

September 17, 2021

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building, Room 445–G  
200 Independence Avenue, SW  
Washington, DC 20201

Re: File Code CMS–1753–P. Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals

Dear Administrator Brooks-LaSure:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to offer our comments to the Centers for Medicare & Medicaid Services (CMS) on the 2022 Hospital Outpatient Prospective Payment (OPPS) proposed rule, published in the *Federal Register* on August 4, 2021 (86 Fed. Reg. 42018).

The AMA continues to support the stated goals of CMS to reduce regulatory burden and increase flexibility for physicians and patients, especially during the SARS-CoV-2 or COVID-19 public health emergency (COVID-19 PHE). The AMA continues to put the concerns of our physicians, our medical students, and the patients they serve at the forefront of everything we do. We are particularly concerned that the impact of some proposals relating to clinical discretion, access to care, and administrative burden, combined with COVID-19 will continue to widen the gap for marginalized and minoritized communities. The AMA is committed to not only reducing health disparities, but to increasing health equity in the wake of the pandemic, the public health emergency, and beyond.

The following is a summary of our key comments followed by detailed comments:

- The AMA urges CMS to review CPT codes 95004 - *Percutaneous tests (scratch, puncture, prick) with allergenic extracts, immediate type reaction, including test interpretation and report, specify number of tests* and 95044 - *Patch or application test(s) (specify number of tests)* and make appropriate revisions that consider the service and associated costs.
- The AMA urges CMS to adopt a more measured approach to the Inpatient Only (IPO) list of services than what is proposed, and to continue the removal of services off the IPO list when supported by data and medical evidence, rather than eliminate the list entirely.
- The AMA is concerned with CMS' proposal to remove 258 codes from the Ambulatory Surgical Center Covered Procedures List (ASC-CPL) that were just added in 2021. We encourage CMS to

reconsider this significant shift backward and to ensure that the appropriate site of care is determined by health care providers.

- The AMA supports CMS' continued use of the hospital market basket as the annual update mechanism for ASC payments.
- The AMA supports the discontinuation of the ASC weight scalar. With the 2019 change in the conversion factor, it is even clearer that removing this secondary scaling adjustment is necessary to truly align the payment systems and enable ASCs to capture the value of the conversion factor, which will afford greater opportunity to motivate increased migration of surgery and lower the cost of care.
- The AMA supports separate payment for non-opioid pain management products that will help reduce the prescription and use of opioids after surgery.
- The AMA urges CMS to conduct a limited scale test of the RO Model on a voluntary basis rather than mandating participation in an untested model. The RO Model represents major changes in payment for services that treat life-threatening illnesses, and it is inappropriate to mandate participation without any testing on a more limited scale with practices who voluntarily participate.
- The AMA supports advancements in data availability and integration for quality improvement and measurement through efforts such as data aggregation, but they must result in data that are easily accessible at the point of care and provide actionable information that can inform shared decision-making while also easing reporting burden.
- The AMA believes that continued stratification of quality data by dual eligibility and race and ethnicity remains insufficient and while the expansion to disability provides useful information, CMS must make significant efforts to advance the data that are used to identify health care inequities. The AMA discourages CMS from strictly relying on dual-eligibility (DE) status when stratifying readmission or admission measures and we continue to believe that relying on algorithms for indirectly estimating race and ethnicity is not an appropriate solution.

#### **A. Hospital Payment Proposed for 2022: APC 5724 \$943.96**

The AMA has heard from our physician members who practice allergy and immunology regarding the charges for skin testing (95004) and patch testing (95044) in the hospital outpatient department. For reference:

- CPT code 95004 - *Percutaneous tests (scratch, puncture, prick) with allergenic extracts, immediate type reaction, including test interpretation and report, specify number of tests* 2002 Medicare Physician Payment Non-Facility = \$3.69
- CPT code 95044 - *Patch or application test(s) (specify number of tests)* 2002 Medicare Physician Payment Non-Facility = \$4.70
- Hospital Payment Proposed for 2022 for 95004 and 95044: APC 5724 = \$943.96

We believe there may have been an error in how CMS classified this service in the hospital outpatient payment system and have previously reached out to CMS for a correction. Our attempts to clarify and correct this error have not been addressed. As a result of this misclassification in Medicare, which often establishes the payment trajectory for other payers, we believe there have been undue charges that are being passed along to patients.

The payment differential between the physician office payment amount and the payment amount in the hospital outpatient setting is also an issue of considerable concern. In 2022, the proposed Medicare

National Payment Amount in the physician office is \$3.69 for skin testing and \$4.70 for patch testing. In comparison, the hospital outpatient payment is proposed to be \$943.96. While not a direct apples-to-apples comparison, CMS assigned these tests with services with much higher costs, including sleep testing, which is more intensive to the same APC. We seek a correction from CMS and believe it also illustrates the significant payment variations that stem in part from Medicare facility fees paid to hospital outpatient departments. **The AMA urges CMS to review these codes and make appropriate revisions that consider the service and associated costs.**

### **B. Inpatient Only (IPO) Procedures List**

CMS is proposing to stop the elimination of the IPO list finalized in the CY 2021 OPSS. After clinical review of the services removed from the IPO list in CY 2021, CMS is proposing to add the 298 services removed, placing them back on the IPO list in CY 2022. CMS is also soliciting comment on whether they should maintain the longer-term objective of eliminating the IPO list entirely or maintain the IPO list but continue to systematically scale the list back so that inpatient only designations are consistent with current standards of practice.

The IPO list was created in 2000 to identify services requiring inpatient care because of their invasive nature, the need for at least 24 hours of postoperative recovery time, or the underlying condition of the patient. In CY 2021, CMS finalized to eliminate the IPO list over three calendar years. To date, CMS has reviewed the list annually and, through its rulemaking, proposed services that should be removed or added to the list based on data and medical evidence, which the AMA has supported.

CMS justified this change by citing comments submitted over the years that have requested elimination of the IPO list, generally based on the tenet that decisions regarding the appropriate site-of-service for a procedure are best made by physicians. While the AMA agrees that decisions critical to high quality patient care should always be the ultimate responsibility of the physician, including the determination of the appropriate site-of-service, hospitals and private payers often influence determinations regarding the appropriate site-of-service for procedures and services and the burden then falls on the physician to convince a hospital or payer that a particular patient should receive a given procedure in an inpatient setting due to patient safety concerns. The AMA supports allowing physicians—together with their patients—to determine the appropriate site-of-service for a procedure or service, however, we also believe that patient safety and quality of care are paramount. Therefore, **the AMA is concerned that removing the IPO list entirely may lead to diminished patient safety and quality of care as facilities and/or payers pressure physicians to perform services in lower cost sites of service and urges CMS to adopt a more measured approach to the Inpatient Only (IPO) list of services than what is proposed, and to continue the removal of services off the IPO list when supported by data and medical evidence, rather than eliminate the list entirely.**

### **C. Updates to the Ambulatory Surgical Center (ASC) Payment System**

#### *1. Proposed Changes to the List of ASC Covered Surgical Procedures for CY 2022*

The AMA is concerned about the complete reversal of the proposal that adds 258 codes to the ASC-CPL based on revised criteria finalized in the 2021 OPSS.

*Lack of clinical data*

In order to retain these codes, CMS is requesting “clinical evidence or literature to support commenters’ views that any of these procedures meet the proposed revised CY 2022 criteria and should remain on the ASC CPL for CY 2022.” The proposed rule indicates that CMS clinicians evaluated all 258 codes proposed for removal from the ASC-CPL, but there is not one data point in the rule, or citation to research or other outcomes data indicating exactly what the safety concerns might be before any of the codes.

*Relying on limited claims to argue lack of adoption*

CMS also indicates that based on an “internal review of preliminary claims submitted to Medicare,” the Agency does not believe ASCs have begun furnishing these procedures on Medicare patients. Because of this, CMS believes it is “unlikely that ASCs have made practice changes in reliance on the policy we adopted in CY 2021. Therefore, we do not anticipate that ASCs would be significantly affected by the removal of these 258 procedures from the ASC CPL.” First, it takes some time to ramp up new procedures in a facility, and the data CMS would have at this point in the year is extremely limited.

In addition, CMS’ addition of codes to the ASC-CPL often opens the door for other payers to reimburse for these procedures, and as such, many facilities may have started with other patient populations before taking on any sort of significant Medicare volume.

*2. Evaluating codes based on the “typical” Medicare beneficiary*

CMS acknowledges that many of the procedures added in CY 2021 would only be appropriate for Medicare beneficiaries who are healthier and have less complex medical conditions than the “typical” beneficiary, and upon further review, they “believe it is appropriate to assess the safety of these procedures in the context of the typical Medicare beneficiary, whose health status is representative of the broader Medicare population.” CMS references the authority granted to HHS in the Social Security Act (SSA) to add codes and implies that by adding codes to the ASC-CPL that Medicare has determined that the procedure is safe to perform on the typical Medicare beneficiary. The SSA does *not* include any language to support this, and as such, CMS is establishing a new standard in this rule which the AMA does not support.

The precedent has long been whether or not a procedure is safe to perform on a “subset of the Medicare population.” Medicare beneficiaries—similar to our country’s population at large—are not a monolith. If CMS is truly setting the precedent of only allowing ASCs to perform procedures that are safe for the “average” Medicare beneficiary, they are severely limiting access to the growing number of Medicare beneficiaries who are relatively young and active. There would also need to be a much more detailed explanation of what constitutes an average beneficiary, because on its face this language could practically eliminate the ASC-CPL altogether.

There are certain subsets of the population who should have surgeries performed in an inpatient hospital due to comorbidities and risk factors. It is much more reasonable—and also a longtime policy of this Agency—to determine whether a subset of the population is suitable and allow for the clinician to then decide which of her patients are eligible for care in an ASC.

CMS indicates that “while a physician can make safety determinations for a specific beneficiary, CMS is in the position to make safety determinations for the broader population of Medicare beneficiaries.” **That said, the AMA urges the Agency to strongly consider that physicians take their role very seriously in considering what is best for their individual patients.**

*3. Incorrect assessment of the requirements for HOPDs vs ASCs*

CMS states that “while there are similarities between the ASC and hospital outpatient departments (HOPD) settings, there are also significant differences between the two care settings.” The rule gives as examples that “hospitals operate 24/7 and are subject to EMTALA requirements, while ASCs are not,” and uses that to conclude that “a procedure that can be furnished in the HOPD setting is not necessarily safe and appropriate to perform in an ASC setting simply because we make payment for the procedure when it is furnished in the HOPD setting.”

An HOPD is simply a department of a hospital – it is not a fully-functioning hospital on its own. Those facilities are not open 24/7, and it would not be the case that a patient would be transferred to an HOPD in case of an emergency, as the facility is not necessarily equipped with—or even close to—an emergency department. Although in general, hospitals must provide 24-7 nursing services, in the hospital Condition of Participation for nursing services found at 42 CFR §482.23 (7) it states, “the hospital must have policies and procedures in place establishing which outpatient departments, if any, are not required under hospital policy to have a registered nurse present.”

ASCs are subject to a rigid set of survey and certification standards designed to ensure patient safety. The requirements for achieving and maintaining CMS certification were increased in 2008 with the overhaul of the ASC Conditions for Coverage (CfCs) and further safeguards have since been implemented to enhance patient safety and quality of care in ASCs.

Of recent note, CMS in last year’s rule, mentioned how the COVID-19 pandemic has “highlighted the need for more health care access points throughout the country,” and that “looking ahead to after the pandemic, it will be more important than ever to ensure that the health care system has as many access points and patient choices for all Medicare beneficiaries as possible.” ASCs throughout the country have been willing to help during this public health emergency. Facilities have continued to take on additional outpatient volume in recent months as surges have occurred to alleviate the backlog of cases caused by postponements and cancellations and to help hospitals in their communities that are still focused on caring for COVID-19 patients. In addition, dozens of ASCs provided expanded capacity by serving as hospitals under the “hospital without walls” program CMS established during the COVID-19 public health emergency.

**D. Annual Payment Update Policies**

**The AMA supports CMS’ continued use of the hospital market basket as the annual update mechanism for ASC payments.** When CMS implemented the revised ASC payment system in 2008, the Agency’s stated goal was to encourage high-quality, efficient care in the most appropriate outpatient setting and align payment policies to eliminate payment incentives favoring one care setting over another. Since 2008, the ASC community has urged CMS to adopt the same update factor for both the ASC and OPPS payments and appreciates that CMS took this first, necessary step toward better alignment of the payment systems.

ASCs have been increasing their share of commercial outpatient surgical volume for many years. That growth has been tempered under Medicare by a lack of parity in reimbursement between hospital outpatient and ASC payment increases. The alignment of conversion factors is a promising sign, and migration will occur across all ASCs as the industry gains confidence that CMS is moving to put it on a more level playing ground with hospital outpatient reimbursement.

### *1. Request for Cost Data*

In the proposed rule, the Agency again expresses a desire to “assess the feasibility of collaborating with stakeholders to collect ASC cost data in a minimally burdensome manner” and “propose a plan to collect such information.” If CMS chooses to collect cost data to develop a market basket, the Agency should consider expanding its research approach to focus on establishing a market basket that can be applied to both the ASC and hospital outpatient setting to ensure that payments using the same relative weights remain aligned over time.

We know that many of the same types of costs incurred by hospital outpatient departments are also incurred by ASCs, but we do not know if they are weighted the same. We urge CMS to recognize the variability among facilities and that cost experience can differ greatly depending on factors such as specialties served, size of the facility and geographic location. There are already excessive administrative burdens placed on ASC staff to meet current regulations and requiring any formal cost reports from ASCs would run counter to the Agency’s desire to promulgate rules and establish policies that allow facilities to maintain efficiency in the Medicare program.

### *2. Updating the ASC Relative Payment Weights*

The AMA encourages CMS to discontinue the ASC weight scalar. CMS provides its annual update to the ASC relative payment weights by first factoring the national OPPS relative payment weights (including the Medicare Physician Fee Schedule non-facility practice expense relative value units-based amounts, as applicable), and then uniformly scaling the ASC relative payment weights. The calculated OPPS relative payment weights are scaled to remain budget neutral for OPPS, and then are rescaled to establish the ASC relative payment weights. The weight scalar is applied so that projected expenditures from the updated ASC payment weights in the ASC payment system equal the current expenditures based on the scaled ASC payment weights.

Since the payment systems were aligned, CMS has taken the relative weights in the OPPS, which have already been scaled, and then applies a secondary weight scalar, known as the ASC weight scalar, before arriving at the ASC payment weights. CMS has asserted that the scaling of the relative weights is a design element that will protect ASCs from changes in the OPPS relative weights that could significantly decrease payments for certain procedures. However, the trend in the OPPS relative weights suggests that the ASC weight scalar will rarely, if ever, result in an increase in ASC relative weights. In 2018, the ASC weight scalar fell under 0.9000 to 0.8995, for a 10.1 percent reduction to the ASC weights, and in 2021, CMS is proposing an adjustment of 0.8591 which, if finalized, would result in a 14.09 percent reduction.

**The AMA recommends that CMS stop its practice of rescaling the ASC relative weights to achieve a perceived budget neutrality objective.** ASC services should apply the OPPS relative weights. CMS should adopt a consistent payment methodology to level the playing field across all sites-of-service. The weight scalar site-of-service differential impedes the provision of high-value care because it incentivizes payment based on the location where a service is provided. No evidence has demonstrated any growing differences in capital and operating costs in HOPDs compared to ASCs. Thus, ASC services should apply the OPPS relative weights to promote outpatient services that are site-neutral without lowering total Medicare payments. Notably, CMS already has the authority to apply the OPPS relative weights to ASC services. CMS previously implemented the scalar pursuant to its own authority and, importantly, this implementation was not pursuant to any identified statutory requirement. Thus, CMS has the similar, discretionary authority to discontinue the scalar and align payment methodologies across these sites-of-service.

### **E. Payment for Non-Opioid Pain Management Treatments**

The AMA applauds CMS for efforts to combat the opioid epidemic, which has only been exacerbated by the COVID-19 pandemic. We support separate payment for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting. As part of our continued desire to align the HOPD and ASC payment systems, we also encourage CMS to establish this same policy for the HOPD setting.

The AMA urges CMS to consider reimbursing for other peri-operative non-opioid pain management tools, such as Ofirmev (IV Tylenol), CPT J0131, which is a highly effective medication that also decreases use of post-op opioids. In addition, CMS should consider reimbursement for pain blocks represented by CPT codes 64415, 64416, 64417, 64445, 64446, 64447, 64448, 64450. Currently these codes are listed on ASC Addenda AA, meaning they are only reimbursed as surgical codes, primarily for chronic pain management. Many physicians, rightly anticipating that a surgical procedure will result in significant post-operative pain, use the pain blocks described by the surgical codes above to mitigate the post-operative pain that is otherwise typically addressed with short-term opioid use. **The AMA supports separate payment for non-opioid pain management products that will help reduce the prescription and use of opioids after surgery.**

### **F. Changes to Beneficiary Coinsurance for Certain Colorectal Cancer Screening Tests**

The AMA appreciates the proposal which implements Section 122 of the Consolidated Appropriations Act (CAA) of 2021 (Pub. L. 116-260), Waiving Medicare Coinsurance for Certain Colorectal Cancer Screening Tests. CAA adopts a modified version of the *Removing Barriers to Colorectal Cancer Screening Act*, legislation ensuring that if a scheduled screening colonoscopy becomes therapeutic, the Medicare beneficiary will not face a copayment. Under the legislation, the Medicare beneficiary cost sharing for colorectal cancer screening will be phased out between January 2022 and January 2030. As the Medicare payment percentage increases, the beneficiary coinsurance percentage decreases until it is gone in 2030. Ultimately, this will greatly reduce patient financial burden, increase access to life-saving screening, and strengthen the fight against colorectal cancer.

### **G. Radiation Oncology Alternative Payment Model (RO Model)**

Radiation oncology practices are required to invest large amounts of money in expensive radiation treatment equipment. The total cost of that equipment to the practice is roughly the same regardless of how many treatments they provide, but under the Medicare physician and hospital outpatient payment schedules, their revenue depends on how many and which treatments they deliver. As a result, delivering fewer treatments could actually put radiation oncology practices out of business. For this reason, radiation oncology specialists and the AMA have long supported creating an alternative payment model that would allow radiation oncologists to be compensated based on how many patients they were treating and what treatments their patients needed, instead how many doses of radiation they received.

In our September 2019 [comments](#) on the previous radiation oncology alternative payment model (RO Model) proposal, the AMA expressed support for the bundled payment approach and recommended several modifications to the proposed RO Model design. We also recommended then and continue to be concerned now that, even with improvements, the RO Model represents major changes in payment for services that treat life-threatening illnesses, and it is inappropriate to mandate participation without any testing on a more limited scale with practices who voluntarily participate. **The AMA urges CMS to**

**conduct a limited scale test of the RO Model on a voluntary basis rather than mandating participation in an untested model.**

1. *Payment Rate Adequacy and Stability*

The proposed RO Model grew out of a November 2017 [report to Congress](#) in which CMS observed that “the agency faces certain challenges in determining accurate prices for services that involve expensive capital equipment. Consequently, PFS rates for services involving external beam radiation have fluctuated over the last decade. Under an episode payment model, more stable prices for radiation therapy services could be tested to determine if they reduce expenditures while maintaining or enhancing quality of care.” Despite recognizing these challenges, CMS’ payment policies for radiation oncology services have not advanced the goal of rate stability. Instead, the currently proposed discount factors of 3.5 percent for professional services and 4.5 percent for technical payments could destabilize the delivery of radiation oncology services. In addition to the payment cuts proposed in the RO Model, CMS has also proposed payment cuts for radiation oncology services that would continue to be paid based on the Medicare physician payment schedule.

In an article in [Science](#), the Director of the National Cancer Institute expressed concern that the COVID-19 pandemic will lead to cancer diagnoses being missed that will come to light at a later stage with worse prognoses. As this pandemic continues to have significant adverse effects for medical practices and for patient care, the AMA is concerned that imposing steep payment cuts for radiation oncology services could make it difficult for patients to obtain the services they need close to home. This may be particularly a problem for patients presenting with more advanced stage disease requiring more expensive treatment due to delays in diagnosis related to COVID-19.

For practices required to participate in the RO Model, the Medicare payment schedule cuts would exacerbate the impact of the RO Model discount factors due to the inclusion of a trend factor in the RO Model payment methodology that accounts for changes in the physician and hospital outpatient payment systems. As the rates in the existing payment systems go up or down, so would the trend factor and consequently payment rates in the RO Model. **The AMA recommends that CMS reduce the discount factors to 3 percent or less for professional and technical services in the RO Model and modify the trend factor to prevent significant payment swings under the RO Model from year to year. Without these two key modifications, there could be unintended consequences for cancer patients whose practices are compelled to participate in the RO Model.**

2. *Quality Reporting Requirements*

RO Model participants would be compelled to manually extract and submit Clinical Data Elements (CDEs) as part of the RO Model’s quality reporting requirements. This data collection process is not aligned with existing Merit-based Incentive Payment System (MIPS) reporting parameters and the proposed RO Model does not adequately recognize the time and resources necessary to comply with the reporting requirements. Practices whose participation in the RO Model would be mandated have reported that CMS’ regulatory impact analysis significantly underestimates the cost of collecting and reporting quality measures and CDEs. **These data collection and reporting costs will compound the adverse financial impact of the RO Model’s payment rate cuts. The AMA recommends that these requirements be delayed in order to allow time for CMS to work with the radiation oncology community to develop a better and less burdensome plan.**



### 3. *Advanced APM and MIPS APM Status*

CMS proposes to establish that those Professional and Dual participants who meet RO Model requirements, including use of certified electronic health records technology (CEHRT), and who are eligible clinicians on a participation list will be in Track One of the RO Model. CMS proposes to define Track One as an Advanced APM and MIPS APM track. RO Model participants in Track One will be considered as Advanced APM participants and CMS will make Qualifying APM Participant (QP) determinations for them. Eligible clinicians who are Track One participants but do not meet the QP thresholds will be considered MIPS APM participants. Professional or Dual participants who fail to meet any of the RO Model requirements, including CEHRT use, as well as all Technical participants, will be placed in a proposed Track Two and will not be considered either Advanced APM or MIPS APM participants.

Under MIPS, small practices are eligible for an exemption from the CEHRT requirements. Small radiation oncology practices often have higher proportions of Medicare patients and lack the capital to invest in newer, more efficient technology, as well as the upgrades in electronic health record (EHR) systems for quality measure reporting. In addition, for Advanced APMs, 75 percent of eligible clinicians are required to use CEHRT, not 100 percent. **The AMA urges CMS to abandon the proposed two-track approach.** Requirements for use of CEHRT for RO Model participants to qualify as Advanced APM or MIPS APM participants should not exceed the requirements for those participating in other models. The two-track approach seems unnecessarily punitive and would make the process of achieving Advanced APM status and even MIPS APM status more difficult for RO Model participants.

The AMA is also concerned that CMS has inappropriately included the incentive payments provided to QPs in its budgetary calculations for the proposed RO Model. With regard to these incentive payments, the Social Security Act at Section 1833(z)(1)(C) states: “Payments under this subsection shall not be taken into account for purposes of determining actual expenditures under an alternative payment model and for purposes of determining or rebasing any benchmarks used under the alternative payment model.” In Table 78 on p. 42351 of the proposed rule, CMS has included the incentive payments for RO Model QPs in its calculations of net savings attributable to the model. The purpose of the QP incentive payments is to help support APM participants as they transition from the traditional fee-for-service system to payment under APMs. These incentive payments should not be considered costs attributable to the model.

#### Monitoring Requirements

The AMA is also very concerned about the CMS statement that “any failure, however minor, to comply with the RO Model Requirements set forth at sec. 512.220(a)(2) will have an impact on whether a RO Model participant is in Track One versus Track Two.” Section 512.220(a)(2) contains the following specific monitoring requirements:

1. discuss goals of care with each Medicare beneficiary before initiating treatment and communicate to the beneficiary whether the treatment intent is curative or palliative;
2. adhere to nationally recognized, evidence-based treatment guidelines when appropriate in treating Medicare beneficiaries or document in the medical record the rationale for the departure from these guidelines;
3. assess the Medicare beneficiaries’ tumor, node, and metastasis (TNM) cancer stage for the CMS-specified cancer diagnosis;
4. assess the Medicare beneficiaries’ performance status as a quantitative measure determined by the physician;

5. send a treatment summary to each Medicare beneficiary's referring physician within three months of the end of treatment to coordinate care;
6. discuss with each Medicare beneficiary prior to treatment delivery his or her inclusion in and cost-sharing responsibilities; and
7. perform and document Peer Review for 50 percent of new patients in performance year 1, 55 percent of new patients in performance year 2, 60 percent of new patients in performance year 3, 65 percent of patients in performance year 4, and 70 percent of patients in performance year 5, preferably before starting treatment, but in all cases before 25 percent of the total prescribed dose has been delivered and within two weeks of starting treatment.

It is reasonable to have standards for successful performance in an APM, but it is not reasonable to shift participants between two different tracks of the model based on "any failure, however minor" to comply with the above requirements. These requirements seem excessive and radiation oncology stakeholder organizations have indicated that CMS has not provided information about how participants would even be expected to document compliance, particularly as EHRs do not collect this information and cannot report it. **The AMA recommends that any compliance with these monitoring standards be voluntary unless and until clearer guidance is available, EHR vendors have developed the technology necessary to assist with collection and reporting, and RO Model participants have had an opportunity to upgrade their systems.**

#### **H. Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs**

##### Data Aggregation

The AMA supports advancements in data availability and integration for quality improvement and measurement through efforts such as data aggregation, but they must result in data that are easily accessible at the point of care and provide actionable information that can inform shared decision-making while also easing reporting burden. Many third-party aggregators such as clinical registries and health information exchanges (HIEs) have demonstrated the great potential that can be experienced through data sharing, such as increasing transparency on patient interactions across the health system to promoting initiatives that inform public health, but we strongly recommend that CMS consider the following issues if they move forward with this effort.

Hospitals, practices, third-party aggregators, and others must have sufficient time and guidance to implement digital quality measures (dQMs) prior to any required reporting of the data and/or measure scores. The recent experience encountered by accountable care organizations (ACOs) with the Medicare Shared Savings Program (MSSP) changes as outlined in the [letter to Secretary Becerra](#) dated May 4, 2021, from multiple health care organizations including the AMA serves as an example on how reporting requirements that are not adequately researched or delineated can create confusion and expend unnecessary and costly resources. Specifically, as ACOs attempt to be responsive to the shift to reporting of electronic clinical quality measures (eCQMs) or the Merit-based Incentive Payment System clinical quality measures (MIPS CQMs) using all payer data, each are encountering multiple challenges, including:

- The significant number of vendor systems from which the data are collected and across multiple practices;
- The extent to which the ACO may or may not have permissions to access and report data on patients beyond their assigned beneficiaries;

- How to best complete patient matching across all participating practices; and
- How to best clean and validate these data, including the extent to which the ACO can assume responsibly for that reporting and validation and likely includes thousands of patients for a single measure.

Perhaps more importantly, many must build the necessary internal infrastructure or identify and pay an external vendor to assist in the data aggregation and reporting and many are spending hundreds of thousands to over a million dollars to enable this transition. These unexpected costs, particularly with little advance warning, will likely require ACOs to shift resources that would traditionally have been used to improve patient care and should not be replicated again.

The AMA also does not believe that it is realistic to assume that any one hospital or physician practice will be asked to coordinate and share data with only one entity unless CMS served as the sole third-party aggregator. Rather, it is not unreasonable to expect that one provider will need to interact and establish data sharing with multiple third-party aggregators and it will further add to the costs and challenges of data sharing. We urge CMS to explore the potential impact that these requirements may have and develop solutions that will minimize costs, address user resistance, and ensure that the reporting burden and expenses do not increase for those entities at the point of care. This analysis should be broad and include those groups that will serve important roles both in providing important data and driving improvements in individuals' health such as public health agencies. In addition, creating some governance and defining a minimum set of standards and capabilities for these data aggregators could minimize the reporting burden experienced by hospitals, practices, and others, particularly if they must interact with more than one group. This information will also ensure that third-party aggregators are able to demonstrate and offer the services that will be required for quality measure reporting such as robust processes around patient matching, ensure adequate privacy and security of the data, and demonstrate data accuracy and validation. Hospitals, practices, and others must be able to ensure that those aggregators with whom they partner will meet CMS expectations/requirements.

In addition, the broader implications to quality measurement if data aggregation is supported must be considered. While the expansion to the broader population could provide a snapshot of care within a community, it is likely not representative of the care provided by the hospital or other providers. It is important to note that the IQR or MIPS is a Medicare program so organizations naturally focus their efforts on Medicare patients, causing them to target services and interventions for their assigned Medicare patient population. The issue with payer mix will become more complicated as CMS moves to measure providers on more outcome and intermediate outcome measures. The AMA performed a query of 2016 National Ambulatory Medical Care Survey (NAMCS) data, looking at blood pressure control rates and on a national level the rates are different by insurance types demonstrating that payer mix and associated patient populations will affect scoring. As a result, performance on quality measures could be skewed based on inequities and differences in patient mix. This misrepresentation does not serve to drive change in a meaningful and useful way and potentially penalizes providers treating more vulnerable populations.

1. *CMS is seeking feedback on developing a common portfolio of measures for potential alignment across CMS regulated programs, federal programs and agencies, and the private sector.*

The AMA supports the two-pronged approach of alignment of the individual measures and specifications separate from the necessary data elements. This division is useful, as it would allow a staged approach to implementation of aligned measures based on the degree to which data elements are standardized and demonstrated to be available within a specific setting or for a specific CMS quality program. We

encourage CMS to be thoughtful on when a dQM might be proposed for inclusion in a quality program and perhaps create thresholds by which these determinations would be made. For example, once a data element that captures a patient-reported outcome result relevant to inpatient care is created, it must first be incorporated into the United States Core Data for Interoperability (USCDI) and relevant implementation guides and have a certain percentage of all electronic health record vendors in the inpatient setting in collaboration with hospitals and others demonstrate that the data element is feasible to collect. At that point, any dQM that seeks to include this data element would be pilot tested in the inpatient setting and provide information on whether the required data elements and resulting measure score are reliable and valid. The dQM could then be considered for CMS inpatient quality programs and others.

We also encourage CMS to continue to advance a dQM that provides more clinically meaningful data within one setting or program even if the measure cannot be aligned across programs initially. Rather, the goal should be to work with the other relevant settings and programs to enable them to also leverage the advanced data as quickly as possible while not holding up the implementation of dQMs that may ease reporting burden and inform patient care.

While we also support the concept of a broad dQM portfolio that can be used by multiple end users, we encourage CMS to identify what has limited our ability to create that portfolio to date and actively address those challenges and barriers. One approach may be to identify one or two dQMs that are ready to be implemented across multiple programs, agencies, and settings and determine what actions or efforts are needed to ensure widespread adoption and success.

2. *CMS is seeking feedback on changes needed to advance to digital quality measures by 2025.*

The AMA appreciates CMS' acknowledgement that it will work with stakeholders to achieve interoperable data exchange and that to transition to full digital measurement requires its programs, where possible, to ensure alignment of: (1) measure concepts and specifications including narrative statements, measures logic and value sets; and (2) the individual data elements used to build these measures specifications and calculate the measures. Further, the required data elements would be limited to standardized, interoperable elements to the fullest extent possible; hence, part of the alignment strategy will be the consideration and advancement of data standards and implementation guides for key data elements. However, the AMA believes to realize the full extent of digital quality measurement requires rethinking EHR certification.

While health IT certification was initially designed to evaluate a product's ability to meet Meaningful Use (MU) requirements, the usability and interoperability of EHRs going forward must be improved, which in part will require the Office of the National Coordinator for Health Information Technology's certification program to be refocused. Many demands by clinicians, hospitals, and other providers to improve EHRs (e.g., better usability, easier access to meaningful information, less time spent documenting or redocumenting data) can be addressed by examining key aspects of eCQMs or dQMs. A more robust approach to certification should focus on the quality, exchange and usability of data and aligned with measure reporting requirements. Generally, this includes:

- Capturing information relative to the clinical needs and goals of patients while leveraging alternative sources of data, instead of direct human documentation, as frequently as possible;
- Using data models that retain the intended meaning of information, including attributes about the data (e.g., provenance);

- Reporting and exchanging information in a structured format using standard terminology where possible; and
- Demonstrating the usability by focusing on integration of the data into their products and the degree of clinical workflow changes that may or may not be needed at the point of care.

Said another way, EHRs that improve the capture, management, and communication of clinical information will better accommodate the actual needs of providers and their patients, ensure the accuracy of quality measurement, and support a broader array of measures. We regularly hear that vendor certification timelines do not always match with CMS quality reporting requirements, such as the MIPS reporting requirements. In addition, vendors are not required to complete robust testing of measure and updates every year and as a result the test cases are insufficient to truly ensure that the measure can be “easily” and “accurately” reported. Currently, all of this is placed on measure developers and participating practices when it should really be a vendor’s responsibility. **Therefore, prioritizing testing and certification that validates strict conformance to the principal aspects of dQMs will improve overall EHR user experience and reduce vendor development burden.**

A key component of the quality data infrastructure requires that payers utilize a single source for code and terminology mappings to ensure greater consistency with measure calculations and comparisons of performance (data mapping). Currently, vendors, practices, health systems, and consultants perform their own mapping, which leads to data inconsistencies and is a reason why no two EHRs can reliably calculate comparable results.

Work is needed to ameliorate data mapping issues by building upon the strengths of existing terminologies. For example, linking a terminology based on a comprehensive ontological model (e.g., SNOMED-CT) and foundational code sets (e.g., CPT) would allow for the seamless collection of information from the clinician at the bedside, the ability to capture and automate coding for fees and billing, extend the capabilities of clinical decision support systems (CDS), save countless hours of manual coding, and reduce errors in the process. Both terminologies provide unique advantages to end users, are fit for the purpose they are used, and together optimize data for clinical care, research, and administrative uses. Data maps, both new and existing, should be leveraged to resolve issues around efficiency and consistency of measures across EHRs and providers. The AMA has already initiated a close collaboration between SNOMED-CT and CPT terminologies.

Importantly, not only should a complete record be accessible, but also the data contained therein must be consistent, understandable, and usable (data consistency). For this to occur, data must be in a recognizable electronic package (data structure or syntax) and maintain a consistent meaning (data semantics). Just as the English language is built from words and grammar, the translation from data to knowledge can only occur if the meaning of data is consistent. However, levels of semantic interoperability vary greatly in the health care system. Most providers agree that the current level of interoperability is inadequate to support the necessary changes, reforms, and innovations desired in health care. As a practical matter, the more data exchanged that lacks both semantic and syntactic interoperability, the less useful it is to providers and patients.

**In order to improve electronic capture, calculation and reporting of quality measures, CMS should incent the use of standardized semantic content from recognized developers.** In the development and specification of a quality measure intended for use in CMS programs, the clinical concepts used in the measure could be derived from recognized clinical content models. For example, if a measure is looking at blood pressure, and using the concepts as defined in one of these models, CMS-recognized data

aggregators and registries could be given incentives to use those concepts and avoid variation in data management. Incorporation of data requires the development, maintenance, and refinement of administrative codes such as ICD, foundational code sets such as CPT, and clinical vocabulary standards such as SNOMED CT, LOINC, and RxNorm. CMS should promote collaborative efforts across these different coding systems and ensure consistency when data are exchanged.

3. *CMS is seeking feedback on leveraging advances in technology (e.g., Fast Health Interoperable Resources Application Programming Interfaces or FHIR APIs) to access and electronically transmit interoperable data for dQMs and other reinforcing activities to support quality measurement and improvement.*

Quality measurement can be labor-intensive, fragmented, and inconsistent. It is also largely retrospective. Eliminating unnecessary or duplicative work and expenditures related to quality measurement can result in cost savings and free up invaluable time for patient care. Physicians need more automated, unified, accurate, prospective, and timely quality measurement and reporting. Moreover, CMS bases many of its performance incentives on insufficiently validated data processed through systems that are prone to error. This undermines CMS' goal of rewarding high quality care and support for value-based arrangements. Furthermore, electronic clinical data requires the validation of clinical data sources—increasingly outside the “four walls” of the medical office—prior to use in quality and incentive programs.

Yet, due to the variability in technology and health care technical standard implementation, we are not yet at a point of achieving standardization nor sufficiently able to leverage advanced technology to accommodate dQMs. The best chance to accelerate adoption of dQMs across parties is to incent technology developers to develop a uniform set of tools in a common, secure environment to facilitate better data flow. Digital quality systems can enable rapid feedback and integrated content development across clinical guidelines and decision support, quality measures, and data specifications—each informing the other. However, **the AMA believes there are fundamental overarching goals that CMS should consider as it looks toward a dQM future. These include:**

- Timeliness of the data and the reporting—moving from batch transactions measured in months to near real-time;
- Facilitating the reuse of data already captured in the EHR, reducing physician and administrative burden; and
- Supporting the opportunity for all stakeholders to interoperate at scale.

Several entities are using or considering FHIR as an approach to develop clinically relevant measures that reduce burden, enhance accuracy, and drive quality improvement. The use of FHIR-based APIs may also allow data verification at hubs such as health information exchanges (HIEs) to a degree not practical for physician offices. HL7's efforts to incorporate clinical quality language (CQL) used to specify dQMs is more precise, provides new options for measure logic, and reduces the opportunity for interpretation errors. Moreover, dQMs allow for preprogrammed packages ready for execution within a digital-ready data environment. dQMs are quicker to disseminate than measures with narrative specification which must be interpreted, programmed, and tested before use.

The AMA has identified several benefits in leveraging FHIR and CQL for digital quality measures. These benefits include:

- Defining quality measures as computable artifacts;

- Automating data collection and quality measure reporting;
- Easing the burden of identifying quality measures applicable to specific patients;
- Facilitating the exchange of gaps in care and quality measures;
- Closing clinical and information gaps prospectively versus retrospectively; and
- Minimizing the burden of manual data abstraction for measure reporting.

However, we stress that CMS must address several fundamental issues prior to moving physicians and other providers to dQM reporting and tying payment and/or quality rating systems to dQM performance. Including that:

- Challenges persist related to level of maturity of FHIR implementation overall. Not all resources are normative/mature; for others, significant work is needed to support dQM use cases;
- Adoption of US CORE profile capabilities by EHR vendors is not yet widespread enough to attempt full migration to FHIR. This is not expected to occur until 2023. CMS should promote alignment between QI CORE and US CORE;
- Digital clinical data are frequently in disparate, non-standard formats. As previously discussed, CMS should incent the use of standardized content;
- Generating the necessary data to support dQM implementation is not practical for most medical practices at this time and readiness is highly variable; and
- Smaller health systems and those serving underserved populations will need resources and technical support. CMS should make supporting these health care facilities a priority.

#### **I. Request for Comment on Potential Future Efforts to Address Health Equity in the Hospital OQR Program**

In recognition of persistent health disparities and the importance of closing the health equity gap, CMS requests information on several CMS programs to make reporting of health disparities based on social risk factors, race, and ethnicity more comprehensive and actionable for hospitals, providers, and patients.

Specifically, CMS is seeking comment on the following:

1. *The potential future stratification of quality measure results by race and ethnicity. Specifically, the potential benefits and challenges associated with measuring hospital equity using an imputation algorithm to enhance existing administrative data quality for race and ethnicity until self-reported information is sufficiently available.*

**The AMA believes that continued stratification of quality data by dual eligibility and race and ethnicity remains insufficient and while the expansion to disability provides useful information, CMS must make significant efforts to advance the data that are used to identify health care inequities.** For example, quality measures should account for risk factors such as lack of access to food, housing, and/or transportation that affect patients' ability to adhere to treatment plans. Continued reliance on existing data that have known deficiencies is not acceptable and we must advance to more accurate and relevant data.

**The AMA discourages CMS from strictly relying on dual-eligibility (DE) status when stratifying readmission or admission measures.** While the 2016 Assistant Secretary for Planning and Evaluation (ASPE) report to Congress on social risk factors and their impact on measures in CMS value-based

purchasing programs<sup>1</sup> may have identified dual eligibility as a strong predictor for disparities, a recent study found that due to the differences in the DE population stratifying by DE-only within the confidential hospital Disparities Report is misleading and further exacerbates inequities, which is counter to the goals of quality and its related incentives to close or minimize health care inequities.<sup>2</sup> The potential addition of race and ethnicity data using the indirect estimation approach, while potentially informative for quality improvement purposes, should not be used for any other purpose.

**The AMA also believes gathering additional information on clinical algorithms in use today and the impact of including race and ethnicity into their calculations is of utmost importance.** Collection of additional information on these specific algorithms is an essential early step towards identifying where racism and bias may exist in clinical decision-making tools and how they should be addressed to ensure clinical care and health of historically marginalized communities are not negatively impacted by their application. Given that the approaches in design and implementation, as well as underlying data provenance, vary, it will be important to seek further input from organizations that have expertise in equity and direct experience with development and use of specific algorithms.

The usage of race and ethnicity as variables, and how both are defined, varies among the clinical algorithms in use today. This is attributable in part to changes in protocols over time, as some of the clinical data registries from which algorithms are derived are more than several decades old. There is also variation among multiple health data systems in how the data are collected (are race and ethnicity patient or investigator/clinician reported?) and the number of choices provided to the reporter. Furthermore, because race is a social construct, there is significant variability in how “races” are defined by society, lawmakers, and others—including individuals themselves. These definitions have changed and evolved in usage and application over time and do not always correspond with biology and genetic ancestry. Accordingly, their inclusion as variables creates challenges in developing meaningful consensus definitions, especially as our society diversifies over time, further clouding how we define these variables.

The AMA House of Delegates in November 2020 passed historic new policy directing our organization “to collaborate with appropriate stakeholders and content experts to develop recommendations on how to interpret or improve clinical algorithms that currently include race-based correction factors.”<sup>3</sup> The AMA is currently undertaking an effort to convene a variety of organizations to gather more information about the use of clinical algorithms and create an action plan for how to address these problems.

We believe that, in addition to efforts like our own, the Agency for Healthcare Research and Quality is ideally situated to conduct and fund additional research into the use of race and ethnicity data in clinical settings and algorithms, their potential contribution to medical racism and/or bias in clinical decision-making, and the methods needed to eliminate such racism.

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<sup>1</sup> U.S. Department of Health & Human Services, Office of the Assistant Secretary for Planning and Evaluation. Report to Congress: Social Risk Factors and Performance Under Medicare’s Value-Based Purchasing Programs. <https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicare-value-based-purchasing-programs>. Washington, DC: 2016.

<sup>2</sup> Alberti, Philip., Baker, Matt., Dual Eligible Patients Are Not The Same- How social risk may impact quality measurement’s ability to reduce inequities.

<sup>3</sup> [AMA Policy Racial Essentialism in Medicine D-350.981.](#)



A new report finds that bias in algorithms is making health care delivery more biased along racial and economic lines, opposed to making health care delivery more objective and precise.<sup>4</sup> Perhaps the most well-known example of an algorithm that contributed to inequitable care is the Optum algorithm which used health care cost as a proxy for health, resulting in lower risk scores being assigned to Black patients who were equally sick to similarly White patients.<sup>5</sup> While assigning higher risk scores to patients who have higher health care costs may have seemed reasonable to the developers because higher health costs are often associated with greater needs, doing so failed to account for the systemic and long-standing inequities in care that have resulted in fewer expenditures on Black patients. This resulted in further inequitable care, including excluding Black patients from care management programs that dedicate additional resources to coordinate care for higher risk programs.

CMS states that its contractors have identified two algorithms to indirectly estimate the race and ethnicity of Medicare beneficiaries. One approach uses Medicare administrative data; first name and surname matching, derived from the U.S. Census and other sources; with beneficiary language preference, state of residence, and the source of the race and ethnicity code in Medicare administrative data to reclassify some beneficiaries as Hispanic or API. The second approach combines Medicare administrative data, first and surname matching, geocoded residential address linked to the 2010 U.S. Census, and uses Bayesian updating and multinomial logistic regression to estimate the probability of belonging to each of six racial/ethnic groups. The second algorithm has two versions, the latter of which has higher levels of validation.

Estimating an individual's race and ethnicity based on name and geography is inappropriate. Women and children often take the names of their husband and father, respectively. Particularly for women, estimating one's race/ethnicity based on surname simply does not make sense. Such estimation would also be insufficient for adopted individuals who take their adoptive family's surname. Additionally, there are discrepancies in how individuals self-report their race on the U.S. Census questionnaire, which would be used in each of the algorithms contemplated by CMS.<sup>6</sup>

**Therefore, we continue to believe relying on algorithms for indirectly estimating race and ethnicity is not an appropriate solution.** If CMS plans to use proxies for race and ethnicity data to help identify and address inequities in care delivery and health outcomes, it must be based on self-reported data. A study by Jarrin, et al explores the accuracy of Medicare's administrative data variables for race and ethnicity data compared with the gold-standard of self-reported data and found inaccuracies, especially related to classification of American Indians/Alaskan Natives and Asian/Pacific Islanders.<sup>7</sup> We also question the accuracy of the algorithms and appropriateness outside of the hospital setting due to concerns of sufficient sample to make such estimations. As we highlighted, it is unclear how well such algorithms capture varied patient populations. In fact, the algorithms under consideration by CMS "are considerably less accurate for individuals who self-identify as American Indian/Alaskan Native or multiracial." To use

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<sup>4</sup> Ziad, Obermeyer et al, "Algorithmic Bias Playbook," Center for Applied AI at Chicago Booth. June 2021. <https://www.chicagobooth.edu/-/media/project/chicago-booth/centers/caai/docs/algorithmic-bias-playbook-june-2021.pdf>.

<sup>5</sup> Obermeyer et al, "Dissecting racial bias in an algorithm used to manage the health of populations," Science (Oct 25, 2019), <https://science.sciencemag.org/content/366/6464/447>.

<sup>6</sup> <https://www.npr.org/2021/08/13/1014710483/2020-census-data-us-race-ethnicity-diversity>.

<sup>7</sup> Jarrín OF, Nyandege AN, Grafova IB, Dong X, Lin H. Validity of Race and Ethnicity Codes in Medicare Administrative Data Compared With Gold-standard Self-reported Race Collected During Routine Home Health Care Visits. *Med Care*. 2020 Jan;58(1):e1-e8. doi: 10.1097/MLR.0000000000001216. PMID: 31688554; PMCID: PMC6904433. <https://pubmed.ncbi.nlm.nih.gov/31688554/>.

an algorithm that is not accurate for multiracial individuals when the country's multiracial population is only growing (the multiracial population has jumped 276 percent between the 2010 and 2020 census) is counterproductive.<sup>8</sup> We urge CMS to focus on longer-term strategies that will truly drive improvements as opposed to spending time on resources to implement “quick fixes” and utilize proxies. The methodologies chosen to stratify and present data for purposes of improvement are multifaceted and it is a complex topic. Therefore, it requires more research to develop an evidence-based approach to account for social risk-factors and reduce inequities.

2. *Current data collection practices by hospitals to capture demographic data elements.*

As CMS begins to consider addressing health inequities and the potential development of a Hospital Equity Score, CMS must consider the potential unintended consequences and provide supportive education to ensure that this score does not exacerbate inequities and that institutions are appropriately educated on best practices for data collection and/or program implementation. As noted above, perhaps the most well-known example of an algorithm that contributed to inequitable care is the Optum algorithm, which used health care cost as a proxy for health, resulting in lower risk scores being assigned to Black patients who were equally sick to similarly situated White patients.<sup>9</sup> While assigning higher risk scores to patients who have higher health care costs may have seemed reasonable to the algorithm developers because higher health costs are often associated with greater needs, doing so failed to account for the systemic and long-standing inequities in care that have resulted in fewer expenditures on Black patients. This resulted in further inequitable care, including excluding Black patients from care management programs that dedicate additional resources to coordinate care for higher risk patients.

Not only is it important to ensure that the risk factors by which a measure or summary score is stratified or calculated accurately represent the characteristics of patient populations as discussed above, CMS must also be thoughtful on the set of measures on which these comparisons are made. It should not be assumed that a score derived from all the outcome measures in a quality program, for example, can be used to identify meaningful differences in performance that are due to health care inequities. CMS should determine what quality metrics would be most informative and not just from those measures that exist but also consider whether additional measures must be developed and implemented. If measure gaps are identified, they must be filled prior to the development of any Hospital Equity Score.

In addition, any consideration of such a measure must also be accompanied by significant resources and education. Often well-intended measures or tools create new problems and only health care facilities and physician practices that are well-financed and capitalized have the necessary resources to invest in quality improvement. For instance, the Hospital Wide Readmission program has substantially increased penalties for hospitals that serve a disproportionate number of low-income patients.<sup>10</sup> **CMS must provide adequate resources to help providers achieve better health outcomes for high-risk patient populations.** All patients with Medicare coverage do not have equal opportunities to achieve good health outcomes, so one-size-fits-all measures or programs are more likely to widen than reduce disparities.

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<sup>8</sup> <https://www.census.gov/library/stories/2021/08/improved-race-ethnicity-measures-reveal-united-states-population-much-more-multiracial.html>.

<sup>9</sup> Obermeyer et al, “Dissecting racial bias in an algorithm used to manage the health of populations,” *Science* (Oct 25, 2019), <https://science.sciencemag.org/content/366/6464/447>.

<sup>10</sup> Zuckerman, R. et al., Effect of a Hospital-wide Measure on the Readmissions Reduction Program. *N Engl J Med* 2017; Oct. 19, 2017. 377:1551-1558 DOI: 10.1056/NEJMsa1701791.

The AMA strongly believes that inequities are best addressed through pilots and thoughtfully scaled initiatives and not within national accountability programs. As a part of the AMA's efforts to reduce health care inequities, we are currently in the process of developing a collaborative with health systems across the country that will leverage data-driven approaches to confront and overcome health disparities. The program, Quality and Safety for Impact on Racial Justice and Equity (FIRE) is designed to drive racial justice and equity in the health care arena by leveraging the foundational concepts of quality and safety improvement practices and making equity improvement an integral part of health care practice. The key objectives cross domains from patient care to operations to quality initiatives to culture and education. The framework for FIRE to guide the AMA's work is based on five key drivers:

- Driver 1: Integrate Equity into all Quality, Safety and Risk Analyses
- Driver 2: Use Equity-Informed High-Reliability Education
- Driver 3: Use Data to Support Equity Improvement
- Driver 4: Leadership Awareness and Engagement
- Driver 5: Organizational Accountability to Stakeholders

As we continue to collaborate with health systems and implement FIRE to determine any unintended consequences, the AMA continues to support efforts to pilot test innovative strategies to improve health equity and reduce disparities.

3. *Potential challenges facing clinicians with collecting a minimum set of demographic data elements in alignment with national data collection standards and standards for interoperable exchange (such as the USCDI incorporated into certified health IT products as part of the 2015 Edition of health IT certification criteria).*

Physicians need the best data available to make clinical decisions. Evidence indicating that a particular demographic characteristic is clinically important due to its association to a condition or support for a particular therapeutic intervention may signal utility of that data. Yet, as stated previously, demographic information is unlikely ever to be the best information available in determining a patient's individual priorities, goals, and concerns about their care. As CMS considers its policies on demographic data use, it must also consider the importance of patients' individualism. All patients deserve the opportunity to articulate their own personal health-related values to their physician. CMS should utilize a thoughtful review of its policy goals and balance those with the clear and real concerns of patients' data use. For example, patients might assume the care will be based on racial or ethnic stereotypes. This could cause individuals to second guess providing their full or accurate demographic data set to their physicians. **CMS must plan for situations where demographic data are limited or nonexistent; these plans must ensure physicians' payment, performance, or quality improvement metrics are not inappropriately impacted by choices patients make (e.g., resulting from small sample sizes or a lack of inhouse statistical expertise need to stratify performance data by demographic groups).**

While the USCDI v2 and the necessary certified health IT to support its use is expected to be available in early 2023, **CMS must consider and expect demographic data captured by certified health IT systems to vary by developer.** While large EHR developers may have well-designed or well-thought-out methods for data capture, our nation's physicians use a wide-array of EHR products—particularly physicians working in specialty or sub-specialty practices. Smaller EHR vendors often lack the resources to develop highly usable products. This leads to inconsistencies in data capture. For instance, the AMA is aware of products that will allow for free-hand text fields for demographic data capture rather than utilizing standardized, structured fields. What sounds like a small detail directly impacts the quality and

consistency of demographic data. As CMS structures its programs, it must account for the inevitable variations in data capture and reporting because of health IT developer decisions. Similarly, these decisions are not easy or free to change. CMS should not expect or assume physicians must pay for modifications to their certified health IT. **Rather, CMS should coordinate with the Office of the National Coordinator for Health Information Technology (ONC) on health IT vendor policy levers to improve demographic data capture. These levers should not lead to physician burden or excessive costs.**

Additionally, the AMA is currently conducting a study on the collection and use of certain demographic information (race, ethnicity, and primary spoken language, abbreviated herein as REaL data). While the study is ongoing, preliminary findings indicate that organizational commitment to collecting REaL data is a key driver to effectively collecting data and minimizing collection errors. Collecting and using REaL data may not be top of mind for health care organizations, so there must be increased awareness and education among staff of why REaL data is important to collect and what it will (and will not) be used for. Accordingly, we suggest that improving the collection and use of REaL data must be recognized as a key organizational priority for health care providers to enact meaningful system-wide changes. CMS should consider positive incentives and provide educational tools to health care organizations to collect and use REaL data, while maintaining patient privacy protections and minimizing clinician burden.

Preliminary findings also have revealed that a variety of stakeholders are typically involved in the collection and use of REaL data, which makes understanding the entirety of the process challenging. Additionally, staff do not always know best or standard practices for collecting REaL data. Workflow changes—driven by organizational prioritization to improve equity through use of REaL data—are critical to improving REaL data collection. Engaging all key parties (front office, information technology, analysts, clinicians, leadership, etc.) and creating feedback loops among parties can help to identify and address issues with data collection. Finally, preliminary survey results indicate that health care organizations need specific training and educational resources on collecting REaL data. Education and training should note that some patient communities may be resistant to providing REaL data. Staff needs to understand and respond (in a culturally appropriate manner) to these dynamics. CMS can help by creating educational resources, fact sheets, training videos, etc. on the importance of REaL data collection, as well as explain what the Agency does (and does not do) with the data. **The AMA further recommends CMS collaborate with ONC in the development of a voluntary certification program for CEHRT that would enable physicians and health systems to adopt EHRs optimized for the collection of REaL data. In ONC's 21<sup>st</sup> Century Cures Act (Cures Act) regulations, ONC proposed and finalized a voluntary certification program for health IT developers specific to pediatric care. The Cures Act directed the National Coordinator to encourage the voluntary certification of health information technology “for which no such technology is available or where more technological advancement or integration is needed.”<sup>11</sup> CMS can significantly advance the collection and use of REaL data by coordinating with ONC to improve CEHRT's capability to meet patient and physician needs in this space.**

Given organizations are only learning about the importance of collecting REaL and the various challenges to data collection, **we believe it is premature to hold physicians and practices accountable for the collection and reporting of the data, including through some sort of quality measure or tying it to an accountability program, such as MIPS.**

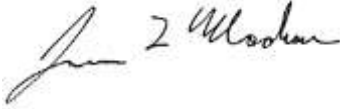
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<sup>11</sup> Cures Act, Sec. 4001.

The Honorable Chiquita Brooks-LaSure  
September 17, 2021  
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The AMA appreciates the opportunity to provide input on this proposed rule. If you have any questions regarding this letter, please contact Margaret Garikes, Vice President of Federal Affairs, at [margaret.garikes@ama-assn.org](mailto:margaret.garikes@ama-assn.org) or 202-789-7409.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is written in a cursive style with a large initial "J" and "M".

James L. Madara, MD