We agree that screening to identify unmet HRSNs can be a useful first step in identifying necessary community partners and connecting patients to community resources. We also believe that focusing on a specific set of HRSNs to start helps to ensure an even focus across hospitals and allocate limited resources. CMS should commit resources to thorough evaluation of the HRSNs and how they might impact quality of care and whether they are the most appropriate HRSNs for screening. Finally, one of the exclusions for the measure is patient opt-out of screening. We believe this is an appropriate exclusion but ask CMS to consider providing hospitals with comparative information on opt-out rates to help them better understand their own opt-out rates. AAMC Center for Health Justice public opinion polling has observed the critical importance of

³⁷ See <u>AAMC Comments on Medicare Inpatient Prospective Payment System FY 2022 Proposed Rule</u> (Jun. 2021), at 44.

³⁸ See 78 Fed. Reg. 50496 (2013) at 50776-77, noting that CMS may satisfy public reporting requirements for the IQR Program for "information that may not be relevant to or easily understood by beneficiaries" by making it "available on other CMS websites that are not intended to be used as an interactive web tool" such as data.cms.gov.

trustworthiness, especially for individuals sharing sensitive information regarding social needs.³⁹ Garnering greater insight into opt-out rates might provide an additional data point for potential trustworthiness gaps.

Screen Positive Rate for Social Drivers of Health

Coupled with the screening rate measure, CMS also proposes a separate measure of the positive screening rates for each of the five HRSNs, also beginning with CY 2024 reporting (following a year of voluntary reporting). This measure would be reported as five separate rates, for each HRSN, as the number of patients who screened positive for the HRSN out of the overall number of patients screened. CMS notes that it believes a separate measure on the results of screening for HRSNs will help to quantify the levels of HRSNs in local communities served by a hospital and visibility into the interaction between HRSNs and health status, healthcare utilization, and quality of care. However, CMS notes "that this measure is intended to provide information to hospitals on the level of unmet social needs among patients served, and not for comparison between hospitals."

The AAMC agrees that the results of screening could be an additional data point that can help inform hospital collaboration with community partners and community investment, and for use by local, state, and federal policymakers in their efforts to improve health equity. We urge CMS to commit to evaluating the interaction between positive rates for these five HRSNs and quality, and to consider how positive rates of HRSNs could be incorporated into measure stratification and risk-adjustment. Additionally, as an acknowledgement that the measure is not meant for hospital comparisons, CMS should report the measure as part of a public data set on data.cms.gov rather than on the Care Compare website. Simply put, it is unclear how this measure data might be interpreted or what it says about a hospital. CMS should monitor use of the measure performance data to evaluate whether there are unintended uses of the data that might misinform or inhibit the measure's value.

Cesarean Birth eCQM

CMS proposes to adopt a mandatory eCQM that assesses a hospital's rate of cesarean births beginning with CY 2024 reporting (following a voluntary reporting period in CY 2023). The AAMC agrees with the importance of reducing the occurrence of non-medically indicated cesarean births and wholeheartedly supports improving maternal health outcomes. However, we urge CMS to thoroughly monitor the measure data for potential unintended consequences and the potential for measure performance "topping out." There is concern that this measure could discourage providers from performing cesareans deemed medically appropriate and necessary for nulliparous term singleton vertex (NTSV) patients. Regarding

³⁹ See Dev et al., For the Common Good: Data, Trust, and Community Health, AAMC Center for Health Justice (Mar. 2022) finding that 53% of responding adults were comfortable sharing social information with health care providers other than their doctor.

⁴⁰ 87 *Fed. Reg.* at 28504.

⁴¹ *Id.* at 28505.

⁴² Supra, citing CMS policy for publicly reporting information not relevant to or easily understood by beneficiaries.

performance "topping out," CMS itself notes that there are no practical clinical guidelines in the US for an optimal rate of C-sections or an appropriate variance rate. Early years of measure reporting might provide such an answer and help guide review regarding if and when measure performance indeed "tops out." Finally, CMS should evaluate the measure's pairing with PC-01 Elective Delivery to better wholistically examine C section rates in the US. The evaluation should consider potential impacts on maternal health inequities given existing racial disparities in cesarean rates, as highlighted by CMS in this proposed rule. In addition to potentially discouraging providers from performing medically necessary c-sections, efforts should be made to ensure that this does not perpetuate racial disparities regarding who gets a c-section and why.

Severe Obstetric Complications eCQM

CMS proposes to adopt a mandatory eCQM that assesses the proportion of patients with severe obstetric complications that occur during inpatient delivery hospitalizations beginning with CY 2024 reporting (following a voluntary reporting period in CY 2023). **The AAMC agrees that measuring maternal outcomes is critical to addressing maternal health inequities.** While we support this measure, we recommend that if the measure is finalized CMS monitor and evaluate the measure data and provider feedback for potential improvements to inform understanding of obstetric complications. For example, this measure rightfully evaluates a wide range of qualifying complications and procedures, but it may, in practice, be challenging for providers to parse out actionable interventions from measure results reported as a rate of all complications per 10,000 deliveries. Similarly, the measure is extensively risk-adjusted, including for patient age, but includes patients as young as 8 and as old as 65. We believe removing such significant patient outliers provides more meaningful data for patients and providers.

Hospital Harm – Opioid-Related Adverse Events eCQM

CMS proposes to adopt an eCQM that assesses hospital opioid-related adverse events, beginning as an optional eCQM hospitals may report for the CY2024 reporting period. The AAMC is supportive of measure concepts that assess the critical patient safety issues surrounding opioid use, though asks CMS to evaluate its reliance on potentially outdated clinical support for the measure. CMS cites several studies of opioid-related harm and the large variation of hospital administration of opioids, yet many of the citations are to studies published from 2009-2014, well before widespread attention was paid to opioid use and prior to the ongoing opioid public health emergency that began in October 2017. We urge CMS to monitor clinical literature for more recent studies of hospital opioid administration practices and in the coming years to evaluate performance to determine whether measurement remains one of critical importance.

⁴³ See 87 Fed. Reg. at 28515, noting studies cited to in footnotes 1057, 1058,1059, 1060, 1062, 1064, 1067, and 1073.

⁴⁴ *See* HHS Office of the Assistant Secretary for Preparedness & Response, <u>Renewal of Determination That a Public Health Emergency Exists</u> (Apr. 2022).

Global Malnutrition Composite Score eCQM

CMS proposes to adopt an eCQM that assesses adults 65 and older admitted to a hospital who received care appropriate to their level of malnutrition risk and malnutrition diagnosis, if properly identified. CMS proposes the measure beginning with the CY2024 reporting period as an optional eCQM hospitals may self-select for reporting. The component measure would be the first to directly address malnutrition of hospitalized patients. Components of the measure include nutrition screening and further assessment, documentation, and nutrition care planning for patients identified as at-risk for malnutrition based on the initial screening. CMS notes recent literature identifying the relationship between the four component measures and hospital readmissions and length of stay and associated improvements following nutrition-related interventions. The AAMC supports the adoption of this measure as a step towards improving outcomes for patients at risk of malnutrition and improving our collective understanding of nutrition on health care outcomes.

Hospital-Level, Risk Standardized Patient-Reported Outcomes Performance Measure (PRO-PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)

CMS proposes to adopt the first PRO-PM in its hospital quality programs, beginning with a measure focused on THA/TKA and requiring hospitals to report the measure with procedures performed July 2024 through June 2025 (following one and a half voluntary reporting periods). The AAMC supports exploring the role of PRO-PMs in hospital quality measurement and agrees that beginning with elective procedures is reasonable. However, we believe the CMS should carefully evaluate the inclusion of this particular PRO-PM due to several concerns.

First, the THA/TKA PRO-PM has been included in the Comprehensive Joint Replacement (CJR) payment model as a voluntarily reported measure since 2016, and after a few years, CMS increased reporting threshold requirements for scoring. We have heard from members that most are not reporting PRO-PM data in the model due to the 80% reporting threshold, which hospitals have been unable to meet. CMS notes in its discussion of the measure that the CJR model "revealed hospital-level variation...although the full degree and extent of variation is unknown." The AAMC believes challenges with survey responsiveness and the high reporting threshold are responsible, at least in part, for the lack of concrete evidence of performance variation despite many years of the measure being in the program. 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.

Second, CMS notes that there are broader payment-related policy changes that could critically impact this measure as currently specified for the inpatient setting. ⁴⁶ CMS has removed THA/TKA procedures from the inpatient only (IPO) procedure list, and these procedures are increasingly occurring in the outpatient and ambulatory surgical center settings. **Considering**

⁴⁵ 87 *Fed. Reg.* at 28524

⁴⁶ 87 Fed. Reg. at 28526

that if finalized this measure would be mandatory for a reporting period that is two years from now, the AAMC urges CMS to thoroughly analyze and monitor the shift in clinical settings in the interim to determine whether the measure will remain valid and reliable for the future. This measure includes a significant investment in survey administration as part of the overall data collection, and we are concerned that this PRO-PM may not be "ripe" for the inpatient setting due to these site of service changes.

Substantive Measure Refinement: Medicare Spending Per Beneficiary (MSPB)

CMS proposes to adopt a substantively refined MSPB hospital measure in the IQR beginning with FY 2024 payment determinations to replace the current version. The AAMC is supportive of the measure refinements and appreciates that the revised measure is NQF-endorsed prior to proposed adoption. We do note, however, that there is a potential for confusion in having two versions of the MSPB measure publicly reported simultaneously. We ask CMS to clarify how the versions of the measure will be distinguished in public reporting.

Substantive Measure Refinement: Hospital-Level Risk Standardized Complication Rate Following Elective Primary THA/TKA

CMS proposes to adopt a substantively refined THA/TKA complications measure in the IQR beginning with FY 2024 payment determinations. A version of the MSPB measure is currently included in the VBP Program measure set, and CMS would likely propose to replace that measure with this refined version after a period of reporting in the IQR program. The AAMC supports the measure refinements and appreciates that the revised measure is NQF-endorsed prior to proposed adoption. We do note, however, that there is a potential for confusion in having two versions of the measure publicly reported simultaneously. We ask CMS to clarify how the versions of the measure will be distinguished in public reporting and which version of the measure will be in use for the Overall Hospital Quality Star Ratings.

Potential Future Measures

CMS seeks feedback on two potential future CDC National Health Safety Network (NHSN) measures. Comments specific to each are as follows.

CDC NHSN Clostridioides difficile (C. diff.) Infection Outcome Measure

CMS is considering the future inclusion of a hospital-level digital quality measure of new *C. diff.* infections among hospital inpatients, using algorithmic determinations based on electronic health record (EHR) data. This measure was included on the December 2021 Measures Under Consideration (MUC) list as part of the required pre-rulemaking process. The MAP conditioned its support for the measure on NQF endorsement following full testing of the revised measure. The AAMC agrees with the MAP assessment, that the measure must be fully tested and vetted as valid and reliable. Additionally, we believe the NQF endorsement process will also ensure that

the measure is reviewed for any potential unintended consequences that might arise from reliance on algorithmic determinations.⁴⁷

CDC NHSN Hospital-Onset Bacteremia and Fungemia Outcome Measure

CMS is considering the future inclusion of a hospital-level digital quality measure of new bacteremia and fungemia among hospital inpatients, using algorithmic determinations based on electronic health record (EHR) data. This measure would expand on currently CDC NHSN measures of organism-specific (e.g., MRSA) and source-specific (e.g., central-line associated or catheter-associated) infections. This measure was included on the December 2021 Measures Under Consideration (MUC) list as part of the required pre-rulemaking process. The MAP conditioned its support for the measure on NQF endorsement following full testing of the revised measure. The AAMC agrees with the MAP assessment, that the measure must be fully tested and vetted as valid and reliable. Additionally, we believe the NQF endorsement process will also ensure that the measure is reviewed for any potential unintended consequences that might arise from reliance on algorithmic determinations.⁴⁸

Quality and Safety of Maternal Care

Establishing a Maternal Care Designation

CMS seeks feedback on a Maternal Care Designation for Hospitals to be published on the *Care Compare* website to help inform patients and communities. To begin in CY 2023, this designation is proposed to be based on the structural measure finalized in last year's rulemaking regarding participation in and implementation of practices from perinatal quality improvement collaboratives. Ideally, CMS then would expand the underlying measures for the designation as they are included in the IQR Program.

The AAMC believes there is a role for greater transparency of maternal health information on hospitals for patients and communities, but we urge CMS to ensure that the name of such a designation meaningfully represents the supporting measure data. For example, if the initial designation is based on a structural measure of hospital quality improvement practices, the initial designation name should accurately reflect that information rather than portray itself as an expansive statement of overall quality of maternal health services and outcomes. CMS should be careful to ensure that patients and communities have trust in such a designation and believe that it provides them with meaningful information.

Additionally, in acknowledging that this designation is intended to grow and develop over time, we urge CMS to be proactive to ensure that the initial version is framed with that iterative intention in mind. Many policy initiatives "calcify" on first impression and struggle to evolve to meet the broader, more expansive goals initially envisioned. Principles for this designation must

⁴⁷ See Cabitza et al., <u>Unintended Consequences of Machine Learning in Medicine</u>, JAMA Viewpoint (Aug. 2017), noting the issue of machine learning algorithms, often referred to as "black box models," where underlying rationale for the outputs is inscrutable by providers and the engineers who develop them.

⁴⁸ Ibid.

be established to support the Agency's ability to remain agile and ensure the designation's success.

Finally, CMS should commit to ensuring that such a designation has the intended impact of adding value for patients and communities and does not have unintended consequences. There is evidence of a significant decline in the number of hospitals maintaining obstetric and delivery units, especially during the pandemic, ⁴⁹ and we must be sure that such designations do not further limit and exacerbate disparities in access to such critical hospital care. Similarly, it is unclear precisely how much choice pregnant patients have when it comes to which hospital they deliver in. Hospital choice can be limited to those hospitals for which their obstetrician has admitting privileges and by their insurance coverage. It can also be limited by physical accessibility barriers and other factors related to the social determinants of health, such as transportation access. CMS should examine whether patients feel the designation is helpful to them in making choices about the hospital where they will deliver their baby.

RFI – Additional Activities to Advance Maternal Health

CMS seeks additional information on other potential policy approaches to advancing maternal health equity. These approaches could include modifications to the Conditions of Participation (CoPs) and quality reporting programs.

The AAMC agrees that maternal health equity is a critical issue facing the United States that must be addressed. The AAMC Center for Health Justice has identified maternal health as one of three key focus areas for its work.⁵⁰ The Center develops resources, convenes experts, and strengthens efforts around maternal health, with a focus on equitable partnerships with communities. The AAMC strongly believes that there must be broad support for innovative research for interventions, both within and outside of the health care system, to eliminate inequities that threaten the health and well-being of all birthing persons.

However, the AAMC also strongly believes there is a difference between maternal health care equity and maternal health equity more broadly, and that CMS efforts should focus on the former for the scope of its considerations. As discussed in the measuring disparities comments of this letter, it is critical to distinguish health care inequities as an important component of health equity, and one that is more directly within the health care system's control. Furthermore, within the realm of maternal health care equity, CMS must acknowledge the broader role of the full range of maternal care providers (e.g., physicians, certified nurse midwives, doulas, mental health providers) who provide prenatal and postpartum maternal care largely outside the hospital inpatient setting. High quality care throughout pregnancy and following delivery are important elements to good outcomes for mother and baby. Hospitals do have a critical role in improving maternal health care equity, especially for labor and delivery outcomes, but cannot be held solely responsible for implementing much needed improvements and solutions. CMS should focus hospital policy approaches on those which are in the hospital's control.

⁴⁹ *See* Dylan Scott, <u>Maternity wards are shuttering across the US during the pandemic</u>, Vox (Mar. 2022), suggesting that the closures could reduce access for pregnant patients in rural areas and for Black and Hispanic patients.

⁵⁰ *See*, AAMC Center for Health Justice, <u>Maternal Health Equity</u>.

The AAMC does not support changes to the CoPs to address maternal health care equity. CoPs are not the right vehicle, considering the significant consequences for failure to comply. CMS has other policy levers, such as its quality reporting programs, to incentivize improvements for maternal health care equity. Additionally, as previously mentioned, there is significant concern with the reduction of labor and delivery units in hospitals and impact on access to care. Additional CoPs could have the unintended impact of further reducing the hospital services available to pregnant patients and further exacerbating disparities in care.

We believe that hospitals have an important role in collaborating with patients and communities as key and equal participants in hospital-based improvements to maternal health care equity. Meaningful engagement with patients and communities served provides critical feedback and insight into how to best implement changes to improve care. Significant inequities in screening patients for mental health complications during or after pregnancy which is the largest reported type of postpartum complication⁵¹ was identified by public polling by the AAMC Center for Health Justice and is an area to consider for fostering collaboration. We believe that hospitals can work to better collaborate with the full range of maternal care providers and with patients and communities to establish best practices around patient screening and care referrals to ensure that all birthing persons receive necessary care, including mental health care. Taking the time to listen and reflect on the needs of patients and communities, as expressed by patients and communities, is a way hospitals can improve maternal health care equity.

MEDICARE PROMOTING INTEROPERABILITY (PI) PROGRAM

Proposed Changes to the Performance-Based Scoring Methodology for the EHR Reporting Period in CY 2023

CMS proposes to shift the points available per category to put greater emphasis on the Public Health and Clinical Data Exchange Objective. While the AAMC agrees that public health related EHR reporting is critically important, we urge CMS to balance increasing emphasis on public health reporting through scoring with the need for greater investments in public health departments to support improvements to reporting and data exchange. Furthermore, CMS must recognize that the COVID-19 pandemic caused hospitals to divert EHR reporting resources. Hospitals need more time to re-establish normal, post-pandemic health IT activities and to adjust to broader changes to EHR reporting as proposed, while public health departments need investment to build robust capabilities to receive and use data exchanged from hospitals.

⁵¹ See Burdette et al., <u>From Pregnancy to Policy</u>, AAMC Center for Health Justice (May 2022), finding that two-thirds (66%) of respondents reported some type of postpartum complication, with the largest share (38%) reporting postpartum depression and/or anxiety. Seven of ten respondents reported being screened for mental health complications, while 30% reported that they were not screened for or asked about depression or anxiety-related symptoms at any point during or after their pregnancy.

Proposed Changes to Query of Prescription Drug Monitoring Program (PDMP) Measure Under the Electronic Prescribing Objective

The Query of PDMP measure has been an optional measure for EHR reporting periods in 2019, 2020, 2021, and 2022 and eligible for 5 bonus points in 2019, 2020 and 2021 and 10 bonus points in 2022. Hospitals electing to report this measure report "yes" if for at least one Schedule II opioid electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH used data from CEHRT to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law. In this rule, CMS proposes in 2023 to require the reporting of the Query of PDMP measure for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program (PIP) with two exclusions. In addition, it proposes to expand the Query of PDMP measure to include Schedule III and IV drugs.

The proposed measure description would read as follows: "For at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or critical access hospital (CAH) uses data from CEHRT to conduct a query of a PDMP for prescription drug history." CMS believes it is feasible to require providers to report the current Query of PDMP measure requiring a "yes/no" response and further proposes to maintain the associated points at 10 points. CMS welcomes comment on any barriers (e.g., technology solutions, cost, and workflow) that should be considered as well as any other exclusions that should be considered for the measure.

The AAMC urges CMS to maintain the PDMP measure as voluntary and supports providing a 10-point bonus if reported, and the yes/no attestation instead of numerator/denominator for this measure. The AAMC recognizes the value of new tools to assist with the opioid addiction epidemic but cautions against making this measure required until there is better evidence of integration of these tools in CEHRT by vendors and into clinical workflows. Currently, CEHRTs do not have widespread integration of the PDMP tools. Providers often need to manually document a query of the PDMP, adding considerable burden.

Federal and private sectors initiatives are underway to improve approaches to integration of PDMPs in EHRs and to implement provisions of the SUPPORT for Patients and Communities Act. The AAMC recommends additional time for work on these initiatives and continued evaluation of the status of PDMPs in the states before making this measure mandatory.

Proposed Changes to the Public Health and Clinical Data Exchange Objective

Currently under the Public Health and Clinical Data Exchange Objective eligible hospitals and CAHs must report on four measures: Syndromic Surveillance Reporting; Immunization Registry Reporting; Electronic Case Reporting; and Electronic Reportable Laboratory Result Reporting. CMS believes those four measures will put public health agencies (PHAs) on better footing for future health threats and a long-term COVID-19 pandemic recovery by strengthening important public health functions.

Antimicrobial Use and Antimicrobial Resistance Surveillance Measure

CMS proposes a new measure regarding antimicrobial use and resistance (AUR) surveillance as a fifth required measure under the Public Health Objective beginning with the CY 2023 EHR reporting period. This measure would require the hospital to report to CMS that it successfully submitted AUR data through active engagement with the CDC's NHSN for the EHR reporting period.

The AAMC is supportive of collaboration with the CDC through the NHSN to collect data that would improve care. The AAMC shares CMS's concern with risking antimicrobial-resistant infections. We support efforts to assess the threat of antimicrobial overuse and resistance and to enable the selection and assessment of interventions aimed at optimizing antimicrobial prescribing. However, we believe that it is premature to establish this as a mandatory measure under the promoting interoperability program. Instead, CMS should consider adopting the measure as a voluntary one, worth bonus points for scoring under the Public Health Objective.

Proposed Revisions to "Active Engagement"

CMS currently has established three options to demonstrate active engagement under the Public Health and Clinical Data Exchange Objective: (1) Complete registration to submit data. (2) Test and validate electronic submission of data and (3) Complete testing and validation of the electronic submission and electronically submit production data to the PHA or clinical data registry (CDR).

CMS proposes to consolidate current options 1 and 2 into one option beginning with the EHR reporting period in CY 2023. The two options would be as follows:

- Proposed Option 1. Pre-production and Validation (a combination of current option 1 and option 2)
- Proposed Option 2. Validated Data Production (current option 3, production).

Currently, there is no requirement for eligible hospitals and CAHs to report their level of active engagement for any of the measures associated with the Public Health and Clinical Data Exchange Objective. Beginning with the EHR reporting period in CY 2023 in addition to submitting responses for the required measures and any optional measures, CMS proposes to require hospitals and CAHs to submit their level of active engagement using the two options proposed for each measure they report. In addition, CMS proposes that beginning in 2023 hospitals may spend only one EHR reporting period at the Pre-production and Validation level of active engagement per measure, and then must progress to the validated Data Production level for the next calendar year (unless the hospital switches between the clinical data registries CDRs or PHAs).

The ongoing public health emergency demonstrates the importance of collecting, analyzing, and exchanging public health data. The AAMC supports reporting to PHAs. Hospitals have increasingly engaged with PHAs to share data. Yet, PHA information technology systems are

often unable to receive data or incorporate data electronically, and these PHA systems vary widely be state. Technology needs to facilitate these reporting options and should be more consistently applicable across states and localities.

Therefore, the AAMC recommends CMS retain the three historical options for "active engagement" and not finalize its proposal to require that the hospital progress to option 2 (validated data production) after one year. We urge CMS not to require validated data production until the technology can facilitate this reporting. Also, demonstrating active engagement should be accomplished by using communications and information provided from either the hospital or the PHA. It is possible that the hospital does not receive a response from the PHA in a timely fashion and therefore should be able to rely on initial communication.

Proposed Public Reporting of Medicare PI Program Performance Data

CMS proposes to begin publicly reporting hospitals EHR reporting scores under the PI Program beginning with CY2023 reporting. The AAMC urges CMS to thoughtfully consider whether this information would be meaningful to patients and communities, and whether scoring across the four objectives would be easily understood by beneficiaries if included on the *Care Compare* website. To this end, we believe that CMS should align PI Program public reporting policy with the IQR public reporting policy,⁵² ensuring that information posted to the *Care Compare* website is only that information that which is easily understood by patients.

Request for Feedback - Patient Access to Health Information Measure

CMS is concerned about potentially low rates of patient use of portals to access their health information and believes that providers and staff may positively influence patient use of a portal. This end, CMS seeks feedback on the development and inclusion of a measure to better incentivize patient access and use of portals as a new measure for the Patient Exchange Objective.

The AAMC supports broader patient access to their own health information as partners in care, but we caution against a future measure of patient access and use of such information. Patients' use of their own health information is well beyond the control of hospitals and simply should not be used to reflect upon a hospital's use of EHR technology. We do not see how generating figures for the frequency of logins, number of messages sent, or lab results viewed will inform improved patient outcomes or validly and reliably measure hospital use of EHR technology. The most a provider can do is to make options for access available and encourage patients to use them. The PI Program should focus on elements of EHR use well within a hospital's control, and not patient choices regarding how and when they access their health information.

⁵² See 78 Fed. Reg. 50496 (2013) at 50776-77, noting that CMS may satisfy public reporting requirements for the IQR Program for "information that may not be relevant to or easily understood by beneficiaries" by making it "available on other CMS websites that are not intended to be used as an interactive web tool" such as data.cms.gov.

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Furthermore, it is unclear how a requirement for hospitals to report tracking of third-party personal health applications and APIs will provide useful data beyond the Health Information National Trends Survey (HINTS) operated by the National Cancer Institute with support from the ONC. Such tracking would add burden to hospital reporting without commensurate benefit and potentially increase inequities by prioritizing measurement of app and API use, which leaves out those who do not own or use smartphone technology.⁵³ The API and health app marketplace is still nascent, and hospitals must balance innovation with the real cybersecurity risks of new vendors in this marketplace.

CONCLUSION

Thank you for the opportunity to comment on the FY 2023 IPPS 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 mmullaney@aamc.org for questions on the payment policy proposals; Phoebe Ramsey at pramsey@aamc.org for questions on the quality proposals; and, Ivy Baer at ibaer@aamc.org and Brad Cunningham at bcunningham@aamc.org for questions about the graduate medical education proposals.

Sincerely,

Janis M. Orlowski, M.D., M.A.C.P.

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Chief Health Care Officer

cc: David J. Skorton, MD
AAMC President and CEO

Ivy Baer, JD, MPH

⁵³ See Pew Research Center, "Who owns cellphones and smartphones," (April 2021), finding that 39% of people aged 65 or older and 24% of people making less than \$30,000 do not have a smartphone.