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Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
ATTN: CMS-1752-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Medicare Inpatient Prospective Payment System Fiscal Year 2022 Proposed Rule

Dear Administrator Brooks-LaSure:

The Association of American Medical Colleges (AAMC or the Association) welcomes this opportunity to comment on the proposed rule entitled “Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2022 Rates,” 86 *Fed. Reg.* 25070 (May 10, 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 through medical education, health care, medical research, and community collaborations. Its members are all 155 accredited U.S. and 17 accredited Canadian medical schools; more than 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America’s medical schools and teaching hospitals and their more than 179,000 full-time faculty members, 92,000 medical students, 140,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

The following summary reflects the AAMC’s comments on CMS’s proposals regarding hospital payment, quality proposals, and requests for information (RFIs) in the Fiscal Year (FY) 2022 Inpatient Prospective Payment System (IPPS) Proposed Rule.

- ***Graduate Medical Education.*** Finalize the second alternative payment methodology, with modifications, for the distribution of residency slots in FY 2023, and work with stakeholders to refine the distribution methodology for future years.
- ***Data Source for Fiscal Year 2022 IPPS Ratesetting.*** Use FY 2019 data for FY 2022 ratesetting.

- ***Organ Acquisition.*** Do not finalize the organ acquisition proposals. Instead engage all stakeholders to evaluate organ acquisition policies to ensure continued availability and access to scarce organs.
- ***Disproportionate Share Hospital and Uncompensated Care Payments.*** Provide clarification of how the Office of the Actuary (OACT) determined the “other” factor included in the calculation of Factor 1.
- ***Medicaid Fraction.*** Do not finalize the proposal that would exclude certain Medicaid beneficiaries receiving coverage under an 1115 waiver from the hospital’s Medicaid fraction calculation.
- ***Wage Index.*** Extend the five-percent transitional cap in a budget neutral manner to all wage index changes for all hospitals for FY 2022.
- ***Collection of Medicare Advantage Negotiated Rates.*** Finalize the proposal to repeal the policy for hospitals to report Medicare Advantage negotiated rates and the policy that would consider using this information for relative weight calculations.
- ***Medicaid Enrollment of Medicare-Enrolled Providers / Suppliers.*** Finalize the proposal to require Medicaid agencies to enroll Medicare-enrolled providers and suppliers for the purpose of determining Medicaid’s cost-sharing liability for beneficiaries eligible for both Medicare and Medicaid.
- ***Closing the Health Equity Gap in CMS Hospital Quality Programs.*** Undertake a thoughtful and considered approach working with stakeholders to improve data collection in order to better measure and analyze disparities in a manner that builds an evidence-based, valid, and reliable framework towards provider accountability for health equity.
- ***Future Stratification of Quality Measures by Race and Ethnicity.*** Invest in data collection improvements that standardize and use data already collected by hospitals and encourage the reporting and use of actionable social risk factor data instead of using indirect estimates of race and ethnicity data to stratify measure reporting. Race and ethnicity themselves are not risk factors and reliance on immutable characteristics alone is not informative for intervention.
- ***Improving Demographic Data Collection.*** Pursue a policy supporting the collection of standardized multi-sector risk information to support improved stratification and risk adjustment beyond individual-level demographic data elements. Data collection and systems for social risk factors at both the individual and community level should be used in conjunction to best identify disparities in quality and equity and guide interventions for improvement.
- ***Potential Creation of a Hospital Equity Score.*** Ensure that measurement of health equity includes and expands on stratified clinical quality measures. CMS should evaluate the development of structural and process measures that will drive improvement for health equity and commit to the evolution and expansion of social risk factors included in a future hospital measure that build off advancement in measure science and expanded collection of valid and reliable social risk data.

- ***Adoption of Measure Suppression Factors in the Pay-for-Performance Quality Performance Programs to Address Impacts of COVID-19 Public Health Emergency.*** Finalize the suppression factors as proposed and commit to studying impact of their use. After further study, CMS should adopt revised measure suppression factors for broader applicability to a future national public health emergency.
- ***Adoption of New Measures for the Inpatient Quality Reporting Program.*** Implement a voluntary reporting period of at least one year in order to sufficiently address critical questions impacting measure design before mandating reporting of the proposed COVID-19 vaccination among health care personnel measure
- ***Potential Reporting of a Structural Measure to Assess Hospital Leadership Engagement with Health Equity Performance Data.*** Engage experts in the development of structural measures as a critical first step to assessing current practices and incentivizing new evidence-based methods that advance our collective health equity goals.
- ***Advancing Digital Quality Measurement.*** Refine the definition of digital quality measures to focus first on currently available valid and reliable digital data sources and set clear and specific parameters for what the Agency hopes to achieve and what it expects of hospitals in its goal to transition to digital quality measurement by 2025.

GRADUATE MEDICAL EDUCATION PROVISIONS

Section 126: Distribution of Additional Residency Positions

As the United States population grows and ages, the demand for physicians continues to outpace the supply. In the latest study, the projected shortfall is between 37,800 and 124,000 primary care and specialty physicians by 2034.¹ The shortage of primary care physicians is projected to be between 17,800 and 48,000 and the physician shortage for non-primary care specialties is projected to be between 21,000 and 77,100 physicians. Last year, a broad bipartisan coalition of members of Congress who represent diverse districts, states, and communities worked together to provide 1,000 new Medicare-supported graduate medical education (GME) positions in the Consolidated Appropriations Act, 2021 (CAA)—the first increase of its kind in nearly 25 years and a critical initial step toward tackling the physician shortage. Addressing the physician shortage is essential if the United States is to improve access to care, particularly for underserved populations which already face many barriers.

In providing for the 1,000 residency slots, Section 126 of the CAA laid out some parameters for slot distribution. Among the requirements are that no more than 200 slots be made available each fiscal year and that no hospital is to receive more than 25 additional full-time equivalent (FTE) residency positions in total. CMS chose to much more narrowly limit the increase to 1.0 FTE per hospital, per year—significantly less than the limit established by statute. The increase applies to both direct graduate medical education (DGME) and the indirect medical education (IME)

¹ The Complexities of Physician Supply and Demand: Projections from 2019 to 2034, <https://www.aamc.org/media/54681/download>.

adjustment. The legislation also calls for no less than 10 percent of the slots to go to each of the following 4 categories of hospitals:

- Located in rural areas or treated as being in a rural area;
- Training residents over their Medicare GME cap;
- Located in states with new medical schools or branch campuses on or after January 1, 2000; and
- That serve areas designated as health professional shortage areas (HPSAs).

These requirements and the short time frame between the CAA's passage and the issuance of the proposed regulations presented CMS with the difficult task of proposing how best to distribute the 1000 GME slots, particularly given the limitation that only 200 can be distributed in each of the next five years. The Agency proposed requirements for the four categories of "qualifying hospitals," and suggested two alternative methods to assign priority for slot awards to hospitals that apply for the slots. Under the first method, the Agency proposes to rank applicant hospitals by HPSA score; those with the highest scores would be awarded the maximum 1.0 FTE. Remaining slots would go to applicant hospitals with the next highest HPSA score until all 200 slots for that fiscal year are awarded. In the case of a tie—hospitals with the same HPSA score and an insufficient number of slots to award each hospital a 1.0 FTE—hospitals would receive a prorated slot, i.e., less than 1.0 FTE.

Under the alternative methodology CMS proposed for FY 2023 only, teaching hospitals would be ranked based on the number of statutorily specified categories they meet, with hospitals meeting all four categories receiving slots first, then those meeting three, two, and one if any slots remain. Again, CMS proposes that no hospital would receive more than 1.0 FTE per year, and ties would result in hospitals receiving a prorated FTE amount or even less than 1.0 FTE.

As will be discussed in detail below, the AAMC supports a distribution system for FY 2023 only to "allow [CMS] additional time to work with stakeholders to develop a more refined approach for future years." (p. 25509). Finalizing a methodology for only one year will also provide an opportunity to evaluate how the process operates and provide real-time information about how the methodology works. We also believe that CMS's FY 2023 alternative proposal should be finalized with significant modifications, which we describe in detail below. Regardless of the methodology finalized, the AAMC strongly opposes the limitation of 1.0 FTE per hospital per year. The 1.0 FTE limitation does not allow for meaningful program expansion, is not sufficient to start a new program, and may disincentivize hospitals from participating at all. We also suggest revisions to other parts of the proposal for the section 126 slot distributions.

1.0 FTE Limitation Should Not Be Finalized

The severe limitation of awarding no more than 1.0 FTE per hospital per year should not be finalized. A 1.0 FTE increase is not adequate to start a new program and is unlikely to meet the needs of established programs that want to expand or fill a full complement of positions already approved by the Accreditation Council for Graduate Medical Education (ACGME).

CMS expects “the majority of [the 300 teaching hospitals that have their main campus located in a primary care or mental health HPSA] would apply for additional residency positions because they would qualify under our proposed Category 4.” (p. 25508). We believe this may well be an overestimate. The AAMC has spoken to many of our members. Some said they would be discouraged from applying at all given the administrative burdens of the application process to receive at most 1.0 FTE. Others have said that 1.0 FTE is not sufficient to allow them to participate in strategic program growth.

The AAMC believes that the purpose of the 1,000 new slots is to create an opportunity for meaningful expansions of residency training. The AAMC urges CMS to allow hospitals to apply for up to fifteen residency slots to allow programs, depending on specialty, a reasonable expansion over 5 years. For example, this would allow a 5-year general surgery program to recruit 3 residents for each year for 5 years. With the assurance of funding for up to fifteen slots, hospitals could meaningfully expand one or more training programs. However, if CMS decides that slots should be distributed to as many teaching hospitals as possible, then at a minimum each hospital should receive 3 to 5 slots. Depending on specialty length, this will allow for an increase of one resident for each year of training, though it may not be sufficient to provide an opportunity to start a new program.

Even by increasing the maximum number of slots that may be awarded to a hospital, CMS may encounter hospitals that are tied by the ranking system that CMS selects. For FY 2023 the AAMC suggests that in the case of a tie CMS give preference to hospitals that are over their FTE cap. Hospitals would have to be at least 10 FTEs over their cap and those with the highest number of current residency slots over their cap would get slots first. AAMC believes it would be preferable to have additional tiebreakers than prorating slots at less than 1.0 FTE to allow full funding of any additional resident slots. Following the FY 2023 slot distribution, CMS can evaluate how well this preference system has worked.

Other CMS Proposals for Slot Distribution

Demonstrated Likelihood of Filling the Positions

CMS proposes separate criteria that hospitals must meet to show that they have a demonstrated likelihood of filling the section 126 residency positions within the first 5 years of training. CMS proposes criteria depending on whether the hospital is applying for (1) a new residency program or (2) an expansion of an existing residency program. The AAMC suggests that CMS update the criteria to use language that is consistent with the terminology currently used by ACGME and the American Board of Medical Specialties (ABMS). For example, the proposed rule refers to hospitals applying to ACGME for “approval” of slots for a new program but ACGME uses the term “accreditation” rather than approval. CMS also talks about the need for hospitals to meet an ACGME deadline when a program wants to expand or when a hospital seeks accreditation for a new program. The AAMC understands from ACGME that each Residency Review Committee sets its own deadlines and they may have multiple deadlines throughout the year.

The CMS proposal does not account for the possibility that a hospital may be at or over its cap and may have previously received ACGME accreditation for one or more programs for slots that have remained unfilled. In this case, the hospital should be able to meet the “demonstrated likelihood” requirement by showing that the number of filled slots is less than the complement of residents accredited by ACGME.

Definitions of the 4 Hospital Categories

CMS is proposing to define each of the four categories of hospitals in the proposed rule. The AAMC supports the proposed definitions of: Category 1: hospitals in rural areas or that are treated as being in rural areas; Category 2: hospitals over their cap; and Category 3: hospitals in states with new medical schools or branch campuses. Below the AAMC suggests changes that should be made to the definition of Category 4: hospitals that serve areas designated as HPSAs. The suggested changes include eliminating the requirements that (1) the hospital or provider-based department be located in the HPSA; and (2) at least 50 percent of the resident’s training must occur in a facility located in the HPSA.

Rural Hospital or Treated as Being in a Rural Location (Category 1)

CMS proposes that a hospital with its main campus in an area outside an urban Core-Based Statistical Area (CBSA) is a rural hospital. CMS also proposes a hospital “treated as rural” is a hospital physically located in an urban area that is treated as being located in a rural area for purposes of payment under IPPS (i.e., the hospital has applied and been approved for an urban to rural reclassification). CMS proposes to use Table 2 or a successor table to make this determination. (p. 25505). The Agency further proposes that if a hospital is not listed as reclassified but is subsequently approved by the CMS Regional Office as being located in a rural area it must submit its approval letter along with its application. The AAMC supports the CMS proposal regarding a determination of whether a hospital is a rural hospital, or a hospital treated as being located in a rural area. The AAMC asks that CMS clarify that rural referral centers meet the definition of a rural hospital or a hospital treated as being in a rural location.

The AAMC notes that under current law, a rural hospital can increase the resident cap whenever it starts a new program. New residency programs at rural hospitals have a 5-year cap-building window. Therefore, the AAMC recommends that CMS ensure that rural hospitals only use these slots to grow existing programs

Hospitals for Which the Reference Resident Level is Greater Than the Otherwise Applicable Resident Limit (Category 2)

This category refers to hospitals that are over the FTE caps. CMS proposes that for this category it will define hospitals by using the 1996 cap adjusted for new programs; participation in a Medicare GME affiliation agreement; participation in an emergency Medicare GME affiliation agreement; participation in a hospital merger; whether an urban hospital has a separately accredited rural training track; applicable increases or decreases under section 422 of the Medicare Modernization Act (MMA), and sections 5503 and 5506 of the Affordable Care Act

(ACA). CMS further proposes to use the resident level for the most recent cost reporting period ending on or before the date of enactment of the CAA. Unweighted allopathic and osteopathic FTE residents are used to determine the reference resident level. The AAMC supports this definition. We ask that CMS confirm that the hospital may qualify when it is over either its DGME or IME cap, or over both caps which is consistent with the section 5503 slot distribution process.

Hospitals Located in States with New Medical Schools or Additional Locations and Branch Campuses (Category 3)

CMS proposes that this category will consist of hospitals located in states with new medical schools that received “Candidate School” status from the Liaison Committee on Medical Education or “Pre-Accreditation” status from the American Osteopathic Association Commission or Osteopathic College Accreditation on or after January 1, 2000; or additional locations and branch campuses established on or after January 1, 2000 by medical schools with full accreditation status or accreditation status on or after January 1, 2000. This category includes hospitals located in 35 states and one territory. The AAMC supports the proposed definition.

CMS Should Revise the Definition of Hospitals That Serve Areas Designated as HPSAs (Category 4)

CMS begins the discussion of the HPSA category by looking to the HPSA Physician Bonus Program as a guide. The Agency describes the HPSA Physician Bonus Program as being created as “an incentive to attract new physicians to medically underserved communities and to encourage physicians in those areas to remain there.” (p. 25506-7). We agree. The HPSA Physician Bonus Program goal is targeted, which we believe differs from the intended purpose of the 1,000 residency slots which is to ease the physician shortage faced by the United States. The CAA does not give preferential treatment to the HPSA category, but rather provides that at least 10 percent of the slots should go to hospitals that serve areas designated as HPSAs; the same 10 percent distribution that are to go to each of the other three categories of hospitals.

Further, CMS notes that “the CAA does not explicitly address the question of how HPSAs for different medical specialties should factor into determining which hospitals serve areas designated as HPSAs.” (p. 25506). The AAMC believes that the plain reading of the legislation is that there is no differentiation based on medical specialty, especially in light of physician shortages in many specialties.

CMS also proposes to use primary care geographic HPSAs and mental health geographic HPSAs to determine if a hospital or its provider-based department is located in the HPSA. CMS further proposes to prioritize applications from “hospitals that serve specific designated underserved population of a population HPSA.” (p. 25508). The legislation does not distinguish among HPSAs but focuses on serving areas designated as HPSAs, a much broader category. If CMS finalizes this proposal, we ask that the Agency clarify whether there is any difference in prioritization between a primary care or mental health geographic HPSA and a population

HPSA. Further, we ask CMS to clarify that for the FY 2023 alternative distribution methodology population HPSA qualify along with, geographic primary care and mental health HPSAs.

- Hospitals or Their Provider-Based Departments Should Not Be Required to be Located in a HPSA

The AAMC strongly opposes the proposed requirement that the hospital or a provider-based department be physically located in a HPSA. To bolster its argument that a hospital should be physically located in a HPSA CMS posited the extreme example of a hospital that qualifies for this category although it treats only one patient from a HPSA. This is not the reality for teaching hospitals that may be outside a HPSA but are the primary point of care for a HPSA population. Patients who live in HPSAs may choose to go to a nearby teaching hospital that is adjacent to, but not located in a HPSA, often because it is the closest facility to their home or it provides specialized services that are needed and are unavailable elsewhere. CMS also offered the option of developing a relative or absolute threshold for the number of patients of the hospital that reside in HPSAs—is more consistent with these patterns. CMS should not finalize its proposal and should instead select a different alternative policy that we detail below.

- Hospitals in Mental Health Geographic HPSAs Should Not Be Limited to Applying for only Psychiatry Residency Slots

The AAMC recognizes the shortage of psychiatrists and all mental health professionals but does not support limiting hospitals in mental health HPSAs to applying only for psychiatric residency slots. The AAMC suggests that CMS give preference to hospitals in mental health geographic HPSAs that apply for psychiatry but not limit hospitals to psychiatry residencies. Given shortages in many other specialties, expansion in any specialty will benefit the population that is served by that hospital and should be allowed.

- CMS Should Not Require That At least 50 Percent of Training Must Occur at Locations in HPSAs

CMS also proposes to require that over the course of the medical residency, at least 50 percent of the resident's training time must occur at facilities located in the HPSA. **The AAMC does not support this proposal.** Unlike the Rural Training Track (RTT) program, the CAA does not include a training location requirement. CMS states in the proposed rule that it prefers that the residency positions not be used “mostly or entirely to serve populations that face no health service shortage.” (p. 25507). As we discussed above, teaching hospitals that are not physically located in HPSAs care for many patients who live in HPSAs. Patients who live in HPSAs often choose to seek care at teaching hospitals located outside the HPSA because those are the hospitals that can provide the specialized care that is unavailable elsewhere. Based on the AAMC's analysis of the FY 2019 American Hospital Association (AHA) Annual Database, AAMC member teaching hospitals represent 5 percent of all inpatient, short-term, non-Federal, non-specialty hospitals, yet they provide 26 percent of all Medicaid inpatient days and incur 32 percent of all charity costs.

Teaching hospitals are best positioned to determine the locations in which to train residents to meet patient needs and accreditation standards. Accreditation standards ensure that residents train in locations with a large enough population to provide the necessary mix of patients and conditions for the resident's specialty. Of equal consideration is where adequate teaching physician supervision is available. To mandate that Section 126 slots meet the "at least 50 percent" requirement means that hospitals must design residency rotations differently for these residents to ensure that the "at least 50 percent requirement is met." This is untenable for teaching hospitals and residency programs and should not be finalized.

The requirement that hospitals would need to attest to the "at least 50 percent requirement" for Section 126 slots would place an extraordinary burden on teaching hospitals which would have to document for each rotation whether the location of the "section 126 slot resident" was in a HPSA. Essentially, hospitals would have to set up dual reporting systems—one for section 126 slots and one for all others. Resident schedules also can change quickly which further increases the burden and can lead to inadvertent errors. This is not the way in which rotation schedules are recorded by institutions or are entered into the Intern and Resident Reporting System (IRIS).

The AAMC strongly urges CMS to revise its definition of the HPSA category. The definition of the HPSA category should be expanded so that a hospital will qualify if (1) it is located within a reasonable distance, for example no more than 25 miles away, of a geographic primary care or mental health HPSA or population HPSA, or (2) is in a geographic primary care or mental health HPSA, or population HPSA. CMS also should not finalize the proposal that requires at least 50 percent of training to occur in the HPSA. Teaching hospitals must have the flexibility to decide the locations in which residents need to train based on a variety of factors. They also should not be burdened by the extraordinary recordkeeping requirements that this requirement would entail.

CMS Should Not Finalize the Proposal to Award Slots Based Solely on HPSA Score

The CAA recognized the need to include consideration of underserved populations in the slot distribution when it added the category of "hospitals that serve areas designated as health professional shortage areas" to the list of hospitals that are to receive no less than 10 percent of the slots. However, the HPSA category is not prioritized over the other three categories of hospitals that are designated in the law. The AAMC strongly opposes the use of HPSA scores to determine priority for awards of residency slots, with hospitals with the highest score receiving up to 1.0 FTE. The AAMC also strongly opposes a prorated FTE being awarded in case there is a tie and an insufficient number of residency positions. **HPSA scores speak to the need for more practitioners in a given state but do not speak to the ability of the hospitals in those states to train more residents or to provide care for patients who live in HPSAs.**

In proposing reliance on the HPSA score to award slots, CMS says that "there is a strong likelihood that . . . the result will be that 10 percent or more of the additional residency positions will be distributed to hospitals in each of the four categories." (p. 25510). If only HPSA scores are used, the AAMC does not agree that there is a strong likelihood that each of the four

categories of hospitals will receive at least 10 percent of the slots. The best way to meet the “at least 10 percent” requirement is to adopt the proposed alternative distribution methodology for FY 2023 with modifications, and then refine the distribution methodology in future rulemaking.

The AAMC understands that HPSA scores are available on the Health Resources and Services Administration (HRSA) website; nonetheless, many of our hospitals are having trouble locating their scores (for example when multiple HPSAs overlap) and CMS has not made available a list of the HPSA scores it will assign to each hospital. Without scores we are unable to assess the impact on residency training and ultimately on patient’s access to physicians.

The AAMC urges CMS to not use HPSA scores as a metric for determining a qualifying hospital or to prioritize which hospitals should receive slots. To prepare for future rulemaking, the AAMC would be pleased to have an opportunity to work with CMS to explore metrics that would help ensure that hospitals qualifying under Category 4 demonstrate, in a meaningful way, that they serve underserved populations.

For FY 2023 CMS Should Finalize the Alternative Slot Distribution Methodology with Modifications

CMS’s proposed alternative slot distribution methodology is that, for FY 2023, hospitals that qualify under all four statutorily-specified categories would receive top priority for slot distribution, followed by those that qualify under any three, then two and lastly one category. Hospitals would be awarded 1.0 FTE or a prorated amount if insufficient slots are available. This approach would allow CMS more time to work with stakeholders to develop a refined approach for the remaining years of distribution.

The AAMC supports the proposed approach for FY 2023 which is to use the four categories of hospitals to determine the slot distribution priority but strongly urges CMS to modify the methodology as follows:

1. A hospital should be able to apply for and be awarded at least the minimum number of slots to allow for the training of 1 additional resident per year for the duration of the specialty, in other words, at least 3-5 FTEs. To provide for meaningful program expansion, or the possibility of starting a new program CMS should award up to 15 residency slots, depending on specialty.
2. A hospital will qualify for the HPSA category if it is within a certain distance of a HPSA or is located in a primary care or mental health HPSA or population HPSA.
3. A hospital located in a mental health only geographic HPSA can apply for slots for any residency program, but preference will be given to hospitals in mental health only geographic HPSAs that apply for psychiatry residency slots.
4. If hospitals scores are tied and an insufficient number of slots remain, CMS should be awarding slots to those hospitals that are 10 FTEs or more above their caps, with those most above their cap receiving slots first.

The AAMC notes that if CMS finalizes the revisions proposed above the application form will need to be revised to be consistent with these changes.

Hospital Attestation to the National CLAS Standards

CMS proposes that all applicant hospitals will have to attest that they meet the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (the National CLAS Standards) “to ensure that the residents are educated and trained in culturally and linguistically appropriate policies and practices.”

The National CLAS Standards are intended to “improve health care quality and advance health equity by establishing a framework for organizations to serve the nation’s increasingly diverse communities.” They were developed by the Department of Health and Human Services (HHS) Office of Minority Health working with stakeholders, including the AAMC. Many of the standards overlap with requirements that hospitals already meet, such as the Internal Revenue Service requirements that 501(c)(3) hospitals must complete a Community Health Needs Assessment and Implementation Plan every three years; the Joint Commission Standards related to language access and interpreter services; and the ACGME core competency that residents must show competence in “communicating effectively with patients, families, and the public, as appropriate, across a broad range of socioeconomic and cultural backgrounds.” (Common Program Requirements, IV.B.1.e).(1).(a)); and the AAMC quality improvement and patient safety competencies in health equity.

AAMC member hospitals are committed to working with their communities and ensuring that individuals who work and train at their facilities provide care that is appropriate for their patients’ medical needs and is respectful of patients’ values and beliefs. A myriad of requirements and strong institutional values that exist outside of—but are consistent with the National CLAS Standards—ensure that residents receive training in health care environments that are culturally and linguistically appropriate.

Below are examples of residency programs taking the lead and providing cultural and linguistic competency training above what is currently required.

- At the University of Pennsylvania, residents learn the social determinants of their patients’ health (SDOH) through an integrative model. The case-based curriculum integrates SDOH with critical care topics in the medical intensive care unit, while knowledge, attitudes, and skills are assessed daily during multidisciplinary rounds. Residents complete a social risk assessment with their critically ill patients. As a result, participating residents state they “love the open dialogue” to reflect on their experiences; an avenue to “debrief on specific patient encounters and [how] SDOH brought [patients] to the ICU.”
- At Michigan State, in order to improve residents’ abilities to provide care for limited English proficiency (LEP) patients, they participate in a detailed program including panel discussions, best-practices presentation, video demonstration, observing scenarios, and pre- and postworkshop objective structured clinical exams (OSCEs).

- At the University of Wisconsin, residents are taught strategies for addressing health disparities for their LGBTQIA patients. The program addresses local gaps in knowledge, equips faculty and resident educators with skills to apply key concepts in teaching activities, and motivates them to examine challenges and opportunities in teaching sexual orientation and gender identity principles in their routine duties.

The AAMC embraces the aims of the National CLAS Standards, which are one step toward achieving a more equitable healthcare system. We also recognize and support the concept that a national standardized or mandated curriculum is inappropriate. Medical schools and teaching hospitals, within accreditation standards and requirements, have local missions and community health needs that necessitate that the faculty have the freedom and ultimate responsibility to design, implement and evaluate the educational program.

Application and Announcement of Slot Awards

CMS proposes that awarded residency position slots would be effective July 1 of each year, and an application must be submitted by January 31 of the prior fiscal year. Slot awards will be announced by January 31 of the Federal fiscal year in which they are effective. For example, for the initial 200 slots which are effective July 1, 2023 (FY 2023) the completed application would be submitted by January 31, 2022 (FY 2022). The slot award announcement would be made January 31, 2023.

The AAMC strongly requests that CMS revise the date by which slots must be announced to October 1 of the federal FY in which the slots are effective. The timing proposed by CMS does is not consistent with the residency recruitment cycle. Most residents obtain their residency positions through the National Residency Matching Program (NRMP). The typical recruitment cycle for residents involves hospitals interviewing potential candidates in the calendar year prior to the year in which the resident will start the residency. The last date by which hospitals can submit the number of residents they will admit (“program quota changes”) is January 31, though rank order lists of residents must be submitted by the first week of March. If hospitals do not know whether they will be awarded slots, or how many, until January 31 of the year in which the slots are effective, they will be extremely disadvantaged in recruiting residents and in showing a “demonstrated likelihood” that the slots will be filled within five years.

Section 127: Promoting Rural Hospital GME Funding Opportunity

AAMC Supports CMS’s Proposal for Implementation of Section 127 of the CAA with Modifications

The AAMC thanks Congress and CMS for addressing longstanding concerns regarding inequities and unintended consequences in Rural Training Track programs in section 127 of the CAA and this proposed rule. Section 127 of the CAA expanded the opportunities for urban and rural hospitals to engage in RTT programs. Rural track programs were first introduced in the Balanced Budget Refinement Act of 1999 (BBRA), and for many years represented a limited option to increase Medicare supported residency positions at urban and rural hospitals. The

changes proposed by CMS will encourage more training in rural areas which may result in more physicians deciding to practice in those areas upon completion of their residencies. Below are the AAMCs comments on the CMS proposals related to the implementation of section 127.

Cap adjustment for Urban and Rural Hospitals Participating in Rural Training Track Programs

Prior to enactment of Section 127 of the CAA, only an urban hospital would receive a cap adjustment for an RTT program unless the rural program was “new” as defined by Medicare, *i.e.* new program director, new residents, etc. Section 127 of the CAA amended the law to allow established rural partner hospitals a cap increase in certain circumstances. CMS proposes that “each time an urban hospital and rural hospital establish an RTT program for the first time, even if the RTT program does not meet the newness criteria for Medicare purposes, both the urban and rural hospital may receive a rural track FTE limitation.” (p. 25513).

The AAMC has long supported the RTT program. It was designed so that a rural hospital can benefit from the graduate medical education infrastructure and support of the urban hospital. Additionally, residents are given the benefit of significant training in a rural location. The RTT program also may encourage some non-teaching rural hospitals, that can meet patient volume and other extensive accreditation requirements, to become teaching hospitals and expand access to their communities. We believe that section 127 change, along with others made to the RTT, will encourage more urban and rural hospitals to form partnerships. **We strongly support the proposal to implement this section of the CAA by allowing rural hospitals participating in RTTs a cap adjustment for programs that do not qualify as “new.” The CMS proposal will help rural hospitals with the cost of participating in RTTs and should have the added benefit to urban hospitals of an increased pool of rural hospital partners.**

Cap Adjustments When the Urban Hospital Adds Additional Rural Training Tracks

Section 127 of the CAA allows an urban hospital that has an RTT to receive further cap adjustments if the urban hospital creates RTTs in more specialties and adds subclause (II) to 1886(h)(4)(H)(iv) of the Social Security Act, which states that for cost reporting periods beginning on or after October 1, 2022, “in the case of a hospital not located in a rural area that established or establishes a medical residency training program (or rural tracks) in a rural area or establishes an accredited program...” would be able eligible for an RTT cap adjustment. (p. 25513). CMS proposes to prospectively allow IME and DGME cap increases of both the urban and rural hospital that expand a qualifying RTT. To describe this proposal, CMS utilizes the example of a hub and spoke model. The urban hospital is the “hub” and the one or more RTTs are the “spokes.” The proposal would allow for urban and rural partners to participate in more than one RTT and receive a cap adjustment for RTTs started in cost reporting periods beginning on or after October 1, 2022.

The change in policy proposed by CMS would provide urban and rural hospitals the option to participate in multiple RTTs. Coupled with the removal of the restriction that RTTs be separately accredited (discussed in the next section), urban hospital that have established RTT programs

may expand RTTs to new specialties. **The AAMC supports the CMS proposal and agrees that this allows “already experienced and successful urban ‘hub’ RTTs to branch out and partner with additional rural communities, rather than relying solely on starting RTTs from scratch.” (p. 25513).**

Urban hospitals will continue to receive a cap increase that is proportional to the amount of time the resident trains at the urban hospital. As before, an RTT requires that more than 50 percent of the resident’s training must occur in the rural location.

CMS also proposes to “limit the provision of an increase to the urban and rural hospitals’ RTT FTE limitations only to the instance where additional residents are recruited to add a new rural RTT ‘spoke’ to the existing urban ‘hub’ and not allow increases . . . to the RTT FTE limitation in instances where the urban and rural hospital add additional FTE residents to an existing rural RTT “spoke.” (p. 25514). Section 127 provides strong support for increasing the number of residents training in rural areas. There may be instances in which an urban hospital could add residents to an existing RTT program but cannot find other rural partners or is unable to add RTTs in other specialties, perhaps because the rural hospital does not have a patient population that would allow residents to receive the variety of training experiences they need. The AAMC appreciates CMS’s concern that allowing expansion of existing programs might render RTT cap limitations meaningless. **However, we urge CMS to create an exceptions process that would allow hospitals with existing RTTs to demonstrate that the only way they can train more residents at a rural hospital is to expand an existing RTT.** CMS could consider making this a one-time exception per program and limit the total number of residents allowed to 3.0 FTEs per program.

Removal of The Requirement That RTTs Be Separately Accredited

The AAMC strongly supports CMS’s proposals to remove the requirement that an RTT be “separately accredited” effective for cost reporting periods beginning on or after October 1, 2022. (p. 25514). Family medicine is the only specialty with an ACGME-accredited RTT track. Therefore, prior to enactment of the CAA, Family Medicine was the only specialty to qualify for the RTT program. The AAMC has advocated for the elimination of the “separately accredited” requirement and is pleased to see CMS’s proposal for the implementation of the broadened definition. Removal of the “separately accredited” requirement would allow any accredited program to participate in an RTT. This is a much-needed recognition that trainees in many specialties would benefit from training in rural areas. The changes proposed by CMS to implement section 127 work together to make RTTs a more expansive and attractive program for urban and rural hospitals.

Requirement That Greater Than 50 Percent of the Program Training Occurs in a Rural Area

Section 127 also requires that greater than 50 percent of the program occur in rural areas. The AAMC agrees with CMS that the statute codifies what CMS already put in regulation, which is that for RTT programs residents must be in “an accredited program where greater than 50

percent of the program occurs in a rural area.” (p. 25515). We support CMS’s proposal to align previous regulatory policy with the updated statutory language of Section 127. (p. 25515).

Exemption from the 3-Year Rolling Average and IME Intern and Resident to Bed (IRB) Ratio Cap During the 5-Year Rural Track FTE Limitation Window

The AAMC supports CMS’s proposal to allow a 5-year cap building window for new RTT programs. This allows hospitals to exclude residents in the RTT cap-building period from their 3-year rolling average FTE calculation. The exemption would also apply to the IRB cap at the previous year’s actual IRB. The AAMC agrees with CMS that this language is statutorily analogous to the provision in the Social Security Act (1886(h)(4)(H)(i)) which allows new programs started on or after January 1, 1995 an exemption from the three-year rolling average during a 5-year cap building window.

Section 131: Addressing Adjustment of Low Per Resident Amounts and low FTE Resident Caps for Certain Hospitals

The AAMC Supports the CMS Proposed Rule Implementation of Section 131 of the CAA

Consistent with section 131 of the CAA, CMS proposes to allow certain hospitals to reset their extremely low FTE IME or DGME resident caps and also to allow certain hospital with a very low per resident amount (PRA) to receive a replacement PRA. To qualify to reset the FTE resident cap, CMS proposes that a hospital must have either a cap based on less than 1.0 FTE before October 1, 1997 (termed Category A hospitals) or a cap based on no more than 3.0 FTEs for cost reporting periods beginning on or after October 1, 1997 and before December 27, 2020 (termed Category B hospitals). Additional requirements discussed below also will apply.

Hospitals that are eligible as Category A or Category B may reset low or zero PRAs (for DGME) and low FTE resident caps (for DGME and IME). The AAMC is aware that certain hospitals, often small community or rural hospitals, inadvertently triggered a low or zero PRA and low FTE resident cap by allowing a small number of residents to rotate at their hospital and reporting those residents on a cost report.

Category A and B hospitals would trigger a new cap building period to reset the FTE count when the hospital trains new residents, in a new program, in excess of the statutory limit in any cost reporting period starting on or after December 27, 2020 and ending December 26, 2025.

Resetting and Calculating the New PRA

Category A and B hospitals would trigger a new PRA when the hospital trains at least 1.0 FTE or more than 3.0 FTEs, respectively, in any cost reporting period starting on or after December 27, 2020 (the date the CAA became law). CMS proposes that for a PRA redetermination the residents may be in either a “new” or existing program. For a Category A hospital CMS proposes that the PRA would not be reset until the hospital trains at least 1.0 FTE in a cost reporting period beginning on or after December 27, 2020 and before December 26, 2025. For a Category B hospital CMS proposes not to reset the PRA until the hospital trains more than 3.0 FTEs in a cost reporting period begin on or after December 27, 2020 and before December 26, 2025. In

other words, CMS proposes that the “relevant factor in determining when to reset the PRAs is if and when the hospital trains the requisite amount of FTE residents in a cost reporting period beginning on or after December 27, 2020 and December 26, 2025 [5 years after enactment of the CAA].” (p. 25521).

The AAMC supports the CMS proposal to reset a qualifying hospital’s PRA hospital with the requisite number of residents training on a given cost report, on or after December 27, 2020. The AAMC also supports establishing as the base period the first period after enactment in which a Category A hospital trains at least 1.0 FTE and a Category B Hospital trains more than 3.0 FTEs. The PRA recalculation is consistent with establishing a PRA at a new training hospital, and the AAMC supports the CMS proposal to treat PRA setting in the same way.

Resetting and Calculating the FTE Count

CMS proposes that the FTE resident caps would be reset when a Category A or Category B Hospital “begins training” FTE residents in a new residency program in cost reporting periods beginning on or after December 27, 2020 and before December 26, 2025. CMS proposes that if a hospital begins training residents in a program prior to December 27, 2020 it would not be able to reset its FTE cap. The AAMC supports resetting qualified hospitals’ FTE counts when training the requisite number of residents in a new program. Further, the AAMC supports adjusting each qualifying hospital’s cap consistent with 42 C.F.R. 413.79(e)(1) which will set the first year of the 5-year cap building period in which a hospital begins training residents in the new program.

Use of the Predicate Facts Rule

The AAMC is concerned with the CMS suggestion that Medicare Audit Contractors (MACs) could use “predicate facts” to establish a new FTE resident amount, using whatever “contemporaneous documentation we would need to establish a PRA” or “contemporaneous documentation we would need to establish the FTE resident caps.” (p. 25522, 25524). This leads to confusion as to how and why CMS will decide which facts are predicate facts, and which ones are not. If the FTE count in a closed cost report indicates zero FTEs, then CMS should be bound by the determination that there was no teaching at the hospital. This uncertainty around “predicate facts” may cause some hospitals to decide not to engage in training residents due to the possibility that they could be caught in a “gotcha” if a MAC discovers information that will leave them with an extremely low PRA or FTE cap.

Section 131 of the CAA, on the other hand, aims to address a persistent problem for hospitals—generally community and rural—that inadvertently set low PRA and FTE counts. The hospitals that benefit from this legislation would like to train residents but are reluctant to do so because there is little or no support from Medicare. As we have established elsewhere in this comment letter, there exists a very real and problematic national shortage of physicians. This is not a time to discourage hospitals that are willing to train residents but for a low PRA or FTE count. The AAMC requests that CMS provide assurance that MACs would not be expected or encouraged to

search for “predicate facts.” A more robust explanation of how predicate facts would apply is needed.

The Intern and Resident Information System (IRIS)

The AAMC is pleased the CMS will be replacing the IRIS diskette with an Extensible Markup Language (XML)-based Intern and Resident Information System file for cost reporting periods beginning on or after October 1, 2021. Diskettes are outdated technology. We appreciate that CMS has developed a new reporting mechanism technology that is in line with current business processes. **However, the AAMC strongly objects to the CMS proposal that a hospital’s cost report would be rejected for lack of supporting documentation unless IRIS data contains the same total counts of direct GME FTE residents (weighted and unweighted) and of IME FTE residents as the total counts on the cost report and ask that CMS not finalize it.** IRIS will continue to catch inadvertent errors and those errors will continue to be fixed. The AAMC believes there is no need to reject cost reports due to an inconsistency in FTE counts between IRIS and the cost report. The AAMC is aware that in the FY 2019 IPPS, CMS finalized similar requirements for other information that must be reported but for the reasons discussed below, IRIS reporting is different.

IRIS was developed to allow MACs to determine when hospitals inadvertently “double-counted” residents. In other words, the creation of IRIS acknowledges that errors occur and provided a way in which to detect and correct those errors. Typically, since IRIS was initially instituted, hospitals receive reports with double-counted residents and then the hospitals worked to resolve those issues. This process ensured accurate counts for Medicare support and was an important role of the IRIS system that hospitals supported.

Hospitals should not be penalized for inadvertent errors that commonly arise due to the complications of recording resident rotations and that ultimately are corrected to ensure proper Medicare payment. CMS acknowledges the way in which IRIS is used when it states in part that “if duplicates are identified, the contractors will make the hospitals that claimed the same time aware of this situation and will correct the duplicate reporting on the respective hospitals’ cost reports for direct GME and IME payment purposes.” (p. 25523).

We also ask that CMS recognize that the adoption of new software program may present a technical issue for hospitals that must transition to an application they have not used before. As we all have learned from experience, it is not unusual for new software to have “bugs” that may cause unintended problems.

HOSPITAL PAYMENT PROVISIONS

DATA SOURCE FOR FY 2022 IPPS RATESETTING

Finalize the Proposal to Use FY 2019 Data for FY 2022 Ratesetting

The AAMC appreciates CMS’s continued acknowledgement and support of the financial impact hospitals continue to face as a result of the COVID-19 public health emergency (PHE). In 2020, the nation’s teaching hospitals cared for 59 percent of all Medicare beneficiaries diagnosed with COVID. Medicare patients treated in the inpatient setting during 2020 tended to be sicker and more resource intensive – 49 percent were treated in the intensive care unit and almost 8 percent required some sort of mechanical ventilation.² At the same time, hospitals saw a dramatic decrease in the number of admissions for elective procedures. As noted in the proposed rule, “FY 2020 inpatient admissions under IPPS dropped by approximately 14 percent compared to FY 2019. Elective surgery declined significantly, and the share of admissions for MS-DRGs associated with the treatment of COVID-19 increased.” (p. 25087). Although more than half of Americans have received at least one dose of a COVID-19 vaccine³, patients seeking treatment for non-COVID-19-related conditions continue to lag as compared to pre-PHE.

In response to these circumstances, CMS seeks comment on whether FY 2020 data sources “are the best available data to use for the FY 2022 ratesetting.” (p. 25086). We agree with CMS that “FY 2020 is not the best overall approximation of inpatient experience in FY 2022.” (p. 25088). **Therefore, the AAMC supports using FY 2019, or FY 2018 where applicable as data sources for ratesetting for FY 2022.** We agree with CMS that the FY 2019 data is more representative of beneficiary utilization and therefore a better approximation of FY 2022 beneficiary inpatient utilization. (p. 25088).

MEDICARE ORGAN ACQUISITION POLICIES

Do Not Finalize the Proposed Organ Acquisition Changes and Codifications for FY 2022 and Convene Stakeholders to Ensure Changes Do Not Impact Organ Availability and Access

For FY 2022, CMS proposes to codify into the Medicare regulations many longstanding and several new Medicare organ acquisition (OA) payment policies. Among these proposals, CMS seeks to modify how Medicare calculates its share of OA costs for transplant hospitals (THs), organ procurement organizations (OPOs), and hospital OPOs (HOPOs). The AAMC has serious concerns that the proposed codifications and changes to OA payment policy and calculation of Medicare’s share will have negative impacts not fully considered in the proposed rule. The AAMC appreciates CMS’s difficult task of ensuring that the Medicare Trust Fund remains solvent, but the changes proposed go well beyond the mere clarification of existing policy. Given

² AAMC analysis of CY 2020 Medicare Standard Analytic Quarterly File. May 2021.

³ COVID-19 Vaccinations in the United States. Centers for Disease Control and Prevention. Retrieved June 11, 2021. <https://covid.cdc.gov/covid-data-tracker/#vaccinations>

the significant complexity of the current OA payment infrastructure, these changes, which may have cascading impacts on organ access and equity in organ distribution, should not be finalized without significant stakeholder involvement and more comprehensive impact analysis. **For the reasons detailed below, the AAMC strongly urges CMS not to finalize any of the proposed OA payment policies. Instead CMS should work with all stakeholders—THs, OPOs, insurers, patient groups, and others—to conduct further study of the potential impact on organ access and equity, and work with stakeholders to find alternative approaches to this issue.**

Currently, Medicare reimburses THs and OPOs for OA costs by “multiplying the total allowable OA costs by the ratio of Medicare usable organs (the numerator) to total usable organs (the denominator) reported on the Medicare hospital cost report.” (p. 25664). Currently and for decades prior, when a TH sends an organ to another TH or to an OPO, Medicare presumes that “some of the unknown transplant recipients are Medicare beneficiaries, and permits those organs to be counted as Medicare usable organs.” (p. 25665). However, CMS notes in the proposed rule that one of the Agency’s longstanding policies directs “that Medicare must only share in organ and kidney acquisition costs for Medicare beneficiaries” and asserts that its assumption that all kidneys and certain non-renal organs are transplanted into Medicare beneficiaries is now incorrect. (p. 25665). Specifically, CMS suggests that current organ tracking capabilities allow THs and OPOs to discern organ recipients’ health insurance coverage information so that OA costs can be accurately assigned to the Medicare program or covered by a third-party payer.

To this end, CMS is proposing to remove its longstanding presumption and specify that, beginning on or after Oct. 1, 2021, “THs/HOPOs must accurately count and report Medicare usable organs and total usable organs on their Medicare hospital cost reports to ensure that costs to acquire Medicare usable organs are accurately allocated to Medicare.” (p. 25667). Further, CMS would require that “Medicare usable organs include only organs transplanted into Medicare beneficiaries.” (p. 25667). As a result, organs that were previously counted as Medicare usable organs would no longer be counted in the numerator, thereby reducing Medicare’s payment to THs for costs associated with OA. The Agency asserts that these changes would “help safeguard the Medicare Trust Fund and ensure that Medicare appropriately pays only its share of organ acquisition costs.” (p. 25666).

We have heard concerns from our TH members that these changes to the Medicare usable organs calculation could significantly impact availability of and access to scarce organs for transplant. The calculation change would also negatively impact Medicare’s support of OA costs. Therefore, as we noted above, we urge CMS not to finalize the OA proposals.

Proposals Do Not Consider the Significant Impact on Organ Access and Equity

For more than three decades, CMS has assumed that kidneys and certain non-renal organs are transplanted into Medicare beneficiaries. CMS has continued this practice in support of its strong commitment to organ transplantation, recognizing the important role Medicare plays to procure organs that are constantly in demand. The current system appears to work effectively: in 2020

less than 15 percent of acute care hospitals with transplant programs contributed 36 percent of deceased donor organs.⁴ Typically, OPOs pay for certain costs associated with OA, and Medicare pays its share of the remaining costs not offset by payment from the OPO. Since all commercial insurers do not typically cover OA costs, any unpaid amounts are the responsibility of the TH. If Medicare removes this critical support, many smaller THs may no longer be able to operate and other THs would no longer be able to provide organs at the volume they currently do.

The AAMC is concerned that the revisions to the current policy would result in fewer organs available for transplant, and will have a negative impact on equity in organ access and distribution for low-income, minority, and pediatric populations. Conservatively, if the policy caused a 10 percent reduction in deceased donor kidneys due to closure of small THs or nationwide reductions in operations for others, there would be 2,348 fewer kidneys available for transplant each year.⁵ The drop in available kidneys alone could serve to exacerbate existing disparities in organ access equity. A 2017 study in the *American Journal of Nephrology* found that significant disparities still exist between African Americans and Caucasian Americans in kidney transplantation, citing “reduced access to kidney transplantation [as] the most serious disparity.”⁶ Moreover, at children’s hospitals, most non-renal pediatric organs are unlikely to be transplanted into Medicare beneficiaries, and would likely result in a disproportionately worse impact on the availability of pediatric organs. Finally, the AAMC wants to ensure that the procurement and allocation of available organs is not negatively impacted, to safeguard the equitable access to organs nationwide.

In addition to these targeted concerns over organ access equity for low-income, minority, and pediatric populations, the likelihood of reducing kidney donations stands in stark contrast to the Executive Order “Advancing American Kidney Health”⁷ that directed HHS to increase utilization of available organs, specifically aiming to “double the number of kidneys available for transplant by 2030.”⁸ **To ensure that access to transplantable organs is not severely impacted, CMS should not finalize the proposed changes to OA payment policies in FY 2022, and instead should work with stakeholders to better assess and understand the potential impact on organ access and equity that might result if the policy were changed.**

⁴ Organ Procurement Transplantation Network (OPTN) Data Report Public Website, Advanced Report Run May 27, 2021. Available at: <https://optn.transplant.hrsa.gov/data/view-data-reports/build-advanced/>; United States Renal Data System (USRDS) 2020 Annual Report. Available at: <https://adr.usrds.org/2020/>; Scientific Registry of Transplant Recipients (SRTR) Center Specific Reports. January 5, 2021. Available at: <https://www.srtr.org/reports/program-specific-reports/>.

⁵ *Id.*

⁶ Harding K, Mersha TB, Pham PT, et al. Health Disparities in Kidney Transplantation for African Americans. *Am J Nephrol.* 2017;46(2):165-175. doi:10.1159/000479480. Accessed on June 11, 2021 at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5827936/>.

⁷ Executive Order 13879, *Advancing American Kidney Health*. July 10, 2019. Accessed at:

<https://www.federalregister.gov/documents/2019/07/15/2019-15159/advancing-american-kidney-health>.

⁸ *Id.*

Estimates of Medicare Savings Do Not Adequately Account for Likely Reduction in Available Organs

Additionally, the AAMC is concerned that Medicare’s estimate of savings associated with this proposal disregards the potential impact of its proposed OA policy on the number of available kidneys. Medicare has long recognized the need to promote kidney transplantation as a means of not only enhancing quality of life for patients, but also generating savings on Medicare dialysis spending. In 1988, CMS noted that “over time, transplantation costs less than maintaining a patient on dialysis . . . based on 1985 data for each transplant opportunity lost to a Medicare beneficiary on a transplant waiting list in 1985, the Medicare program would spend an estimated \$62,000 for the marginal cost of dialysis over a five-year period.” (53 FR 6674). In 2021, this fact remains true; however, Medicare’s estimated cost for dialysis has risen significantly and is now roughly \$91,000 per beneficiary, *per year*.⁹ As a result of this proposal, THs estimate that over 3.5 years—the median waiting time for a kidney in the U.S.—the decrease in kidneys would result in approximately \$1.6 billion (or \$453 million annually) in additional dialysis costs to sustain patients that would no longer be able to receive a kidney transplant.¹⁰ For this reason, CMS may be paying less for OA costs but will be paying significantly more for additional dialysis costs that would result from fewer organs being available for transplant. Therefore, CMS’s proposals to codify several longstanding policies, along with its change to the calculation of Medicare’s share of OA costs, may have serious impacts that are unaccounted for in the proposed rule.

The Proposal’s Financial Impact on Transplant Hospitals is More Significant than CMS Anticipates

CMS estimates that the proposed changes to the calculation of Medicare’s share of OA costs would result in “annual cost savings to the Medicare trust fund of \$230 million in FY 2022, \$1.74 billion over 5 years, and \$4.150 billion over 10 years.” (p. 25771). However, independent analyses of HCRIS data suggest the estimated impact on THs would be approximately \$383 million per year.¹¹ AAMC member THs agreed that the impact would be significant; their individual estimates of these changes ranged from \$500,000 to \$14 million, per year.

In addition to this noteworthy discrepancy in estimated impact put forth by CMS, the Agency asserts that “the cost associated with the kidneys not used by Medicare beneficiaries must be borne by the responsible individual or third-party payer.” (p. 25665). **The AAMC believes that CMS incorrectly assumes commercial payers will bear the additional costs associated with organ acquisition that would no longer be covered by Medicare.** Discussions with AAMC member THs reveal that not all commercial insurers provide comprehensive coverage for organ

⁹ Medicare per patient per year costs based on the USRDS 2020 Annual Report, Tables K.6, K.9. Available at: <https://adr.usrds.org/2020/>.

¹⁰ *U.S. Median time to transplant for waiting list candidates*: 1/5/2021 release of the SRTR Center Specific Reports; *Cost estimate*: OPTN Data Report Public Website, Advanced Report Run 5/27/2021, USRDS 2020 Annual Report, SRTR January 5, 2021 Center Specific Reports.

¹¹ Analysis of Medicare Hospital Cost Report Data. Available at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Cost-Reports-by-Fiscal-Year>.

transplantation, and some coverage mirrors the Medicare rates. Additionally, THs would be burdened with renegotiating contracts with insurers where insurers are not required to pay for OA costs, which would be a massive and time-consuming undertaking. Without certainty that commercial insurers would bear additional OA costs, it is likely the financial impact of the policy would fall entirely on the THs. Further, if these costs are not borne in part by commercial insurers, it could create additional equity issues since some under and uninsured individuals with limited or non-existent coverage could disproportionately be affected. Since the Health Resources and Services Administration (HRSA) contracts with the United Network of Organ Sharing (UNOS)—which manages and maintains the database that contains all organ transplant data—CMS should consider working with HRSA to study OA costs and determine those attributable to Medicare, those attributable to third party payers, and to develop a plan for reimbursement that is more comprehensive and equitable. This would ensure that the impact of these changes do not squarely rest on THs.

Proposals Place Significant Burden on Transplant Hospitals

In support of its proposal to require THs to identify and report payer information of organ recipients, CMS asserts that “organ tracking capability allows THs and OPOs the ability to know the identity of all organ transplant recipients and the donor from whom the recipient's transplanted organ was excised.” (p. 25666). **The AAMC believes that CMS has severely underestimated the administrative and financial burden on THs associated with this requirement.** While THs may be able to track an excised organ to its eventual transplant recipient, the TH also would need to contact and rely on other transplant programs to determine the insurance coverage for each and every recipient of a deceased donor organ recovered at their hospital. This would fall primarily on TH administrative staff, and AAMC member THs suggest that doing so would not necessarily guarantee that the payer information is complete, updated, and accurate.

For instance, CMS recognizes that it is merely optional for THs to use these organ-tracking capabilities, and notes that THs enter data into the Organ Procurement Transplantation Network (OPTN) database in UNet, which links all OPOs, THs and histocompatibility labs to list patients for transplant, match patients with available donor organs and submit required OPTN data. (p. 25666). The underlying assumption of the proposal is that the data in the OPTN provided by the OPO would be current; however, it is common that payer information is not updated for organ recipients on the waitlist, which would exclude many organs transplanted into individuals that age into or become eligible for Medicare based on end-stage renal disease (ESRD). Moreover, AAMC member THs shared concerns beyond the potential inaccuracy of payer information, noting that THs can only view patient information for patients they add to the waitlist. Stakeholders have additional concerns, that in certain situations, the OPTN does not maintain payer information for individuals that are not on the OPTN waitlist. Finally, OPOs have limited access to payer information in many instances and may only be able to access clinical information. Under the proposal, it will be incumbent upon THs to sort these varied issues out. Further, there is only a field for primary payer on the OPTN database. However, CMS's

proposed policy would allow an organ to be a Medicare organ if Medicare was either the primary or secondary payer of the recipient. Absent any way to identify whether the organ recipient has Medicare as a secondary payer, there would be no way to count the organ as a Medicare organ consistent with Medicare policy.

CMS also asserts that “THs that do not use an organ tracking capability still track organs they send to other THs or OPOs by using manual, written methodologies” and can determine payer information by contacting the OPO, which would be able to relay recipients’ information to the TH. (p. 25666). The proposal further assumes that if a TH manually contacts the OPO to ask for recipients’ payer information, the OPO will send timely, updated information that would be accurate for cost reporting purposes; however, nothing in statute or regulation compels OPOs to provide recipients’ payer information, nor is there a guarantee that the information is up-to-date. As noted earlier, the AAMC recommends working with HRSA and UNOS to ensure these issues do not fall on THs alone. Additionally, OPOs have many, potentially unforeseen, reasons why they would be hesitant or unwilling to provide this information to THs, such as concerns over violating privacy laws or providing proprietary contract information. In short, these administrative hurdles would need to be addressed before finalizing a proposal. It is possible that some solutions, especially those related to privacy or information sharing, might require regulatory changes by another agency or legislative action. State laws also must be taken into account.

Finally, the AAMC has also heard concerns from members that other aspects of the proposed policy need more consideration. For instance, the proposal is silent on the treatment of the offset of OPO payments when, as proposed, THs would no longer be able to count an organ transplanted in a non-Medicare beneficiary. Currently, the excising THs must offset payment from OPOs for excised organs even when the recipient is a non-Medicare beneficiary. If the organ is no longer reflected in its Medicare share, as CMS proposes, then THs should not also have to offset the allowable OA payment related to an organ for which Medicare is no longer paying its share. Doing so would exacerbate the already significant financial impact of this proposal on THs.

MEDICARE DISPROPORTIONATE SHARE HOSPITAL AND UNCOMPENSATED CARE PAYMENTS

Clarify Estimation of the “Other” Factor in Calculation of Factor 1 of the UCP Methodology

Using its standard uncompensated care payment (UCP) methodology, CMS proposes an estimated UCP amount of \$7.628 billion that would be available for distribution in FY 2022. (p. 25449). Compared to FY 2021’s final UCP amount of \$8.290 billion, the proposed FY 2022 UCP amount represents an alarming \$662 million decrease in available funds for distribution to disproportionate share hospital (DSH) qualifying hospitals.

This year, the reduction in the proposed FY 2022 UCP amount appears to be primarily tied to the lower Factor 1 amount (proposed as \$10.573 billion for FY 2022) in the UCP methodology.

CMS calculates Factor 1 of its UCP methodology to estimate 75 percent of the estimated DSH payments that would otherwise be made in the absence of Section 1886(r) of the Social Security Act. CMS's estimate for DSH payments in a given FY is partially based on CMS's 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 does not update these projections subsequent to the publication of its projections in the final rule, making it essential that these projections be based on the latest available information. (p. 25445).

Among the factors used to update the Factor 1 estimates, the OACT makes changes to its projection updates based on Medicare rates, discharges, case mix, and a residual “other” factor that includes Medicaid enrollment. For FY 2022, CMS notes that the “other” factor “includes the estimated impacts on Medicaid enrollment from the COVID-19 pandemic” as well as the change in rates for the 2-midnight stay policy and the 20 percent add-on for COVID-19 discharges. (p. 25446). CMS estimates that “Medicaid enrollment increased by 2.9 percent in FY 2020 and will increase by an additional 1.2 percent in FY 2021.” (p. 25446).

The “other” factor is +0.23 percent for FY 2020 and -2.46 percent for FY 2021. (p. 25446). Of the factors mentioned, the 2-midnight rule is not likely to explain the difference as that policy has been in effect for many years. The 20 percent add-on for COVID-19 discharges would contribute to an increase, not a decrease in the “other” factor. The only other factors mentioned that could account for this difference is the adjustment is the difference between total inpatient hospital discharges and IPPS hospital discharges, or the change in Medicaid enrollment. In the proposed rule, the Agency provides limited insight into its calculation of the “other” factor but clarifies that the factor reflects that its actuaries “have assumed that the new Medicaid enrollees are healthier than the average Medicaid recipient and, therefore, use fewer hospital services” due to the “better health of these beneficiaries.” (p. 25446). We believe that the enrollees reflected in this projection are showing a lower utilization of services due to patients' reluctance to seek care and instead opting to delay care and elective procedures during the PHE. Despite the anticipated increase in Medicaid enrollment, the “other” factor does not appear to strongly reflect this estimate and as a result the UCP Factor 1 calculation may be depressed. The OACT estimate also stands in stark contrast to CMS's own data, which indicates that Medicaid enrollment increased by 15.2 percent—or 9,731,89 enrollees—between February 2020 and January 2021.¹²

The AAMC strongly urges CMS to provide transparency on how OACT determines the “other” factor—including both the calculation and individual numbers included in the estimate—so that stakeholders can adequately understand and assess the appropriateness of both the Factor 1 amount and the considerably lower UCP pool proposed for FY 2022. In an ordinary year, a substantial drop in the UCP pool is of significant concern to the DSH

¹² CMS, December 2020 and January 2021 Medicaid and CHIP Enrollment Trends Snapshot, “Figure 1. National Medicaid and CHIP enrollment, February 2020 to January 2021, CMS Performance Indicator Data.” Accessed on Jun. 22, 2021 at: <https://www.medicare.gov/medicaid/national-medicare-chip-program-information/downloads/december-2020-january-2021-medicare-chip-enrollment-trend-snapshot.pdf>.

hospitals that rely on UCPs to partially offset the costs associated with providing care to many low-income patients. During the ongoing COVID-19 PHE, this issue is magnified due to the intensive shift in resources, dramatic and fluctuating changes to the levels of uninsured and low-income patients, and the expectation that patients across all socioeconomic statuses have delayed care and procedures during the PHE. **For FY 2022, it is imperative that CMS is more transparent about both the calculation and constituent elements that contribute to how the “other” factor is determined so that hospitals can accurately understand the cause behind the \$662 million dollar decrease to the UCP pool.** Without transparency regarding the “other” factor, stakeholders are unable to determine whether CMS’s proposed Factor 1 amount is appropriate or not. Again, the AAMC does not agree with OACT’s assumption that the new Medicaid enrollees are likely to “be healthier” and utilize less services. While OACT’s assumption regarding these new Medicaid enrollees may contribute to the perceived discrepancy in the Factor 1 amount, there is no way to determine exactly what other information contributes to how the “other” factor is calculated. Since it is unclear the extent to which Medicaid enrollment impacts the “other” factor in comparison to other unidentified influences, the Association cannot be certain of the likely or direct cause of the decrease in the proposed UCP amount, and therefore cannot assess the amount’s reasonableness or appropriateness.

Update the Data Source Used to Determine the Factor 1 Amount

The proposed rule indicates that the Medicaid discharge figures used in determining the Factor 1 amount are based on the OACT’s January 2021 Medicare DSH estimates, which were based on data from the September 2020 update of the Medicare Hospital Cost Report Information System (HCRIS) and the FY 2021 IPPS/LTCH PPS final rule IPPS Impact File, published in conjunction with the publication of the FY 2021 IPPS/LTCH PPS final rule.” The rule further indicates “OACT intends to use more recent data that may become available for purposes of projecting the final Factor 1 estimates for the FY 2022 IPPS/LTCH PPS final rule.” (p. 25445).

As CMS is using data for the Factor 1 estimate for FY 2022 from September of 2020 and March of 2020 (as that is the data source for the FY 2021 IPPS impact file), it is critically important that these data be updated to reflect the latest discharge information for FY 2022 to ensure that hospitals are accurately paid for their uncompensated care costs. While the proposed rule indicates that the data sources and timing is consistent with past IPPS proposed rules, CMS uses later information (the December update of Medicare cost reports and claims data) to model proposed rule impacts and for other purposes. **The AAMC urges CMS and the OACT to use a later update to the claims data consistent with what CMS otherwise uses to model IPPS impacts and set relative weights in a typical year.**

MEDICAID FRACTION

Individuals Receiving Benefits Under an 1115 Waiver Are Medicaid Beneficiaries and Should Be Included in the Medicaid Fraction

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

CMS is proposing to revise the regulation to "state explicitly" that a patient would be included in the numerator of the Medicaid fraction "only if the patient is eligible for inpatient hospital services under an approved State Medicaid plan that includes coverage for inpatient hospital care on that day or directly receives inpatient hospital insurance cover on that day" under an 1115 waiver. (p. 25459). CMS states the reason for this policy change is that it was not their intent to include patient days associated with certain 1115 waivers that are not similar to traditional Medicaid and may be provided to individuals with much higher incomes. (p. 25459).

The AAMC does not support this change and urges CMS not to finalize the proposal. The purpose of DSH is to compensate hospitals that serve a disproportionate share of low-income patients. Even if an 1115 waiver does not include inpatient care, the individuals who qualify under the waiver are low-income Medicaid beneficiaries and should be counted in the numerator. Removing the ability for teaching hospitals to include these individuals in the Medicaid fraction will financially disadvantage hospitals' that serve a high volume of low-income individuals. For many AAMC members the impact of this change could be dramatic. In 2019, AAMC members accounted for 26 percent of all Medicaid inpatient days.¹³

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

In the proposed rule, CMS specifically identifies for exclusion from the Medicaid fraction beneficiaries receiving premium assistance under an 1115 waiver. Some of the 39 states and the District of Columbia that to date have chosen to expand Medicaid have elected to provide

¹³ AAMC analysis of FY 2019 American Hospital Association hospital data. Analysis conducted March 2021.

coverage through premium assistance rather than under traditional Medicaid.¹⁴ While these individuals technically do not receive inpatient hospital services under the Medicaid program as CMS notes, they nonetheless should be viewed as Medicaid beneficiaries because they are receiving the benefit under a Medicaid waiver. Inclusion in the Medicaid fraction should not solely rest with who provides the insurance benefit; in this case, these individuals secure insurance coverage through the individual market. The important point is that individuals included in the expansion population are Medicaid beneficiaries and should be included in the Medicaid fraction.

MEDICARE WAGE INDEX

In FY 2020, CMS finalized several policies to address disparities between high and low wage index hospitals present in the wage index system. 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 future wage index data. The policy directly raised wage indexes of the lowest quartile wage index hospitals by half the difference between the 25th percentile wage index value and the hospital's individual wage index, 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 2022 CMS proposes to continue its wage index policy to raise the wage indexes of low wage hospitals. The AAMC appreciates the changes to the FY 2020 finalized policy that addressed several concerns outlined in our comments on the FY 2020 IPPS proposed rule and reaffirms our support for CMS's continuation of this policy in FY 2022. However, the AAMC details several concerns with aspects of this year's wage index proposals given the unique impact the COVID-19 PHE continues to have on both hospital finances and area wages.

Extend the Transitional Cap for All Changes to Hospitals' Wage Indexes

In FY 2020, CMS finalized a transitional one-year, five-percent cap on reductions to hospitals' wage index between FY 2019 and FY 2020. The cap limited reductions to a hospital's wage

¹⁴ Kaiser Family Foundation. Status of State Medicaid Expansion Decisions: Interactive Map. Published June 7, 2021. <https://www.kff.org/medicaid/issue-brief/status-of-state-medicaid-expansion-decisions-interactive-map/>

index to no more than five percent between the two fiscal years to mitigate the impact of the finalized wage index policies and allow hospitals to prepare for payment reductions.

In the following year, FY 2021, CMS adopted the labor market delineation updates described in OMB Bulletin No. 18-04. As both CMS and commenters noted, the modifications outlined in the bulletin were more significant in comparison to typical interim bulletins issued between decennial censuses. (p. 25396). These changes had significant impacts on the wage indexes of hospitals in several areas and were anticipated to have a cascading impact on hospitals with wage index reclassifications. With this understanding, CMS again finalized a five-percent cap on all reductions to hospitals' wage indexes between FY 2020 and FY 2021. (p. 25397). CMS noted that the five-percent cap applied to all wage index changes, regardless of the cause of the decrease, but was specifically included to mitigate the effects of the revised CBSA delineations and its corresponding impact on the wage index, and "to promote greater wage index predictability." (85 FR 58754).

For FY 2022, CMS is not proposing to continue the transitional five-percent cap but is soliciting comments on "whether it would be appropriate to continue to apply a transition to the FY 2022 wage index for hospitals negatively impacted by [the Agency's] adoption of the updates in OMB Bulletin 18-04" (p. 25397). The Agency also seeks comment on "making this transition budget neutral . . . in the same manner that the FY 2021 transition was made budget neutral." (p. 25397).

The AAMC urges CMS to apply the five-percent transitional cap in a budget neutral manner to all wage index changes for all hospitals for FY 2022 regardless of whether the reduction resulted from the new CBSA delineations or other factors. The AAMC echoes CMS's sentiment that it would be appropriate to continue the transitional cap not only due to delineation updates from OMB Bulletin No. 18-04, but to mitigate the financial impacts related to the "unprecedented nature of the ongoing COVID-19 PHE" as well. (p. 25397). While some hospitals are beginning to recover from the impacts of the PHE, many continue to financially struggle. **Given the severity and continuing impact of changes related to the OMB updates, the low wage index policy, and the lingering financial burden caused by the COVID-19 PHE, the AAMC believes that it would be appropriate to continue the five-percent transitional cap policy for FY 2022 and urges CMS to do so.**

The continuation of a five-percent cap on all wage index changes will ensure that hospitals can continue to recover. Additionally, the AAMC believes that the extended transition period aligns with past CMS policy and will more appropriately enable hospitals that are negatively affected to address significant reductions. The Association notes that as recently as FY 2015 CMS provided a three-year transition policy for hospitals negatively impacted by CMS's adoption of OMB's delineations based on the 2010 decennial census. (79 FR 49957).

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

The AAMC continues to be concerned that wage data collected during the COVID-19 PHE will be less reflective of regional wages and asks CMS to consider excluding affected wage

data in future calculations of the wage index. We reiterate that due to the financial strain felt by hospitals as they continue to face the demands of managing the COVID-19 PHE, the pandemic's impact on wages remains uncertain and CMS needs to collect more data in this area. As a result, wage data collected during the PHE stands to drastically impact the hospital wage index adjustment for heavily impacted areas once used to determine area wage indexes. Considering CMS's FY 2022 proposals to use data sources prior to the pandemic—for instance considering the use of 2019 data for ratesetting instead of 2020 data—the AAMC believes it would be appropriate to proactively consider this for wage index calculations in the near future. **The AAMC recommends that CMS proactively address 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.**

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

MEDICARE ADVANTAGE NEGOTIATED RATES COLLECTION AND RELATIVE WEIGHT METHODOLOGY

Finalize the Repeal Hospital Reporting of Medicare Advantage Negotiated Rates and Relative Weight Calculation Policies

In the FY 2021 IPPS final rule, CMS finalized a policy that effective for cost reporting periods ending on or after January 1, 2021 hospitals must report payer-specific negotiated charges by MS-DRG for all of their Medicare Advantage organizations on their Medicare cost report. CMS is proposing to repeal the requirement and amend 42 CFR 413.20(d)(3) to be consistent with repeal. In addition, CMS is proposing to repeal the MS-DRG relative weight calculation policy also finalized in the FY 2021 IPPS final rule. CMS cites stakeholder comments as a reason to further examine the usefulness of the data collection and potential change in the relative weight methodology. (p. 25527). **The AAMC thanks CMS for its recognition of the need to repeal these policies and study the usefulness of the data collection. We support repeal of this policy and ask CMS to finalize this proposal.**

MEDICAID ENROLLMENT OF MEDICARE-ENROLLED PROVIDERS AND SUPPLIERS

Finalize the Proposal to Require States to Enroll Medicare-Enrolled Providers and Suppliers in the Medicaid Program for Bad Debt Documentation

In the FY 2021 IPPS final rule, CMS codified several Medicare bad debt policies, many of which were outlined in the Provider Reimbursement Manual, Chapter 3, Section 308. Specifically, to satisfy the reasonable collection effort requirement under the Medicare bad debt policies a provider that furnished services to a Medicare beneficiary who is eligible for both Medicare and Medicaid (i.e., a dual-eligible beneficiary) must determine whether Medicaid is responsible for all or a portion of the dual-eligible beneficiary's Medicare deductible and/or coinsurance amounts. In order for any unpaid deductible or coinsurance amounts to be included as an allowable Medicare bad debt, the provider must obtain from the state Medicaid agency a remittance advice (RA) acknowledging that Medicaid is not responsible for the cost sharing. If the provider does not bill the state and submit the Medicaid RA to the Medicare with its claim for bad debt reimbursement for the dual eligible beneficiary, the unpaid deductible and coinsurance amounts cannot be included as an allowable Medicare bad debt.

States are required to process cost-sharing claims for dual-eligible beneficiaries through the Medicaid Management Information System (MMIS). The proposed rule notes that "the state MMIS must be able to process all claims for Medicare cost-sharing liability even if the Medicaid state plan does not recognize a service or provider category." (p. 25655). The proposed rule goes on to state that "some states in the past have inhibited enrollment of certain providers or suppliers that are not explicitly included in their State plan." As a result, the state Medicaid program may not be able to adjudicate the cost-sharing claim for certain providers or suppliers not included in the MMIS and thus unable to issue a RA to the providers for the purposes of computing Medicare bad debt. CMS is proposing that Medicaid programs must accept enrollment of all Medicare-enrolled providers and suppliers, even if not recognized as eligible to enroll in the state Medicaid program, if the provider or supplier otherwise meets all Federal Medicaid enrollment requirements. **The AAMC supports this proposal and urges CMS to finalize it. This proposal will facilitate providers' attempts to ascertain a state Medicaid's liability for dual-eligible beneficiaries' cost sharing.**

HOSPITAL QUALITY PROVISIONS

REQUEST FOR INFORMATION - CLOSING THE HEALTH EQUITY GAP IN CMS HOSPITAL QUALITY PROGRAMS

CMS requests feedback on making the reporting of health disparities based on social risk factors more comprehensive and actionable for hospitals, clinicians, and patients. The AAMC applauds CMS for its efforts to inform future proposals to address inequities in outcomes in its hospital quality programs. As noted elsewhere in this letter, the COVID-19 pandemic laid bare the realities of longstanding inequities in our communities that must be addressed. This work is

critical to building a healthier future for all, and the AAMC strongly supports efforts to move the needle and ultimately eliminate inequity. To this end, the AAMC recently launched a 10-point strategic plan¹⁵ to drive systemic change, including the creation of a new AAMC Center for Health Justice and an action plan dedicated to improving access to health care for all. The AAMC is helping to build academic medicine's capacity to contribute to advancing community health systems and to strengthen our sector's commitment to partnerships and policies that promote health equity and health justice.

A critical aspect of this work is the need for clarity on the role of health care quality and measurement in promoting health equity and community health. The AAMC believes that there is valuable overlap in these aims, but also that there are important distinctions that must be made when using quality measurement as a tool for improving equity. Health equity rightfully includes health care but must also evaluate and address broader community resources and needs. More and more evidence show that health care and genetics play a limited role in one's health compared to behavioral, social, and environmental risk factors.¹⁶ Improving quality of care is only a factor within the broader health equity aim and should have the goal of evaluating and driving improvement in care delivery for all patient populations.

To this end, when measuring equity, we must measure and shine light on the broad mix of factors at play in order to find appropriate solutions, including the role of measurement. Quality measurement of health care must measure factors which are in the control of providers and not the social factors that are outside the realm of health care delivery.¹⁷ The role of improved risk adjustment that addresses clinical, social and functional status risk factors is crucial for ensuring accurate and fair assessment and ensuring that the safety net is not penalized by losing the very resources it needs. When paired with stratification, we can and should ensure that adjustment does not mask inequities, but rather highlights them in a way that points to appropriate intervention and guides investments needed to drive improvement. We believe that CMS can and should drive toward broader health equity through its value-based payment programs as a next step and use stratified measures to incent progress and demonstrate improvement in local care gaps over time. Joining health care quality and equity with validated health equity measurement¹⁸ must be tested as a means of driving improvement prior to adoption in the Agency's hospital quality programs.

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

¹⁵ See [A Healthier Future for All: The AAMC Strategic Plan](#).

¹⁶ See National Quality Forum, [Social Risk Trial Final Draft Report](#) at 5 (April 19, 2021).

¹⁷ See [National Quality Forum Issues Quality Roadmap for Reducing Healthcare Disparities](#)

¹⁸ See US Department of Health and Human Services Assistant Secretary for Planning and Evaluation, "[Developing Health Equity Measures](#)" (May 20, 2021).

framework towards provider accountability for health equity. Efforts should be routinely evaluated to ensure they are accomplishing intended goals.

Future Potential Stratification of Quality Measures by Race and Ethnicity

CMS seeks feedback on the potential future application of an algorithm to indirectly estimate race and ethnicity to support stratification of quality measures for hospital-level disparity reporting, building off current confidential disparity reporting provided to hospitals for readmissions measures using dual-eligibility.¹⁹ CMS is clear that “[s]elf-reported race and ethnicity data are the gold standard for classifying an individual,”²⁰ but that the Agency does not currently collect such self-reported data and that data accuracy of race and ethnicity data it receives from the Social Security Administration is not accurate or comprehensive enough for such stratification efforts. In response, CMS is exploring the use of indirect estimation methods as a short-term solution to identify better race and ethnicity data while developing sustainable and consistent programs to collect and leverage data on social risk, including self-reported race and ethnicity data.

As CMS describes in this RFI, indirect estimation relies on a statistical imputation method that infers a missing variable or improves an imperfect administrative variable using a related set of readily available information.²¹ The other data sources that may be predictive of race and ethnicity include language preference, correlation of first and last names to specific national origin groups, and the racial and ethnic composition of surrounding neighborhoods matched with an individual’s address. CMS notes that while its efforts to develop indirect estimation efforts can be statistically reliable for calculating population-level results for groups of individuals, a risk remains of unintentionally introducing measurement bias.²² The potential harm and ethical risks²³ must be more thoroughly evaluated and carefully considered to ensure that use of the indirect estimation method does not unintentionally mislead improvement efforts.

The AAMC shares the goal to expand data capture and data harmonization in order to ensure providers have actionable information to inform improvement. However, efforts should be made to incent valid collection of demographic and social risk factor data that will best

¹⁹ While current stratification based on dual-eligibility is not the issue of discussion with this request for feedback, the AAMC would be remiss if it did not point to a recent study finding that broad differences in dual-eligible populations could mislead between-hospital comparisons using dual eligibility as a social risk factor. See Philip Alberti and Matthew C. Baker, “[Dual eligible patients are not the same: How social risk may impact quality measurement’s ability to reduce inequities](#),” *Medicine* Vo. 99, Issue 38 (September 28, 2020).

²⁰ 86 *Fed. Reg.* at 25558.

²¹ *Id.*, citing a 2009 Institute of Medicine 2009 report, “Race, Ethnicity, and Language Data Standardization for Health Care Quality Improvement.”

²² *Id.* at 25559.

²³ Megan Randall, Alena Stern, and Yipeng Su “[Five Ethical Risks to Consider before Filling Missing Race and Ethnicity Data](#),” Urban Institute (March 16, 2021).

inform intervention. **Race and ethnicity are not themselves risk factors^{24, 25} and reliance on immutable characteristics alone is not informative for intervention.** Furthermore, measuring a gap is not the same as measuring equity. Disparities surveillance does not tap into patient populations' perception²⁶ of (or the reality of) equitable opportunity for optimal care. Stratified quality measurement's ability to reduce inequities is only as good as the stratification factors used – and dual eligibility and race and ethnicity as proxies for actual social risk factors likely reduces the intended impact. **The AAMC urges CMS not to use indirectly estimated race and ethnicity data in confidential reporting due to our concerns with the accuracy and actionability of such data. Instead, CMS should invest in supporting data collection improvements, including how to standardize and use the data already collected by hospitals, and encourage the reporting and use of actionable social risk factor data, such as a number of ICD-10 z-codes identified as actionable,²⁷ in quality and payment programs.**

Improving Demographic Data Collection

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

Many AAMC member teaching hospitals and health systems use electronic health records (EHR)-based social risk screening tools in data collection to be better informed about the broader unmet health-related social need in their communities. While several organizations have developed standard screening tools and core questions,²⁸ we have heard from members that they often modify the templates to ensure culturally appropriate dialogue with the patients and

²⁴Angela King and Kim Shepard, "[Race is not a health risk factor. Racism is.](#)" National Public Radio (July 21, 2020), quoting Dr. Roberto Montenegro "When people look at health inequities, and they focus on differences by race, and they argue that race is a risk factor, it clouds the numerous factors that are really behind what people are intending to capture with race."

²⁵Sheets et al, "[Unsupported labeling of race as a risk factor for certain diseases in a widely used medical textbook.](#)" Journal of Academic Medicine (October 2011), which found that roughly two-thirds of assertions that different risk factors exist for Black patients found in a widely used pathology textbook could not be supported by the published literature.

²⁶For example, refer to the Minnesota Department of Health's Guild, "[HEDA: Conducting a Health Equity Data Analysis.](#)" Version 2 (February 2018), which recommends that health equity data analysis (HEDA) requires engaging populations that experience health inequities in the assessment process, including a principle for community engagement that stakeholders must learn about the community's perceptions of those initiating the engagement activities. Additionally, the AAMC's "[Principles of Trustworthiness](#)" project builds on foundational principle that trust is crucial for equitable community partnerships.

²⁷See AAMC Washington Highlights, "[AAMC Submits Comments to CMS on Additional ICD-10 Codes for Social Determinants of Health](#)" (May 2019)

²⁸Examples include CMMI's [Accountable Health Communities \(AHC\) Health-Related Social Needs \(HRSN\) Screening Tool](#), The National Association of Community Health Center's [Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences \(PRAPARE\)](#), and the [Health Leads Screening Toolkit](#).

communities they serve. Addressing inequity in communities requires integrating local perspectives in partnership with health care organizations that have demonstrated trustworthiness. Dialogue and screening about social risk factors must be culturally competent and help to establish trust between patients and the providers. As this field continues to develop, **we believe that CMS should pursue a policy supporting the collection of standardized multi-sector social risk information to support improved stratification and risk adjustment, balanced with allowing hospitals local flexibility to promote community-based innovation and solutions.**

CMS should also explore whether there are ideas and solutions from the data science and research community on how best to standardize a roll-up of granular data for community use into a format for broader evaluation and analysis. This is a massive undertaking led by the GRAVITY Project²⁹ to advance interoperable social determinants of health data, beginning with three social risk factors: food security, housing stability and quality, and transportation access. CMS could partner on an effort led by the Office of the National Coordinator for Health Information Technology (ONC) to evaluate interoperability standards that roll data collected through screening tools up into ICD-10 z-codes to capture social risk factors and provide actionable data to inform intervention. From that, we could then evaluate which z-codes are best suited to incorporation in a minimum set of social risk factor data elements to require through EHR certification.

While exploring the utility of additional individual demographic and social risk factor data elements, CMS should also evaluate the use and validity of community-based factors for improving data analysis necessary to inform quality and equity improvement activities. For example, research³⁰ shows that community-defined social risk factors cause substantial shifts in projected performance on the Readmission Reduction Program's readmission models above and beyond individual level proxies. A clear benefit of community-based analysis compared to individual-level analysis is the reduced risk of compromising individual privacy in addition to ensuring the use of holistic approaches to broad, structural inequities. To this end, the AAMC urges CMS to evaluate the opportunity to partner with public health departments, who may already have robust data that supports neighborhood stratification. **Overall, data collection and systems for social risk factors at both the individual and community level should be used in conjunction to best identify disparities in quality and equity and guide interventions for improvement.**

Finally, CMS should consider a variety of policy levers to improve hospital data collection. While mandating minimum data collection as a requirement may be one solution, we urge evaluation of incentives for hospital to improve data collection in part through a commitment to improving risk adjustment models for the inclusion of social risk factors and/or for additional stratification in hospital quality programs. **The AAMC believes that patients, payers, and**

²⁹ See Social Interventions Research & Evaluations Network (SIREN)'s [The Gravity Project](#).

³⁰ Baker et al., Health Affairs Vol. 40, No. 4, "[Social Determinants Matter for Hospital Readmission Policy: Insights From New York City](#)," (April 2021).

providers will all benefit from partnership to improve health equity. CMS should lead the effort to demonstrate the benefit of better data to inform solutions.

Potential Creation of a Hospital Equity Score to Synthesize Results Across Multiple Social Risk Factors

CMS seeks feedback on the potential development of a Hospital Equity Score (HES) similar to (and built from) the Health Equity Summary Score (HESS) recently developed for Medicare Advantage contracts and plans. The HESS is based on standardized and combined performance scores synthesized across dual-eligibility and race and ethnicity across performance measures, in addition to summarizing results across a within-plan method and an across-plan method, similar to the disparity methods used for confidential reporting of the readmissions measures as previously discussed. CMS seeks to use a similar mechanism to create a HES that would potentially mirror the HESS, except it would summarize hospital performance across social risk factors (initially dual eligibility and race and ethnicity, as proposed for expanded reporting) and across the two disparity methods (within-hospital and across-hospital).

As previously noted in these comments, **the AAMC urges CMS to be intentional in measuring health equity and ensure that such measurement includes and expands on stratified clinical quality measurement.** To this end we believe that a composite equity score should reflect the broader health equity efforts within a hospital's community. Similar to the creation and development of health care quality measurement, **CMS, engaging experts in the field, should consider and evaluate the development of structural and process measures that will drive improvement and are within the scope of hospital control.** Such measures could incentivize equity-focused, evidenced-based best practices, such as screening for social risk factors, performing community needs assessments with community-based partners, appointing a community-based advisory board to evaluate community benefit investment, partnership with state and local public health departments, etc. Hospitals cannot drive equity improvements alone. **Now is the time to be expansive in our development and evaluation of equity metrics that drive improvement and are inclusive of community-based partnerships.**

CMS describes a potential HES that initially summarizes hospital performance across dual eligibility and race and ethnicity as the initial social risk factors. We point the Agency to our previous comments in this letter that do not support expanded confidential reporting of the disparity methods for quality measures using the indirect estimation method, due to the intended temporary nature and potential risks of using the indirect estimation method. Considering these concerns, we urge CMS to not only ensure that a future HES can be feasibly and accurately calculated, but also that if race and ethnicity are used as a social risk factors that scoring be based on self-reported race and ethnicity data, and not indirectly estimated data. The entire health care community rightfully wants to act quickly to address health inequities, and many AAMC members currently are responding to the best to their abilities. However, a summary score of how providers are addressing health inequity requires thoughtful work to avoid unintended consequences by pushing forward unvetted measurement. **If CMS moves forward with developing a future HES, the Agency should commit to the evolution and expansion of**

social risk factors included that build off of advancement in measure science and expanded collection of valid and reliable social risk data.

QUALITY PERFORMANCE PROGRAMS: HOSPITAL READMISSION REDUCTION PROGRAM, VALUE-BASED PURCHASING PROGRAM, AND HOSPITAL-ACQUIRED CONDITION REDUCTION PROGRAM

Cross-Program Measure Suppression Factors to Address Impacts of COVID-19 Public Health Emergency

CMS proposes to adopt a cross-program measure suppression policy, based on four proposed suppression factors, to address the impacts of the current COVID-19 PHE on quality performance by hospitals. The four factors proposed are: (1) significant deviation in national performance on the measure during the PHE; (2) clinical proximity of measure's focus to the relevant disease, pathogen, or health impacts of COVID-19; (3) rapid or unprecedented changes in clinical guidelines, care delivery or practice, treatments, drugs, etc., or generally scientifically accepted understanding of the disease; and (4) significant national shortages or rapid, unprecedented changes in healthcare personnel, medical supplies and equipment, or patient case volumes or facility case mix. If adopted, CMS would use the measure suppression factors to guide proposals to suppress a measure for one or more program years that overlap with the COVID-19 PHE. **The AAMC applauds CMS for taking a cross-program approach to ensuring there is appropriate flexibility within the programs to address the changing conditions during a global pandemic that have an impact on quality performance beyond hospitals' control.** We agree with CMS that adopting the same measure suppression factors in each of the programs ensures consistency in the Agency's measure evaluations across programs and support the suppression factors identified for suppression determinations due to the COVID-19 PHE.

CMS seeks feedback on whether it should consider adopting a measure suppression policy in in the event of a future national PHE to enable suppression of measures without undergoing notice and comment rulemaking. As proposed, three of the four measure suppression factors are specific to COVID-19. While each suppression factor could potentially apply to a future PHE, CMS would not be able to apply those factors to a separate non-COVID-19 related PHE if they are finalized as proposed. **The AAMC suggests that CMS study the impact of these measure suppression factors to inform future revision for broader applicability to a future national PHE, while also acknowledging that additional or alternative distinct suppression factors may be necessary depending upon the specifics of such a future pandemic.**

The following sections represent the AAMC's comments to each of the quality performance programs, including CMS's proposed application of the suppression policy to each program.

Hospital Readmission Reduction Program

Application of COVID-19 Measures Suppression Policy to Readmissions Reduction Program

CMS proposes to suppress the 30-day Pneumonia Readmission Measure for the FY 2023 program year under proposed measure suppression factor 2 (clinical proximity of measure to the relevant disease or pathogen). The AAMC supports suppression of the pneumonia readmission measure for FY 2023 since COVID-19 often causes pneumonia. Additionally, CMS proposes to make a technical update to measure specifications to exclude COVID-19 patients from the remaining condition/procedure-specific readmission measures (AMI, CABG, COPD, HF, and THA/TKA) beginning with FY 2023, but otherwise retain those measures in the program for scoring and assessing payment adjustments. **The AAMC supports this policy and urges CMS to evaluate the need to extend its application beyond FY 2023.**

Possible Future Stratification of Readmission Measures

CMS requests comments on the possibility of confidentially reporting stratified results to hospitals using indirectly estimated race and ethnicity, in addition to the currently reported results stratified using dual eligibility. In addition, CMS is interested in feedback on whether it should publicly report stratified results using both indirectly estimated race and ethnicity and dual eligibility on Care Compare in the future.

The AAMC shares the goal to expand data capture and data harmonization in order to ensure providers have actionable information to inform improvement. However, efforts should be made to incent valid collection of demographic and social risk factor data that will best inform intervention. Race and ethnicity alone are not risk factors^{31, 32} and reliance solely on immutable characteristics is not informative for intervention. We understand that CMS cannot let perfect be the enemy of the good, **but the AAMC's concerns with the accuracy and actionability of indirectly estimating race and ethnicity data lead us to urge CMS not to use it in confidential reporting. Instead CMS should invest in supporting data collection improvements and the use of actionable social risk factor data, such as a number of ICD-10 z-codes identified as actionable, in its quality and payment programs.** In addition, we ask CMS to consider broader evidence-based community-based social determinants in its

³¹Angela King and Kim Shepard, "[Race is not a health risk factor. Racism is.](#)" National Public Radio (July 21, 2020), quoting Dr. Roberto Montenegro "When people look at health inequities, and they focus on differences by race, and they argue that race is a risk factor, it clouds the numerous factors that are really behind what people are intending to capture with race."

³²Sheets et al, "[Unsupported labeling of race as a risk factor for certain diseases in a widely used medical textbook.](#)" Journal of Academic Medicine (October 2011), which found that roughly two-thirds of assertions that different risk factors exist for Black patients found in a widely used pathology textbook could not be supported by the published literature.

stratification of measures in the Readmissions Reduction Program, based on evidence^{33, 34} as the current use of dual-eligibility alone is insufficient. The agency could explore the use of social risk factors at both the individual and community level to best identify disparities in quality and equity and guide interventions for improvement.

Value-Based Purchasing (VBP) Program

Application of COVID-19 Measures Suppression Policy to VBP Program

CMS proposes different measure suppressions for FY 2022 and FY 2023 payment years, in part due to differing impacts of measurement performance periods and the COVID-19 PHE. For FY 2022, CMS proposes to suppress measures under three of four domains: Efficiency and Cost Reduction, Person and Community Engagement, and Safety. Due to this expansive suppression proposal, CMS proposes to apply a neutral payment adjustment for FY 2022, where no hospital will receive a penalty or bonus, and hospitals will not receive a Total Performance Score. For FY 2023, CMS proposes to only suppress the 30-day pneumonia mortality measure, and otherwise exclude COVID-19 patients from the remaining Clinical Outcomes domain measures for purposes of calculating a hospital's Total Performance Score and assessing payment impacts. CMS also proposes changes to the baseline periods for FY 2024 for Efficiency and Cost Reduction, Person and Community Engagement, and Safety domains to avoid use of 2020 data while providing sufficiently reliable data for evaluating performance.

The AAMC supports this approach for addressing the impact of COVID-19 on the VBP Program. We recommend CMS continue to assess the pandemic's impacts on measures beyond FY 2022, particularly the Medicare Spending Per Beneficiary (MSPB) and Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) measures, and whether additional suppressions are appropriate for FY 2023. **Additionally, CMS should consider the impact of the Calendar Year (CY) 2020 response to COVID-19, particularly delays in care,³⁵ on performance in the program in 2021 and whether adjustments to the baseline periods are needed to better compare performance and improvement.** For example, the 2021 performance period for MSPB for FY 2023 program year will compare to a 2019 baseline and the mortality measures will include the first six months of 2021 compared back to a period between 2013-2016. CMS should monitor 2021 performance and determine whether there is a fair and valid comparison to pre-pandemic baselines.

³³ See [Baker et al.](#), finding that including social determinants of health (SDOH) data constructed with granular geographic data, along with social risk factor variables, substantially affects projected penalties for hospitals treating the highest proportion of patients with high SDOH scores, even after including peer-group stratification in the program's model based on proportion of dual-eligible patients served.

³⁴ See [Alberti and Baker](#), evaluating stratification of the pneumonia readmission measure under the HRRP and finding that broad differences in dual-eligible populations could mislead between-hospital comparisons using dual eligibility as a social risk factor.

³⁵ See Czeisler et al., CDC Morbidity and Mortality Weekly Report (MMWR), "[Delay or Avoidance of Medicare Care Because of COVID-19 – Related Concerns, United States, June 2020](#)," finding that 4 in 10 U.S. adults reported avoiding medical care because of concerns related to COVID-19. (September 11, 2020).

Removal of PSI-90

Currently the PSI-90 measure is planned to return to the Clinical Outcomes domain of the VBP Program beginning with FY 2023 performance. In reviewing the current measure set, CMS proposes to remove the PSI-90 measure effective with FY 2023 (i.e., no longer reintroduce the measure), on the basis that the cost of maintaining the measure in the VBP Program outweighs its benefit. If reintroduced to the VBP Program, hospitals would be measured on the measure twice for the same performance periods – under the VBP and the HAC Reduction Program – yet under different scoring methodologies. CMS believes using the same measure in different programs creates additional administrative costs and burden for hospitals rather than incentivizing improved performance. The AAMC has long raised concerns with the PSI-90 measure,³⁶ notably that some components of the measure focus on surgical care, disadvantaging hospitals with a larger volume of surgical care while other components are susceptible to surveillance bias and disadvantage institutions with robust infection control programs. **We strongly support the proposal to remove the PSI-90 measure from the VBP and forego its reintroduction into the program in FY 2023.**

Hospital Acquired-Condition (HAC) Reduction Program

Application of COVID-19 Measures Suppression Policy to HAC Reduction Program

In a slightly different approach to suppression proposals as compared to the Readmissions Reduction and VBP Programs, CMS proposes to suppress a period of performance from FY 2022 and FY 2023 performance scoring under the HAC Reduction Program rather than suppress a measure. In other words, CMS proposes not to use any data from CY 2020 to measure performance for assessing penalties. **The AAMC supports this approach as the best balance to address the impacts of the COVID-19 PHE with the statutory requirements for the HAC Reduction Program set by Congress.** The AAMC asks CMS to continue to monitor and evaluate the data available to ensure reliable and valid assessment of hospitals for impacted payment years.

Inpatient Quality Reporting (IQR) Program

Adoption of New Measures

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

Maternal Morbidity Structural Measure

Through annual reporting beginning with the fourth quarter of CY 2021, CMS proposes to adopt a maternal morbidity structural measure that assesses hospital participation in a state or national perinatal quality improvement (QI) collaborative initiative and implementation of patient safety practices or bundles within that QI initiative. The measure would require hospitals to attest to their participation in such a qualifying QI initiative and implementation of QI practices or

³⁶ See [AAMC Comments on FY 2018 Inpatient Prospective Payment System Proposed Rule](#) (June 13, 2017).

bundles. CMS proposes this measure as a step to addressing the maternal health crisis in the United States, and inconsistent obstetric practice as a contributing factor to maternal morbidity in particular.

The AAMC agrees that there is significant work to be done to improve pregnancy outcomes and that maternal health should be a quality improvement priority. As with other health care priority areas, we recognize the importance of baseline structural data to better understand the current QI landscape and build toward valid and reliable outcomes measurement. One area not addressed in the measure as proposed is patient and community engagement with the QI initiative. QI practices should formally include input from patients, particularly those from racial and ethnic minority groups most impacted by maternal mortality disparities. CMS should consider the feasibility of incorporating a third question asking whether a hospital has engaged patients in its participation in a QI program. **Overall, the AAMC supports this adoption of this maternal morbidity measure as a first step in the development of new quality measures intended to move the needle and drive improvement in this critical area of care.** We look forward to working with CMS and other stakeholders towards expanding and innovating quality measurement to improve outcomes for all pregnant and postpartum patients.

COVID-19 Vaccination Among Health Care Personnel Measure

To address the ongoing COVID-19 PHE, CMS proposes to adopt a new COVID-19 vaccination among health care personnel (HCP) measure that calculates the percentage of HCP eligible to work in the hospital for at least one day during the reporting period who received a complete vaccination course. The measure would exclude persons with medical contraindications to the COVID-19 vaccination as described by the Centers for Disease Control and Prevention (CDC), but otherwise all personnel—including licensed independent practitioners affiliated with but not directly employed by the hospital and students, trainees and volunteers—are included in the denominator, regardless of clinical responsibility or patient contact. The measure would be reported using CDC's National Healthcare Safety Network (NHSN) Healthcare Personnel Safety Component submission framework. CMS proposes to require hospitals report the measure a minimum of one week each month to CDC, beginning with October 2021.

The AAMC strongly supports COVID-19 vaccinations of both our members' HCPs and the communities they serve. We have partnered³⁷ with the CDC to build confidence in vaccines in part by engaging member medical schools and teaching hospitals in outreach efforts to communicate transparently and dispel myths, with the goal of increasing vaccination rates. Still, we are only six months into deploying the three available COVID-19 vaccines and questions remain regarding the period of immunity conferred and whether (and how frequently) booster shots may be required. And if boosters are required, whether one should receive the same type as the original vaccine one received? And critically, will vaccine supply remain sufficient to ensure HCP can receive boosters if necessary? These questions directly impact the design and feasibility

³⁷ See AAMC Press Release, "[AAMC Receives CDC Award to Build Confidence in COVID-19 Vaccines and Move the Nation Forward](#)," (March 19, 2021).

of a vaccination measure, and thus we believe such a measure may be premature due to unpredictable shifts in reporting requirements that could result in unhelpful data to CMS, hospitals, and the public. **The AAMC urges CMS to delay mandatory reporting of the measure for at least one year, until October 1, 2022, and instead implement a voluntary reporting of the measure in the interim to allow time to address these critical questions impacting measure design.**

Hybrid Hospital-Wide Mortality Measure

CMS proposes to adopt a hybrid hospital-wide all-cause risk standardized mortality measure, using both patient claims and electronic health record data. CMS proposes to adopt the hybrid hospital-wide mortality (HWM) measure with an initial voluntary reporting period beginning July 2022 and transitioning to mandatory reporting beginning with July 2023 reporting, affecting FY 2026 payment. This approach is similar to the hybrid hospital wide readmission (HWR) measure currently adopted as voluntary and becoming mandatory for FY 2026 payment determinations in the IQR,

The AAMC supports exploring the benefits of hybrid quality measurement and building off of success in improving mortality rates since the widespread adoption of condition-specific mortality measures. **We recommend CMS adopt the HWM measure with two voluntary reporting periods in order to ensure all hospitals have sufficient opportunity to familiarize themselves with hybrid measure reporting requirements.** To improve reporting success, CMS should evaluate and make public whether it has observed any EHR data extraction or submission issues with voluntary reporting of the HWR measure. Additionally, CMS should clarify whether reporting for the HWM measure can be combined with the HWR measure, or whether two separate submission processes will be required, with four quarters of data for the HWR submitted separate from the files for the four quarters of data for the HWM. If valid and reliable data can be reported in combination for the two measures in one submission containing all core clinical data elements (CCDEs) and linking variables needed for both measures, reporting burden on hospitals could potentially be reduced. **The agency should also take steps to test the feasibility of using non-clinical EHR-derived data elements, such as education, location, and data from social risk screening, to inform development of appropriate adjustment for social risk factors.**

Hospital Harm eQMs – Severe Hyperglycemia and Severe Hypoglycemia

CMS proposes to adopt two new electronic clinical quality measures (eQMs) to the IQR measure set beginning with CY 2023 reporting from which hospitals may choose to report: Hospital-Harm – Severe Hypoglycemia and Hospital Harm – Severe Hyperglycemia. The AAMC agrees that it is important to include measures that focus on reducing the most common adverse drug events and that hospitals should implement protocols to manage blood glucose levels for critically ill patients. **To this end, we support the adoption of these balancing eQMs as part the IQR measure set as optional measures a hospital may choose to report.**

Removal of Measures

CMS has reviewed the current portfolio of measures in the IQR and proposes to remove five measures: (1) Death Among Surgical Inpatients with Serious Treatable Complications (PSI-04); (2) Exclusive Breast Milk Feeding eQIM; (3) Admit Time to ED Departure Time for Admitted Patients (ED-2); (4) Anticoagulation for Atrial Fibrillation/Flutter (STK-03); and (5) Discharged on Statin Medication (STK-06). **The AAMC appreciates CMS's efforts to continuously review measures and supports the proposed measure removals.**

Potential Future Measures

CMS seeks feedback on three potential future measures. Comments specific to each are as follows.

COVID-19 Mortality Measure

CMS is considering the development and inclusion of a hospital-level measure of all-cause mortality for Medicare beneficiaries admitted with COVID-19 infection to assess how the burden of the PHE impacts hospitals' abilities to care for COVID-19 patients. This would be a claims-based measure that would likely resemble the other condition-specific mortality measures currently in use. The AAMC agrees that it is important to learn more about the impact of COVID-19; however, we recommend careful evaluation of the investment of measure development resources in a novel disease that may or may not remain a long-term priority for measurement. **The AAMC believes it is too soon to support such a measure.**

CMS should balance the potential of COVID-19 as a long-term national health care priority area for quality measurement with the investment necessary to develop a valid and reliable measure during a period of continuous understanding of a novel disease. This is especially critical for building a risk adjustment model that is appropriately responsive to both clinical and social risk factors that may impact a hospital's performance in treating COVID-19 cases. Additionally, the AAMC continues to believe that all new measures must be fully vetted and endorsed by the National Quality Forum (NQF) prior to inclusion on a future Measures Under Consideration (MUC) list for public comment and review by the Measure Application Partnership as part of the required pre-rulemaking process.

Patient Reported Outcomes (PRO) Measure Following Elective Total Hip/Knee Arthroplasty

CMS is considering future inclusion of a Patient Reported Outcomes (PRO) measure following elective total hip and/or total knee arthroplasty (THA/TKA) procedures. The AAMC is supportive of exploring the role of PRO measures in hospital quality measurement and agrees that beginning with elective procedures is reasonable. However, we believe the CMS should evaluate carefully the inclusion of this particular PRO due to several concerns. First, the THA/TKA PRO has been included in the Comprehensive Joint Replacement (CJR) payment model as a voluntarily reported measure since 2016, and recently CMS has issued increased reporting threshold requirements for scoring. We have heard from members that most are not

reporting PRO data in the model due to the 80percent reporting threshold, which hospitals have been unable to meet. CMS should further analyze survey response rates, especially since this measure requires pre-and post-procedure responses and consider how it can support hospitals in efforts to increase responsiveness. Second, CMS notes that measure developers have implemented a risk adjustment approach to in part address response bias. Such an approach must be critically evaluated to ensure that it addresses such bias in responses, particularly considering language and other socioeconomic barriers that may affect survey completion and response. A recent study³⁸ noted broader equity challenges with the CJR model, and the AAMC urges CMS to consider such broader payment incentives on equity and disparities when considering inclusion of this measure. Finally, as CMS notes in its request for feedback, there are broader payment-related policy changes that could critically impact this measure as currently specified. The recent finalized proposal to remove the procedures from CMS's inpatient only (IPO) procedure list is likely to result in dramatic shifts in care setting for THA/TKA procedures. CMS should thoroughly analyze the potential impacts on whether the measure should be specified across facility types to assess performance across hospital inpatient/outpatient departments and ambulatory surgical centers in addition to impact on survey response rates.

Potential Future Efforts to Address Health Equity in the IQR Program

CMS seeks feedback on addressing inequities in health care outcomes in the United States in part by identifying potential opportunities specific to the IQR, including potential future confidential stratified reporting and the potential for a future structural measure to assess hospital leadership engagement in health equity performance data. Comments specific to each are as follows.

Potential Future Confidential Stratified Reporting of the All-Cause Readmission Measure

As mentioned previously in this comment letter, **the AAMC shares the goal to expand data capture and data harmonization in order to ensure providers have actionable information to inform improvement.** However, efforts should be made to incent valid collection of demographic and social risk factor data that will best inform intervention. Race and ethnicity are not themselves risk factors and reliance on immutable characteristics alone is not informative for intervention. **We understand the importance of addressing inequities in health care outcomes, but our concerns with the accuracy and actionability of indirectly estimated race and ethnicity data lead us to urge CMS to not use it in confidential reporting. Instead, we recommend CMS invest in supporting data collection improvements and the use of actionable social risk factor data, such as a number of ICD-10 z-codes identified as actionable, in its quality and payment programs.**

³⁸ See Thirukumar, et al., Journal of the American Medical Association Open Network, "[Association of the Comprehensive Care for Joint Replacement Model with Disparities in the Use of Total Hip and Total Knee Replacement.](#)" (May 28, 2021).

Potential Future Reporting of a Structural Measure to Assess Hospital Leadership Engagement in Health Equity Performance Data

CMS seeks feedback on the future reporting of a structural measure of the role of organizational leadership and culture as an essential role in advancing equity goals. Measure(s) to be developed would be attestation-based and assess domains related to organizational commitment to health equity including: regular examination of existing algorithms for presence of bias and sharing of such information with hospital leadership and board of directors, presence of organizational statements and plans regarding disparities, language access, and communications access tied to respective CMS Office of Minority Health publications, EHR capabilities for collecting demographic data elements, and hospital staff training on best practices in the collection of such data. CMS envisions an incremental approach to required reporting, and that future technical specifications or plans for the measure would be made through future rulemaking.

The AAMC supports the development of structural measures as a critical first step to assessing current practices and incentivizing new evidence-based methods that advance our collective health equity goals. To that end, the AAMC suggests that CMS also consider the inclusion of topic areas such as use of social risk screening tools and organizational leadership engagement with community needs assessments and community benefit investments. Measure development should engage expert stakeholders and include a review of existing federal and state requirements³⁹ hospitals must comply with to ensure structural measurement is consistent with and adds value to what is already being done. One area that we believe is *outside* the scope of an equity measure is EHR-related capabilities. We believe those should instead be left to the ONC for setting certification standards and requirements for EHR vendors and technologies that then flow down to hospitals through the Medicare Promoting Interoperability Program (PIP) and measuring meaningful use of EHRs. Hospitals and hospital leaders often do not control EHR capabilities, but rather work with EHR developers and vendors to ensure EHR products meet ONC's certification standards as required for meeting requirements under the PIP. Finally, any measure should be endorsed by the NQF as valid and reliable, before its use in a Medicare hospital quality program and certainly before it is reported publicly on CMS's *Care Compare* website.

MEDICARE PROMOTING INTEROPERABILITY PROGRAM

Proposed Changes to the Performance-Based Scoring Methodology for the EHR Reporting Period in CY 2022

CMS proposes to increase the minimum performance threshold for EHR reporting beginning in CY 2022 to 60 points out of a proposed 115 points (inclusive of bonus points), from a current minimum threshold of 50 points. CMS notes that 2019 performance shows that more than 98

³⁹ See, for example, [Internal Revenue Service rules](#) requiring a triennial Community Health Needs Assessment (CHNA) for 501(c)(3) hospitals.

percent of participating hospitals met the 50-point minimum threshold. **While the AAMC agrees that such performance demonstrates hospital success with the performance-based methodology for EHR reporting, we urge CMS to delay the increased threshold at least one year in recognition of the COVID-19 pandemic (and resultant diversion of EHR reporting resources) and the Agency’s concurrent proposals modifying EHR reporting objectives.** Hospitals need more time to re-establish normal, non-pandemic health IT activities and to adjust to broader changes to EHR reporting as proposed.

Proposed Changes to Provide Patients Electronic Access to Their Health Information Measure Under the Provider to Patient Exchange Objective

CMS proposes to modify the measure to require hospitals to ensure that patient health information remains available to the patient (or patient-authorized representative) to access *indefinitely* and using any application of their choice that is configured to meet the certified technical specifications of the application programming interface (API) in the eligible hospital’s certified EHR technology (CEHRT). Eligible hospitals would be required to ensure indefinite availability of information beginning with the CY 2022 EHR reporting period and include all patient health information from encounters on or after January 1, 2016.

The use of the term “indefinitely” is described as “that is, not merely for a defined period of time,” could mean that a hospital may be required to maintain patient health information well beyond a patient’s death. This not only assumes that future generations will have the appropriate legal authority to access an ancestor’s health information but also that electronic storage capacity is infinite. There are limits to data retention, and increased data stored simply means increased time for computing to filter the information and delays in the response time of EHR systems, directly impacting patient care. Increased data storage comes at a cost, which would have to be born somewhere. Furthermore, requiring indefinite data access would necessitate a drive to storing records via “cloud” services, where control and security of data is less certain or guaranteed to be safe from bad actors. This of course says nothing to the environmental impact of data storage.⁴⁰ **For these reasons, requiring indefinite access is simply unreasonable, costly, and unsafe. The AAMC urges CMS to limit the requirement for patient health information to be accessible for a fixed minimum retention period such as ten years from last patient contact, matching its own current records retention requirements.**⁴¹

Proposed Change to Health Information Exchange (HIE) Objective

CMS proposes a new optional alternative measure, "Engagement in Bi-directional Exchange Through Health Information Exchange (HIE)". CMS proposes to add this new measure under the

⁴⁰ AJ Dellinger, Mic.com, “[The environmental impact of data storage is more than you think – and it’s only getting worse.](#) (June 19, 2019), describing in general the environmental costs of expanded data storage, including citing to a 2015 report that found data centers to be responsible for about 2 percent of global greenhouse gas emissions, similar to that of the aviation industry.

⁴¹ See CMS MLN Matters® SE1022 “[Medical Record Retention and Media Formats for Medical Records](#)” (August 2012).

HIE objective beginning with the 2022 performance period. This new measure would be an optional alternative to the two existing measures: “Support Electronic Referral Loops by Sending Health Information” and “Support Electronic Referral Loops by Receiving and Incorporating Health Information.” Hospitals could either report the two existing HIE measures and associated exclusions or the new alternate measure. The new measure would be worth 40 points, the total of the two current measures. The new measure would be reported by attestation, with a yes/no response, rather than tracking and incrementing numerators and denominators.

The AAMC supports this proposed optional measure approach for the HIE objective, including the ability to report by attestation rather than tracking and reporting numerators and denominators. The ongoing capability for bi-directional exchange, and use of such a capability, is critical to advancing effective interoperability.

Request for Feedback – Patient Access Outcomes Measures

We support broader patient access to their own health information as partners in care, but we caution against a future measure of patient access and use of such information. Patients use of their own health information is well beyond the control of hospitals and simply should not be used to reflect upon a hospital’s use of EHR technology. We do not see how generating figures for the frequency of logins, number of messages sent, or lab results viewed will inform improved patient outcomes or validly and reliably measure hospital use of EHR technology. The most a provider can do is to make options for access available and encourage patients to use them. **The PIP should focus on elements of EHR use well within a hospital’s control, and not patient choices regarding how and when they access their health information.** Furthermore, it is unclear how a requirement for hospitals to report tracking of third-party personal health applications and APIs will provide useful data beyond the Health Information National Trends Survey (HINTS) operated by the National Cancer Institute with support from the ONC. On the flipside, such tracking would add burden to hospital reporting without commensurate benefit and potentially increase inequities by prioritizing measurement of app and API use, which leaves out those who do not own or use smartphone technology.⁴²

Request for Feedback – Clinical Notes

Currently the ONC’s rules for certified EHR technology require inclusion of clinical notes as a health data class as part of the United States Core Data for Interoperability (USCDI) to support the access, use, and exchange of electronic health information under the information blocking rules. With the information blocking rules in full effect as of April 2021, providers must provide access to clinical notes. It is unclear how incorporating measurement of access to clinical notes is separate and distinct from maintaining compliance under the information blocking rules and using CEHRT under the PIP. **The AAMC supports transparent communication among patients, families, and clinicians, but we believe this is best left to the purview of the ONC**

⁴² See Pew Research Center, “[Who owns cellphones and smartphones](#),” (April 2021), finding that 39% of people aged 65 or older and 24% of people making less than \$30,000 do not have a smartphone.

CEHRT and information blocking rules and should not be a new measure of meaningful use of EHR technology.

Request for Feedback – Designating High Performing Hospitals

CMS seeks feedback on industry-sponsored models to recognize and distinguish hospitals for their adoption and utilization of EHR functionality, including whether CMS should create a similar designation program, or potentially develop a Star Rating for Promoting Interoperability or otherwise incorporating EHR functionality into the existing Overall Hospital Quality Star Ratings. **The AAMC opposes this proposal and urges CMS to leave such rankings and designations to the purview of the marketplace and private enterprise expertise in assessing EHR innovation.** Furthermore, we strongly caution against the inclusion of Promoting Interoperability metrics into the current quality star ratings program until it can be demonstrated that measures of hospital EHR functionality are valid and reliable measures of the hospital, and *not* its health IT vendors, and that such metrics are of importance to patients and families when evaluating hospital choice.

REQUEST FOR INFORMATION - ADVANCING DIGITAL QUALITY MEASUREMENT

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

Definition of Digital Quality Measures (dQMs)

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

The definition presented in this Request for Information is incredibly broad, and lists data sources including “administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated health data), health information exchanges or registries, and other sources.” Not all of these data sources are ready for “prime time” and inclusion in quality measurement. For example, wearable devices and patient-generated health data hold great promise for the future but have not been vetted as valid and reliable interoperable data sources or as usable for clinical quality improvement and assessment. CMS should more clearly define what it expects the future of dQMs to look like, and how those expectations differ from the current state of quality measurement. The agency should also outline plans for piloting new data sources for quality measurement, identifying reasonable near-term and longer-term priorities. As we have seen with

the transition to eCQMs from chart-based measurement, the goal for a future state might not be as easily met as initially envisioned. Finally, CMS should engage NQF in this work, to ensure that digital measure specifications are appropriately evaluated for utility in improving quality of care. The AAMC and our members are excited to partner with CMS and to collaborate on more specific plans for digital quality measurement for the future.

Changes Under Consideration to Advance Digital Quality Measurement: Potential Actions in Four Areas to Transition to Digital Quality Measures by 2025

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

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

Digital Quality Measures as Self-Contained Tools

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

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

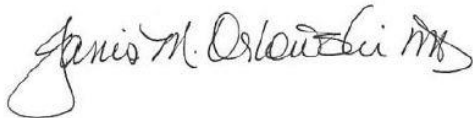
The AAMC strongly supports efforts to better align quality measures across federal, state, and private payer programs. To do so with fully interoperable data is likely to require leadership from HHS, including CMS and the ONC, and a potential rethinking of its health IT certification activities. This is because health IT certification was initially designed to evaluate a product’s ability to meet minimum meaningful use requirements, and not necessarily on the quality, exchange and usability of data aligned with requirements for robust quality measurement. To realize the full extent of digital quality measurement requires EHRs that improve the capture, management, and communication of clinical information and better accommodate the needs of providers and their patients. Relatedly, quality measurement

development does not always require inclusion of health IT developers to complete robust testing, resulting in insufficient test cases that do not ensure actual ease and accuracy of measure reporting in addition to ensuring that measurement is clinically useful. CMS will need to partner with ONC to prioritize concurrent certification requirements that validate dQMs and improve overall EHR user experience with measure development and implementation policy. Additional opportunity for alignment could relate to the collection and use of standardized social risk factor data collection and use in measurement. CMS should investigate potential incentives for encouraging alignment with providers and other payers.

CONCLUSION

Thank you for the opportunity to comment on the FY 2022 IPPS proposed rule. We would be happy to work with CMS on any of the issues discussed above or other topics that involve the academic medical community. If you have questions regarding our comments, please feel free to contact Mary Mullaney at mmullaney@aamc.org and Andrew Amari at aamari@aamc.org for questions on the payment policy proposals; Phoebe Ramsey at pramsey@aamc.org for questions on the quality proposals; and, Ivy Baer at ibaer@aamc.org and Brad Cunningham at bcunningham@aamc.org for questions about the graduate medical education proposals.

Sincerely,



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

cc: Ivy Baer