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Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
ATTN: CMS-1735-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 System and Proposed Policy Changes and Fiscal Year 2021 Rates (CMS-1735-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 Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2021 Rates,” 85 *Fed. Reg.* 32460 (May 29, 2020), 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 comprise all 155 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, 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 173,000 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 AAMC’s comments on CMS proposals regarding hospital payment and quality proposals and requests for information.

- ***Graduate Medical Education.*** AAMC strongly supports the proposal that will allow residents to be considered “displaced” at the time the hospital or program closure is announced.
- ***Medicare Bad Debt.*** CMS must make clear that implicit price concessions are considered bad debt and should be included on the Medicare cost report. We strongly oppose making any of the proposed changes effective retroactively.

- ***Chimeric Antigen Receptor (CAR) T-cell Therapy.*** We support the proposal to create a new Medicare Severity-Diagnosis Related Group (MS-DRG) for CAR T-cell cases as an interim step until more data are collected. We remain concerned that reimbursement is still inadequate.
- ***Collection of Third-Party Negotiated Rates.*** CMS should not finalize the proposal to collect third-party negotiated rates. Furthermore, relative weights should be based on hospital resource use not on negotiated rates.
- ***Wage Index.*** CMS should continue to work with stakeholders to develop a comprehensive wage index reform. CMS should not adopt proposed changes to the labor market delineations outlined in Office of Management and Budget (OMB) Bulletin No. 18-04.
- ***Disproportionate Share Hospital and Uncompensated Care Payments.*** AAMC supports using one year of audited data to calculate uncompensated care (UCC) payments for fiscal year (FY) 2021. The CMS Office of the Actuary (OACT) should adjust its Factor 1 projection to accurately account for the increased number of Medicaid beneficiaries due to the COVID-19 Public Health Emergency (PHE). Additionally, CMS should amend its calculation of Factor 2 to account for the increased number of uninsured individuals in 2020. Lastly, implicit price concessions must be included in the definition of uncompensated care costs and in the calculation of Factor 3.
- ***Comprehensive Care for Joint Replacement (CJR).*** AAMC supports the proposal to create two new MS-DRGs for hip replacement with the primary diagnosis of hip fracture. CMS should adjust the CJR target prices to account for both the new base year costs, as well as the associated payments for these new MS-DRGs.
- ***Data Collection to Address and Eliminate Inequities:*** CMS must take the lead to standardize the collection of accurate data to help hospitals and communities meaningfully mitigate the impacts of social determinants of health (SDOH) factors and end inequities in care and outcomes.
- ***Hospital Quality Star Ratings:*** CMS should suspend updating the ratings in consideration of COVID-19's impacts on quality measurement and remove publication of current ratings until it is able to address significant methodology concerns through future rulemaking.
- ***eCQM Data Reporting Requirements and Public Reporting:*** CMS should adopt a more incremental approach to increasing eCQM reporting requirements to balance benefits with burdens and maintain reliability and validity for measurement. CMS should delay public reporting of eCQM performance until there is one consistent measure reported across all hospitals.

GRADUATE MEDICAL EDUCATION

AAMC Strongly Supports CMS' Proposal to Change the Definition of "Displaced" Resident and Asks that It Be Made Retroactive

The AAMC thanks CMS for acknowledging that both residents and teaching hospitals face challenges when a hospital or residency program closes and for proposing to change the

definition of a “displaced” resident. As we describe below, the AAMC strongly supports the proposal that CMS will consider a resident displaced at the time the hospital or program closure is publicly announced. This change will give residents added flexibility to identify another program to continue their training and will provide assurance to teaching hospitals that agree to train displaced residents that they will receive the temporary cap adjustment to which they are entitled.

Training the next generation of our nation’s physicians is a key mission of teaching hospitals. In part, because of the Medicare resident “caps,” teaching hospitals are constrained in the number of residents they can train. When a teaching hospital or a program closes even more stress is created on the graduate medical education system to ensure that the displaced residents can find programs to continue their training and the slots are preserved.

Under current policy Medicare provides for a temporary cap adjustment for hospitals that are above their cap and accept residents (the “receiving hospital”) from a hospital or program that is closing. This allows the receiving hospital to receive Medicare direct graduate medical education (DGME) and indirect medical education (IME) funding for the displaced residents for the duration of their training. However, Medicare policy defines a displaced resident as “one that is physically present at the hospital training on the day prior to or the day of hospital or program closure.” (p. 32785).

We have heard from AAMC members that took in displaced residents in the past that they have been denied the temporary cap increase because a resident was not on-site the day before or the last day of the hospital or program closed. This was particularly evident during the Hahnemann University Hospital closure when so many residents were displaced. And with few patients in the hospital for weeks prior to the official closing the training was of little to no value. These receiving hospitals accepted displaced residents in good faith with the promise that they would receive DGME and IME payments for the duration of the residents’ training. These hospitals should not be penalized because they did what was best for the residents – gave them an opportunity to continue their training. We appreciate that you are proposing a permanent rule change.

CMS acknowledges in the proposed rule that it has heard the concerns that “limiting the “displaced residents” to only those physically present at the time of closure” is burdensome for all residents who are attempting to find alternative programs to complete their training and may impose barriers to the “originating and receiving hospitals with regard to seamless Medicare IME and direct GME funding.” (p. 32785). Therefore, CMS is proposing to change the definition of a “displaced resident.” Under the proposal, a resident would be considered “displaced” if the resident was training in the hospital on “the day the closure was publicly announced.” (p. 32786). Displaced residents would also include residents who have matched into a residency program but not yet begun to train and residents that are on rotation at another hospital on the date the hospital program closure is announced but intend to return to training to the closing hospital/closing program. The AAMC was a strong advocate for this change.

We agree with CMS that it would “provide greater flexibility for the residents to transfer while the hospital operations or residency programs were winding down.” (p. 32786). The AAMC fully supports the proposal. We also ask that it be made retroactive to ensure that none of the hospitals that accepted residents who were displaced when Hahnemann University Hospital closed in the summer of 2019 are disadvantaged by the application of the old policy which CMS states was “not explicitly stated in regulations text.” (p 32785).

Under section 1871(e)(1)(A)(ii) of the Social Security Act (the Act), a substantive change in regulations shall not be applied retroactively unless the failure to apply the change retroactively would be contrary to the public interest. AAMC believes that failure to apply this change to the regulation retroactively would be contrary to the public interest. In the case of Hahnemann University Hospital, hundreds of residents were displaced and needed to quickly find alternative positions at other hospitals or risk being unable to become Board certified physicians – a critical qualification to practice medicine. Despite the additional costs and some uncertainty as whether they would receive DGME and IME for these residents, other hospitals provided training positions to these residents to allow them to continue their training in the career of their choice. It would be in the public interest for these hospitals to receive DGME and IME funding for taking in these residents.

MEDICARE BAD DEBT

CMS has proposed changes and clarifications to certain Medicare bad debt policies in response to litigation and questions from stakeholders. The changes related to Financial Accounting Standards Board’s (FASB) Account Standards Update (ASU) 2014-09, Revenue from Contracts with Customers (Topic 606) generally involve changes in terminology, many of which have been adopted by hospitals on their financial statements but have not been incorporated for purposes of the Medicare cost report. However, the proposals related to reasonable collection efforts and the determination of non-indigent beneficiaries, some of which are being made effective retroactively, do not merely codify guidance that is found in the Provider Reimbursement Manual (PRM). Rather, they may increase burden on some hospitals that already must comply with Federal and state requirements related to financial assistance and determination of eligibility to maintain their tax-exempt status. Additionally, AAMC requests that CMS incorporate the appropriate accounting standards and terminology in conformity with both the FASB and the Governmental Accounting Standards Board (GASB) and to recognize that there may be differences between FASB and GASB.

Most tax-exempt hospitals already must comply with requirements imposed by section 501(r) of the Affordable Care Act to retain their Federal exemption under section 501(c)(3) of the tax code. While the purpose of these provisions differs from the purpose of the CMS bad debt rules, there are some commonalities. For example, under 501(r) hospitals are required to have a financial assistance policy (FAP) and post it on their website. The FAP includes information

about the criteria for qualifying for free or discounted financial services and applies to all individuals who are unable to pay for all or a portion of their medical expenses.

In proposing revisions to portions of the bad debt policy, and codification of others portions that are in the PRM, Chapter 3, CMS is imposing a new set of requirements, not merely putting into regulation long-standing policy. Included in the PRM is guidance that the provider “should take into account a patient’s total resources” and also that the provider “should take into account any extenuating circumstances.” The codification of this part of the manual is not suggestive (i.e., does not use “should”) about what the provider must do, but is directive, requiring that “the provider must do all of the following” which includes a list of five actions. (p. 32896, emphasis added). Even after indigence is determined, the provider must conclude that “there has been no improvement in the beneficiary’s financial status” before the bad debt may be deemed uncollectible without applying a collection effort. (p. 32896). This increases burden to providers who now must comply with the requirements of their FAP, and then for Medicare purposes follow five steps and even then, cannot determine that an unpaid amount is uncollectible without looking again at the beneficiary’s financial status to see if it has changed. CMS should allow hospitals that must comply with 501(r) to use the criteria that they have established to determine a patient’s indigence and whether a debt can be deemed uncollectible.

CMS should not finalize its proposal that providers must reduce allowable Medicare bad debt by any amount that the state is obligated to pay, either by statute or under the terms of its approved Medicaid plan, regardless of whether the state actually pays its obligated amount to the provider. For example, when beneficiaries are covered by both Medicare and Medicaid (known as dual eligibles) states will often set payment policies that the state payment for the service satisfies the minimum payment requirement; this means the state is not required to cover the beneficiary copayment. Hospitals should not be penalized by the fact that a state does not meet its financial obligations. Unpaid amounts that are owed would under common circumstances be considered bad debt and should be counted as such by hospitals and would be considered “bad debt” under the proposed definition since they would be considered “uncollectible from accounts that were created or acquired in providing services.” (proposed 413.89(b)(A)).

The AAMC strongly opposes making proposals effective retroactively. The CMS proposals do not merely codify existing policy, but make changes to which hospitals may not have been complying in the past as the PRM is considered guidance and is not mandatory. Efforts to go back and change accounting processes for Medicare bad debt reporting for prior periods is not consistent with the Administration’s efforts to minimize burden on providers. CMS’ proposal to make these bad debt policies retroactive is also in conflict with its own General Counsel’s advice. In a memorandum from October 31, 2019, the Office of General Counsel (OGC) advised CMS that:

The Supreme Court held in *Allina* that under the Social Security Act Section 1871, any Medicare issuance that establishes or changes a “substantive legal standard” governing

the scope of benefits, payment for services, eligibility for individuals to receive benefits, or eligibility of individual, entities, or organizations to furnish services, must go through notice and comment rulemaking....

The payment rules you develop often form the basis for enforcement actions and therefore it is important the Center for Medicare appropriately conform its guidance documents to the rulemaking obligations set forth in *Allina*. Where the Department of Health and Human Services...or the Centers for Medicare and Medicaid Services issued guidance that, under *Allina*, should have been promulgated through notice-and-comment rulemaking, the Department's ability to bring enforcement actions predicated on violations of those payment policies is restricted.¹

As noted above, manual guidance is not mandatory. Therefore, the promotion of manual guidance to regulatory requirements is establishing a substantive legal standard where there was not one previously. As noted by OGC, CMS is establishing a substantive legal standard that must be in compliance with the Supreme Court's *Allina* standard and can only be adopted prospectively through notice and comment rulemaking to be enforceable. **The AAMC requests that CMS not adopt any proposals with retroactive effective dates.**

Clarify that Implicit Price Concessions are the Same as Bad Debt and Should Continue to Be Reported on the Medicare Cost Report as Bad Debt

The proposed rule states that "Under ASU Topic 606, an amount representing a bad debt would generally no longer be reported separately as an operating expense in the provider's financial statements but will be treated as an "implicit price concession," and should be included as a reduction in patient revenue." (p. 32875). CMS is proposing to amend §413.89(b)(1) to specify that "for cost reporting periods beginning on or after October 1, 2020, bad debts, also known as "implicit price concessions" are amounts considered to be uncollectible from accounts that were created or acquired in providing services." (p. 32875). However, the proposed regulatory language amending §413.89(b)(1) does not include a statement that implicit price concessions are considered to be bad debt. (p. 32895).

For purposes of financial reporting hospitals view implicit price concessions and bad debt as the same; they are amounts that will never be collected. Therefore, for cost reporting purposes implicit price concessions should be included on the same line of Worksheet S-10 as bad debt. The AAMC asks that CMS clearly state in the final rule that when reporting bad debt on Worksheet S-10 hospitals should include "implicit price concessions" on the same line as bad debt. Furthermore, there is no reference to "implicit price concessions" in the PRM. To ensure

¹ Kelly M. Clearly, Deputy General Counsel & CMS Chief Legal Officer and Brenna E. Jenny, Deputy General Counsel Memorandum to Demetrios Kouzoukas, Principal Deputy Administrator & Director of the Center for Medicare, October 31, 2019. Available at: https://d1198w4twoqz7i.cloudfront.net/wp-content/uploads/2019/12/05141151/CMS-Memo_Impact-of-Allina-on-Medicare-Payment-Rules.pdf

that this change is applied correctly, CMS must educate both **hospitals and Medicare Administrative Contractors (MACs) that for purposes of the Medicare cost report implicit price concessions are the same as bad debt – both are considered uncompensated costs – and should be included in the reporting of bad debt on Worksheet S-10. We request that CMS clarify this interpretation in the new language and issue revised guidance explicitly stating that this is how hospitals should report implicit price concessions. Moreover, CMS should consider either adding a line to Worksheet S-10 for implicit price concessions or add “implicit price concessions” to the same line as bad debt to clarify that the reported information contains both.**

We strongly urge CMS to delay the effective date of the change in bad debt reporting until clear guidance has been communicated to both hospitals and the MACs. CMS is proposing to make the changes effective October 1, 2020. Even though hospitals are reporting this information on their financial statements, we feel this is an ambitious timeline for requiring these changes be reported on the cost report. CMS should provide clear reporting requirements to relieve the burden on hospitals to speculate what should or should not be reported. **AAMC requests that CMS delay the effective date of these proposals until CMS issues updated reporting guidance or no sooner than October 1, 2021, whichever is later. CMS must provide both hospitals and MACs with clear guidance on how to apply these changes – specifically how hospital should report implicit price concessions on the cost report – in order to allow for a seamless transition for reporting.** Additionally, CMS should consider a phased-in approach to ensure that all entities are aware of the requirements and lessen the chance that a cost report is denied over perceived reporting discrepancies.

Medicare-Medicaid Crossover Bad Debt Proposal Will Increase Provider Reporting Burden

In the proposed rule, CMS states that providers are “incorrectly writing off Medicare-Medicaid crossover bad debt to a contractual allowance account” (p. 32876) because they are unable to bill the beneficiary – some of whom are indigent – for the difference between the billed amount and the Medicaid claim payment amount.

Providers generally write off this crossover bad debt to a contractual allowance account. A contractual allowance is a concept within Generally Accepted Accounting Principles (GAAP) that refers to the difference between a provider's charge and the contractual discounted payment. Crossover bad debt is typically considered to be a contractual allowance because providers are bound by their Medicaid provider agreements (i.e., contracts) to accept the amounts paid by the state plan as payment in full. The MACs have historically found this contractual allowance classification to be acceptable and considered these crossover balances as part of reimbursable bad debt. **The AAMC recognizes the importance of accurately recording bad debt amounts in the Medicare cost report; however, this proposal does not enhance accuracy of cost report data or improve the bad debt reporting process. We ask CMS not to finalize this proposal.**

Accept Provider Documentation in Place of State Remittance Advice to Determine Medicare Bad Debt for Dual-Eligible Beneficiaries

State policies may require Medicaid to pay for all or part of the beneficiary's cost sharing – deductible or coinsurance – for certain services. In order for a provider to be able to claim unpaid Medicare cost sharing that should be covered by the state as bad debt, the provider must bill Medicaid and receive a remittance advice in order to document the state's liability for this cost sharing. CMS notes that the remittance advice is the best "documentation to a State's Medicare cost sharing liability for a dual eligible beneficiary." (p. 32874). However, some states will not process crossover claims, leaving the provider without a remittance advice. In this instance, a provider would have to provide alternative documentation from the state that reflects the state's Medicare cost sharing liability or lack thereof. The burden to produce documentation of the state's cost sharing obligation rests with the provider and CMS would not accept a provider's estimate of the state's cost sharing liability. Not accepting the provider's estimate of the state's cost sharing liability could negatively impact hospitals' financial health and could lead to diminished access to care for beneficiaries eligible for both Medicare and Medicaid if they perceive a significant financial burden. **We request that CMS accept the provider's estimate of the state's cost sharing when a provider submits documentation that it has billed the state, but the state does not provide a remittance advice.**

Do Not Restart the 120-day Collection Period if a Partial Payment is Received

CMS is proposing to add a requirement that a bill cannot be considered uncollectible until at least 120 days have passed since the provider first attempted to receive payment. The provider would be able to end the collection effort at the end of a 120-day period if no payments have been received. However, if a partial payment is received, CMS is proposing to require that "the provider must continue the collection effort and the day the partial payment is received is day one of the new collection period." (p. 32869). CMS does not define "partial payment." We believe this requirement is administratively burdensome to hospitals and that hospitals have policies in place to help them determine which beneficiaries will be able to pay some amount and which have made a payment but are judged unlikely to pay anything additional. Hospitals should be able to make the decision whether to continue collection efforts based on their written policies. Additionally, some hospitals have been under intense public scrutiny for their collection practices. These requirements may be seen as contrary to the corrective actions that hospitals have taken to address these concerns. **We request that if a hospital undertakes a reasonable collection effort and makes a determination consistent with its written policies that continuing those efforts would not result in increased collections, regardless of whether a partial payment is received, the hospital can cease collection efforts and report the outstanding balance as bad debt.**

CMS is also proposing to clarify that any payment on an account received after the write-off date but before the end of the cost reporting period, must be used to reduce the final bad debt for the

account claimed in that cost report. If the collection is made in a cost reporting period after the debt has been written off as uncollectible, “the recovered amount must be used to reduce the provider’s reimbursable cost in the period in which the amount is recovered.” (p. 32870). The amount of such reduction in the period of recovery must not exceed the actual amount reimbursed by the program for the related bad debt in the applicable cost reporting period. CMS is proposing to make this policy effective retroactively. **The AAMC opposes making proposals effective retroactively. Since this particular proposal has not been Medicare policy to date, it will be extremely burdensome to both hospitals and the MACs to make this retroactive.**

CHIMERIC ANTIGEN RECEPTOR (CAR) T-CELL THERAPY

Teaching hospitals are the institutions where patients receive innovative cutting-edge treatment such as CAR T-cell therapy. These institutions are committed to advancing medical knowledge of new therapies and technologies to prevent and treat disease. CAR T-cell therapy is an example of a cutting-edge therapy that is predominantly furnished at teaching hospitals. New technologies often come with high price tags and CAR T-cell therapy is no exception. As we anticipate more cutting-edge therapies entering the market, we look forward to working with CMS to guarantee that reimbursement to hospitals is adequate and reflects the condition of the patient being treated.

Ensure Future Payments for CAR T-Cell Therapies are Adequate

The AAMC supports CMS’ proposal to create MS-DRG 018 for CAR T-cell therapies and to exclude cases that are part of a clinical trial from the relative weight determination and to also pay these cases exclusive of the cost of the CAR T-cell product. We agree with CMS’ clinical advisors that CAR T-cell therapy is sufficiently different clinically from other treatments to warrant its own MS-DRG. We continue to be concerned, however, that the reimbursement for CAR T-cell therapies is inadequate and could place significant financial stress on teaching hospitals to ensure patients have access to this important treatment. Insufficient inpatient reimbursement may lead some programs to begin outpatient CAR T-cell therapy too soon. CMS payment policies should not influence the safety of new therapies prior to appropriate experience with the treatment protocol. Additionally, given the low volume of CAR T-cell claims to date, CMS must continue to accurately identify claims to be included in the calculation of the relative weight. In addition, CMS should consider requiring the National Drug Code (NDC) be included on the claim to accurately identify CAR T-cell claims and also specify the immunotherapy used for that claim.

Due to the extremely high cost of the CAR T-cell therapy and its concomitant inpatient care including increase utilization of ICU stays, the Medicare reimbursement that hospitals receive barely covers the costs of the therapy, leaving little for the myriad medical services that the hospital provides when it administers this therapy. Based on claims data review, the proposed rule states that the estimated sales price for a CAR T-cell therapy is \$373,000. However, based

on analysis by Watson Policy Analysis, Inc., the base payment – that includes MS-DRG add-ons but excluding outliers – hospitals receive from Medicare for a non-clinical trial case will be roughly \$360,000 in FY 2021, which does not even cover the cost of the treatment.² Moreover, analysis shows that 80 percent of the non-clinical trial CAR T-cell cases would qualify for outlier payments, further underscoring the discrepancy between the cost for CAR T-cell cases and Medicare’s reimbursement.

The advent of therapies such as CAR T-cell shows the promise of cutting-edge treatments for diseases once thought incurable. As the Medicare Payment Advisory Commission (MedPAC) describes the Medicare inpatient prospective payment system, “[t]he payment rates are intended to cover the costs that reasonably efficient providers would incur in furnishing high-quality care.”³ The payment for CAR-T cell therapies does not accomplish that goal. **It remains an evolving area of treatment and as more CAR T-cell therapies come to market, Medicare’s reimbursement must be sufficient to not only cover the cost of the CAR T-cell therapy but to cover the medical costs associated with administering these therapies.** Due to the limited number of CAR T-cell cases that CMS is using to set the relative weight, AAMC recommends that CMS consider this new MS-DRG as a transitional payment for CAR T-cell therapy. As more claims data becomes available, CMS should consider whether grouping all CAR T-cell therapies into one MS-DRG will achieve reimbursement that covers these costs or should there be separate MS-DRGs for each therapy, for example based on diagnosis. Regardless, **CMS must ensure that the reimbursement for CAR T-cell treatment is adequate to reflect the costs of an efficient hospital providing this care.** Furthermore, as new treatments come on the market that may not qualify for the New Technology Add-on Payment, hospitals will face an even greater reimbursement shortfall in the coming years. CMS must also work to address the issue that a large part of the cost is the result of the high prices set by the pharmaceutical companies that develop these treatments, a cost over which hospitals have no control since there is no competitive market for the therapy.

CMS’ payment for this therapy must also take into account factors such as a CAR T-cell patient’s burden of illness, comorbid conditions and complications associated with receiving this treatment when determining payment. Patients receiving CAR T-cell therapy tend to be sicker and can often experience post-infusion complications – some of which are life threatening – that require prolonged hospitalization, including longer stays in the intensive care unit. For example, patients may experience post-infusion complications such as cytokine release syndrome and potentially fatal side effects such as brain swelling. These patients are resource intensive. Even if these patients do not experience these complications, hospitals 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

² Watson Policy Analysis, Inc. analysis. Centers for Medicare & Medicaid Services. Medicare Provider Analysis and Review (MedPAR) FY 2019 data.

³ Medicare Payment Advisory Commission. Hospital Payment Basics. Available at: http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_19_hospital_final_v2_sec.pdf?sfvrsn=0

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. **The AAMC urges CMS to consider complication or comorbidity (CC) or major complication or comorbidity (MCC) codes when evaluating reimbursement for CAR T-cell therapies as more clinical data becomes available.**

Ensure CAR T-Cell Therapy Clinical Trial Cases are Correctly Identified

We are supportive of CMS' decision to exclude CAR T-cell clinical trial cases from the calculation of the relative weight for MS-DRG 018. We agree with CMS' proposal to apply an adjustment to the payment amount for clinical trial cases to calculate the relative weight of the new MS-DRG because the cost of the CAR T-cell therapy is a significant portion of the costs of the treatment. Removing the clinical trial cases will assist CMS in evaluating the true costs of CAR T-cell cases given that many of the clinical trial CAR T-cell cases do not include the cost of the CAR T-cell therapy. Analysis performed by Watson Policy Analysis revealed that standardized mean drug charges for clinical trial cases is estimated to be approximately \$57,703. Based on the CMS published national average CCR for drugs of 0.190⁴, this would translate to a cost of approximately \$11,000⁵, well below the true costs of non-clinical trial CAR T-cell therapy.

The proposed rule notes that CMS identified CAR T-cell clinical trial cases as those claims with the ICD-10-CMS diagnosis code Z00.6 which is used to identify all clinical trial cases, not just CAR T-cell or have standardized drug costs of less than \$373,000. We are concerned that strictly identifying a clinical trial case by Z00.6 without also looking at the drug costs, could exclude cases from the relative weight determination that include the full cost of the CAR T-cell therapy. Hospitals that incur the full cost for the CAR T-cell therapy would also be underpaid. For example, a patient may receive CAR T-cell therapy that is not associated with a clinical trial while also receiving a treatment that is associated with the clinical trial. In this scenario, the hospital would pay the full cost of the CAR T-cell therapy. However, if the claim is identified based solely on the Z00.6 diagnosis code for a clinical trial that reflects the use of a CAR T-cell therapy, then the relative weight calculation would exclude the case despite it having the full cost for the product and the hospital would be underpaid for the treatment. We recommend that CMS look at both the diagnosis code and drug costs reflected in revenue code 0891 to ensure that hospitals are adequately reimbursed for clinical trial cases that include CAR T-cell therapy but are not associated with a CAR T-cell clinical trial. Alternatively, CMS should consider requiring the inclusion of the NDC or the CAR T-cell therapy acquisition cost on the claim. This will ensure that the Medicare program pays accurately for clinical trial cases that are for other treatments but also include CAR T-cell therapy.

⁴ FY 2021 IPPS Proposed Rule

⁵ Watson Policy Analysis, Inc. Centers for Medicare & Medicaid Services. Medicare Provider Analysis and Review (MedPAR) FY 2019 data.

COLLECTION OF THIRD-PARTY NEGOTIATED RATES

Do Not Finalize the Proposal to Collect Third-Party Negotiated Rates to Change the Methodology for Calculating MS-DRG Relative Weights Beginning in FY 2024

CMS is proposing to collect market-based rate information on the Medicare cost report. Specifically, hospitals would be required to report on the Medicare cost report “median payer-specific negotiated rates” by MS-DRG for Medicare Advantage organizations and all third-party payers for cost reporting periods ending on or after January 1, 2021. (p. 32791, 32793). For third party payers that base their payments on the MS-DRG patient classification system, the payer-specific negotiated rates would be based on “the system used by that third party payer, such as per diem rates or APR-DRGs.” (p. 32791). Hospitals would be required to crosswalk these charges to an MS-DRG. **This proposal will increase burden on hospitals to report these negotiated charges on the Medicare cost report and crosswalk rates that are not based on MS-DRGs.**

CMS states that collection of this information will satisfy the Administration’s goals of increasing consumer choice and promoting competition as outlined in Executive Orders 13813 and 13890. (p. 32790). The AAMC disagrees. Reporting negotiated rates on the Medicare cost report does not achieve the objective of providing consumers with information to inform their choice of health care options. As the AAMC has stated on numerous occasions, CMS must take a different approach to provide patients and their families with meaningful, actionable information about their potential out-of-pocket costs. **We urge CMS not to finalize this proposal.**

CMS Does Not Have Statutory Authority to Change the Methodology for Calculating MS-DRG Relative Weights

CMS is also considering using this market-based data to “adjust the methodology for calculating the MS-DRG relative weights to reflect a more market-based approach under our existing authority” section 1886(d)(4)(A) of the Social Security Act. (p. 32793). As set forth in section 1886(d)(4)(A), relative weights are intended to reflect “the relative hospital resources used with respect to discharges classified within that group” and not the relative price paid. CMS currently uses “a cost-based methodology to estimate an appropriate weight for each MS–DRG.” (p. 32791). In proposing to use median payer-specific negotiated charges to set MS-DRG relative weights, CMS has not adequately explained why it thinks market price rather than costs is a better measure of hospital resources used. Instead, the agency appears to conflate market price with cost.

The Hospital Price Transparency Final Rule is scheduled to go into effect on January 1, 2021, but it has been challenged by the AAMC and other hospitals on statutory, procedural and constitutional grounds. Although the district court denied hospitals’ motion for summary judgment,⁶ the hospitals have appealed that decision to the United States Court of Appeals for

⁶ *American Hospital Assn, et al. v. Azar*, No. 19-CV-3619 (D.D.C. June 23, 2020).

the District of Columbia Circuit. Briefing before the D.C. Circuit Court of Appeals will be complete August 28, 2020, and we expect oral argument to be scheduled in early October. The AAMC and other hospitals associations also have requested that Secretary Azar and Administrator Verma delay the effective date of this rule until the litigation concludes. The rule is extremely burdensome on hospitals at a time when they are still immersed in battling the COVID-19 PHE.

Because the information to be furnished under the proposed rule would be derived from information collected under the Hospital Price Transparency Final Rule, the new information collection requirement suffers from the same legal infirmities: It is not authorized by statute and violates both the Constitution and Administrative Procedure Act. Moreover, if the hospital price transparency final rule is found unlawful, then CMS's requirement for disclosure of median payer-specific charge information by MS-DRG would similarly be unlawful. If it is determined by the courts that it is unlawful to require disclosure of median payer-specific negotiated charge information by MS-DRG as required under the Hospital Price Transparency Final Rule, then CMS could not use that information to change relative weights. **We urge CMS not to finalize this proposal.**

MEDICARE WAGE INDEX

In Fiscal Year (FY) 2020, CMS finalized several policies to address disparities between high and low wage index hospitals present in the wage index system. Most significantly, CMS finalized 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 the 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, which CMS intended to apply 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 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. In its finalized policy, CMS found this argument persuasive and instead opted to maintain budget neutrality through a uniform adjustment to the standardized amount. (84 FR 42331).

For FY 2021 CMS proposes to continue its wage index policy to raise the wage indexes of low wage hospitals between FY 2021 and FY 2023. The AAMC appreciates the changes to the FY 2020 finalized policy that address several concerns outlined in our comments on the FY 2020 IPPS proposed rule. However, as CMS proposes to adopt this policy for the next three years, the AAMC continues to have concerns with several aspects of this and other wage index proposals, as detailed below.

Consider Impact of COVID-19 Public Health Emergency on Area Wage Indexes

Across the U.S., the COVID-19 PHE has strained hospital resources and has severely impacted their ability to continue operations as prior to the PHE. Due to the financial strain felt by hospitals as they face the demands of COVID-19, many made the difficult decision to temporarily or permanently reduce wages. As a direct result, depressed wages represented in the wage data during the PHE stand to lower the hospital wage index adjustment for certain areas once hospital wage index data from FY 2021 is used to determine area wage indexes. **For this reason, the AAMC recommends that CMS proactively address the COVID-19 PHE's impact on hospital wages and their wage indexes by excluding wage index data collected during the PHE from calculation of area wage indexes.**

Work with Stakeholders to Develop Comprehensive Wage Index Reform

Although AAMC supports CMS' goal to address difficulties faced by low wage index hospitals in recruiting and retaining staff, we continue to believe that a better solution is for CMS to reform the wage index in a more comprehensive manner. While the wage index has undergone numerous targeted legislative and regulatory changes since its inception, its disparities and issues persist. **At a point in the future when the PHE is not front and center, the AAMC urges CMS to engage with stakeholders to develop more comprehensive wage index reform to address the disparities that exist within the current system.** Comprehensive reform will enable CMS to achieve its overarching goals of creating a wage index system that accurately represents the geographic differences in the cost of labor.

Do Not Adopt OMB Bulletin No. 18-04 Delineations Until After the Decennial Census

In FY 2020, CMS finalized a transitional one-year, five-percent cap on reductions to a hospital's wage index between FY 2019 and FY 2020. The cap limited reductions to a hospital's wage index to no more than five percent between the two fiscal years in order to mitigate the impact of the finalized wage index policies and allow hospitals to prepare for payment reductions.

In FY 2021 CMS is proposing again to implement a five-percent cap on changes to a hospital's wage index between FY 2020 and FY 2021. (p. 32706). CMS notes that the proposal to apply the five-percent cap again applies to all wage index changes but was specifically included to mitigate the effects of the revised core-based statistical area (CBSA) delineations and its corresponding impact on the wage index.

For FY 2021 CMS proposes to adopt the labor market delineation updates described in the OMB Bulletin No. 18-04. As CMS notes in the proposed rule, modifications to CBSAs in OMB bulletins issued between decennial censuses are typically minor. However, the new CBSA delineations outlined in OMB Bulletin No. 18-04 are more significant in comparison to other interim bulletins. (p. 32696). These changes include several new CBSAs, urban counties becoming rural, rural counties becoming urban, and some existing CBSAs would be split apart. Additionally, the changes are anticipated to have a cascading impact on hospitals with wage index reclassifications.

To address and mitigate the material changes that would be caused by adopting the OMB Bulletin No. 18-04, CMS proposes to implement a five-percent cap on changes to a hospital's wage index between FY 2020 and FY 2021. The AAMC is concerned that the impact from the revised delineations may be more severe than CMS is indicating. In past rulemaking, CMS provided hospitals with more generous transitional policies when the Agency adopts more comprehensive OMB labor market delineations. For instance, as recently as FY 2015, CMS provided a three-year transition policy for hospitals negatively impacted by CMS' adoption of OMB's delineations based on the 2010 decennial census. (79 FR 49957). Hospitals in urban counties becoming rural were allowed to retain an urban wage index for three years while CMS implemented other changes through two-year transition period with wage indexes based on a 50 percent blend of the old and new delineations the first year.

The AAMC urges CMS to delay adoption of the changes outlined in OMB Bulletin No. 18-04 for FY 2021. The negative impacts on hospitals are material, and the 2020 decennial census will require more material changes to OMB delineations in the near future. CMS is proposing a 5 percent cap on wage index decreases for the first year or a two-year phase-in of the policy. However, our analysis shows that some of our members could see up to a 15 percent decrease in their wage indexes as a result of the proposal.⁷ As a result, in year 2, there will be a sharp decrease in the wage index for these hospitals. This decrease is on top of the significant revenue decreases hospitals are experiences due to COVID-19. CMS should not adopt updated OMB delineations until the 2020 decennial census data are available. **However, if CMS finalizes the adoption of delineations outlined in OMB Bulletin No. 18-04, the AAMC urges CMS to apply a two and three-year transitional policy as the material changes caused by the delineations will have a significant impact on some hospitals.** The transition period aligns with past CMS policy and would better enable hospitals that are negatively affected to prepare for reduction.

Finalize Changes to Applications and Appeals for Medicare Geographic Classification Review Board (MGCRB) Wage Index Reclassifications

Currently, CMS requires a weighted three-year average of wage data to support an MGCRB reclassification application. For FY 2021, CMS proposes that new hospitals without three years of average hourly wage data applying for MGCRB wage index reclassification could support their applications using either one or two years of wage data. **AAMC supports CMS' proposal and appreciates the added flexibility for hospitals that seek to reclassify their wage index through the MGCRB.**

Regulations require that appeals of MGCRB applications must be mailed to the Administrator in care of the Office of the Attorney Advisor with a hardcopy to CMS' Hospital and Ambulatory Policy Group (HAPG). Appeals may be not submitted by facsimile or other electronic means.

⁷ AAMC analysis. Source: Table 2 – Proposed Case Mix Index and Wage Index Table by CCN of the FY 2021 IPPS Proposed Rule, with AAMC membership as of May 2020.

CMS proposes to revise the regulation to remove the prohibition on electronic or facsimile submissions to the MGCRB or HAPG. AAMC supports this proposal.

MEDICARE DISPROPORTIONATE SHARE HOSPITAL AND UNCOMPENSATED CARE PAYMENTS

Account for Impact of COVID-19 Public Health Emergency in the Uncompensated Care Payment Methodology

CMS calculates Factor 1 of its uncompensated care payment methodology to estimate 75 percent of the estimated disproportionate share hospital (DSH) payments that would otherwise be made in the absence of Section 1886(r) of the Social Security Act. CMS' estimate for DSH payments in a given FY is partially based on CMS' Office of the Actuary's (OACT) Part A benefits projection model – the OACT's most recent available projections of Medicare DSH payments for the FY are used as a baseline and are updated through a projection model to ensure the estimate accounts for several update factors. CMS typically updates these projections one time and are not revised after. (p. 32747).

Among the factors used to update the Factor 1 estimates, OACT makes projection updates changes based on changes in Medicare rates, discharges, case mix and a residual "other" factor that will include Medicaid enrollment. OACT's estimate uses the same projections and assumptions that were used for the President's Budget that precedes the COVID-19 PHE. OACT's estimates do not indicate an increase in Medicaid enrollment. However, other sources indicate Medicaid enrollment is estimated to increase substantially during the PHE because of the increase in unemployment and the loss of employer sponsored insurance (ESI). According to the Urban Institute, between 12 and 21 million people will gain Medicaid coverage as a result of losing ESI due to the COVID-19 PHE.⁸ Kaiser Family Foundation estimates that of the 27 million people losing ESI as of May 2, 2020, nearly half (12.7 million) are eligible for Medicaid.⁹ Federal Reserve Chair Jerome Powell expects the economic dislocation resulting from the COVID-19 PHE to continue into the FY 2021.¹⁰

For CMS through OACT to most accurately represent Factor 1, it will be necessary to account for the large increase in Medicaid enrollment in FY 2020 and FY 2021 that is resulting from large-scale unemployment. **To ensure the FY 2021 Factor 1 amount accurately reflects the impact of the COVID-19 PHE on DSH payments, AAMC urges OACT to recalculate its update projection again with a model that accurately accounts for the increased number of Medicaid beneficiaries.**

CMS calculates Factor 2 of the methodology to determine the total available uncompensated care

⁸ Bowen Garrett and Anuj Gangopadhyaya, How the COVID-19 Recession Could Affect Health Insurance Coverage, Urban Institute, May 2020.

⁹ Kaiser Family Foundation, Eligibility for ACA Health Coverage Following Job Loss. May 13, 2020. Available at: <https://www.kff.org/coronavirus-covid-19/issue-brief/eligibility-for-aca-health-coverage-following-job-loss/>

¹⁰ Federal Reserve Chairman Jerome Powell, *60 Minutes Interview*, May 17, 2020.

payment pool, which is then distributed to individual hospitals based on Factor 3 of the methodology. Factor 2 is an annually determined percentage amount that represents the percent change in the rate of uninsured in FY 2013 and the estimated percent of uninsured in the most recent year where data is available. OACT determines Factor 2 using National Health Expenditure Accounts (NHEA) data estimates of the rate of uninsured based on data from the census bureau, and then applies a weighted average of the projections in order to ensure that the rate of uninsurance reflects both calendar years (CYs) represented within a given fiscal year. CMS relies on NHEA estimates because of their availability and timeliness – features the Agency cites as critical because the estimates need to be updated annually. (p. 32751). OACT determines its own estimates by “using the projected growth in the sum of enrollment across all public and private insurance categories together with a projection of the overall population of the U.S.”¹¹ For FY 2021, CMS proposes to use a weighted average of the CY 2020 and CY 2021 OACT projections to determine the proposed Factor 2.

OACT’s Factor 2 estimates also do not incorporate the impact of the COVID-19 PHE will have on the number of uninsured treated by hospitals. On the CMS website in a document dated March 24, 2020, OACT indicates that “the models used to project trends in health care spending are estimated based on historical relationships within the health sector, and between the health sector and macroeconomic variables. Accordingly, the spending projections assume that these relationships will remain consistent with history, except in those cases in which adjustments are explicitly specified.”¹² Clearly, circumstances have changed since this was written and economic trends in FY 2020 and FY 2021 will not be consistent with the sustained economic growth experienced in recent years. **The AAMC urges CMS to account for the impact of the COVID-19 public health emergency in its CY 2020 uninsured estimate used for Factor 2.**

For CY 2020, the spike in uninsured rates caused by the PHE alone will result in the provision of uncompensated care at significantly higher levels than anticipated in the NHEA’s current projected rates of uninsured for CY 2020. If Factor 2 fails to reflect the uncompensated care provided at hospitals across the country, then the uncompensated care payment pool will understate the actual level of uncompensated care provided. Data analysis by Watson Policy Analysis estimates that an uninsured rate of 11 percent as applied to Factor 2 for FY 2021 would raise the UCC payment pool by \$1.5 billion.¹³ Since CMS’ proposed uncompensated care payment pool for FY 2021 of \$7.816 billion already represents a significant \$534 million reduction from the final FY 2020 pool of \$8.351 billion, CMS must ensure the FY 2021 Factor 2

¹¹ Centers for Medicare & Medicaid Services, Office of the Actuary, Projections of National Health Expenditures and Health Insurance Enrollment: Methodology and Model Specification. March 24, 2020. Available at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology.pdf>

¹² CMS Office of the Actuary, Projections of National Health Expenditures and Health Insurance Enrollment: Methodology and Model Specification, page 1. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology.pdf>

¹³ Watson Policy Analysis, Inc. National Health Expenditure data and data releases with FY IPPS proposed rule. NHEA data available at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected>

calculation and resulting uncompensated care payment pool reflects the unanticipated rate of uninsured in CY 2020.

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

In FY 2020 CMS finalized the use of a single year (FY 2015) of audited Worksheet S-10 data to calculate Factor 3 of its uncompensated care payment methodology. FY 2020 represents the first year CMS used a single year of Worksheet S-10 data as the data source for Factor 3. In years prior, CMS shifted from using low-income insured proxy data to Worksheet S-10 data by employing a three-year average of both data sources that gradually incorporated Worksheet S-10 over a three-year period. In anticipation of the completed transition to using Worksheet S-10 data, in FY 2020 CMS solicited comments on whether it should use more recent unaudited Worksheet S-10 data (FY 2017), or audited Worksheet S-10 data from an earlier cost-reporting period (FY 2015). The AAMC and others requested that CMS prioritize the use of audited data, but also expressed concern that Worksheet S-10 data reported without the revised reporting instructions introduced in October 2017 would reflect uncompensated care costs less accurately and less consistently. Commenters agreed that Worksheet S-10 data that is both audited and reported under the clarified instructions would be the most accurate data source for calculating Factor 3. CMS agreed and began auditing FY 2017 Worksheet S-10 data, the first year reflecting the clarified reporting instructions, for use in FY 2021.

Following its decision to audit FY 2017 Worksheet S-10 data, CMS is proposing to use a single year (FY 2017) of audited Worksheet S-10 data that also reflects the clarified reporting instructions to calculate Factor 3 for FY 2021. AAMC maintains that audited FY 2017 Worksheet S-10 data represents the most accurate and consistent data source for determining Factor 3 since it is the only year of audited data that was reported under the clarified reporting instructions for Worksheet S-10. AAMC appreciates that CMS directed its audit efforts to ensure FY 2017 Worksheet S-10 data was audited for use in FY 2021 uncompensated care payment calculation. **For these reasons, CMS should finalize the use of a single year of audited FY 2017 Worksheet S-10 data that reflects revised reporting instructions for calculation of uncompensated care payments for FY 2021.**

Use a Three-Year Average of Audited Worksheet S-10 Data

The proposed rule also addresses the Factor 3 data source beyond FY 2021. For FY 2022 and subsequent years, CMS proposes to use the most recent single year of audited Worksheet S-10 cost report data for calculating Factor 3. Before FY 2020, CMS used a three-year average of data for Factor 3 to address year-to-year volatility in uncompensated care data but elected in FY 2020 to use a single year of audited Worksheet S-10 data. CMS' decision reflected its concerns of "mixing audited and unaudited data," which remains an issue due to the limited availability of audited Worksheet S-10 data with revised reporting instructions. However, CMS noted in the FY 2020 IPPS final rule that it would "consider returning to the use of a 3-year average in rulemaking for future years." (84 FR 42366).

The Agency's proposal to indefinitely use a single year starting in FY 2022 for Worksheet S-10, as opposed to a three-year average once sufficient audited data is available, does not address the concerns of year-to-year volatility in uncompensated care payments that comes from using a single year of data. Additionally, CMS' justification for using a single year of audited Worksheet S-10 data would no longer apply as early as FY 2023 if CMS audits continue on track over the next two years.

CMS believes that its proposal to address the Factor 3 data source for FY 2022 and beyond would provide added certainty and "help providers have greater predictability for planning purposes." (p. 32756). Importantly, using a three-year average would also mitigate the year-to-year volatility that can cause significant and unanticipated negative impacts on uncompensated care payments to many hospitals. **AAMC asks CMS to adopt a three-year average of audited Worksheet S-10 data once sufficient audited data under the revised reporting instructions are available. To this end, CMS should begin auditing FY 2018 Worksheet S-10 data for use in FY 2022, and then FY 2019 Worksheet S-10 data for use in FY 2023. Alternatively, CMS could adopt a phased-in approach and average two years of audited Worksheet S-10 data (FY 2017 and FY 2018) for FY 2022, and then average three years of audited Worksheet S-10 data in FY 2023.**

CMS should work with MACs to streamline the audit process in order to accelerate auditing of cost reports to increase the amount of audited Worksheet S-10 data that can be used to calculate Factor 3. We have heard from members that MACs or their subcontractors require hospitals to recreate the data using auditors' own templates, resulting in a burdensome duplication of effort and requiring redirection of scarce resources. The AAMC asks that CMS issue instructions to MACs that hospitals cannot be compelled to resubmit the data in a different template.

Implicit Price Concessions Must be Included in the Calculation of Factor 3 and the Definition of Uncompensated Care

The bad debt proposals included in this proposed rule could result in the elimination of implicit price concessions from bad debt reporting on Worksheet S-10. Whether labeled as bad debt or implicit price concessions, the result is that both terms mean uncompensated costs. AAMC is concerned that without clear reporting instructions from CMS, implicit price concessions may no longer be reported on Worksheet S-10 which will reduce a hospital's reported bad debt. Not including implicit price concessions as bad debt on Worksheet S-10 would mean that some of our members would report no bad debt which would not accurately reflect the uncompensated care and bad debt they incur. Moreover, this would negatively impact a hospital's uncompensated care payment. Worksheet S-10 data is used to determine a hospital's uncompensated care payment. **CMS must make clear that implicit price concessions are to be included as bad debt on Worksheet S-10 in order to accurately calculate Factor 3 and hospitals' uncompensated care payments.**

CMS is again proposing that for the purpose of determining uncompensated care costs and Factor 3 for FY 2021 and subsequent fiscal years, "uncompensated care" would continue to be

defined as the amount on Line 10, charity care, and Line 29, the cost of non-Medicare bad debt and non-reimbursable Medicare bad debt on Worksheet S-10. (p. 32757). **For the reasons discussed previously in this letter, CMS must include implicit price concessions in the definition of uncompensated care.**

COMPREHENSIVE CARE FOR JOINT REPLACEMENT: ESTABLISHMENT OF MS-DRG 521 AND MS-DRG 522

Finalize Proposal to Establish MS-DRG 521 and MS-DRG 522 for Patients with a Primary Diagnosis of Hip Fracture

The AAMC supports CMS' proposal to develop new MS-DRG 521 (Hip Replacement with Principal Diagnosis of Hip Fracture with MCC) and MS-DRG 522 (Hip Replacement with Principal Diagnosis of Hip Fracture without MCC) to account for hip replacements with hip fracture as the primary diagnosis and to incorporate these new MS-DRGs into the Comprehensive Care for Joint Replacement (CJR) Model ("Model"). By incorporating these new MS-DRGs, fracture status would remain in the CJR Model for the duration of the proposed CJR extension, maintaining consistency across model years and supporting effective evaluation of the CJR model.

If MS-DRGs 521 and 522 are not incorporated into the Model, then Participants will no longer have access to the data regarding hip replacements with a primary diagnosis of hip fracture. This would mean Participants would lose data on their riskiest and highest-cost lower extremity joint replacement patients, limiting Participants' ability to identify and address quality improvement opportunities for this patient population.

To incorporate these MS-DRGs into the Model, CMS must adjust the target prices to account for both the new base MS-DRGs' costs, as well as the associated payments for these new MS-DRGs. In other words, the target prices will need to be adjusted so that costs tied with the new MS-DRGs are commensurate with the new MS-DRGs' payments. **The AAMC recommends that CMS adjust the target prices by identifying fracture episodes through the CJR data flag that indicates fracture status by MS-DRG.** This would allow CMS to easily identify the episodes that would have fallen into the new MS-DRGs 521 and 522. Associated cost and utilization data can then be used to determine appropriate target prices for these new MS-DRGs that are specific to hip fractures.

HOSPITAL QUALITY PROGRAMS

The COVID-19 Pandemic Has Amplified Racial Health Disparities and the Impact of Social Determinants of Health. Together with CMS the Health Care Community Must Work to Change the Situation

Health care inequities remain a serious issue that must be addressed by our nation, CMS and the health care system. The United States has long been aware of racial/ethnic and sociodemographic differences in morbidity, mortality, and other healthcare quality and outcome metrics. The COVID-19 pandemic and the renewed movement for racial justice have pushed this harsh reality to the forefront of our collective consciousness. For example, researchers from The Brookings Institution have found “[i]n every age category, Black people are dying from COVID at roughly the same rate as [W]hite people more than a decade older.”¹⁴ Similarly, on June 22, CMS released preliminary data on COVID-19 derived from Medicare claims and Medicare Advantage encounter data between January 1 and May 16, 2020, showing that COVID-19 has disproportionately impacted Black, Latinx, and American Indian beneficiaries and beneficiaries with lower incomes.¹⁵

CMS in recent years has used the IPPS rulemaking to expand the role of quality measurement to identify inequities, specifically in rolling out (and subsequently expanding) confidential hospital-specific reporting of stratified data using two disparity methods for readmission measures. The AAMC believes confidential reporting to hospitals is an important step to mitigating inequities in care, but reporting must be done based on appropriate methods of accounting for social risk (and not simply dual eligibility status). In order for quality measurement to be a useful tool in improving quality of care, which includes ending racism and bigotry in health care, hospitals need access to meaningful measurement data as part of their work to address and eliminate inequities within their own walls. To this end, **there is a great need for the collection of consistent, accurate data on social risk factors, including patient-level health related social needs and community-level determinants of health. While collecting information on race is a start, other data elements, such as homelessness, food scarcity and patient census tract or block group, are essential to identifying communities that are in most need.** Collaborating with under-resourced communities is one of the missions of academic medicine. Hospitals and health systems may not be able to correct societal inequities, but they are crucial members of the multi-sector collaboratives necessary to achieve social justice and health equity. The AAMC has long supported ensuring that individuals have adequate insurance and that every person must

¹⁴ See Tiffany Ford, et al., “Race gaps in COVID-19 deaths are even bigger than they appear,” June 16, 2020. Available at: https://www.brookings.edu/blog/up-front/2020/06/16/race-gaps-in-covid-19-deaths-are-even-bigger-than-they-appear/appear/?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream=top (last visited June 22, 2020).

¹⁵ Centers for Medicare & Medicaid Services, “Preliminary Medicare COVID-19 Data Snapshot,” June 22, 2020. Available at: <https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf> (last visited June 24, 2020).

also have the same access to - and ability to utilize - high quality health care. Academic medicine and the rest of the health care community must lead the effort to end health care inequities and partner to address broader health inequities.

The AAMC has previously submitted comments to CMS on the expansion of ICD-10 CM-codes to better capture additional data on social risk factors,¹⁶ and, in response to the CMS proposal for new race data elements for the Long-Term Care Hospital (LTCH) quality reporting program in last year's FY 2020 IPPS/LTCH PPS proposed rule,¹⁷ to build off of the Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity¹⁸ in addition to more granular data on ethnicity (as recommended by the National Academy of Medicine).¹⁹ CMS must take the lead to standardize the collection of accurate data to help hospitals and communities meaningfully mitigate the impacts of social factors and end inequities in care and outcomes. The AAMC is supportive and will work with CMS to educate our members and help to identify other opportunities to work with CMS to end racial inequities.

In a blog post accompanying the data release, Administrator Verma includes “A Call to Action” for “a value-based system [where] providers are rewarded for actually keeping patients healthy and improving quality and outcomes.”²⁰ CMS’ support of value-based systems that reward providers for keeping populations healthy, and that ensure that quality measures are accurately risk adjusted so that they are meaningful to consumers and providers. The AAMC believes in the importance of alternative payment models, as evidenced by our members’ longstanding commitment to participation in these models and demonstrations. Standardized, accurate data for social factors will improve value-based payment models and enable innovative approaches to eliminating inequities but more is needed. At a minimum there also must be assurance that individuals have access to care and efforts must be devoted to the reduction and eventual elimination of health-harming social determinants in our communities. In addition, we must work to improve access not just to physicians and hospitals but to pharmacies, visiting nurses, and other elements of the health care system as well.

The AAMC and our community continue to explore how to best move forward to eliminate the factors that drive racial bias and help manage the social risk factors. As part of this commitment, the AAMC has a newly adopted strategic plan that includes launching the AAMC

¹⁶ See “AAMC Comments on Proposal to Expand ICD-10 Codes for Social Determinants of Health,” May 9, 2019. Available at: <https://www.aamc.org/system/files/c/1/497496-aamccommentsonproposaltoexpandicd-10codesforsocialdeterminantso.pdf> (last visited June 19, 2020).

¹⁷ See “AAMC Comment Letter on FY 2020 IPPS Proposed Rule,” page 22-23, June 24, 2019. Available at: <https://www.aamc.org/system/files/c/1/498220-aamccommentletteronfy2020ippsproposedrule.pdf> (last visited June 19, 2020)

¹⁸ See 62 Fed. Reg. 58782 (October 30, 1997)

¹⁹ See Institute of Medicine, “Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement.” (2009) Available at: <https://www.nap.edu/catalog/12696/race-ethnicity-and-language-data-standardization-for-health-care-quality> (last visited June 19, 2020) .

²⁰ Seema Verma, “Medicare COVID-19 Data Release Blog,” June 22, 2020. Available at: <https://www.cms.gov/blog/medicare-covid-19-data-release-blog> (last visited June 24, 2020).

as a national leader in population health and health equity innovation. To help support this action, researchers from the AAMC have partnered with the New York City Department of Health on a study evaluating the use of nine-digit zip codes to quantify social risk that will be presented later this month.²¹ We also have curated a collection of articles and resources²² to assist our member institutions, constituents, and the public in learning more about and exploring the complex issues and strategies to combat racism and make health care more diverse, equitable, and inclusive. We look forward to working with all stakeholders, including CMS and other health care payers, in this important work.

HOSPITAL COMPARE OVERALL QUALITY STAR RATING PROGRAM

CMS previously announced²³ that it would use the FY 2021 IPPS rulemaking to propose updates to the Overall Quality Star Rating methodology. Due to the impact of the COVID-19 public health emergency, CMS clarified in its fact sheet²⁴ for the proposed rule that it had not included these proposals and instead would look to do so in future rulemaking. The AAMC supports the Agency's decision to limit this rulemaking to essential policies and proposals to reduce provider burden and aid providers in their COVID-19 response. **We urge CMS to suspend the Star Ratings** in consideration of the unknown impact of COVID-19 and suspended quality measurement in 2020 on measure performance and the need to address the flaws with the current methodology that have been present for years as this does not provide accurate information to the public

We look forward to working with CMS on improving the Star Ratings methodology, including support for peer grouping and stratified comparisons and the development of an explicit calculation approach to replace the latent variable modeling approach. **One of our key recommendations to CMS has been to explore template matching, or other approaches that directly compare patient groups as an alternative model for rating hospitals.** Considering that the *Hospital Compare* Overall Quality Star Rating is meant to assist patients and consumers to choose hospitals based upon quality information *and* help guide hospitals in their quality improvement activities, the template matching model may be a valid alternative worthy of full

²¹ *Forthcoming* Podium Presentation: "Does Accounting for Community-Level SDOH Matter for Readmission Policy? Insights from New York City," AcademyHealth Annual Research Meeting 2020.

²² See AAMC, "Racism and Health" webpage (2020). Available at: <https://www.aamc.org/news-insights/racism-and-health> (last visited June 22, 2020).

²³ See CMS Press Release "CMS Announces Upcoming Enhancement of Overall Hospital Quality Star Ratings," August 19, 2019. Available at <https://www.cms.gov/newsroom/press-releases/cms-announces-upcoming-enhancement-overall-hospital-quality-star-ratings> (last visited June 16, 2020)

²⁴ See CMS Fact Sheet "Fiscal Year (FY) 2021 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long Term Acute Care Hospital (LTCH) Proposed Rule (CMS-1735-P)," May 11, 2020. Available at <https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2021-medicare-hospital-inpatient-prospective-payment-system-ipps-and-long-term-acute> (last visited June 16, 2020)

consideration. Please refer to the AAMC's full comments²⁵ in response to the Agency's 2019 request for comment on how to improve the Star Rating methodology.

HOSPITAL INPATIENT QUALITY REPORTING PROGRAM (IQR)

CMS proposes to (1) progressively increase the quarters of data on which hospitals must report for electronic clinical quality measure (eCQM) reporting requirements, (2) begin publicly reporting eCQM performance on the Hospital Compare website, and (3) modify its data validation program to align validation for chart-abstracted measures and eCQMs. The AAMC submits comment on the first two proposals and is supportive of the proposal related to aligning the data validation program without additional comment.

Progressively Increasing eCQM Data Reporting Requirements

CMS specifically proposes a three-year incremental increase to the hospital eCQM reporting requirements, specifically by increasing the number of quarters of data a hospital must submit from one calendar quarter for FY 2022 payment (CY 2020 reporting period) to four quarters, or a full year's worth of data, for FY 2025 (CY 2023) and subsequent years. In the two years in between, hospitals would be required to increase reporting by an additional calendar quarter of data each year. CMS states that this progressive increase balances hospital burden with the intended benefit that more quarters of data better captures trends in performance and provides hospitals with a more continuous information stream to monitor performance. Relatedly, increased data reporting requirements would increase the required data for validation, if applicable.

This proposal amends previously finalized policies²⁶ for FY 2023 (CY 2021) and FY 2024 (CY 2022) requiring hospitals to report one, self-selected calendar quarter of data. Hospitals have relied on these finalized policies to allocate limited resources for both staffing and electronic health record [EHR] vendor-related coordination in preparation for near-term future reporting and validation requirements. Such planning was also undertaken before the COVID-19 pandemic, which has placed additional financial stress that likely impacts staffing resources and EHR-related projects for the foreseeable future.

We previously voiced concerns from our members about the challenges of mapping the necessary data elements from the EHR to the CMS Quality Reporting Data Architecture (QRDA) reporting format, and that vendors control that functionality for proper collection and transmission of the data through the CMS portal. The Office of the National Coordinator for

²⁵ See "AAMC Submits Comments on Future Improvements to Hospital Star Ratings Methodology," March 28, 2019. Available at: <https://www.aamc.org/system/files/c/1/496514-aamccommentsonfutureimprovementstohospitalstarratingsmethodology.pdf> (last visited June 15, 2020)

²⁶ FY 2020 IPPS/LTCH PPS Final Rule, 84 *Fed. Reg.* 42044, 42501-42505 (August 16, 2019)

Health Information Technology (ONC) only recently finalized a rule²⁷ impacting requirements for vendors in regard to supporting CMS' QRDA to remove certification requirements that do not support quality reporting for CMS programs as part of 2015 Edition Certified EHR Technology. Hospitals will need time and resources to manage EHR changes broadly in response to the ONC's rulemaking and increases in hospital burden related to eCQMs. **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.

The AAMC urges CMS to adopt a more incremental approach to increasing eCQM reporting requirements in light of these concerns. Specifically, we suggest that CMS increase the calendar quarters of data by one quarter every other year, still beginning with FY 2023 (CY 2021). This would mean that two quarters of data would be required for FY 2023 (CY 2021) and FY 2024 (CY 2022), three quarters for FY 2025 (CY 2023) and FY 2026 (CY 2024), and a full year for FY 2027 (CY 2025) and subsequent years. This gives hospitals more time to balance increased reporting requirements with the financial realities during and following the public health emergency and implementing broader changes to EHR systems, while still committing to the Agency's goal of increased insight into performance trends and continuous information for monitoring performance.

Public Reporting of eCQMs

CMS also proposed to begin publicly reporting eCQM performance on its *Hospital Compare* website beginning in the fall of 2022 with eCQM data reported by hospitals for FY 2023 payment determinations (CY 2021 reporting period). This proposal is in addition to other efforts the Agency is taking to modernize and simplify its portfolio of *Compare* websites and to improve the functionality and accessibility of healthcare quality data for patients and consumers.

CMS previously finalized a policy²⁸ where, beginning with FY 2024 determination (CY 2022), hospitals will be required to report on four eCQMs: three self-selected eCQMs from the IQR program's nine available measures and one required eCQM (Safe Use of Opioids – Concurrent Prescribing). For FY 2023 determinations, hospitals can self-select all four measures reported. This has the potential to cause confusion, as a patient (or patient's family) could select hospitals for comparison with the website tool and find that the hospitals selected do not report the same measures. Public reporting of self-selected measures is a novel approach for *Hospital Compare*. CMS must conduct user testing on how best to communicate the self-selection nature so that patients and their families understand the potential for incongruity.

²⁷ 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule, 85 *Fed. Reg.* 25642, 25686-25690 (May 1, 2020).

²⁸ 85 *Fed. Reg.* at 42501-42505.

The AAMC supports the Agency’s commitment to empowering patients and their families to make informed decisions about their healthcare but believes CY 2021 reporting might be too soon to add eCQM performance to *Hospital Compare*. Instead, the AAMC suggests that CMS delay public reporting until CY 2022 reporting at the earliest (published to the *Hospital Compare* website in fall of 2023). This would provide the Agency sufficient time to focus on its current efforts to improve the *Compare* websites and ensure that there is at least one consistent eCQM reported across all hospitals.

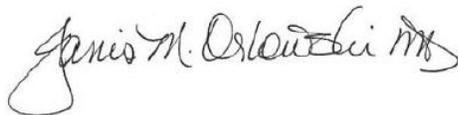
MEDICARE AND MEDICAID PROMOTING INTEROPERABILITY PROGRAMS

CMS is proposing the same eCQM reporting requirements for CY 2021 through CY 2023 reporting and beyond as for the IQR, including the proposed increase to the amount of data for eCQMs and public reporting of eCQM performance. Additionally, CMS is proposing modest changes including retaining the Query of Prescription Drug Monitoring Program (PDMP) Measure as a voluntary measure worth bonus points for CY 2021 reporting and to rename a measure to more accurately reflect the measure’s intent. Please refer to our comments above in response to the eCQM proposals. We support the agency’s proposal to retain the Query of PDMP measure as voluntary and the renaming of the Health Information Exchange measure to “Support Electronic Referral Loops by Receiving and Incorporating Health Information” without additional comment.

CONCLUSION

Thank you for the opportunity to comment on the FY 2021 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. Orłowski, M.D., M.A.C.P.
Chief Health Care Officer

cc: Ivy Baer