June 7, 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–1748–P. Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2022 and Updates to the IRF Quality Reporting Program

Dear Administrator Brooks-LaSure:

On behalf of our physician and medical student members, the American Medical Association (AMA) appreciates the opportunity to offer our comments to the Centers for Medicare & Medicaid Services (CMS) on the FY 2022 Inpatient Rehabilitation Facility Prospective Payment System and Updates to the IRF Quality Reporting Program proposed rule, published in the Federal Register on April 12, 2021 (86 Fed. Reg. 19086). The AMA commends CMS for taking the essential step of soliciting input from stakeholders on how to best close the health equity gap, as well as improve the quality of health care for beneficiaries through measurement, transparency, and public reporting of data.

I. Closing the Health Equity Gap in Post-Acute Care Quality Reporting Programs—Request for Information

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

Specifically, CMS is seeking comment on the following:

• Recommendations for quality measures or measurement domains that address health equity, for use in the IRF QRP.

As CMS begins to consider addressing health inequities and the potential development of a quality measure for use in an accountability program, CMS must consider potential unintended consequences and provide supportive education to ensure that a measure, tool, or quality reporting program component does not exacerbate inequities and that institutions are appropriately educated on best practices for data collection and/or program implementation. 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. 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.

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. 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. 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.

Therefore, if CMS moves forward with development of a quality measure or measurement domains that address health equity, we recommend that CMS consider exploring the following concepts through an open and transparent measure development process that involves extensive opportunity to provide input:

- Stratify by race, ethnicity for root cause analysis;
- Incentivize reduction of inequities;
- Access to interpreters; and
- How well are determinants of health collected and addressed.

- CMS is seeking guidance on any additional items, including SPADEs that could be used to assess health equity in the care of IRF patients, for use in the IRF QRP.

The AMA recommends that CMS consider the following additional items:

- Level of community participation in development of measures;
- Neighborhood disinvestment index;
- Retail food environment index;
- Pollution burden score;
- Alcohol outlet density;
- Community safety;
- Academic achievement; and
- Racism index.

- Recommendations for how CMS can promote health equity in outcomes among IRF patients. For example, we are interested in feedback regarding whether including facility-level quality measure

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results stratified by social risk factors and social determinants of health in confidential feedback reports could allow facilities to identify gaps in the quality of care provided. For example, methods similar or analogous to the CMS Disparity Methods, which provide hospital-level confidential results stratified by dual eligibility for condition-specific readmission measures which are currently included in the Hospital Readmission Reduction Program.

- Provide feedback – Social Determinants of Health are important but also need to include other factors and not be strictly deficit-based.

While stratifying by social risk factors and social determinants of health are important, there is a need to include other factors and not be strictly limited to deficit-based factors. For example: What are the social support structures like family members who check in; what religious or other social network opportunities (virtual or face-to-face) are available; are there cultural traditions that contribute to well-being?

We discourage CMS from strictly relying on dual-eligibility (DE) status when stratifying readmission measures. 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.3 The methodologies chosen to stratify and present data for purposes of improvement is multifaceted and a complex topic. Therefore, it requires more research to develop an evidence-based approach to account for social risk-factors and reduce inequities.

- Methods that commenters or their organizations use in employing data to reduce disparities and improve patients’ outcomes, including the source(s) of data used, as appropriate.

As 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 pilot program, named 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

- Given the importance of structured data and health IT standards for the capture, use and exchange of relevant health data for improving health equity, the existing challenges providers encounter for effective capture, use, and exchange of health information, such as data on race, ethnicity, and other social determinants of health, to support care delivery and decision making.

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3 Alberti, Philip M. PhD; Baker, Matthew C. MS* Dual eligible patients are not the same, Medicine: September 18, 2020 - Volume 99 - Issue 38 - p e22245 doi: 10.1097/MD.00000000000022245. https://journals.lww.com/md-journal/Fulltext/2020/09180/Dual_eligible_patients_are_not_the_same__How.68.aspx.
The usage of race and ethnicity data, and how both are defined, varies among health systems and tools used today. This is attributable in part to changes in protocols over time, as some of the clinical electronic tools, such as registries where much of the data are housed, are 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 reported inclusion options such as reporting mixed-race, “other,” or an individual’s preference not to report. Furthermore, because race is a social construct, there is significant variability in how “races” are defined by society, lawmakers, and others. These definitions have changed and evolved in usage and application over time. 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.

There is also a need to disaggregate race and ethnicity data so how we currently collect the data may need to change such as asking about ancestry or cultural affiliation. When developing new data collection processes American Indian tribe specificity and data sovereignty should also be considered.

II. Fast Healthcare Interoperability Resources (FHIR) in support of Digital Quality Measurement in Quality Programs - Request for Information

In alignment with Meaningful Measures 2.0, CMS is seeking feedback on future plans to define digital quality measures (dQMs) for the Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP) and the potential use of FHIR for dQMs within the IRF QRP to align possibly with other quality programs. CMS also seeks feedback on the agency’s future plans to adopt a standardized definition of “digital quality measures” and on the potential use of FHIR.

The AMA strongly supports a shift to measures that are derived from electronic data generated at the point of care, as we believe that these types of measures are more meaningful and actionable to physicians and patients. However, we do not support CMS’ current definition of digital quality measures which includes the sole use of administrative data to form a quality measure score. While administrative claims are in fact digital in nature, and administrative data itself can enhance a physician’s view of their patients’ longitudinal care, we do not believe that measures based solely on data pulled directly from claims should be included in the definition. Claims based information for purposes of quality improvement and comparisons lacks granularity, often provides a retrospective view of care, and as a result are less actionable for the physician or may lead to less well-informed decision making by patients. Efforts around improving the nation’s data infrastructure must emphasize information that is timely and derived at the point of care.

Over time, measure developers have moved away from administrative claims measures due to concerns over attribution, retrospective analysis, the inability to measure individual physicians or providers, and outcomes. Organizations have shifted to the development of electronic clinical quality measures (eCQMs) and Qualified Clinical Data Registries (QCDRs) due to the shortcomings with administrative claims measures, including the inability to move to clinically meaningful outcome measures. QCDRs and eCQM electronic tools provide for a much richer data source than administrative claims measures. For example, it is very difficult to get to intermediate outcomes, such as diabetes HbA1c levels or blood pressure level measures, without requiring additional data beyond what is collected for administrative claims. Therefore, CMS will be left to select measures that may be sufficient from the community or population perspective but are not appropriate to attribute to an individual physician, practice or facility. As a result, the measure becomes so far removed from practice that it cannot not provide meaningful or actionable data at the point of care.
To date, we have yet to see a reliable attribution model developed for any existing administrative claims measures. CMS also relies on a retrospective attribution approach, which greatly decreases the ability of a physician or a practice to drive improvements in care, as they will not be working with a pre-determined set of patients. We are also concerned that the measures may incentivize the provision of poor care or lead to other unintended consequences.\(^4\) For example, the literature is beginning to show that readmission measures, which are based on administrative claims, may be leading to increased mortality.

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

We appreciate CMS’ acknowledgement of the need to work with stakeholders to achieve interoperable data exchange and that to transition to full digital measurement requires its programs, where possible, 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 that realizing the full extent of digital quality measurement requires rethinking electronic health record (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
- Demonstrate 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 vendors’ certification timelines do not always match with CMS quality reporting requirements, such as the Merit-based Incentive Payment System (MIPS) reporting requirements. In addition, vendors are not required to complete robust testing of measures 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

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measure developers and participating practices when it really should be a vendor’s responsibility. 

**Therefore, prioritizing testing and certification that validates strict conformance to the key 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 an administrative/billing terminology (e.g., Current Procedural Terminology® (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 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 also 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 and 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.

The AMA offers the following feedback on the questions CMS is seeking input on to enable the transformation of CMS’ quality measurement enterprise to be fully digital:

- **What EHR/IT systems do you use and do you participate in a health information exchange (HIE)?**

A challenge with moving to dQMs is the significant number of vendor systems from which the data are collected and across multiple TINs. While one might assume that EHR vendor systems with 2015
Certified Electronic Health Record Technology (CEHRT) would be able to easily report the most recent version of an eCQM, for instance for MIPS with minimal manual effort, that is not the case. CEHRT requirements do not standardize the capture and reporting of individual eCQM data elements across vendor systems, and IRFs, physicians and providers still need to tailor data extracts and uploads across systems and participating TINs, which requires software to integrate and extract quality data from participating TIN EHRs.

Depending on the program and structure required to participate in a Medicare program, there are questions around the extent to which reporting and validation can be assumed by an entity, like an ACO as opposed to the participant TINs. Under the current Medicare Shared Savings Program (MSSP) rule and requirements, it is the APM entity that reports on behalf of the participant TINs. Therefore, it is possible that an ACO that contracts with participating practices may require those practices to bear the burden of the data mapping, extracting, and reporting to the ACO due to contractual and legal issues of an ACO accessing data for individuals who are not within the ACO. These issues are a result of the all-payer reporting requirement. Therefore, we have significant concerns with a dQM strategy that requires all-payer data without any reprieve or influence into the design of private-payer quality reporting programs.

In addition, 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 IRF 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.

III. IRF Quality Reporting Program Quality Measures Under Consideration for Future Years

A. Opioid Use and Frequency

The AMA continues to express our concerns and opposition to measure concepts focused on opioid use and misuse as neither are aligned with the evidence and there are significant unintended negative consequences that could be experienced with their use. The AMA believes that all care provided to patients must be individualized and quality measurement should not arbitrarily or unintentionally focus on preventing and/or reducing opioid use. Rather measurement should address the larger clinical issue—how well patients’ pain is controlled, whether functional improvement goals are met, and what therapies are being used to manage pain while also lowering the risk of opioid use disorder.

In general, the AMA disagrees with the fundamental premise of measures that focus on daily dose and duration of therapy involving prescription opioid analgesics because on its own it is not a valid indicator of high-quality patient care. The ongoing singular focus on the dose and duration of opioid prescriptions disregards the important steps that have already been taken to address the national epidemic of drug overdose deaths, which the AMA strongly supports. The final report of the Department of Health and Human Services (HHS) Interagency Pain Management Best Practices Task Force, for example, made a compelling case for the need to focus on patients experiencing pain as individuals and to develop
treatment plans that meet their individual needs and not employ one-size-fits-all approaches that assume prescriptions of long duration are indications of overuse. Likewise, a Centers for Disease Control and Prevention (CDC) publication in the New England Journal of Medicine expressed concern that the CDC’s opioid prescribing guidelines have been misapplied and wrongly used to discontinue or reduce prescriptions for patients with pain, with some actions likely to result in patient harm. The CDC stated that its guideline should not be used to create hard and fast policy.

In fact, since the CDC guideline was issued, there have been many reports of patients who have been successfully managed on opioid analgesics for long periods of time. For many patients, the benefits of such therapy exceed the risks, but the misapplication of the CDC guideline by payers, pharmacy benefit management companies and pharmacies results in patients being forced to abruptly reduce or discontinue their medication regimens. Such involuntary tapers are associated with sometimes extremely adverse outcomes, including depression, anxiety and emergence of other mental health disorders, loss of function and the ability to perform daily activities, and even suicide. Compelling testimony of these unintended consequences was provided at meetings of the HHS Interagency Pain Management Best Practices Task Force.

The narrow and reactionary federal response to the drug overdose epidemic has exacerbated the stigma experienced by patients with pain and the physicians who treat them. This stigma makes it more difficult for patients with pain or opioid use disorder to get treatment. Research continues to demonstrate that individuals may or may not have access to pain management therapies based on their race/ethnicity and measures that may further exacerbate this problem should be avoided. In addition to stigmatization of those with substance use disorder, patients with other complex pain management conditions (such as sickle cell) are often viewed as opioid-seeking when presenting in the emergency department. Therefore, development of a measure around opioid use, regardless of incorporation of exclusions, will further exacerbate health care inequities due to the varied and arbitrary manner in which opioid analgesic policies have been designed and implemented, which continue to leave patients without access to needed therapies.

- **Appropriate pain assessment and pain management processes**

The AMA supports a measure concept around appropriate pain assessment and pain management. For years, we have advocated and recommended that measures addressing opioid use should focus on how well patients’ pain is controlled, whether functional improvement goals are met, and what therapies are being used to manage pain while also lowering the risk of opioid use disorder. The AMA believes that all care provided to patients must be individualized.

CMS should explore a biopsychosocial model of pain assessment, measuring physical, emotional, social, and cultural variables, which has been shown to be effective and gives a much deeper understanding of a

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patient’s pain than a score on a one-dimensional numerical scale. Comprehensive pain assessment includes taking a complete history, physical exam, mental health screening, functional history, medication review and diagnostics to establish underlying causes of pain and assess for co-occurring disorders. There are many evidence-based and validated pain and other assessment tools that can be utilized by physicians.9

- **SARS-CoV-2 Vaccination Coverage among Healthcare Personnel**

The AMA supports the inclusion of this measure. We encourage the CDC to revise and/or update the measure as new evidence comes forward and based on feedback received from the field.

**B. Health Equity Measure**

CMS is seeking input on the importance, relevance, appropriateness and applicability and concept of a health? equity measure. The AMA has long recognized that racial and ethnic health inequities are an unjust and major public health reality in the United States. Understanding that race is a social and political construct and not a biological risk factor for disease and death, the AMA has publicly acknowledged that racism impacts public health and is a barrier to effective medical diagnosis and treatment. Much of medicine still looks for cultural, behavioral or even genetic explanations to understand and justify the gaps in life expectancy, diabetes-related mortality and potential years of life lost amongst populations when analyzing data. Furthermore, because race is a social construct, there is significant variability in how “races” are defined by society, lawmakers, and others. These definitions have changed and evolved in usage and application over time. 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. Therefore, the potential development of a measure related to health equity must consider how race/ethnicity data are collected and are used in clinical environments as they vary from system to system. There is also variation among health data systems (patient self-reported or investigator/clinician reported) and the number of choices provided to the reporter including options such as reporting mixed-race, “other,” or an individual’s preference to not report.

Any measure should be inclusive of disparities, but not limited to disparities. Consequently, we recommend CMS capture inequities rather than disparity, if possible. Some items to consider are Government Alliance on Race and Equity (GARE) racial equity assessment or Health Equity Impact Assessment tool (HEIA). As we stated earlier, CMS must consider potential unintended consequences and provide supportive education to ensure that inequities are not exacerbated as they begin to consider addressing health inequities and the potential development of a quality measure for use in an accountability program and that institutions are appropriately educated on best practices for data collection and/or program implementation.

Often, well-intended measures or tools create new problems and only organizations that are well financed and capitalized have the necessary resources to invest in quality improvement programs. 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. For instance, the Hospital Wide Readmission program has substantially increased penalties for hospitals that

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serve a disproportionate number of low-income patients.\textsuperscript{10} Quality measures must account for risk factors such as lack of access to food, housing, and/or transportation that affect patients’ ability to adhere to treatment plans.

The AMA appreciates the opportunity to provide input on this proposed rule and looks forward to working collaboratively with CMS’ ongoing initiatives to close the health equity gap. If you have any questions regarding this letter, please contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,

James L. Madara, MD