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Submitted electronically via www.regulations.gov

June 25, 2018

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1694-P
P.O. Box 8010
Baltimore, MD 21244-1850

RE: Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates *(CMS-1694-P)*

Dear Ms. Verma:

The Association of American Medical Colleges ("the AAMC" or "Association") welcomes this opportunity to comment on the proposed rule entitled "Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates," 83 *Fed. Reg*. 20163 (May 7, 2018), issued by the Centers for Medicare & Medicaid Services (CMS).

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 151 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. Together, these institutions and individuals are the American academic medicine community.

Summary of Major Payment Policy Issues on Which AAMC Provides Comments

The following items reflect the AAMC's top recommendations for hospital payment issues:

- ***Medicare Cost Report Requirements***: Do not finalize the new reporting requirements associated with submission of the Medicare cost report.
- ***Chimeric Antigen Receptor T-cell (CAR-T) Therapy***: Consider carving these very costly technologies out of the MS-DRG and paying for them on a pass-through basis until a

more accurate payment method can be found that will provide beneficiaries with access to this therapy, and providers with adequate payment.

- ***Public Listing of Hospital Standard Charges***: Do not finalize the proposals for hospitals to publicly list standard charges. Instead, work with providers, insurers, consumer groups and other stakeholders to determine how to make available the type of information that will be most actionable to consumers who want to know what their out-of-pocket costs will be.
- ***Replication of CMS Weight-Setting***: Apply the existing methodology appropriately to ensure the weights are accurate for payment purposes.
- ***Medicare Disproportionate Share and Uncompensated Care Hospital Payments***: Delay use of S-10 data, audit S-10 data, and provide a stop loss policy for significantly impacted hospitals.
- ***Multi-campus Hospital Urban to Rural Reclassification***: Provide additional information on the policy as well as provide explicit guidance on what should be done in situations where the policy would apply.
- ***Affiliated Groups for New Urban Teaching Hospitals***: Finalize the proposal to increase flexibility for new urban teaching hospitals entering into affiliation agreements, but clarify the term "new urban teaching hospital" as it relates to this provision.
- ***Inpatient Admission Requirements***: Finalize the proposal to remove the written inpatient admission order requirement, but clarify whether the documentation of an inpatient admission order must be maintained and consider modifying 42 CFR §413.3(c) so that the order must be furnished at or before the time of discharge, rather than the time of admission.

The following highlights the AAMC's top recommendations for CMS's inpatient hospital quality programs and the Medicare and Medicaid Promoting Interoperability Programs.

- ***Quality Measure Removals***: Finalize the proposals to remove measures that are duplicative, burdensome, or otherwise do not meet the goals of CMS's Meaningful Measures framework.
- ***Value-Based Purchasing (VBP) Program Scoring***: Finalize the policy to remove the Safety Domain and increase the weight of the Clinical Outcomes Domain to 50 percent in Fiscal Year (FY) 2021.
- ***Hospital Acquired Condition Reduction Program (HACRP) Scoring***: Do not weight measures equally in the HACRP program and instead compare cohorts of hospitals based upon the measures for which they have scores.
- ***Star Ratings***: Publish information demonstrating the impact of measure changes on the overall star ratings and examine whether a reduced measure set more fairly compares quality across all inpatient hospitals.
- ***Risk Adjust for Sociodemographic Status***: Take additional steps to account for SDS factors in hospital quality programs.
- ***Certified EHR Technology (CEHRT)***: Allow for hospitals to use both 2014 and 2015 Editions of CEHRT in Calendar Year (CY) 2019.

- ***eCQM Reporting***: Finalize the policy that hospitals report on a minimum of four select selected measures for a self-selected calendar year quarter and maintain this policy beyond CY 2020 for consistency.
- ***Meaningful Use Scoring***: Eliminate the threshold-based methodology and replace it with a modified version of the points- based performance scoring approach proposed in the rule. Finalize a new scoring policy to allow hospitals to report one self-selected measure per objective and receive bonus points for reporting additional optional measures to maximize flexibility and reduce burden. CMS should retain the Stage 2 methodology for meaningful use if it does not finalize a modified scoring approach.
- ***API Systems and Use of Apps***: Establish rigorous standards that applications must meet before requiring that hospitals allow patients to select apps to use to access their data due to concerns with data breaches.
- ***Conditions of Participation***: Do not require interoperability in the conditions of participation as they are not the right vehicle to encourage interoperability given the significant consequences if not met, particularly since interoperability is still in its early stages.

MEDICARE COST REPORT REQUIREMENTS

CMS Should Not Finalize the Burdensome Proposed Medicare Cost Report Submission Requirements

Providers participating in the Medicare program are required to annually submit cost reports that cover a 12-month period to CMS. As part of the cost report submission requirements, providers are required to maintain financial records and statistical data supporting their cost report. If a provider submits a cost report without required supporting documentation then the cost report is rejected. Currently, however, hospitals are not required to submit all the supporting data outlined in the proposal with their Medicare cost report, nor are all the numbers in the cost report and supporting data expected to align perfectly when submitted. Rather, as the proposed rule notes, "the provider must furnish such information to the contractor as may be necessary to assure proper payment." (83 *Fed. Reg*. 20545).

Beginning with cost reports filed on or after October 1, 2018, CMS proposes to require that certain information – intern and resident information system (IRIS) data, Medicare bad debt reimbursement, disproportionate share hospitals (DSH) payment adjustment, and charity care and uninsured discounts – must be consistent with the numbers on the cost report; if the data is inaccurate or missing the cost report will be rejected. Cost reports remain open for three years after submission to allow time for audit and reconciliation. AAMC believes that these requirements will create significant administrative burden for hospitals, contrary to the Administration's goal to decrease regulatory burden – a goal we share. **The AAMC strongly urges CMS not to finalize the proposal.**

Hospitals work diligently to file complete and timely cost reports as directed by statute. However, there are times when the data submitted on the cost report is estimated due to a variety of circumstances outside of the institution's control. For example, in some states the information

on Medicaid beneficiaries is provided after submitting the cost report. To date, Medicare Administrative Contractors (MACs) have accepted Medicare cost reports with this interim data. Currently, after submission, a hospital works with its MAC to identify and remedy any discrepancies in the cost report and to supply amended information and data as it becomes available. CMS's proposal, in effect, accelerates the process so that the MAC will have 30 days to determine whether a cost report is acceptable. AAMC does not believe it is feasible or advisable for the MAC to determine whether a cost report is acceptable, a duty normally reserved for the audit process, in this short window permitted by the regulations. **A cost report should not be rejected because it lacks comprehensive and complete documentation of items claimed in the cost report that are normally furnished later or in response to a MAC audit. If the cost report contains all information currently required in the regulation we believe it should be considered complete and be accepted by the MAC.** Any discrepancy in the numbers reported will be reconciled at the time of audit.

Our specific concerns about the proposals are below.

IRIS Data. In this proposed rule, CMS is proposing that direct graduate medical education (DGME) and indirect medical education (IME) full time equivalent (FTE) counts on a hospital's cost report must identically match the IRIS data. CMS attempts to justify this proposal by citing a Department of Health and Human Services (HHS) Office of Inspector General (OIG) report[1] urging CMS to ensure that residents are not double-counted. Ensuring that a resident is not counted as more than 1.0 FTE can only be done with a review of all the hospitals where residents train and can be counted by a hospital; it cannot be done through having a single hospital submit data and supporting documentation with that single hospital cost report. **The AAMC urges CMS to not finalize this proposal.**

Hospitals collect and document total resident FTE counts for direct GME and IME payments on the cost report. Historically, there have been some discrepancies of DGME/IME FTE counts when the cost reports are initially submitted. MACs have routinely accepted cost reports with estimated GME/IME FTE counts and subsequently reconciled those numbers with the IRIS system during their reviews. This process is effective and is well understood by both parties. **Consequently, CMS should not adopt the proposal that a cost report should be rejected if the cost report GME and IME FTE total counts do not match the IRIS data at the time of submission.**

DSH Payment Adjustment. CMS also proposes that a hospital submit a listing of its Medicaid eligible days with its cost report that corresponds to the number of Medicaid eligible days claimed on its cost report. Currently, hospitals must maintain this information and provide it upon request, but are not required to submit this information as part of their cost report. The proposed rule again states that for a cost report to be considered acceptable, this detailed listing of Medicaid eligible days must be included and match the amounts being claimed for the DSH

[1] U.S. Department of Health and Human Services, Office of Inspector General Report No. A-02-13-01014, August 2014.

payment adjustment. If this documentation is not included and does not match the DSH amount claimed, the cost report will be rejected. However, this information is commonly not available at the time of the cost report submission, as some hospitals are reliant upon their state to provide additional information. Even though CMS notes in the proposed rule that hospitals will have the opportunity to supply updated data up to 12 months after the initial cost report submission, an amended listing or an addendum to the original listing would have to be furnished. This requirement is highly burdensome as it would require supporting documentation that hospitals must maintain, but may not have readily available in a format that can be submitted at the time of the cost report submission. In many cases the information will have to be amended later as hospitals may not have complete Medicaid information at the time the cost report is submitted. **Therefore, we urge CMS not to finalize this proposal.**

Medicare Bad Debt. CMS proposes that hospitals provide a document known as the "Medicare bad debt listing" with their cost report. If the bad debt listing does not correspond to the bad debt amount claimed on the cost report, CMS's proposed policy dictates that the cost report be rejected for lack of supporting documentation. The bad debt listing includes information such as the patient's name, dates of service, the beneficiary's Medicaid status, and the deductible and coinsurance amounts. We believe this information should only have to be furnished at the time of an audit. CMS's policy, in effect, accelerates what would typically be produced if there is an audit to occur during the cost report submission process. **Therefore, we urge CMS not to finalize this proposal.**

CHIMERIC ANTIGEN RECEPTOR T-CELL (CAR-T) THERAPY

AAMC is Concerned About Payments for Chimeric Antigen Receptor T-cell (CAR-T) Therapies

Rapid advances in treatments for life-threatening illnesses and diseases have been made in recent years. These new therapies hold great promise, but they can be extremely expensive and require extensive hospital care. Still, these therapies are the innovative care of the future and are changing rapidly, offering treatment advances for previously untreatable diseases. Teaching hospitals – many of the institutions where patients will receive these expensive treatments – share a commitment to advancing medical knowledge, therapies, and technologies to prevent disease, alleviate suffering, and improve quality of life.

As these new therapies enter the market and the total costs of providing these treatments continues to increase, there needs to be stewardship to maintain access without bankrupting the health care system. These treatment breakthroughs include immunotherapies – therapies that enlist and strengthen the power of a patients' immune system to attack tumors – that have taken an important role in the treatment of some forms of cancer. According to the National Cancer Institute, the immunotherapy therapy that has advanced the furthest in clinical development is

called CAR T-cell therapy.[2] CAR-T therapies are usually used in the treatment of patients who have exhausted all other treatments.

In 2017, two CAR-T therapies – Kymriah™ and Yescarta™ – were approved by the federal Food and Drug Administration (FDA). In these applications, drug manufacturers estimate that there may be as many as 25,000 patients per year eligible to receive these therapies. The price tags for the treatments alone approach half a million dollars – $475,000 for Kymriah™ and $373,000 for Yescarta™. When paired with the number of patients who may be eligible for these treatments, it highlights the potential unsustainability of these new technologies.[3]

The AAMC is concerned about beneficiary access in the long-term, and whether hospitals that administer these high-cost therapies will be adequately reimbursed. Patients receiving this therapy are admitted to the hospital and tend to be sicker due to having an advanced disease state. 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. One of the most frequent complications is cytokine relapse syndrome (CRS).[4] As the proposed rule notes, 24 percent of patients that developed CRS required an ICU admission (p. 20292). Another serious and potentially fatal side effect is swelling of the brain.[5] Furthermore, because of the finite number of hospitals currently approved to provide this treatment, there will be increased financial burden on these hospitals. The payment for this therapy is likely to set a precedent for other therapies that are likely to become available in the future. CMS needs to give beneficiaries and providers certainty in terms of coverage determinations and appropriate payment, and must address the unsustainably high drug costs for these cases.

Additional comments on the impact of these new CAR T-cell technologies are below.

Assignment to MS-DRG 016. In the proposed rule, CMS states that the manufacturers of these CAR-T therapies submitted separate applications for new technology add-on payments for FY 2019. **The AAMC supports assigning the procedure to the MS-DRG 016** – Autologous Bone Marrow Transplant with CC/MCC. We note that this will yield a payment amount that is inadequate to cover the costs of treatment, but if paired with other policies –specifically the new technology add-on payment (see below) and likely outlier payment – could provide a minimum rate that will help ensure beneficiary access to CAR-T. CMS should monitor the impact of this policy and consider future changes that will result in more accurate reimbursement for the therapy.

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[2] National Cancer Institute. CAR T Cells: Engineering Patients' Immune Cells to Treat Their Cancers. www.cancer.gov/about-cancer/treatment/research/car-t-cells.
[3] 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
[4] National Cancer Institute. CAR T Cells: Engineering Patients' Immune Cells to Treat Their Cancers. www.cancer.gov/about-cancer/treatment/research/car-t-cells.
[5] Ibid.

New Technology Add-On Payment (NTAP). **We support utilizing the new technology add-on payment,** which is not subject to budget neutrality and thus will not reduce payments for other inpatient services. Yet, we are concerned that, because NTAPs are made at a rate of 50 percent of the marginal cost of the technology, this payment would not ensure beneficiary access to care. Therefore, the AAMC strongly urges CMS to make NTAPs for CAR-T at a rate of 100 percent of its marginal cost. Without this increase, hospitals would face losses in the hundreds of thousands of dollars. Such losses are not sustainable and pose a threat to beneficiary access. These payments will allow for targeted reimbursement of the therapy as a transition to a more permanent payment rate.

Outlier payments. Outlier payments provide IPPS hospitals with an additional payment to help defray the costs associated with high-cost cases. This pool of money, however, is limited by law. We are concerned that due to the anticipated high cost of CAR-T treatments, all of these treatments and cases will qualify for an outlier payment for FY 2019, possibly resulting in no other cases qualifying for outlier payments. This will push the fixed loss threshold higher in subsequent years thereby eliminating other very high-cost treatments from qualifying for the outlier payment. This is not sustainable long term as more patients become eligible for CAR-T treatments, and more therapies are approved. If CMS adopts the MS-DRG assignment of 016 for CAR-T in FY 2019 as proposed and recognizes the true drug acquisition cost when computing the new technology add-on and outlier payments, as the volume of these cases increases, it will affect the outlier payments. **We urge CMS to monitor and evaluate the impact of CAR-T payment policy on outlier payments when determining how to pay for the service in future years.**

Reimbursement of CAR-T drugs. To safeguard patient access to CAR-T therapies, CMS should ensure adequate reimbursement of CAR-T drugs. CMS should consider whether to reimburse CAR-T drugs separately based on the average sales price (ASP), which would be a proxy for cost. CMS would then pay for the hospital services associated with the infusion of this therapy under an appropriate MS-DRG. Conversely, CMS could separately reimburse providers for the CAR-T acquisition costs based on the invoice. This proposal would eliminate the need for the technology add-on payment and should not have a significant impact on the outlier payment for future years.

New MS-DRG for CAR-T therapies. CMS invites comments on how the administration of CAR-T therapy and associated services meet the criteria for the creation of a new MS-DRG. While creating a new MS-DRG for these therapies would take away the need for a new technology add-on payment, it is hard to accurately assess the full costs of these services and hence assign a proper DRG weight before sufficient claims data become available. Due to the budget neutrality requirements, if the weight is not assigned properly to the new DRG, it may affect weight assignment to other DRGs in future years. The AAMC recommends that CMS, before creating a new DRG for CAR-T inpatient stays, collect comprehensive data on the total costs of inpatient care when these new therapies are utilized. Finally, the AAMC supports the Administration's role as outlined by the President on reigning in high cost of care by drug manufacturers.

PUBLIC LISTING OF HOSPITAL STANDARD CHARGES

AAMC Urges CMS to Not Finalize the Public Listing of Hospital Standard Charges Policy, and Instead Work to Identify More Helpful Information Patients Need to Understand Their Hospital Care Costs

Under the proposed rule, beginning January 1, 2019, hospitals will be required to publicly report a listing of the hospital's standard charges via the internet in a machine-readable format. It is CMS's belief that providing information about hospital charges and patients' potential financial liability will enable patients to compare charges for similar services across hospitals. We do not believe that posting hospitals standard charges will provide patients with the information that is of most importance or usefulness to them – their financial obligation based on their insurance plan, including whether they have met their deductible, and their co-pay amount, if any. This information may not be easily obtained by hospitals. **Therefore, we urge CMS not to finalize this requirement, and instead work with hospitals, insurers, consumers, and other stakeholders to identify information that patients need to better understand the costs they will incur for hospital care.**

The complexity of health care costs and the fragmented health care system are core reasons why achieving price transparency in health care is so difficult. The cost of performing a service in a hospital may depend not only on the hospital's costs, but also on the socioeconomic status of the patients treated, as well as on the cost of medications and medical supplies. There are times when hospitals can negotiate prices, but in many instances, a pharmaceutical company or another supplier sets a price which the hospital must pay. Further, hospitals do not usually set the charges for the services of the physicians from whom patients receive care while in the hospital.

Ultimately, the cost that is likely to be of most importance to patients is their out-of-pocket cost. This is especially true for individuals with high-deductible health plans. According to a Kaiser Family Foundation survey, 28 percent of individuals are enrolled in a high-deductible plan – an increase of 9 percentage points since 2012.[6] The Federal Reserve found that 40 percent of Americans would not be able to cover a $400 expense, or would cover it by selling something or borrowing money.[7] The IRS defines a high deductible health plan as any plan with a deductible of at least $1,350 for an individual or $2,700 for a family. [8] This suggests that the need for consumers to have information tailored to their specific insurance situation is the way to provide meaningful, actionable information. At a minimum it is imperative that CMS engage insurers, who are likely to be able to provide more details to the out-of-pocket estimate, to move forward with its price transparency efforts. The AAMC supports transparency in price but believes that a

[6] Kaiser Family Foundation. Employer Health Benefits: 2017 Summary of Findings. Available at: http://files.kff.org/attachment/Summary-of-Findings-Employer-Health-Benefits-2017.
[7] Report on the Economic Well-Being of U.S. Households in 2017, May 2018, https://www.federalreserve.gov/publications/files/2017-report-economic-well-being-us-households-201805.pdf.
[8] https://www.healthcare.gov/glossary/high-deductible-health-plan.

more comprehensive approach needs to be taken to provide patients and their families with meaningful, actionable price transparency information.

REPLICATION OF CMS WEIGHT-SETTING

CMS Should Ensure Weights Are Computed Accurately for the Final Rule

In our replication of the CMS weight-setting, we concluded that the National Average cost-to-charge ratios (CCRs) used in the rate-setting were computed improperly. This computation error did not materially affect the weights, but we found that all the weights were slightly incorrect. As the weights are being updated for the final rule with more up-to-date information, we request that CMS apply the existing methodology appropriately to ensure the weights are accurate for payment purposes.

MEDICARE DISPROPORTIONATE SHARE AND UNCOMPENSATED CARE HOSPITAL PAYMENTS

AAMC urges CMS to Delay Use of Worksheet S-10 Data, Provide a Stop-Loss Policy to Protect Vulnerable Hospitals from Financial Harm, and Audit S-10 Data

CMS started incorporating the cost report Worksheet S-10 data on hospital charity care and bad debt in FY 2018, and proposes in FY 2019 to continue its transition. Specifically, CMS proposes to use FY 2014 and 2015 Worksheet S-10 data with FY 2013 Medicaid days and Supplemental Security Income (SSI) ratios to determine the distribution of uncompensated care payments. As AAMC stated in comments to the FY 2018 IPPS proposed rule, and in previous years' comment letters, the transition to Worksheet S-10 is likely to have a significant impact on the redistribution of uncompensated care payments. This concern is still applicable as CMS proposes to transition use of S-10 data in FY 2019. Consequently, CMS should be mindful of the impact of the redistribution and the extent of its authority ensure that DSH and uncompensated care (UC) money goes to hospitals with higher rates of caring for poor, complex patients, as was Congress's intent. Therefore, **the AAMC continues to recommend that CMS explore ways to mitigate the effect on hospitals by lengthening the transition to the Worksheet S-10 from the proposed 3 years. The first step would be delaying the continued use of Worksheet S-10 in calculating DSH payments by one year.** This would allow hospitals to prepare for potential losses due to policy changes. **In addition, CMS should impose a stop loss policy to prevent significant financial harm to hospitals that would limit the amount a hospital can lose during any redistribution of UC funds.** AAMC also noted in its FY 2018 comments the S-10 data issues with accuracy, consistency, and completeness. AAMC maintains its recommendation that CMS should **establish a full audit process for the S-10 data to ensure the data are sufficiently accurate and consistent.**

MULTI-CAMPUS HOSPITAL URBAN TO RURAL RECLASSIFICATION

AAMC Urges CMS to Clarify and Provide Guidance for Its Policy on Hospital Urban to Rural Reclassification

In response to questions related to urban hospitals that reclassify as rural hospitals under §412.103, CMS proposes to codify that the reclassification would only affect the IME adjustment, not the direct GME payment. The Agency also proposes that the reclassification would only be available if both the main campus and its remote locations are each either geographically located in a rural area, or reclassified as rural under §412.103.

CMS has not provided sufficient justification as to why both the main hospital and all remote locations must meet the same geographic criteria, nor has it stated what will happen to multi-campus hospitals that have already reclassified. Before finalizing this proposed policy, the AAMC urges CMS to provide additional information on the policy as well as provide explicit guidance on what should be done in situations where the policy would apply.

AFFILIATED GROUPS FOR NEW URBAN TEACHING HOSPITALS

CMS Should Clarify the Term "New Urban Teaching Hospital" as it Relates to Affiliated Groups

The proposed rule offers expanded flexibility for new urban teaching hospitals[9] that seek to form Medicare GME affiliated groups. The proposal allows new urban teaching hospitals that wish to form an affiliated group with other new urban teaching hospitals to do so and be eligible to receive both decreases and increases to their FTE caps. This proposal will allow teaching hospitals to expand residency training programs and provide residents the opportunity to practice in areas that were previously unavailable to them due to this restriction. **The AAMC applauds CMS's recognition of this constraint and encourages CMS to finalize this proposal.**

The AAMC asks that CMS consider clarifying the term "new urban teaching hospital" as it relates to this provision. As CMS defines the term "new teaching hospital," it refers to hospitals that started training residents after 1996, over 20 years ago. However, to the academic medical community, a new teaching hospital means one that is in its cap-building period. To avoid confusion, CMS should, at a minimum, clarify that a new teaching hospital eligible for this new flexibility is one that has already established its FTE cap.

INPATIENT ADMISSION REQUIREMENTS

CMS Should Clarify Inpatient Admission Requirements and Consider Modifying When the Physician Order Must Be Furnished

CMS is proposing to amend the requirement that a written inpatient admission order be present in the medical record as a specific condition of Medicare Part A payments. As part of the FY 2014 IPPS final rule, CMS adopted a set of policies collectively known as the "2 midnight"

[9] §412.105(f)(1)(vii) or §413.79(e)(1).

payment policy codifying the policy that a beneficiary becomes an inpatient if formally admitted pursuant to a physician order. However, as CMS has acknowledged, some "otherwise medically necessary inpatient admission[s] are being denied payment due to technical discrepancies with the orders." (83 Fed. Reg. 20448).

The AAMC supports CMS's decision to remove this requirement in an effort to reduce administrative burden. Additionally, we agree with CMS that medical reviews should focus on whether the inpatient admission was "medically reasonable and necessary" (83 *Fed. Reg*. 20448) rather than the inadvertent omission of a written inpatient admission order. However, we ask CMS to consider modifying 42 CFR §413.3(c) so that the order must be furnished at or before the time of discharge, rather than the time of admission.

While the AAMC is pleased with the proposed change, it applies only to the inpatient prospective payment system. To encourage consistency across payment systems and reduce documentation burden, CMS should make the same change to documentation requirements at other sites where there will be an inpatient admission, such as in psychiatry and rehabilitation. The AAMC acknowledges that this will require rulemaking and encourages CMS to make these changes as soon as possible.

HOSPITAL QUALITY PROGRAMS

CMS Must Take Additional Steps to Account for Sociodemographic Status (SDS) Factors in Hospital Quality Measurement

The AAMC is supportive of the efforts by CMS to implement the requirements under the 21st Century Cures Act to create a fairer Hospital Readmissions Reduction Program (HRRP), but it is not a panacea. Most outcome measures, particularly readmission measures, are affected by sociodemographic status (SDS) factors, which are beyond the control of the hospital. The nation's teaching hospitals, which provide excellent patient care[10] and disproportionately treat disadvantaged and vulnerable patient populations, may be unfairly penalized by the performance and penalty programs due to the lack of adequate SDS adjustment. The penalty adjustments implemented under the HRRP result only in slightly reduced penalties for those hospitals most in need of resources to treat underserved and complex patient populations. Most importantly, 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. **The AAMC believes that stratifying performance by the hospital's number of dual-eligible patients 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.**

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[10] Laura Burke, MD, et al. *Association Between Teaching Status and Mortality in US Hospitals*. JAMA, 2017. Retrieved from: http://jamanetwork.com/journals/jama/article-abstract/2627971%20

The literature recognizing the impact of SDS factors on patient outcomes is substantial.[11,12] Recent government entities tasked with examining the impact of SDS have also been clear about the impact of SDS. The reports released by the Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine (NAM) on accounting for social risk factors in the Medicare performance programs have provided evidence-based confirmation that accounting for patients' sociodemographic and other social risk factors is critical in validly assessing the quality of providers. The reports demonstrate that hospitals caring for large numbers of disadvantaged patients are more likely to receive penalties in the performance programs and that the lack of SDS adjustment can worsen health care disparities because the penalties divert resources away from hospitals and other providers treating large proportions of vulnerable patients. The failure to account for SDS variables also misleads and confuses patients, payers, and policymakers by shielding them from important community factors that contribute to poor health outcomes. Finally, as noted by ASPE, the cumulative effect of the penalties across the Medicare performance and penalty programs could significantly hinder the work of those institutions that disproportionately serve beneficiaries with social risk factors.[13] Both reports clearly show that there are implementable mechanisms by which SDS data elements can be incorporated into quality measurement today. The AAMC urges CMS to incorporate the recommendations below to account for SDS factors and ensure that all hospitals are assessed on an even playing field. The AAMC is eager to work with CMS as the agency implements these changes.

AAMC Recommendations to Account for SDS Factors in the Medicare Hospital Reporting and Performance Programs

- Require measure developers to test a range of national-level sociodemographic data elements, identified in the ASPE[14] and NAM[15] reports, into the risk adjustment methodology of accountability metrics. Both reports discuss in detail data elements that are publicly available and could be immediately tested to determine whether an empirical relationship exists between SDS and the measure's outcomes. Such elements could include but not be limited to income, education, neighborhood deprivation, and marital status.
- Provide hospitals with timely, confidential reports of performance on accountability measures stratified by dual eligible status or other nationally available data elements.
- Once hospitals have had sufficient opportunity to review and understand their performance on these stratified measures through their confidential reports, CMS should

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[11] Michael Barnett, MD, et al. *Patient Characteristics and Differences in Hospital Readmission Rates*. JAMA, 2015. Retrieved from: http://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2434813
[12] Jianhui Hu, et al. *Socioeconomic status and readmissions: evidence from an urban teaching hospital*. Health Affairs, 2014. Retrieved from: http://content.healthaffairs.org/content/33/5/778.full
[13] "Office of the Assistant Secretary for Planning and Evaluation." *Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program*. December, 2016. Pg, 92 Retried from https://aspe.hhs.gov/system/files/pdf/253971/ASPESESRTCfull.pdf
[14] ibid
[15] "National Academies of Medicine." *Accounting for Social Risk Factors in Medicare Payment: Criteria, Factors, and Methods*. 2016. Retrieved from https://www.nap.edu/download/23513#

work with stakeholders to publicly report this data in a manner that is accurate and understandable to patients.

- CMS should implement demonstration projects to encourage hospitals to collect SDS data through their electronic health records (EHR). These elements could be used to supplement the claims data already captured by CMS to greatly improve the measure's risk adjustment methodology. It is essential that CMS include vendors in these discussions.
- Where meaningful and comprehensive neighborhood level SDS-data currently exist, CMS should encourage empirical tests of quality metrics adjusted for those factors to assess the impact of the adjustments on local provider performance metrics. Based on the results of these tests CMS and other agencies will be able to prioritize the national collection of data that are most essential for valid risk adjustment methodologies.

CMS Should Consider the Removal of Additional Measures from the Inpatient Hospital Quality Programs as Part of its Meaningful Measures Work

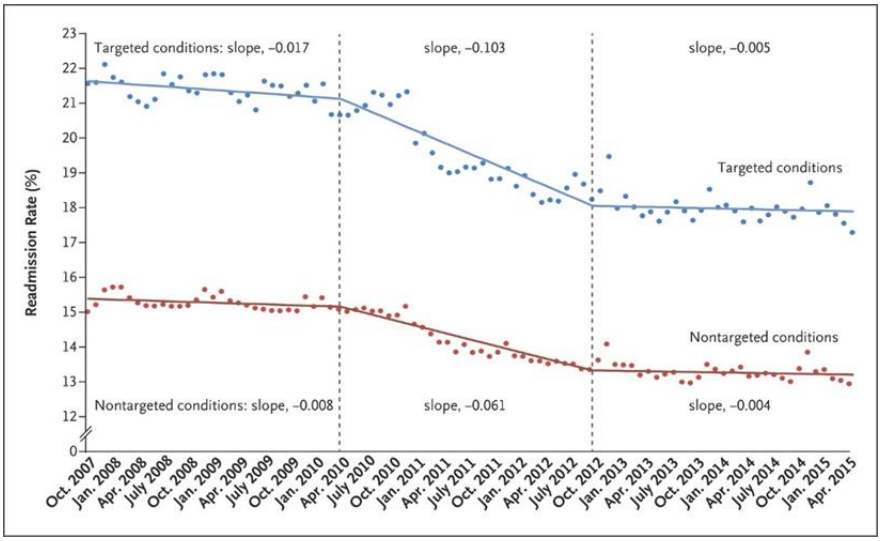
The AAMC supports the agency's Meaningful Measures framework and the proposals to remove measures across the inpatient hospital quality programs to align programs and to better address quality priorities. We urge CMS to continue to review its portfolio to consider the removal of additional measures from its programs.

The AAMC reiterates its prior recommendation that CMS undertake a comprehensive review of the readmission measures in the Hospital Readmission Reduction Program to determine whether the readmission rates on any of these conditions have not significantly changed from previous performance years. and whether performance has reached a natural plateau. Hospitals will be assessed on six conditions in FY 2019, three of which have been in the program since FY 2013. These three conditions are acute myocardial infarction (AMI), heart failure (HF), and pneumonia (PN). An article in the New England Journal of Medicine shows that readmissions for HRRP-targeted conditions declined significantly following passage of the Affordable Care Act in March 2010, but have declined much more slowly starting in late 2012.[16] (Please see Figure 1 from NEJM article below that highlights performance on these conditions between 2007 through 2015). Hospitals have undertaken significant efforts to implement care improvement strategies to address excess readmissions in their communities. As displayed in the graph below, the gains from the readmissions program could be reaching a limit for certain conditions with hospitals no longer being able to move the needle on further readmissions reductions. Retaining measures that are "topped out" may result in quality performance assessments that are based on natural statistical variation rather than meaningful differences.

[16] Rachael B. Zuckerman, M.P.H., et al. *Readmissions, Observation, and the Hospital Readmissions Reduction Program*. New England Journal of Medicine. 20016. Retrieved from: https://www.nejm.org/doi/full/10.1056/NEJMsa1513024

Studies have also shown that there is a direct correlation between higher readmission rates and lower mortality for HF, PN, and AMI.[17, 18] Hospitals with low mortality rates for patients with HF also have higher readmission rates.[19] This is likely because these hospitals are successful at keeping the patient alive, thereby resulting in more readmissions. At some point, CMS must accept that a certain level of readmissions is necessary for patient care as defined by medical research on this subject. If hospital performance on these measures has reached a natural plateau, CMS should take steps to remove the conditions from the program.

Figure 1: Change in Readmission Rates for Targeted Conditions and Non-targeted Conditions within 30 Days after Discharge.



HOSPITAL VALUE-BASED PURCHASING PROGRAM

CMS proposes to remove 10 measures from the VBP program, including PSI-90 Patient Safety Composite, and to adopt the Inpatient Quality Reporting (IQR) Program's factors for considering measure removal. In addition, the Agency plans to change the scoring methodology beginning in FY 2021 by removing the Safety Domain, and re-weighting the remaining domains by doubling the weight of the Clinical Outcomes Domain.

AAMC Supports the Removal of Measures and Urges CMS to Further Review the Validity and Inclusion of the PSI-90 Measure in Other Inpatient Quality Reporting and Performance Programs

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[17] Harlan M. Krumholz, MD, SM, et al. *Relationship Between Hospital Readmission and Mortality Rates for Patients Hospitalized With Acute Myocardial Infarction, Heart Failure, or Pneumonia*. JAMA. 2013. Retrieved from: https://jamanetwork.com/journals/jama/fullarticle/1570282?resultClick=1

[18] Ankur Gupta, MD, PhD, et al. *Association of the Hospital Readmissions Reduction Program Implementation With Readmission and Mortality Outcomes in Heart Failure*. JAMA. 2018. Retrieved from: https://jamanetwork.com/journals/jamacardiology/article-abstract/2663213

[19] Eiran Z. Gorodeski, MD, MPH, et al. *Are All Readmissions Bad Readmissions?* NEJM. 2010. Retrieved from: https://www.nejm.org/doi/full/10.1056/NEJMc1001882#t=article

The AAMC is encouraged by this initial proposal to remove duplicative safety and condition-specific cost measures from the VBP program as a first step towards alignment across inpatient quality reporting programs and reducing provider burden. The AAMC strongly supports the removal of PSI-90, as the AAMC has long recommended that CMS eliminate the measure overlap between the HACRP and VBP programs to reduce the likelihood of mixed signals on performance due to different versions of the measure in use under the programs in FY 2018.

AAMC Recommends that CMS Modify the MSPB Cost Measure to Account for SDS Factors

The AAMC recognizes the importance of measuring Medicare cost and resource use associated with inpatient care as a component of value within the VBP program, but we believe that CMS should improve the Medicare Spending Per Beneficiary (MSPB) measure to include adjustment for SDS factors. A recent article observed that "[a]fter adjustment for dual status, difference in MSPB performance between safety-net and non-safety-net hospitals were no longer significant."[20] Failure to account for SDS factors leaves the MSPB measure open to unintended consequences – reducing payment to safety-net hospitals that disproportionately treat care for dually- enrolled patients. CMS should stratify MSPB measurement by proportion of duals as a first effort, to ensure that hospitals are more equitably scored on their Medicare spending measure. This would make consistent policy in following suit with the stratification in the Readmissions Reduction Program, considering that MSBP accounts for all costs, including those associated with a readmission.

Adopting Measure Removal Factors, Including an Additional Factor Related to the Costs Associated With a Measure, Provides Clarity to Stakeholders

The AAMC is supportive of CMS's efforts to add clarity to its process when considering measure removals. The eight factors proposed for adoption in the VBP program are well-established and ensure that a variety of valid reasons to remove a measure should be considered by CMS.

The AAMC supports the addition of a new factor related to costs associated with a measure. Regarding this new factor, the AAMC suggests that CMS consider the following when evaluating a measure's cost burden:

- Whether the provider needs to contract out or otherwise pay external vendors to collect and report the data necessary for the measure,
- Whether clinicians will need to add processes to collect data to inform the measure,
- Whether new processes added to collect data on the measure will duplicate efforts with existing tasks, or

[20] Lok Wong Samson, et al. *Dually Enrolled Beneficiaries Have High Episode Costs On the Medicare Spending Per Beneficiary Measure*, Health Affairs. 2018. Retrieved from: https://www.healthaffairs.org/doi/10.1377/hlthaff.2017.0914

- Whether the process involves completing more steps or tasks as it produces outputs for measurement.

AAMC Supports Changes to Proposed Weighting of VBP Domains in FY 2021

CMS is proposing to change the weighting of the remaining VBP domains beginning in FY 2021, when based upon its measure removal proposals, no measures will remain in the Safety Domain prompting CMS to propose removing the domain altogether. CMS's preferred approach to reweighting is to double the weight of the Clinical Outcomes Domain to 50 percent, and retain the 25 percent weights for the Person and Community Engagement and Efficiency and Cost Reduction Domains.

The AAMC supports this preferred approach because it most fairly weights the individual measures within the program, considering that the Clinical Outcomes Domain has five measures, while the other two domains are comprised of a single measure (HCAHPS and MSPB, respectively). This is significant, as it responds to the Government Accountability Office (GAO) report that observed the prior equal domain weighting scheme allowed hospitals with performance below the national average on the clinical quality measures yet perform well on the MSPB cost measure to receive an incentive payment under VBP.[21] The AAMC recommends that CMS consider further deemphasizing the weight of the Cost Domain if it continues to observe this phenomena under the proposed approach.

HOSPITAL ACQUIRED CONDITIONS REDUCTION PROGRAM

CMS is proposing to modify the weighting of measures in scoring for the Hospital Acquired Conditions Reduction Program (HACRP), in addition to adopting HACRP-specific data collection and validation policies for measures that are proposed for removal from the VBP and IQR programs.

CMS Should Mitigate the Disproportionate Penalties in the HACRP

The AAMC remains concerned that the HACRP continues to overwhelmingly and disproportionately impact the nation's major teaching hospitals. By CMS's own estimate, its proposed approaches to modifying the scoring methodology will cause more large hospitals to be penalized under the program in FY19, increasing the projected total penalties ($19M under its preferred approach and $7.5M under the alternative approach) compared to the current methodology. Unlike VBP and HRRP, penalties under the HACRP are also applied to a hospital's add-on mission payments, such as IME, DSH, and UC. This broader application further penalizes teaching and safety net hospitals disproportionately. Hospitals are being identified as poor performers due to limitations in the scoring methodology (most notably that not all hospitals have measure scores for every measure included), risk adjustment, and the size of teaching facilities, rather than to true differences in the quality of care. Furthermore, the arbitrary statutory design of the program requires CMS to impose penalties on 25 percent of

[21] Government Accountability Office. *Hospital Value-Based Purchasing – CMS Should Take Steps to Ensure Lower Quality Hospitals Do No Qualify for Bonuses*. June 2017. Retrieved from: https://www.gao.gov/assets/690/685586.pdf

hospitals each year even if there are improvements in reducing infections within a hospital or across the nation. This major flaw in the creation of the program makes it that much more essential that CMS ensure measurement is as fair as possible and does not create systematic bias that disadvantages a particular type of hospital.

AAMC Recommends Alternatives to the Proposed Scoring Changes to Ensure Scoring Does Not Disproportionately Penalize Teaching Hospitals

CMS proposes to change the weighting of HACRP domains in calculating a hospital's Total HAC Score beginning in FY 2020. CMS believes a change is needed to account for smaller hospitals, which are less likely to have scores on all six measures in the program, resulting in skewed weighting of measures between the domains under the current approach. CMS's proposed approach would eliminate the two domains entirely, and instead apply equal measure weights when calculating the Total HAC Score. The alternative approach considered is a variable domain weighting approach, which would retain the 2 domains, but apply weights dependent upon the number of measure scores a hospital has under Domain 2.

The AAMC does not support CMS's proposals to change the weighting of domains under the HACRP beginning in FY 2020, as both approaches increase the likelihood that teaching hospitals will be penalized in the program without meaningfully distinguishing differences in performance, which will only further exacerbate a program that disproportionately penalizes teaching hospitals. Instead, the AAMC recommends that CMS consider alternatives either focusing on improving the measures or comparing hospitals based upon the number of measures scores they have. A measure improvement approach might, for example, consider changes to the measures themselves that would result in smaller hospitals being more likely to have measure scores on the National Healthcare Safety Network (NHSN) measures in Domain 2 (such as reducing the number of qualifying infection events to less than 1). A more systematic approach would be to modify the program's scoring such that it is comparing cohorts of hospitals based upon the measures for which they have scores (rather than comparing performance across varying measure score completeness). Considering these approaches based on comparable safety measurement is more appropriate than the proposed approaches simply intended to reduce the number of small hospitals penalized under the program.

The AAMC Supports CMS's Adoption of HACRP-specific Data Collection and Validation Policies, but Urges that CMS Enact a Policy to Prevents Dual Data Validation Selection for the Same Reporting Period

The AAMC understands that the HACRP will need its own data collection, validation, and reporting policies if CMS finalizes its proposals to remove duplicative CDC NHSN Hospital-Acquired Infection (HAI) measures from the Inpatient Quality Reporting (IQR) Program. The AAMC urges CMS to enact a policy that prevents dual data validation selection for the same reporting period. As is currently proposed, it would be possible for a hospital to be selected for data validation under both the HACRP and the IQR for the same reporting period.

Finally, in response to CMS's proposal to rename the review and correction procedures under the HACRP to the "Scoring Calculations Review and Correction Period," the AAMC recommends that CMS make the various review periods clearer by distinguishing when a hospital is reviewing the underlying data versus the scoring of that data under the HACRP Program. A clarifying name change for the period is a first step, but more is needed on CMS's quality reporting websites to ensure transparency of the differing review periods in programs.

All Measures Proposed for the HACRP Should Be NQF Endorsed, Approved by the MAP, and Publicly Reported

CMS also requests stakeholder feedback on future addition of measure topics for the HACRP, with specific questions about the potential for future adoption of eCQMs in the program. We provide feedback on the general adoption of eCQMs in our comments for the IQR Program, which we reiterate here – primarily that there still is considerable burden required to map data and that eCQM reporting depends on vendors using the correct version of specifications. These concerns are amplified when an eCQM is included in a penalty program.

The AAMC will provide feedback on new HACRP measures once they are proposed. We strongly recommend that all new measures be NQF- endorsed to ensure that the measure is scientifically valid, reliable, and feasible, and determine whether it is appropriate for review in the NQF SDS trial period. Any new measure for the HACRP should also be included in IQR and reported on Hospital Compare for one year and approved by the Measure Applications Partnership (MAP) before the measure is proposed. Finally, considering CMS's Meaningful Measures framework, any new measures should be evaluated within the framework and appropriate corresponding measure removals should be considered to balance a measure's addition. Until this occurs, relevant stakeholders do not have the necessary information to make a critical assessment as to whether a measure is appropriate for the program.

The AAMC Urges CMS to Remove the PSI-90 Measure from the HACRP Until the Measure is Properly Risk -Adjusted

The AAMC remains concerned that the modified PSI-90 composite, finalized for inclusion into the HACRP starting in FY 2018, does not meet the criteria outlined in our comments above for the inclusion of new measures in the HACRP. The modifications to the measure did not address the lack of SDS adjustment and observed bias in performance against certain providers. The AAMC urges CMS to remove this measure from the HACRP and to re-propose the measure when the data demonstrates stability and reliability for performance measurement.

HOSPITAL INPATIENT QUALITY REPORTING PROGRAM (IQR)

CMS is proposing to remove 39 measures from the IQR Program for payment determinations made for FYs 2020 through 2023 as part of the agency's commitment to its Meaningful Measures Initiative. The removals are mostly to remove duplicative reporting, as 19 of the measures removed from the IQR will continue to be used in the other inpatient hospital quality reporting program with performance reported publicly on *Hospital Compare*. CMS is not

proposing to add any measures to the program, though the agency requested feedback on eCQMs generally and three possible future measures for the program: two new hospital-wide mortality measures (claims-based and hybrid versions) and a new opioid-related adverse events eCQM. CMS submitted all three measures to the MAP as part of the 2017 Measures Under Consideration List. CMS proposes to extend the 2018 eCQM reporting requirements to 2019 for both the IQR and the Medicare EHR Incentive Program (now the Promoting Interoperability Program), to which the AAMC responds in its comments on the latter program.

The AAMC Supports the Proposed Measure Removals, and Urges CMS to Clarify the Impact of Measure Removals on its* Hospital Compare *Star Ratings Methodology

As discussed earlier in these comments, the AAMC is supportive of these initial efforts to review and remove measures across the programs as part of CMS's work to apply its Meaningful Measures framework. One concern has arisen related to the proposed removal of certain measures from the IQR that are not being retained in other inpatient quality reporting programs and the impact that those measure removals might have on CMS's Hospital Compare Star Ratings methodology. Questions were raised to CMS during its May 9th webinar on the proposed rule asking whether there are any impacts on the Star Ratings. CMS staff presenting were unable to answer. We urge CMS to clarify the impact of the measure removals on the Star Ratings program, as it is unclear if a measure is wholly removed from the inpatient quality reporting programs, and no longer publicly reported on *Hospital Compare*, at what stage it is also removed from the Star Ratings methodology.

The AAMC is committed to improving quality and supports public reporting that is reliable, valid, and meaningful to patients and their families. We are thankful that CMS agrees in these principles and is delaying updates to the Star Ratings indefinitely while it seeks critical feedback necessary to improve the ratings methodology. **CMS should publish information demonstrating the impact of these changes on overall star ratings, and specifically examine whether a reduced measure set more fairly compares quality across all inpatient hospitals.** This could be responsive to broader concerns that the Star Ratings disproportionately give higher ratings to hospitals that report fewer overall measures, such as specialty hospitals.[22]

Request for Feedback – Future Adoption of Hospital Hybrid Measures in the IQR

The AAMC appreciates that an all-cause mortality measure is of great importance to patients and could potentially encourage facilities to work more collaboratively with other providers and improve continuity of care. However, serious concerns relating to risk adjustment, unintended consequences for end-of-life care, and misinterpretation of the measure score by consumers were raised by the MAP; it is essential that these concerns be vetted through the NQF endorsement process.

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[22] Maria Castellucci. *CMS star ratings disproportionately benefit specialty hospitals, data show*. Modern Healthcare. March 14, 2018. Retrieved from: http://www.modernhealthcare.com/article/20180314/NEWS/180319952

Claims-based risk adjustment by 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. The AAMC agrees with the MAP that appropriate risk adjustment is necessary to ensure that the measure does not disproportionately penalize facilities who treat more complex patients.

The AAMC believes that condition-specific mortality measures already in use in the IQR may be more actionable for hospitals and may provide more detailed information to patients to support consumer decision-making. We agree with the MAP members who cautioned that performance scores on an all-cause mortality measure could be potentially misleading to consumers, as this may simply reflect a lower acuity facility and not necessarily a facility's overall quality.

The concerns for the claims-based mortality measure were the same for this measure, in addition to concerns with the challenges of extracting EHR data and EHR fragmentation. The AAMC believes that integrating EHR data with claims data is a positive step, but we recommend that the focus of efforts at this stage should be on the use of EHR data to adjust condition- specific mortality measures that are currently being used in the programs. Introduction of the hybrid measure should have a voluntary reporting period before it becomes a mandatory measure.

Request for Feedback – Future Adoption of Hospital Harm Opioid Measure in the IQR

The AAMC recognizes the need for more quality measures to assess opioid-related adverse events. There is potential with this measure, but based upon the assessment of the MAP it is clear the measure is not yet ready for inclusion in CMS's inpatient quality reporting programs. The MAP noted that the measure has not yet been tested at enough hospitals to assess the measure's reliability and validity across facilities, which should be demonstrated before the measure is submitted for NQF endorsement. It was also unclear from the MAP's discussion whether the measure developer has fully considered potential unintended consequences of the measure and whether there is a need for exclusions to assess appropriate use of naloxone and adequate pain control.

The AAMC understands the desire to address the growing opioid crisis and that quality measurement is one tool towards that end. However, we remain concerned that this measure is not truly ready for implementation. The MAP provided feedback to CMS on the measure to revise and resubmit the measure to the MAP via inclusion on a future Measures Under Consideration (MUC) list. The AAMC strongly encourages that this measure not be added to the program, even on a voluntary basis, until the measure is fully vetted and endorsed by the NQF.

Request for Feedback – General Adoption of eCQMs

The AAMC is supportive of CMS' efforts to improve the quality of care by developing measures on dimensions of patient harm or adverse patient safety events. We note that CMS has previously recognized and responded to the challenges regarding the feasibility of electronically-submitted

measures and has reduced the number of eCQMs hospitals must report for FYs 2019 and 2020 payment determinations. The Agency proposes to extend this to FY 2021 payment. There is considerable burden required to map the necessary data elements from the EHR to the appropriate Quality Reporting Data Architecture (QRDA) format, and some vendors are not properly equipped to collect and transmit such data through the CMS portal.

Mandatory 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. The Association continues to have concerns that hospitals and vendors may not be adequately prepared to fully report eCQMs. We ask CMS to focus resources on sufficiently addressing current concerns with eCQM reporting rather than on developing additional eCQMs for inclusion in hospital reporting programs for the future. Focusing on the inclusion of a small number of measures in the eCQM program that are meaningful and not overly burdensome will provide hospitals with additional time and bandwidth to address the considerable challenges of electronic data reporting.

The AAMC recognizes the value of e-versions of measures. Moving away from chart abstraction has the potential to reduce burden on providers, but it should not be done in an all-or-nothing approach because there still is a great deal of learning that is needed. Hospitals need to train clinicians to document properly within the EHR system to ensure accurate data capture. We propose a hybrid approach to eCQM adoption where hospitals submit data on eCQMs, but in the event of a measure failure, the hospital may supplement the data with manual chart abstraction. This would be mutually beneficial: CMS would receive more accurate data and hospitals would learn their workflows and documentation gaps for improvement efforts. It would be less burdensome than manual abstraction, without the fear of penalizing hospitals who are still working through the burden to transition to e-measures.

Finally, the AAMC advises that completed testing of these eCQMs under development should demonstrate reliability and validity in the acute care setting and these measures should be submitted to NQF for review and endorsement. CMS should vet these new eCQMs across a selection of vendors and hospitals prior to considering the measures for addition to a CMS quality reporting program for implementation.

MEDICARE AND MEDICAID PROMOTING INTEROPERABILITY PROGRAMS

In the proposed rule, CMS announces that it is renaming the Medicare EHR Incentive Program the Medicare and Medicaid Promoting Interoperability Programs. CMS proposes use of 2015 certified EHR technology (CEHRT), retaining 2018 requirements for eCQM reporting, and substantial changes to the scoring methodology used to determine whether a hospital has met the meaningful use requirements. Additionally, CMS is proposing to add two new e-prescribing measures beginning in 2019.

AAMC Recommends that CMS Retain Flexibility for Hospitals to Use 2014 and 2015 Editions of CEHRT in CY 2019

The AAMC understands the benefits of the 2015 Edition of CEHRT, including the application programming interface (API) functionality, but **recommends that CMS allow the 2014 Edition for meaningful use determinations in 2019 in addition to the 2015 Edition**, or a combination of both editions. Some hospitals need additional time to deploy the 2015 Edition, which involves major transitions to systems and significant staff training.

AAMC Encourages CMS to Retain the CY 2018 eCQM Reporting Requirements Beyond CY 2020 Reporting

CMS has previously finalized a requirement that reduced the number of eCQMs that hospitals must submit to a minimum of four over a minimum of one self-selected calendar quarter (continuous 90-day period) for CYs 2017 and 2018 (FYs 2019 and 2020 payment determinations). The Agency is proposing to continue this policy for CY 2019 and CY 2020 reporting (FY 2021 and FY 2022 payment determinations). The AAMC appreciates CMS's recognition and response to the challenges regarding feasibility of electronically-submitted measures. Maintaining the reduced reporting burden through CY 2020 would be consistent and provide predictability and allow hospitals the additional time and bandwidth to address the considerable challenges of electronic data reporting.

The AAMC continues to have concerns that hospitals and vendors may not be sufficiently prepared to fully implement broader eCQM reporting in the near term. As noted previously in these comments, there is considerable burden, and CMS should continue its outreach to EHR vendors, hospital quality staff, and other affected stakeholders to identify underlying structural problems and barriers to successful reporting of these measures. Until these issues are sufficiently addressed, the **AAMC recommends that CMS maintain the policy requiring hospitals to submit one quarter of data on four required measures beyond CY 2020**.

AAMC Supports a Scoring-Based Approach to Determining Hospital Meaningful Use, and Encourages CMS to Provide Adequate Notice of Any Changes to the Future Scoring Requirements

CMS's proposed new scoring methodology would require hospitals to report on fewer objectives and measures and would eliminate the burdensome pre-defined performance thresholds for a point system based upon performance on the measures. A minimum score of 50 points would satisfy the meaningful use requirement. **The AAMC applauds this change to scoring, as it allows hospitals more flexibility with a performance-based scoring approach**. The smaller set of objectives more clearly reflects the agency's priorities, and allows hospitals to better focus resources on improvement activities.

As an alternative, the AAMC recommends that CMS require reporting of one measure in each objective (instead of all measures) and allow hospitals to select which measure to report within

an objective. In addition, CMS should allow the hospitals to receive bonus points by reporting additional optional measures. This approach would maximize flexibility and reduce burden.

Regarding the evolution of the program in future years, the AAMC urges CMS to provide adequate notice and transparency of any changes to its future scoring requirements. There is considerable burden on providers to adapt to constant changes to the CEHRT or meaningful use objectives and measures. Hospitals need to pay for upgrades made by vendors in response to changes, and need time to adapt to the modifications to the systems. CMS should engage stakeholders to better ensure that any future refinements to scoring minimums do not unnecessarily ramp up requirements for hospitals to be considered meaningful users.

AAMC Opposes the Stage 3 Methodology if CMS Does Not Finalize the Modified Scoring Approach

CMS should retain the Stage 2 methodology for meaningful use determinations if it does not finalize the modified scoring approach, instead of implementing the Stage 3 methodology (with the additional measures proposed, if the measures are finalized). **Stage 3 requirements are onerous and would add considerable burden if implemented** due to the costs hospitals would need to spend to upgrade their EHRs solely for the purposes of meeting the requirements.

Measures Proposed for the Promoting Interoperability Programs Should Be NQF-Endorsed, Approved by the MAP, and be Transitioned Over a Period of Public Reporting Before Factored into Meaningful Use Scoring

CMS is proposing to add two new e-prescribing measures to the Medicare Promoting Interoperability Program to align with the Department's Opioid Strategy. The two measures are: Query of Prescription Drug Monitoring Program (PDMP) and Verify Opioid Treatment Agreement. These two measures would be bonus measures for scoring in 2019 and required measures for 2020. The AAMC recognizes the value of new tools to assist with the opioid addiction epidemic but cautions against making these measures required as early as 2020 due to the need for better integration of these tools with CEHRT. CMS should not consider including these measures in the program until they are more adequately defined and there is better evidence of integration of these tools into CEHRT by vendors and into clinical workflows by providers. When these measures are better developed, we recommend implementing them as bonus measures until there is sufficient time to integrate them into systems.

Currently, CEHRTs do not have widespread integration of the PDMP tools. Providers often need to manually document a query of the PDMP to score the measure, adding considerable burden. The AAMC recommends that ONC consider adopting standards and certification criteria to support the query of PDMP before the measure is required under the program. Adding to that burden is that in some states, providers are charged for each query. CMS should examine more closely the impact of the fees charged by states on the performance of this measure. Finally, we are concerned that the measure is not adequately defined, as it does not include measure limits to the number of queries during a hospital stay. The AAMC recommends further discussion with stakeholders before the measure is finalized and implemented in the program. If finalized, CMS

should simplify the PDMP measure by scoring it as a yes/no measure instead of by a numerator and denominator.

Regarding the treatment agreement measure, the AAMC notes that there is a lack of clarity of what would constitute a treatment agreement sufficient for meeting the goals of the measure. There are also questions of precisely how electronic the agreement must be – does it require an electronic signature, or can it be a paper agreement that is scanned into the EHR? This is of concern as some of our members have considered investment in electronic agreement tools in the inpatient setting, such as electronic signature pads, and found the cost to be prohibitive. If the tools were necessary for meeting performance standards on the measure, providers would have to make a resource determination unrelated to the value of the agreements at the heart of the measure. Additionally, some hospitals have implemented treatment agreements into ambulatory care setting clinical workflows and would need time to redesign workflows and transition them into inpatient setting.

Overall, we continue to strongly recommend that all new measures be NQF- endorsed to ensure that the measure is scientifically valid, reliable, and feasible. Measures under the Promoting Interoperability Programs should be approved by the MAP before the measure the measure is proposed. Finally, considering CMS's Meaningful Measures framework, any new measures should be evaluated within the framework and appropriate corresponding measure removals should be considered to balance a measure's addition. Until this occurs, relevant stakeholders do not have all the necessary information to make a critical assessment as to whether a measure is appropriate for the program.

AAMC Supports Removal of the Coordination of Care Through Patient Objective

The AAMC recommends that CMS finalize its proposal to remove the Coordination of Care Through Patient Objective and three associated measures. Measures that require patient actions, such as the "Removal of View, Download, or Transmit" Measure can be difficult for providers to meet as they are not able to dictate a patient's actions. Also, the "Patient Specific Education measure" is overly burdensome as patient education resources do not need to be maintained or generated through CEHRT. There are other resources available to educate patients. The "Secure Messaging Measure" also has significant burden associated with tracking secure messages and creates new workflows that do not improve clinical care.

CMS Should Align Interoperability Programs as Much as Possible

CMS's proposal to amend the scoring for Meaningful Use determinations will only apply to state Medicaid programs where that state chooses to adopt the new scoring methodology, causing issues of lack of alignment across the broader program which is seeking to increase interoperability. CMS states that it does not expect states to adopt the CMS's new methodology, due to costs associated with implementing these changes and the relatively small number of providers who are eligible for an incentive payment solely under a Medicaid Meaningful Use determination. We question whether the policy will be able to meet the broader goal of encouraging greater interoperability. Eligible hospitals and critical access hospitals (CAHs)

should be evaluated across the same standards for meaningful use regardless of whether Medicare or a state Medicaid program is completing that assessment. CMS should consider revising its policy and making the proposed scoring methodology consistent across both Medicare and Medicaid programs.

Request for Feedback – Future Directions of Promoting Interoperability Programs

The AAMC is supportive of future recognition of certain health IT activities, like participation in the Trusted Exchange Framework and Common Agreement (TECFA) or maintaining an open API for patient access to their health records, as alternatives to traditional program measures because it would provide hospitals greater flexibility and promote innovative engagement with health IT. The flexibility could decrease burden by allowing hospitals more choice in implementation and deployment of health IT to demonstrate meaningful use. Aligning this flexibility with the promoting interoperability requirements under the Quality Payment Program would reduce burden, especially for hospital-based eligible clinicians.

One area **we urge CMS to take caution with is moving too quickly towards API systems due to potential security concerns.** As we have seen in other industries, there is a general concern about lack of security with API causing significant data breaches and demonstrating that API security risks are not simple. Considering the added level of importance with health data, CMS should take steps to set strict API security standards and ensure that approved APIs meet or exceed those standards.

One way to potentially mitigate security concerns would be to have hospitals be required to enable at least one application chosen by the hospital for patients to access patient information from, instead of having patients choosing the application to use. If the patient wants to access his/her data, the patient would need to use the application selected by the hospital. There could be an exception for hospitals that are unable to find an application that fits with their security. We recommend that CMS work with stakeholders to develop a secure ecosystem in the future that would set minimum security requirements that applications must meet.

Relatedly, CMS, Office of the National Coordination (ONC), and the Federal Trade Commission (FTC) should work on model language that explains to patients that their data is no longer protected by HIPAA when a patient chooses to release information to an application. It must be clear to patients that providers would not be responsible, and patients should work with the FTC to resolve issues if information is compromised.

REQUEST FOR INFORMATION

CMS Should Not Create Additional Conditions of Participation (CoPs) as Part of the Agency's Efforts Towards Promoting Interoperability and Electronic Healthcare Information Exchange

While the agency's goals of interoperability are increasingly important to transforming health care in the digital age, the AAMC does not support requiring interoperability in the conditions of participation. CoPs are not the right vehicle to encourage interoperability given the importance of CoPs and the significant consequences if not met, particularly since interoperability is still in

progress. CMS has other policy levers to promote broader interoperability and use of electronic healthcare information exchanges, most notably the Promoting Interoperability Programs.

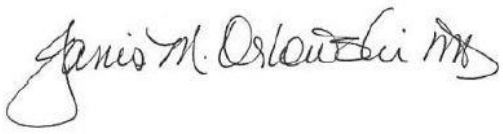
If CMS proposes to implement modifications to the conditions of participation (CoPs) regarding interoperability, CMS generally should:

- Allow for post-discharge follow-up programs to be based on individual patient needs and available social support recognizing that a one-size-fits-all approach will not benefit all patients
- Provide clarity in how to appropriately document exceptions to the requirements
- Ensure that any new requirements are consistent with and not counter or be redundant to state requirements, particularly for the Prescription Drug Monitoring Program (PDMP) or Meaningful Use objectives, such as discharge and transfer summaries
- Recognize the true financial impact and administrative burden incurred by hospitals in implementing these requirements. **We believe CMS has significantly underestimated both in their impact analysis.**

Conclusion

Thank you for the opportunity to comment on the FY 2019 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 provisions and Phoebe Ramsey at 202.448.6636 or pramsey@aamc.org for questions on the quality provisions.

Sincerely,



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