Submitted electronically via www.regulations.gov

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June 24, 2019

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
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Re: Medicare Program: Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2020 Proposed Rule (CMS-1716-P)

Dear Administrator Verma:

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 System for Acute Care Hospitals and the Long-term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year (FY) 2020," 84 *Fed. Reg*. 19158 (May 3, 2019), issued by the Centers for Medicare & Medicaid Services (CMS or the Agency).

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members are all 154 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

The following summary reflects the comments on hospital payment and quality proposals and requests for information addressed in this letter.

- ***Chimeric Antigen Receptor (CAR) T-Cell Therapy***. For FY 2020 CMS should assign CAR T-cell therapy to Medicare Severity Diagnosis Related Group (MS-DRG) 016 and should continue the new technology add-on payment (NTAP) program. If a separate MS-DRG is

created in the future, it must include the indirect medical education (IME) and disproportionate share hospital (DSH) payment adjustments.

- ***Hospital Wage Index***. CMS should explore other ways to ensure that the data for the wage index is accurate and that those hospitals at the low end of the wage index are paid appropriately.
- ***Disproportionate Share and Uncompensated Care Payments (UCPs) (Factor 3)***. For FY2020 CMS should finalize the proposal to use a single year of FY 2015 Worksheet S-10 data to calculate uncompensated care payments. CMS should begin auditing FY 2017 Worksheet S-10 data to ensure that it is ready for FY 2021.
- ***New Technology Add-On Payments (NTAP)***. CMS should finalize the proposal to increase the NTAP to 65 percent of the additional cost of the new service or technology or 65 percent of the amount by which costs exceed the standard DRG.
- ***Peripheral Extracorporeal Membrane Oxygenation (ECMO)***. The Agency should finalize the proposal to reassign peripheral ECMO to Pre-MDC MS-DRG 003.
- ***Critical Access Hospitals (CAHs) as Nonprovider Sites for Purposes of Direct Graduate Medical Education (DGME) and Indirect Medical Education (IME)***. The Agency should finalize the inclusion of CAHs as nonprovider sites for purposes of DMGE and IME. The Agency should allow inpatient prospective payment system (IPPS) hospitals that are in cap-building periods to count the time residents spend training at CAHs provided they incurred the costs of the residents' salaries and benefits, which is the current requirement for other nonprovider sites.
- ***Urban-to-Rural Reclassification Applications and Cancellations***. CMS should finalize both the added flexibility for hospitals to apply for 42 C.F.R. 412.103 reclassifications using electronic means or fax and the cancellation requirements that would not require being paid as rural for one 12-month cost reporting period before cancelling.
- ***Quality Measure Adoption:*** Measures must be National Quality Forum (NQF)-endorsed and approved by the Measure Applications Partnership (MAP) before they are proposed for adoption in the IQR program.
- ***Electronic Clinical Quality Measure (eCQM) Reporting***: CMS should retain the current eCQM reporting requirements beyond CY 2021 reporting for both the IQR and the Promoting Interoperability Program.
- ***Long-Term Care Hospital Quality Reporting Program***: CMS should not finalize the adoption of a new race data element for the LTCH continuity assessment record and evaluation data set (LCDS) data collection due to serious flaws in its question framing.

CHIMERIC ANTIGEN RECEPTOR (CAR) T-CELL THERAPY

CAR T-cell therapy holds great promise in the treatment of life-threatening illnesses; however, these treatments can be extremely expensive and require extensive hospital care. Still, these therapies are the innovative care of the future and offer treatment advances for previously untreatable diseases. Research into CAR T-cell therapy continues to grow with CAR T-cell

therapy comprising approximately 25 percent of the 2019 oncology Next-Generation Biotherapeutics pipeline.[1] Teaching hospitals are the institutions where many patients will receive these expensive treatments as these are the institutions best-positioned to provide cutting edge care and deal with the complications (often life threatening) that are encountered as the patient goes through this course of care. Teaching hospitals share a commitment to advancing medical knowledge, therapies, and technologies to prevent disease, alleviate suffering, and improving quality of life and have the staff and resources needed to make the most advanced care available to patients.

AAMC Supports Assigning CAR T-Cell Therapy to MS-DRG 016 and Continuing the NTAP in FY 2020

The AAMC supports CMS's decision to continue assigning CAR T-cell therapy to MS-DRG 016 for FY 2020 and allowing these services to be eligible for NTAP and outlier payments. However, as we discuss in more detail below, the AAMC remains concerned that Medicare reimbursement is not keeping pace with the costs of new therapies and treatments.

CMS is proposing to continue the NTAP for CAR T-cell therapy for FY 2020. The AAMC supports this proposal, and also CMS's proposal to increase the NTAP limit to $242,450 (discussed below). However, even with the increase in the NTAP, the cost of the CAR T-cell therapy alone far exceeds Medicare's reimbursement, leaving hospitals that provide CAR T-cell therapy facing losses in the hundreds of thousands of dollars in the inpatient services that are required for this care. Such losses are unsustainable for hospitals and pose a threat to patient access for this treatment as well as other care in general. If CMS chooses to create a new MS-DRG for CAR T-cell therapy cases, it is imperative that the Agency ensure adequate reimbursement that reflects the true costs of the treatment and its associated complications. Furthermore, if new CAR T-cell therapies currently in the pipeline do not qualify for the NTAP then hospitals will face an even greater reimbursement shortfall in the coming years as these emerging therapies change the modalities used for cancer care.

All Future Payments for CAR T-Cell Therapy Must Be Adequate and Must Include IME and DSH as Required by Statute

We are encouraged by CMS's willingness to address high-cost therapies such as CAR T-cell therapy, a goal we share; however, we are concerned that CMS' standard payment methodologies are unable to accurately value very high cost technologies. Failing to adequately reimburse providers for the cost of the care will threaten beneficiary access to CAR T-cell therapy. CMS has yet to address the driver behind the high cost of these treatments – manufacturers' pricing of new therapies. In addition, these therapies often require intensive care unit stays or other intensive inpatient therapy that requires multiple medical specialist providing

[1] IQVIA. Global Oncology Trends 2019. Therapeutics, Clinical Development and Health Care Implications. Institute Report. May 30, 2019.

integrated care. Hospitals that provide CAR T-cell therapy must ensure that they have all related services available for immediate use, even if they are only required for a subset of patients.

Due to the extremely high cost of the CAR T-cell therapy process, the Medicare reimbursement that hospitals receive barely covers the costs of care leaving little for the myriad of medical services that the hospital provides when it administers this therapy. The price tags for the treatments alone approach half a million dollars – $475,000 for Kymriah™ and $373,000 for Yescarta™.[2] Analysis by Watson Policy Analysis, Inc. showed that the mean total reimbursement for CAR T-cell therapy cases, excluding clinical trials, was approximately $282,000 (including outlier payment) in 2018, significantly below the cost of the therapy.

CMS questions whether IME and DSH should be applicable if a new MS-DRG is created after FY 2020. According to the Agency, "these percentage add-on payments could arguably result in unreasonably high additional payments for CAR T-Cell therapy cases *unrelated to any significant empirical way to the costs of the hospital in providing care.*" (p. 19182, emphasis added). However, as Congress made clear when it added IME when the IPPS was originally developed in 1983, its purpose is to be "a proxy to account for a number of factors which may legitimately increase costs in teaching hospitals."[3] Even as new therapies and DRGs emerge, these costs continue to exist and must be paid on every MS-DRG. **The AAMC strongly opposes any exclusions or reductions to these or other MS-DRG add-on payment adjustments and believes that the Agency does not have the authority to impose these changes.**[4]

While Section 1886(d)(5)(I) of the Social Security Act (the Act) permits CMS to make **other** exceptions or adjustments, those adjustments would be *in addition to* the exceptions and adjustments that are specified in the statute, which include IME and DSH. The statute authority does not extend to modifying existing exceptions and adjustments both of which are mandated by the clear language of the statute. For example, Section 1886(d)(5)(B) of the Act states that the Secretary "shall provide for an additional payment amount for subsection (d) hospitals with indirect costs of medical education." The use of the word "shall" directs the Secretary to make the payment and does not leave this up to his discretion. We urge CMS not to include this proposal in future rulemaking.

Teaching Hospitals Are the Institutions Where Beneficiaries Receive CAR T-Cell Therapy; CMS Must Guarantee This Access Is Maintained by Providing Adequate Reimbursement

According to a list of Treatment Centers Authorized to Administer CAR T-Cell Therapy provided by the American Society of Clinical Oncology[5] virtually every center is a teaching hospital. This demonstrates that the only institutions currently with the resources and personnel capable of providing this treatment and managing these complex patients are located at academic

[2] Institute for Clinical and Economic Review. A look at CAR-T Therapies. March 2018. https://icer-review.org/wp-content/uploads/2018/03/ICER_CAR-T_RAAG_032318.pdf
[3] House Ways and Means Committee Rept, No. 98-25, Mar. 4, 1983; Senate Finance Committee Rept, No. 98-23, Mar. 11, 1983.
[4] Ibid.
[5] https://ascopost.com/issues/may-25-2018/treatment-centers-authorized-to-administer-car-t-cell-therapy/

institutions and thus the extra costs of providing the care will be reflected in the data. **Reducing or eliminating the IME add-on payment will harm teaching hospitals' ability to provide these critical health care services as well as the other services that the IME and DSH payments support. IME and DSH are not based on a requirement that the costs for <u>each</u> service at a teaching hospital are greater than at a non-teaching hospital, but on a recognition that <u>overall</u> the costs are greater at teaching hospitals due to numerous factors, including treating the most complex patients, the provision of trauma and burn care and other specialty resources for the community, stand by capacity and being sites of clinical education and research studies.**

Furthermore, the AAMC is concerned about beneficiary access to CAR T-cell therapy in the long-term, and whether hospitals that administer these high-cost therapies will be adequately reimbursed by Medicare. Patients receiving this therapy are admitted to the hospital and tend to be sicker due to having an advanced disease state as well as multiple complications of the therapy itself. Hospitals caring for these patients expect to have higher costs – *e.g.*, longer hospitalizations with an increased number of intensive care unit (ICU) days – due to the potential for post-infusion complications such as cytokine relapse syndrome (CRS)[6] and potentially fatal side effects such as swelling of the brain.[7] In other words, these are very resource intensive patients that require teaching hospitals for their care. Even if the patient does not experience these complications the teaching hospital must maintain the resources to intervene when needed. Furthermore, because of the finite number of hospitals currently approved to provide this treatment, there will be increased financial burden on hospitals, the vast majority of which are teaching hospitals. CMS must provide beneficiaries and providers with certainty that coverage determinations and appropriate payment will address the unsustainably high costs for these cases. In addition, the Agency must address the high prices set by the pharmaceutical companies that develop these treatments, a cost over which hospitals have no control.

Inadequate Medicare reimbursement to hospitals has the potential to jeopardize beneficiary access to CAR T-cell therapy and other high-cost therapies as institutions weigh reimbursement challenges with their ability to provide this costly care. Hospitals' Medicare margins remain low; according to the Medicare Payment Advisory Commission (MedPAC), major teaching hospitals' aggregate Medicare margin was ***<u>minus</u>*** 9.0 percent in 2017.[8] MedPAC projects that overall Medicare margins will continue to decline in 2019.[9] In other words, Medicare's reimbursement rate is much lower than the actual costs of providing care and hospitals that treat large Medicare populations, commonly teaching hospitals, are most negatively impacted. This payment disparity continues to grow wider with the introduction of newer, more costly treatments.

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[6] National Cancer Institute. CAR T Cells: Engineering Patients' Immune Cells to Treat Their Cancers. www.cancer.gov/about-cancer/treatment/research/car-t-cells.
[7] Ibid.
[8] Medicare Payment Advisory Commission. March 2019 Report to Congress. Chapter 3: Hospital Inpatient and Outpatient Services: Assessing payment adequacy and updating payments. http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch3_sec.pdf?sfvrsn=0.
[9] Ibid.

The cost for many new therapies and treatments far outweighs the Medicare reimbursement hospitals receive to cover the costs of treating these patients, exacerbating hospitals' already low Medicare margins. CAR T-cell therapy is included in the cost of the MS-DRG, in addition to the associated inpatient medical costs, meaning hospitals must pay for the CAR T-cell therapy and then seek reimbursement from Medicare for both the cell therapy and the care under the same MS-DRG. Analysis by Watson Policy Analysis of all CAR T-cell cases in the FY 2018 Medicare Provider Analysis and Review (MedPAR) data, not just those used in rate-setting, showed that the mean total charges for CAR T-cell therapy cases, excluding clinical trials, was more than $1.5 million per case. [10] This analysis included all CAR T-cell cases as opposed to just those used in rate-setting, because the cases removed in the rate-setting process are statistical outliers in the context of all MS-DRG 016 cases, but are not necessarily outliers within the context of CAR T-cell cases. To ensure beneficiary access to CAR T-cell therapy and other cutting-edge therapies that we anticipate will be available in the future, it is imperative that CMS provide adequate reimbursement to providers, including both PPS hospitals and PPS-exempt cancer hospitals.

Currently There Is Insufficient Clinical and Cost Data to Create a New MS-DRG

In the proposed rule, CMS acknowledges the need to collect more comprehensive clinical and cost data before creating a new MS-DRG for CAR T-cell therapies. CMS states it believes "it may be premature to consider creation of a new MS-DRG" for CAR T-cell cases for FY 2020. (p. 19181). The Agency also questions whether clinical trials should be excluded when developing the MS-DRG relative weights since "the absence of the drug costs on claims for cases involving clinical trial claims could have a significant impact on the relative weights." (p. 19181). We support this decision to collect additional clinical and cost data to ensure the proper relative weight for a new MS-DRG which would continue to have the IME and DSH add-ons. CMS should also consider the use of new revenue codes associated with cell/gene therapy to more accurately track usage and costs of these treatments.

If in the Future a New MS-DRG Is Created, Clinical Trial Cases Must Be Excluded from the Rate Setting Calculation

Currently, CMS includes clinical trial cases involving CAR T-cell therapy in rate setting for the assigned MS-DRG. As CMS notes in the proposed rule, "the absence of the drug costs on claims for cases involving clinical trial claims could have a significant impact on the relative weight." (p. 19181). **The Association agrees with CMS and strongly urges the Agency to not include clinical trial cases when calculating the relative weight for CAR T-cell cases.** Data analysis by Watson Policy Analysis, Inc. of FY 2018 MedPAR CAR T-cell cases used in FY 2020 rate setting revealed that there were 124 cases included in rate setting. Of these, 84 cases were clinical trial cases involving CAR T-cell therapy each with average total charges of

[10] Centers for Medicare & Medicaid Services. Medicare Provider Analysis and Review (MedPAR) FY 2018 data. https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/MEDPARLDSHospitalNational.html.

approximately $270,000. This is dramatically less than the average charge of approximately $835,000 for 40 CAR T-cell cases that were not associated with clinical trials.[11]

This disparity is likely the result of the exclusion of CAR T-cell charges from the clinical trials cases because the drug is supplied by the manufacturer free of charge for these trials and certain other costs also are paid by the clinical trial sponsor. Including the much lower average charges from clinical trials distorts the actual costs of this treatment and will severely and inappropriately reduce Medicare's reimbursement for CAR T-cell cases.

MEDICARE WAGE INDEX

The Medicare wage index was incorporated as an essential feature of IPPS when the payment system was implemented in 1983 to account for geographic variation in labor costs. The index adjusts the labor-related share of the standardized payment amounts to account for area differences in hospital wage levels relative to the national average hospital wage level. Since its inception, the wage index has undergone numerous targeted legislative and regulatory changes resulting in adjustments, special exceptions, and reforms addressing specific issues impacting the system. CMS is proposing several new changes to the Medicare wage index to address disparities between high and low wage index hospitals for FY 2020.

As noted in the proposed rule, the Medicare wage index exists to recognize differences in resource utilization across different geographic locations – different labor markets require different wages to competitively attract and maintain labor. The wage index adjusts the labor-related share of institutional payment rates for those geographic variations, which reflects the relative hospital wage level in specific geographic areas as compared to the national average. CMS states in the proposed rule that "current wage index policies create barriers to hospitals with low wage indexes from being able to increase employee compensation." (p. 19394). Despite its acknowledgement of calls for comprehensive wage index reform, CMS is proposing to address a symptom of the wage index's underlying defects – the inability of low wage hospitals to raise their wages – by modifying the wage indexes of two specific groups of hospitals.

CMS is proposing direct changes to certain hospitals' wage index values. Beginning in FY 2020, low wage index hospitals would have their wage indexes increased, while high wage index hospitals would have their wage indexes decreased to maintain budget neutrality. CMS notes in the proposed rule that this policy would provide low wage index hospitals with the opportunity to increase employee compensation over several years. **Although AAMC supports CMS's goal to address difficulties faced by low wage index hospitals, it urges CMS to tackle these issues in a more thoughtful and comprehensive manner that improves the standing of low wage index hospitals without impairing the standing of high wage index hospitals. However, if**

[11] Centers for Medicare & Medicaid Services. Medicare Provider Analysis and Review (MedPAR) FY 2018 data. https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/MEDPARLDSHospitalNational.html.

CMS finalizes this proposal, the AAMC believes that CMS is not statutorily required to apply this policy in a budget neutral manner.

AAMC Has Concerns About the Proposed Changes to Specific Quartiles of the Wage Index

CMS is proposing to increase low wage index hospitals' wage indexes with intent to provide them with an opportunity to increase employee compensation, which, if that were to occur, would then be reflected in the wage index data. The proposal would raise the wage indexes of the lowest quartile wage index hospitals by half the difference between the 25th percentile and the hospital's individual wage index. At a minimum, CMS proposes that this policy would apply each year for the next four years, beginning in FY 2020.

CMS is also proposing to reduce the wage index for high wage index hospitals to maintain budget neutrality for its proposed raises to the lowest quartile hospitals. Specifically, CMS seeks to reduce the highest quartile hospitals' wage indexes by 4.3 percent of the difference between each hospital's wage index and the 75th percentile for FY 2020. The proposal would also be effective for at least four years, but because the reduction is dependent on the yearly changes to the wage index this percentage would fluctuate for the remaining three years of implementation.

Finally, CMS proposes to implement a five-percent cap on any reductions that hospitals may face in FY 2020 as a result of the proposed wage index changes. Specifically, the cap would apply only in FY 2020 and would limit any reductions from a hospital's final FY 2019 to its FY 2020 wage index values to five percent. The cap applies to all wage index proposals, including the rural floor wage index policy. Due to the cap, a budget neutrality adjustment will be applied to all standardized rates; in other words, all hospitals will pay for this proposal.

Proposal to Raise Low Wage Index Hospitals Does Not Address the Underlying Issues of Wage Index Disparities

While recognizing the problems that the current wage index system causes for low wage index hospitals, the AAMC believes that CMS's proposal improperly and fundamentally disrupts IPPS and runs contrary to the purpose of the wage index by implementing targeted raises for one quartile of the wage index at the expense of another quartile. The wage index is meant to reflect area wages, which acknowledges that some hospitals pay higher or lower wages to remain competitive in their labor market compared to the national average. Reducing a select quartile of hospitals' wage indexes artificially to create an opportunity for another quartile of hospitals to raise wages means that the wage indexes of impacted hospitals do not actually reflect the relative hospital wage levels in their geographic areas.

Ultimately, the wage index values for one group of hospitals should not be adjusted to address the needs of another group of hospitals. CMS should address concerns of the low wage index market to better align their ability to find and retain skilled employees. The underlying purpose of the wage index is that it should reflect area wages, including those of hospitals that operate in more competitive markets. **The AAMC also questions CMS's authority to make this change through regulation and, in particular, believes that the statute does not require such**

changes to be budget neutral. Therefore, the AAMC encourages CMS to work with stakeholders, including Congress, to identify a way to address the flaws in the current wage index.

It is troubling that CMS has addressed the superficial consequences of the wage index's flaws without addressing its foundational issues. CMS acknowledges that there are fundamental issues in the wage index but notes that it "does not need to wait for comprehensive wage index reform" to address these disparities. (p. 19395). However, there have been few indications that comprehensive legislative reform is imminent, and CMS has not addressed any of these issues in this year's wage index proposals. The AAMC does not believe that CMS's proposal will attain the Agency's overarching goal to accurately represent the geographic differences in the cost of labor through the wage index.

The AAMC Questions CMS's Authority to Implement These Wage Index Policies

The wage index proposals exceed CMS's authority under Sections 1886(d)(3)(E) and (d)(5)(I) of the Act. In addition to concerns regarding the specific details of the FY 2020 wage index proposals, AAMC believes that CMS has broadly and inappropriately interpreted its authority to artificially raise the wage index values of the bottom quartile hospitals at the expense of the top quartile hospitals. Under 1886(d)(3)(E) of the Act, CMS has the authority to:

> [A]djust the proportion...of hospitals' costs which are attributable to wages and wage-related costs, of the DRG prospective payment rates computed under subparagraph (D) for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level.[12]

The wage index proposals, which raise only the bottom quartile hospitals' wage indexes and reduce only the top quartile hospitals' wage indexes, do not reflect the "relative hospital wage levels" for half of the IPPS hospitals. AAMC believes that the CMS proposal ignores the requirement that the adjustment factor must reflect the relative hospital wage level in its geographic area compared to the national average hospital wage level. As a result, CMS has exceeded the statutory authority it is afforded by Congress through these wage index proposals. Additionally, finalizing this major proposal allows CMS to override a result that is mandated in statute.

Should CMS Finalize the Proposal, Limit the Duration of the Wage Index Proposals

AAMC is also concerned that the proposed policies lack a clear duration. As CMS notes in the proposed rule, the policy would be effective for "***at least*** 4 years… in order to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index." (p. 19395, emphasis added). CMS acknowledges that after four years of implementation "additional time may be necessary" and they "intend to revisit the issue of the

[12] Social Security Act § 1886 (d)(3)(E).

duration of the policy in future rulemaking." (p. 19395) If the proposal is finalized, AAMC urges CMS to limit its duration to four years or less. While it is possible the proposal's aims would be fully reflected in the wage index by year four, it is also likely that changes to employee compensation may not be reflected due to a variety of reasons (*e.g*. hospitals are not actually raising wages with their additional payments or hospitals chose to gradually raise wages). If, at the end of four years, there is no evidence that wages have been raised, then it is incumbent on CMS to determine the reason underlying that result rather than continuing a flawed policy.

Do Not Exclude Hospitals from the Wage Index

In the proposed rule, CMS identified and excluded data from 81 providers with aberrant data for FY 2020, including eight hospitals from a health care delivery system with union-represented wages. AAMC urges CMS to include these excluded hospitals in the FY 2020 wage index calculation and in this and future rulemaking. The negotiated salaries of these hospitals are also a factor of a competitive labor market and do not reflect aberrations in the market data.

Address Issues Created by the Repeal of the Imputed Rural Floor

CMS repealed the imputed rural floor in FY 2019,[13] a temporary solution to address an anomaly in the wage index for three all-urban states: Rhode Island, New Jersey, and Delaware. These states do not have a rural floor and therefore lack the protection for hospitals located outside of predominant labor markets that the rural floor is intended to provide. The imputed rural floor provided a temporary solution to address these disparities since FY 2005. Because CMS repealed the imputed floor and did not address the unique disparities facing hospitals in these states in its FY 2020 proposals, AAMC encourages CMS to reestablish the imputed rural floor until it addresses these issues in a more permanent manner.

MEDICARE DISPROPORTIONATE SHARE AND UNCOMPENSATED CARE PAYMENTS (UCPS)

Finalize Proposal to Use a Single Year (FY 2015) of Audited Worksheet S-10 Data to Calculate Uncompensated Care Payments for FY 2020, Begin Auditing FY 2017 Worksheet S-10 Data for Use in FY 2021

In FY 2018, CMS began incorporating Worksheet S-10 data in its Factor 3 calculation of the UCP methodology after concluding that Worksheet S-10 data was a "better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured" than available alternatives. (82 *Fed. Reg.* 38212). CMS proceeded to incorporate Worksheet S-10 data gradually, phasing it in over three years. However, in response to comments by AAMC and other stakeholders from prior rulemaking, CMS began auditing FY 2015 Worksheet S-10 data for accuracy and consistency in Fall 2018 for selected hospitals.

CMS is proposing to use a single year (FY 2015) of audited Worksheet S-10 data to calculate UCPs for FY 2020. CMS cites concerns that "mixing audited and unaudited data...could

[13] 83 *Fed. Reg.* 41377.

potentially lead to a less smooth result," counter to its original justification to use three years of Worksheet S-10 data. (p. 19418). Moreover, CMS is also soliciting feedback on whether a single year of FY 2017 Worksheet S-10 data would be a more appropriate data source than FY 2015. Although FY 2017 Worksheet S-10 data is unaudited, it is the first to reflect revised reporting instructions, which CMS believes resulted in "improved relative consistency and accuracy across hospitals" in reporting uncompensated care costs. (p. 19419).

AAMC supports CMS's proposal to use a single year of audited FY 2015 Worksheet S-10 data for calculation of the UCP payment for FY 2020. AAMC has commented in recent years that CMS should both establish a full audit process for Worksheet S-10 data to best ensure the data's accuracy and consistency, as well as clarify the reporting instructions for Worksheet S-10. AAMC appreciates that FY 2017 data reflects the clarified instructions but maintains that audited data is the best option to ensure accuracy and consistency in calculating UCPs.

AAMC also urges CMS to skip FY 2016 and begin auditing FY 2017 Worksheet S-10 data for potential use in FY 2021, ensuring data is as accurate and consistent as possible. Although FY 2015 Worksheet S-10 data is preferable for FY 2020, AAMC believes that Worksheet S-10 data should be **both** audited and reflect clarified reporting instructions as soon as practicable. Given that FY 2017 Worksheet S-10 data is the first year of data to reflect the revised reporting instructions, CMS should audit these data before the FY 2021 cost reporting period to ensure that the UCP data source is as accurate and consistent as possible. CMS should not consider auditing FY 2016 Worksheet S-10 data. As noted in the proposed rule, reporting instructions for FY 2016 Worksheet S-10 data were "similar to the reporting instructions for the FY 2015 reports." (p. 19419). Auditing FY 2016 Worksheet S-10 data would result in the same issues that CMS seeks comment on in this year's proposed rule. For this reason, FY 2017 Worksheet S-10 data is the first single year of available Worksheet S-10 data that would also reflect the clarified reporting instructions. In order to maximize the accuracy and consistency of Worksheet S-10 data, CMS should skip FY 2016, begin auditing FY 2017 Worksheet S-10 data as soon as possible, and plan to use the audited FY 2017 Worksheet S-10 data in FY 2021.

Finally, AAMC requests that CMS clarify whether the proposal to move to a single year of Worksheet S-10 data is a permanent decision. It is unclear whether CMS's proposal to use a single year of Worksheet S-10 data in FY 2020 is intended to be a permanent change from its original intent to use three years of Worksheet S-10 data. CMS's primary justification for using a single year of data reflects concerns of "mixing audited and unaudited data" over three years, but this reason will be rendered obsolete once the Agency has audited three years of Worksheet S-10 data. (p. 19419).

Recommendations for Future Worksheet S-10 Audit Practices

The AAMC commends CMS's ongoing efforts to audit existing S-10 data. However, the Association has received ongoing member feedback identifying inherent issues with the FY 2015 Worksheet S-10 audits. Notably, members identified their Medicare Administrative Contractor's (MAC's) incomplete understanding of the charity care processes, inconsistency handling errors

found during sampling, large extrapolations dependent on the sampling interval size, and the limitations of having only one MAC auditing bad debts. The AAMC urges CMS to ensure the MACs are better equipped to address the issues our members have identified. To address these issues, the AAMC recommends that CMS improve its Worksheet S-10 auditing process by establishing a standardized process across auditors, targeting particular information for audit, developing a transparent timeframe for audits, establishing a process for timely appeals, and considering approaches to audit all hospitals over time.

Use FY 2014 Data for Hospitals with Aberrant Uncompensated Care Data

CMS proposes that if a hospital's uncompensated care costs are an extremely high ratio relative to its total operating costs and the hospital cannot justify the reported amount, then the Agency would determine the ratio of uncompensated care costs to the hospital's total operating costs from another available cost report. The ratio would then be applied "to the total operating expenses for the potentially aberrant fiscal year to determine an adjusted amount of uncompensated care costs." (p. 19421). Specifically, for FY 2020, if CMS finalizes the use of FY 2015 Worksheet S-10 data it proposes to use FY 2016 data to calculate the ratio. If CMS finalizes its alternative proposal to use FY 2017 Worksheet S-10 data, it proposes to use FY 2015 Worksheet S-10 data to calculate the ratio.

If CMS finalizes its proposal to use FY 2015 Worksheet S-10 data to calculate uncompensated care costs, the AAMC urges CMS to use FY 2014 data for the ratio calculation to address aberrant uncompensated care costs. AAMC believes that FY 2014 is a better alternative because it has been utilized in previous cost reporting years.

NEW TECHNOLOGY ADD-ON PAYMENT (NTAP)

AAMC Supports Finalizing the Proposed Change to the Calculation of the Inpatient NTAP

CMS makes an add-on payment for a new medical service or technology if the estimated costs incurred by discharges involving the new service or technology is inadequate. The current add-on payment is limited to 50 percent of the additional cost of the new service or technology or 50 percent of the amount by which costs exceed the standard MS-DRG. Unless the discharge qualifies for an outlier payment, the additional Medicare payment is limited to the full MS-DRG payment plus 50 percent of the estimated costs of the new technology or medical service.

In the proposed rule, CMS states that it agrees with previous stakeholder feedback that in some cases the current 50 percent cap on add-on payment no longer provides "sufficient incentive for the use of the new technology" (p. 19373). Therefore, CMS is proposing to increase the NTAP to 65 percent of the costs of the new medical service or technology or 65 percent of the amount by which the costs of the case exceed the standard MS-DRG payment beginning October 1, 2019. **The AAMC supports CMS's proposal to raise the NTAP in order to ensure adequate payment for new high-cost services and technologies.**

PERIPHERAL EXTRACORPOREAL MEMBRANE OXYGENATION (ECMO)

AAMC Supports the Re-Assignment of Peripheral ECMO

In the FY 2019 IPPS final rule, CMS finalized the policy to assign new procedure codes for peripheral ECMO procedures to the same MS-DRG as the predecessor code for open (central) ECMO in pre-MCD MS-DRG 003. CMS clinical advisors did not agree peripheral ECMO should be designated as an operating room (O.R.) procedure as they considered these procedures to be less resource intensive when compared with open ECMO procedures.

This change resulted in a significant decrease in Medicare's reimbursement to hospitals that provide this life-saving treatment. Patients – both adult and pediatric – who require treatment with ECMO are critically ill and, without treatment, will likely not survive. The cost and complexity of care provided to these critically ill patients is unrelated to the method of cannulation. CMS must ensure that payment for these services is adequate.

In response to stakeholder feedback, in this proposed rule CMS is proposing to reassign procedure codes – ICD-10-PCS codes 5A1522G and 5A1522H – describing peripheral ECMO procedures to Pre-MDC MS-DRG 003 (ECMO or Tracheostomy with Mechanical Ventilation >96 hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedure). **The AAMC supports this proposal and urges CMS to finalize it in the IPPS final rule.**

CRITICAL ACCESS HOSPITALS (CAHS) AS NONPROVIDER SITES FOR PURPOSES OF DGME AND IME PAYMENT CALCULATIONS

Finalize Proposal to Include CAHs as Nonprovider Sites

Currently, IPPS hospitals that incur residents' salaries and fringe benefits (among other requirements) are able to claim the time that full-time equivalent (FTE) residents spend training at nonprovider sites for both DGME and IME purposes.[14] To date, CAHs have been considered providers for all purposes. Therefore, if a teaching hospital rotated residents to the CAH it could not count the time those residents spent training there. Many CAHs are unable to support residency training programs. "In order to support the training of residents in rural and underserved areas", (p.19448) CMS is proposing to permit IPPS hospitals to count the time residents spend training at CAHs, so long as the nonprovider site requirements are met. **AAMC strongly supports the added flexibility to count time residents spend training at CAHs and urges CMS to finalize the proposal.**

The Association believes this proposal would expand clinical rotation opportunities to sites of care that cannot alone bear the costs associated with starting and maintaining approved residency programs. As CMS notes in the proposed rule, excluding CAHs from its current policy has "hinder[ed] collaborative efforts between hospitals and CAHs" and "create[ed] barriers to training residents in rural areas." (p. 19447). This proposal would allow IPPS hospitals that are

[14] 42 C.F.R. §§ 412.105(f)(1)(ii)(E) and 413.78(g)

under their residency caps greater flexibility in offering residents a broad array of clinical rotations in approved residency training programs, including in rural areas. AAMC emphasizes that this change not only provides resident physicians with diverse clinical exposure but expands access to care in rural and underserved areas and raises opportunities for CAHs to recruit and retain physicians in those areas. While AAMC appreciates this proposed change, it will not help the many teaching hospitals that have resident counts above their 1996 resident counts and still choose to rotate residents to CAHs and other sites. We urge CMS to support bipartisan legislation, the Resident Physician Shortage Reduction Act of 2019 (S. 348/ H.R. 1763), which will provide moderate increases to these caps.

Allow Flexibility for IPPS Teaching Hospitals Within Their Cap-Building Period to Count All Residents for Cap-Calculation Purposes

AAMC also encourages CMS to allow IPPS teaching hospitals that are currently within their cap-building period to count the time residents previously spent training at CAHs at any point during their cap-building period. This would apply for cap-calculation purposes only and would not require CMS to reopen previous years' cost reports. There are many teaching hospitals that are several years into, or at the end of, their cap-building period that have struggled to accommodate rotations to CAHs as a result of this restriction. Permitting these hospitals to count FTEs that would have otherwise been counted toward their cap development under the proposed policy would allow for additional training in rural and underserved areas each year.

URBAN-TO-RURAL RECLASSIFICATION APPLICATIONS AND CANCELLATIONS

Finalize the Changes to Applications and Cancellations for 42 C.F.R. 412.103 Urban-to-Rural Reclassifications

Under current CMS policy, urban hospitals that wish to reclassify as rural under 42 C.F.R. 412.103 must mail their applications to the appropriate CMS Regional Office (RO). In addition to mailing applications, CMS is proposing to allow hospitals to submit applications electronically or by fax to the appropriate CMS RO.

CMS is also proposing to change the requirements for cancelling an urban-to-rural reclassification under 42 C.F.R. 412.103. Currently, cancellations by hospitals that have reclassified as rural referral centers (RRCs) are not effective until they have "been paid as rural for at least one 12-month cost reporting period, and not until the beginning of the Federal fiscal year following both the request for cancellation and the 12-moth cost reporting period." (p. 19388). CMS proposes to remove the 12-month requirement and instead apply uniform cancellation requirements that would allow hospitals to cancel reclassifications 120 days before the end of the Federal FY. **The AAMC supports these proposed changes to 42 C.F.R. 412.103 reclassification applications and cancellations and urges CMS to finalize both proposals.**

HOSPITAL QUALITY PROGRAMS

The AAMC Supports Expanded Confidential Reporting of Stratified Data to Account for Social Risk Factors

The AAMC supports the efforts by CMS to better account for, and improve understanding of, sociodemographic status (SDS) factors in hospital quality measurement, and to help hospitals implement targeted improvement efforts to reduce disparities in the quality of care. These efforts currently include providing confidential reporting to hospitals on performance on the pneumonia (PN) readmissions measure using two disparity methods. CMS proposes to expand this confidential reporting in CY 2020 to include stratified readmission rates for the remaining measures used in the Hospital Readmission Reduction Program (HRRP): Acute Myocardial Infarction (AMI), Coronary Artery Bypass Grafting (CABG), Chronic Obstructive Pulmonary Disease (COPD), Heart Failure (HF), and Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (THA/TKA). AAMC believes that continuing penalties while these factors are being explored is inappropriate and withdraws needed dollars for hospitals caring for the most disadvantaged.

The AAMC believes confidential reporting to hospitals is useful and supports the expansion of such reporting. While this data is valuable to hospitals, **the AAMC believes that hospitals must have sufficient opportunity to review and understand stratified performance on these measures.** The AAMC appreciates that CMS has restated its intention to remain engaged with hospitals and stakeholders about their experiences and recommendations for the stratification of measure data and to ensure the reliability of such data before any future proposal to publicly report it. The Association encourages CMS to continue to partner with stakeholders to ensure that stratified performance data is accurate and understandable to patients before it is made public.

Adopting Formal Measure Removal Criteria for the Hospital Readmission Reduction and Hospital-Acquired Condition Reduction Programs Provides Clarity to Stakeholders

The AAMC is supportive of CMS's efforts to add clarity to its process when considering measure removals in future rulemaking. The eight factors currently in use for the Hospital Inpatient and Outpatient Quality Reporting Programs and the Hospital Value-Based Purchasing (VBP) Program proposed for adoption in the Hospital Readmissions Reduction Program (HRRP) and the Hospital-Acquired Condition Reduction Program (HACRP) are well-established and ensure that a variety of valid reasons to remove a measure should be considered by CMS.

HOSPITAL READMISSION REDUCTION PROGRAM

For HRRP payment adjustment purposes, CMS is proposing to modify the definition of dual eligible for patients who die in the month of discharge. For those patients, CMS proposes to use

the previous month's data source to determine dual eligible status, beginning with FY 2021. Otherwise, CMS will retain its definition to identify dual eligibility based on full benefit status in the State Medicare Modernization Act (MMA) files for the month the beneficiary was discharged. This minor revision to the definition is intended to avoid undercounting, and CMS notes that the proposed change will not have a "substantive impact." In order to make such nonsubstantive modifications to payment adjustment factor components in the future, CMS also proposes to adopt a subregulatory process for such nonsubstantive changes, similar to the process the agency uses to make nonsubstantive changes to quality measures in the program.

CMS Should Modify the Definition of Dual-Eligible to Avoid Undercounting of Dual Status in Addition to Accounting for SDS Factors in Measure-Level Risk Adjustment Models.

The AAMC supports the change to the definition of dual eligible to ensure the most accurate counting of dual eligibility status for the purposes of stratifying penalties under the HRRP. Stratifying performance by the hospital's number of dual-eligible Medicare patients is an important first step towards accounting for SDS factors in hospital quality measurement and must be accurate. However, the move towards peer grouping by dual eligibility in the HRRP does not address the serious flaws in the risk adjustment methodology for the readmissions and other outcomes measures that are influenced by SDS factors beyond the hospital's control. The penalty adjustments implemented result only in slightly reduced penalties for those hospitals most in need of resources to treat underserved and complex patient populations. **The AAMC continues to believe that stratifying by dual-eligibility is a temporary solution, and strongly recommends that CMS take steps to ensure that individual measures account for SDS in the measure-level risk adjustment model. AAMC believes that continuing penalties while these factors are being investigated is inappropriate and withdraws needed dollars for hospital caring for the most disadvantaged.**

AAMC Supports Adoption of a Subregulatory Process for Nonsubstantive Changes to HRRP Payment Adjustment Factor Components, But Urges CMS to be Judicious in its Use

While supportive of CMS's proposal to adopt a subregulatory process for nonsubstantive changes to the payment adjustment factor components, the AAMC asks CMS to provide greater clarity on how it would determine whether a potential change is "nonsubstantive" and thus subject to the subregulatory process. Additionally, and in light of the recent Supreme Court decision in Azar v. Allina Health Services,[15] **if a potential change could be considered in any way a substantive one, CMS should use notice and comment rulemaking** to ensure that the agency is appropriately informed of public views on the matter.

[15] Azar v. Allina Health Services, No. 17-1484 (U.S. Jun. 3, 2019)

HOSPITAL INPATIENT QUALITY REPORTING PROGRAM (IQR)

CMS is proposing to adopt three new measures for the IQR program: two opioid-related eCQMs and the Hybrid Hospital Wide Readmission (HWR) Measure with claims and electronic health record (EHR) data. The Hybrid HWR measure is intended to replace the claims-only HWR measure currently in use, which CMS proposes to remove if it finalizes the adoption of the hybrid measure. CMS also seeks feedback on three potential future measures for inclusion in the program and proposes eCQM reporting requirements for CY 2020 and CY 2021 reporting.

Hospital quality measures are typically reported through the IQR program and publicly reported on the *Hospital Compare* website before they are included in the hospital performance and penalty programs and should therefore meet a certain standard. **These measures, with very few exceptions, should be National Quality Forum (NQF)-endorsed and approved by the Measure Applications Partnership (MAP) before they are proposed for adoption in the IQR program**. Finally, considering CMS's Meaningful Measures framework, any new measures should be evaluated within that framework and appropriate corresponding measure removals should be considered to balance a measure's addition.

Individual Measure Comment: Safe Use of Opioids – Concurrent Prescribing eCQM

The AAMC appreciates the efforts to halt the growing opioid crisis. Our member hospitals have participated both in our education programs, research and patient care to make an impact on this crisis. We also agree that quality measurement is potentially one tool towards that end. **The Association supports the adoption of the Safe Use of Opioids – Concurrent Prescribing measure as an optional eCQM that a hospital may select to report beginning in CY 2021, but we do not support CMS's proposal to make the measure mandatory beginning with CY 2022 reporting.** While the AAMC supports the adoption of the measure for the program, due to its potential to assist hospitals in providing information on high-risk prescribing, we remain concerned that hospitals should have more time to voluntarily report the measure (and receive feedback based upon that reporting) before the measure is made mandatory. Accurate eCQM reporting depends on hospitals using the correct version of specifications, which is generally in the control of the EHR vendors, not the hospitals.

Individual Measure Comment: Hospital Harm – Opioid-Related Adverse Events eCQM

The AAMC is supportive of measure concepts that assess the critical patient safety issues surrounding opioid use but has significant concerns about the opioid-related adverse events eCQM. We urge CMS not to add this measure, even as a self-selected eCQM, until the measure is fully vetted and endorsed by the NQF due to concerns of potential unintended consequences and the lack of risk adjustment.

Regarding unintended consequences, including all uses of naloxone outside of the operating room in the numerator may discourage appropriate treatment. For example, in cases of an adverse respiratory event after the administration of opioids current medical guidelines include the immediate use of naloxone without waiting to determine if other abnormalities such as low blood sugar are ultimately determined to have caused the event. The inclusion of all uses of naloxone places a potential chilling effect on the standard guidelines and might incentivize the avoidance of naloxone in favor of a more invasive treatment option such as intubation or delay in care as other options are considered and eliminated. In addition, the use of naloxone is a standard treatment in hospitalized patients with a change in mental status even where opioids are not the cause of the change in status. Implementing the use of naloxone as an indicator may reshape currently accepted clinical practice inappropriately. CMS should always be careful that its requirements do not interfere with or negatively impact current practice guidelines without clear demonstration of the effectiveness of these new practices. We question whether placing a quality metric on an antidote's use is the appropriate leverage to use for improved opioid care. Certain cases of the administration of naloxone should be removed from the measure to prevent the unintended consequence of more invasive care in response to this measure.

Additionally, this measure lacks appropriate risk adjustment for consideration of opioid sensitivity. Physicians should be able to take clinical risk factors into account for the appropriate administration of opioids, and the measure should be designed to balance measurement of rare harm events with adequate pain control.

Individual Measure Comment: Hybrid Hospital-Wide Readmission (HWR) Measure to Replace the Claims-Only Hospital-Wide Readmission Measure

The AAMC supports the removal of the claims-only HWR measure beginning with FY 2026 payment determinations. We have long held concerns that claims-based risk adjustment using HCC data is unlikely to adequately account for appropriate clinical and social risk factors and does not broadly capture the patient's health status. Hospitals that disproportionately care for vulnerable patient populations are disadvantaged when SDS factors are not considered in the risk adjustment or scoring methodology.

While the hybrid measure raises concerns about the challenges of extracting EHR data and EHR fragmentation, we believe that integrating EHR data with claims data is a positive step towards improvements to risk adjustment. The AAMC also appreciates that CMS is proposing the hybrid HWR initially as a voluntary measure to allow hospitals to become comfortable submitting this data before it is publicly reported or used for payment purposes. CMS should use the additional voluntary reporting periods to address any EHR extraction and submission issues. That being said, the AAMC recommends that the Agency focus its efforts on adjusting condition-specific measures that are currently being used in the Medicare readmissions penalty program. The Agency should also take steps to test the feasibility of using non-clinical EHR-derived elements, such as education, location, and other factors, to develop appropriate SDS adjustments.

Request for Feedback: Future Adoption of Hospital Harm- Pressure Injury Measure in the IQR

The Hospital MAP conditionally supported the pressure injury eCQM (MUC18-107) pending NQF review and endorsement once the measure is fully tested. The AAMC believes that pressure injuries are important to measure and can reduce patient harm and agrees with the MAP that the measure should be vetted further before its inclusion in Medicare quality reporting programs. Specifically, CMS should complete testing and submit the measure for NQF endorsement, with a recommendation that the NQF Disparities Committee review and provide input on adjusting for social risk factors. The AAMC is concerned that implementation of the measure without appropriate risk adjustment is likely to disproportionately impact academic medical centers and safety net providers that treat more complex patients. The AAMC agrees with the MAP's suggestion that the measure exclude patients with certain conditions or undergoing certain types of treatments that may not be appropriate to receive the evidence-based pressure injury reducing interventions (e.g., ECMO). The AAMC asks CMS to consider whether the measure should be further modified prior to its use in CMS programs to capture other risk factors outside the control of the hospital that predispose a patient to a pressure injury.

Request for Feedback: Future Adoption of Hospital Harm- Severe Hypoglycemia Measure in the IQR

The AAMC agrees that it is important to develop measures that focus on reducing the most common adverse drug events and that hospitals should implement protocols to manage hypoglycemia for critically ill patients. That said, we agree with the MAP that this measure must be fully tested and vetted through the NQF endorsement process.

Furthermore, administering an anti-hyperglycemic agent is the standard of care to lower the glucose for a patient that is hyperglycemic. A measure to incentivize management of hypoglycemia should not have the indirect potential to cause second guessing of that standard of care. Instead, it should incent care workflows to ensure that there is appropriate glucose monitoring after the administration of the anti-hyperglycemic agent. We echo the MAP recommendation that the measure, if implemented, should be continuously assessed to monitor for whether the low blood glucose threshold (less than 40 mg/dL) and time interval (5 minutes between tests) lead to unintended consequences.

Request for Feedback: Future Adoption of Cesarean Birth eCQM in the IQR

The MAP conditionally supported the Cesarean Birth (MUC18-52) eCQM for rulemaking. While the AAMC agrees with the importance of reducing early unnecessary deliveries and improving maternal health outcomes, we do not support this measure as currently specified. This is due to concerns about the failure to exclude high-risk conditions such as pre-eclampsia/eclampsia from the measurement population and potential unintended consequences

of increased maternal mortality in states that use the chart-abstracted version of the measure. The MAP also discussed concerns with the data collection process for this measure, cautioning that inclusion of a measure before the data collection process is ready may have the unintended consequence of stalling the improvement of data quality. CMS should ensure that feasibility testing of this measure demonstrates that data are readily available and can be captured form the EHR without undue burden.

AAMC Encourages CMS to Retain the Current eCQM Reporting Requirements Beyond CY 2021 for Both the IQR Program and the Promoting Interoperability Program

CMS has previously finalized a requirement that hospitals must submit a minimum of four self-selected eCQMs over a minimum of one self-selected calendar year quarter (continuous 90-day period) for CYs 2017 through CY 2020 (FYs 2019 through 2022 payment determinations). The Agency is proposing to continue this policy for CY 2021 and modify that policy for CY 2022 reporting (FY 2023 and FY 2024 payment determinations). The modification CMS proposes for CY 2022 is to make one eCQM mandatory, the proposed Safe Use of Opioids – Concurrent Prescribing measure, in addition to three self-selected eCQMs over a minimum of one self-selected quarter.

The AAMC appreciates CMS's recognition and response to the challenges regarding feasibility of electronically submitted measures. **Maintaining the reduced reporting burden through CY 2021 would provide consistency and predictability while allowing hospitals the additional time and bandwidth to address the considerable challenges of electronic data reporting. Additionally, the AAMC urges CMS not to finalize its proposal to make the Safe Use of Opioids measure mandatory to report in CY 2022.** The measure is proposed for addition to the list of the eCQMs for which a hospital may elect to report in CY 2021, essentially leaving only one year to "test" reporting the measure before it is made mandatory.

While the AAMC supports the adoption of the measure for the program, due to its potential to assist hospitals in providing information on high-risk prescribing, we remain concerned that hospitals should have more time to voluntarily report the measure (and receive feedback based upon that reporting) before the measure is made mandatory. Accurate eCQM reporting depends on hospitals using the correct version of specifications, which is generally in the control of the EHR vendors, not the hospitals. **The AAMC urges CMS to continue outreach to EHR vendors, hospital quality staff, and other affected stakeholders to identify underlying structural problems and barriers to successful reporting of these measures.** We remain concerned that hospitals and vendors may not be adequately prepared to fully report eCQMs, especially new eCQMs only recently adopted by CMS.

MEDICARE AND MEDICAID PROMOTING INTEROPERABILITY PROGRAMS

CMS is proposing the same eCQM reporting requirements for CY 2021 and CY 2022 reporting as for the IQR, including the adoption of the two opioid-related eCQMs. Additionally, CMS is proposing to remove the Verify Opioid Treatment Agreement measure effective for CY 2020 and to modify the Query of the Prescription Drug Monitoring Program (PDMP) measure, retaining that measure as a bonus measure for one additional year and restructuring the measure to a "yes/no" measure instead of one scored upon a numerator/denominator. Please refer to the AAMC's full comments in support of the continuation of current eCQM reporting requirements and the adoption of the Safe Use of Opioids measure as an optional eCQM and in opposition to the adoption of the Opioid-Related Adverse Events measure in our comments above to the same proposals for the IQR program.

AAMC Supports Removal of the Verification of Treatment Agreement Measure

The AAMC recommends that CMS finalize its proposal to remove the Verify Opioid Treatment Agreement measure. We agree with other stakeholders that the lack of clarity around definition and standards created an undue burden and results in a measure that provides little clinical value to providers and patients. We appreciate CMS's acknowledgement of stakeholder feedback on the measure in proposing to remove this measure beginning with CY 2020.

CMS Should Finalize Modifications to the PDMP Measure

The AAMC supports the proposed modification to the PDMP measure and retaining the measure as a bonus measure for an additional year. We appreciate CMS's acknowledgement of the burden by proposing to modify the measure to a "yes/no" attestation measure in response to the unnecessary added process of developing custom reports to manually track queries of the PDMP outside of the EHR (due to the lack of PDMP integration into CEHRT). This modification is especially timely considering the recently released "Pain Management Best Practices Inter-Agency Task Force Report" that recommends providers not repeatedly check the PDMP if it was already performed on admission and pending discharge.[16] By moving to a yes/no structure, hospitals can follow this recommendation and attest to appropriate PDMP query use with CEHRT, without worrying about measurement of each query or incentivizing over-querying. We agree that this measure may be effective in helping to combat the opioid epidemic and believe it should remain in the Promoting Interoperability Program as modified, as a step towards bridging the measure with future innovations that may help improve PDMPs.

[16] *See* United States Department of Health and Human Resources, "Pain Management Best Practices Inter-Agency Task Force Report." (May 9, 2019) Recommendation 1D on page 55. Available at: https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf (last visited June 11, 2019).

LONG-TERM CARE HOSPITAL QUALITY REPORTING PROGRAM (LTCH QRP)

CMS is proposing several new Standardized Patient Assessment Data Elements (SPADEs) for LTCH quality reporting to collect data on social determinants of health using existing PAC data collection mechanisms to meet the requirements of the IMPACT Act to assess adjustments to quality and resource use measures to reflect social risk factors. The proposed Race data element asks, "What is your race?" with CMS proposing to include fourteen response options under race: (1) White; (2) Black or African American; (3) American Indian or Alaska Native; (4) Asian Indian; (5) Chinese; (6) Filipino; (7) Japanese; (8) Korean; (9) Vietnamese; (10) Other Asian; (11) Native Hawaiian; (12) Guamanian or Chamorro; (13) Samoan; and, (14) Other Pacific Islander.

CMS Should Not Finalize the Adoption of a New Race Data Element for LTCH Continuity Assessment Record and Evaluation Data Set (LCDS) Data Collection Due to Serious Flaws in its Question Framing

The AAMC supports gathering accurate, standardized information on patient race, but the proposed question is not a good vehicle for doing so. The proposed question is not consistent with the Office of Management and Budget (OMB) Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity.[17] Specifically, OMB does not include "Guamanian" or "Filipino" as racial categories. Instead, OMB has set the standard two-question format with the minimum designations as: "Race: (1) American Indian or Alaska Native; (2) Asian; (3) Black or African American; (4) Native Hawaiian or Other Pacific Islander; and (5) White and Ethnicity: (1) Hispanic or Latino or (2) Not Hispanic or Latino."[18] A high level principle from those standards is that "[a]ny changes in the categories should be based on sound methodological research and should include evaluations of the impact of any changes not only on the usefulness of the resulting data but also on the comparability of any new categories with the existing ones."[19] CMS does not provide an evaluation of impact to support its proposed changes to the minimum categories for race demonstrating that the proposed change is outside the bounds of OMB's standards.

Furthermore, the proposed question is not consistent with the 2009 Institute of Medicine (IOM) report on Standardized Collection of Data on Race, Ethnicity, and Language, which recommends collection of existing OMB race and Hispanic ethnicity categories in addition to more granular data on ethnicity.[20] **We are concerned that the question as proposed may interfere with successful ongoing efforts to collect data in standardized ways consistent with that**

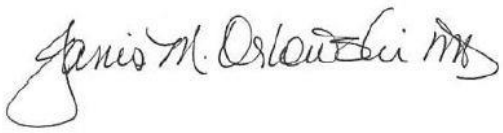
[17] *See* 62 Fed. Reg. 58782 (October 30, 1997)
[18] Ibid. at 58789.
[19] Ibid. at 58783.
[20] *See* Institute of Medicine, "Report Brief Race Ethnicity, and Language Data: Standardization for Health Care Quality Improvement." (August 2009) Available at: http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2009/RaceEthnicityData/Race%20Ethnicity%20report%20brief%20FINAL%20for%20web.pdf (last visited June 14, 2019).

recommendation. In addition, its use may offend large numbers of patients whose own preferred national or ethnic labels are not included. There is a perfectly good way to collect data on "fine-grained categories of ethnicity" (e.g., Japanese, Filipino, German, Pakistani, etc.) that does not incorrectly identify these groups and labels as races.[21]

CONCLUSION

Thank you for the opportunity to comment on the FY 2020 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 202.909.2084 or mmullaney@aamc.org or Andrew Amari at 202.828.0554 or aamari@aamc.org for questions on the payment policy proposals and Phoebe Ramsey at 202.448.6636 or pramsey@aamc.org for questions on the quality proposals.

Sincerely,



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

Cc: Ivy Baer

[21] Ibid.