



Charles N. Kahn III
President and CEO

June 7, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1748-P
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2022 and Updates to the IRF Quality Reporting Program, Proposed Rule 86 Fed. Reg. 19086 (April 12, 2021); [CMS-1748-P]

Dear Administrator Verma:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, D.C and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services.

The FAH appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) regarding its proposed rule, *Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2022 and Updates to the IRF Quality Reporting Program*, ("Proposed Rule") published in the Federal Register (86 Fed. Reg. 19086) on April 12, 2021.

Case-Mix Group Weights

For the reasons CMS noted in the Proposed Rule, that "the FY 2019 claims data does not reflect any of the changes to the CMG definitions or data used to classify IRF patients into CMGs" beginning in FY 2020, the FAH supports CMS's proposal to update CMG relative weights and average length of stay values using FY 2020 IRF claims and 2019 IRF cost

reporting data. Applying FIM-based FY 2019 claims data in FY 2022 will not reflect the effects of numerous changes that occurred during the PHE.

The FAH appreciates CMS's consideration of FY 2019 claims, and but for the unique circumstances of the IRF PPS and the broad changes to that system introduced in FY 2020, we would lean towards recommending CMS using FY 2019 claims, which we believe are more likely to reflect IRF cases in FY 2022 rather than FY 2020 cases which were heavily impacted by the intensity of the COVID-19 pandemic, which continues to subside.

We would also note the absence of comprehensive, detailed analyses and discussion regarding the impact of the pandemic on the IRF sector generally as well as the various payment elements. Including this analysis would have facilitated a more robust, comparative analysis of FY 2019 versus FY 2020 data and more fully informed stakeholder comments. We would hope to see such analyses and discussion in the final rule.

Facility-Level Adjustment Factors

The FAH recommends that CMS monitor and report on these factors, which have been frozen since FY 2015. This is especially warranted in light of the redistributive payment impacts of the FY 2020 policy change to use Section GG items instead of FIM scores to classify patients, in addition to COVID-19 effects. This will help ensure a dynamic and accurate IRF payment system that recognizes and responds to change in the cost of care and promotes the delivery of efficient and effective IRF services.

Wage Index

Consistent with past comments the FAH has submitted, we recommend that CMS adopt wage index policies that apply to IPPS hospitals such as geographic reclassifications and the policy modifying wage indices for low wage index areas. This will help level the playing field among providers who often compete for the same labor pool by applying to IRFs a wage index concurrent with other post-acute care settings as well as acute care hospitals. In addition, we recommend that CMS apply a non-budget neutral five percent cap on decreases to a hospital's wage index value to help mitigate wide annual swings that are beyond a hospital's ability to control, and which could otherwise undermine operations.

High-Cost Outliers

The FAH supports a three percent outlier pool in FY 2022. We are concerned, however, notwithstanding our support for using FY 2020 claims data for FY 2022 rate-setting purposes, that the use of 2020 data in establishing the fixed-loss threshold results in an excessively high fixed loss threshold that is disconnected from the expected characteristics of patients in FY 2022 as the pandemic continues to subside. The net result would be a substantial underpayment of outliers. Therefore, the FAH respectfully requests that CMS adjust the FY 2022 threshold by the method of, for example, freezing the fixed-loss threshold amount at the FY 2021 level, which was based on FY 2019 claims. This would help ensure that actual outlier cases in FY 2022

results in payments that approach the three percent of payments set aside for the outlier pool and would obviate the need for an additional budget neutrality adjustment.

Request for Information: Closing the Health Equity Gap in Post-Acute Care Quality Reporting Programs (Equity RFI)

Overview

CMS notes substantial variation nationwide in health outcomes and the association between poor outcomes documented for some chronic and acute conditions with certain social risk factors;¹ for example, rates of chronic heart disease and hospitalizations for COVID-19 differ by race. CMS uses the terms health disparities and inequity when discussing health outcome variations linked to social risk factors and cites the provision of lower quality health care to at-risk patients as a contributing factor to variable outcomes. Through its Equity RFI, CMS seeks input about measure revisions and other changes to the IRF QRP that would better identify disparities and facilitate addressing any inequities uncovered therein. The agency focuses particular attention on the utility of capturing social risk factors through standardized patient assessment data elements (SPADEs) and of reporting IRF QRP performance results stratified by social risk factors as approaches for improving health equity for all IRF patients.

The Federation welcomes the opportunity to respond to the Equity RFI on behalf of our members, who include hospital-based and freestanding IRFs that vary widely in size and location, and who are committed to providing the highest-quality care to all patients regardless of their social risk factors. We have long believed and supported that appropriately accounting for social risk factors is essential for accurately assessing health care provider performance for CMS' public reporting and accountability programs, including the IRF QRP. We also believe that when social risk factors affect patient outcomes in ways that are beyond the control of health care providers, quality measures and any related payment consequences must be carefully constructed to avoid unfairly penalizing providers and thus potentially worsening inequities by reducing care access for at-risk patients.

CMS requests suggestions for measures and measure domains that would address health equity in the IRF QRP. The FAH believes that responding at that level of specificity at this time may be premature and non-productive, as the agency has not clearly outlined next steps to be taken with comments received, saying only that input will "inform future policy development". Without more information, we think a more productive line of comment is for us to state some essential characteristics of measures and measure domains focused on health equity.

New IRF QRP measures or domains should first be data-driven; that is, be developed based upon well-documented outcome disparities with clear associations to well-defined social risk factors. Second, measures must be designed to yield performance results that are actionable for providers. Accumulation of interesting but non-actionable data is better undertaken as a research initiative than through an ongoing quality program like the IRF QRP. Process measures may be useful, especially initially, as achievable metrics that can point the way to important

¹ Social risk factors as used herein includes items sometimes also categorized as demographic variables, sociodemographic status (), socioeconomic status (SES) and social determinants of health (SDOHs).

outcome measures. Third, measure construction should facilitate timely performance result calculations and prompt feedback to providers, as aging data can quickly become irrelevant. Lastly, realistic consideration of provider burden and CMS operational capabilities must precede any new IRF QRP measure adoption. The pursuit of equity and quality cannot occur in a vacuum in which there is no regard for the potential diversion of provider and CMS resources from essential care delivery to new reporting requirements of unproven value. Alignment with collection and reporting requirements of states and other third-party payers also is critical for new burden avoidance and should precede adoption of any new measure; alignment also will strengthen the validity of performance results.

Stratified Results Reporting

CMS asks whether including facility-level quality measure results stratified by social risk factors such as race and dual eligibility in confidential feedback reports to IRFs could allow facilities to identify inequitable quality of care. The FAH believes that stratification when properly designed and implemented can be a useful tool in identifying and understanding facility performance disparities, particularly as a stop-gap tool pending availability of other approaches that have been rigorously validated in real-world testing and proven actionable. Dual eligibility, race, and ethnicity are reasonable initial stratification variables, building on CMS experience in providing stratified reporting to hospitals subject to the Hospital Readmission Reduction Program (HRRP) and to Medicare Advantage (MA) plans. Consideration must be given to the distribution patterns of the risk factors within a given program (e.g., the IRF QRP) and adjustments made as necessary rather than simply importing measures and calculations already in use elsewhere by CMS.

Further, the FAH strongly encourages CMS to explore stratification in the IRF QRP that would account for the community-level social risk factors of facilities based on their locations, such as access to transportation, food, pharmacies, and other community and home services. We also encourage CMS to investigate the application of social-risk-stratified results analysis and reporting to patient-reported outcome measures. Additionally, we continue to urge CMS to account for social risk factors in the methodology for resource use measures, such as Medicare Spending Per Beneficiary (MSPB), in acknowledgement of the relatively higher resource consumption often required to provide appropriate and equitable care to at-risk patients.

The FAH fully supports that stratified result reporting to IRFs of these extremely sensitive data should be confidential; results also must be accompanied by a review and correction process, and be subject to data validation. We further support public reporting, but only after the data collected have demonstrated a high degree of reproducibility and after a period of confidential reporting that is sufficient to identify unintended consequences. Prior to public reporting the FAH strongly urges CMS to undertake focus groups to test messaging and understanding of the data, so that the results reported are clear and actionable for patients, families, and caregivers.

Standardized Patient Assessment Data Elements (SPADEs)

CMS notes having previously finalized requirements for IRFs and other post-acute care providers to report certain standardized patient assessment data (SPADEs) on social risk factors including race, ethnicity, preferred language, interpreter services, health literacy, transportation and social isolation. Implementation has been delayed as part of the CMS response to the COVID-19 public health emergency (PHE) until at least one full fiscal year after the end of the PHE. In the Equity RFI, the agency seeks input on additional SPADEs for use in assessing the equity of IRF care.

While the Federation applauds the proactive approach to social risk and health equity exemplified by the current Equity RFI and related prior work by CMS, we view the request for suggestions to expand the required collection of SPADEs by IRFs as extremely premature. SPADE development was not without controversy and required a multi-year process to get to the current set of social risk elements. Due to uncontrollable impacts of the COVID-19 PHE, the social risk SPADEs have yet to be implemented; the true burden of SPADE collection and reporting as well as its potential unintended consequences, therefore, have yet to be observed. We strongly advise CMS not to change or expand the finalized social risk SPADE set until several years of experience in their real-world use by IRFs and other post-acute care providers has accumulated.

Provider Experiences

CMS requests information about methods in use by IRFs that employ data to reduce disparities and improve patient outcomes and about current and anticipated challenges related to the capture, use, and exchange of relevant health data to equitably support care delivery and decision making. Due to the delayed implementation of required SPADE social factor collection and reporting, the experiences of our members have been somewhat limited. They have, however, shared the following observations:

- Because CMS provides only aggregate annual reports to IRFs and does not provide patient-level data for claims-based measures, IRFs are seriously hampered in their ability to optimize the range of potential modifications to their patient care practices and procedures.
- Data provided to IRFs are so distant from real-time as to be unusable for prompt root-cause analyses of significant adverse events.
- State laws and regulations for social risk factor data collection and reporting are quickly evolving, such as Nevada's mandate that providers modify their EHRs to collect sexual orientation/gender identity. Absent federal coordination and guidance an unwieldy and burdensome patchwork of requirements will result rather than a cohesive, aligned approach that is far more likely to yield valid and actionable data to address disparities. Multi-state health care systems are especially vulnerable to the patchwork approach.
- Downstream providers such as IRFs typically rely on race, ethnicity, and other variables collected by the previous treating facility. CMS should specify a set of standard definitions for use across its programs which other payers would then almost surely adopt.

- CMS should use its regulatory flexibilities to empower providers and health plans to develop programs and services for at-risk patients, such as by modifications or waivers of the Medicare Beneficiary Inducement Statute.

The FAH supports the essential work that CMS continues to do related to health care disparities and inequities as represented by the Equity RFI. We urge a deliberative and iterative approach to measure development, including SPADEs, and to confidential stratified results reporting to IRFs. Only in this way can the promise of promoting health care equity through quality reporting be achieved. The FAH looks forward to collaborating with CMS in moving this important work forward.

Revisions and Updates to the IRF Quality Reporting Program (IRF QRP)

New and Updated Measures for FY 2023

- New measure: COVID-19 Vaccination Coverage among Healthcare Personnel

This proposed measure would assess the percentage of COVID-19 vaccination coverage in health care personnel providing care in IRFs.

The FAH supports the intent of this measure but urges CMS to consider postponing its inclusion in the IRF QRP until the measure specifications have been finalized and the COVID-19 vaccines have been given full FDA approval, not just for Emergency Use Authorization. The underlying evidence for this measure is still emerging, additional vaccines are in development, methods for addressing measure collection challenges related to anticipated “booster” shots may be required, full approval by the National Quality Forum (NQF) has not yet occurred, and feedback from the field is needed to ensure that this measure reflects the most current knowledge and evidence and can be easily collected and reported.

Additionally, this measure would be duplicative at present because CMS already has vaccination status data from hospitals, including IRFs, through HHS’s contract with Teletracking. Further, because we anticipate that this measure will undergo substantial changes within and across reporting years, the FAH does not believe that it should be used for payment decisions, nor should it be publicly reported until the underlying evidence is stable and reporting of the measure has occurred for several years. Ultimately, the FAH generally believes that measures that increase the reporting burden and leverage specifications that are not aligned with other measures should be avoided.

- Updated Measure: Transfer of Health (TOH) Information to the Patient-Post-Acute Care

CMS proposes to update the specifications for this measure to exclude patients discharged home under the care of an organized home health service or hospice.

The FAH supports the addition of this exclusion as it serves to avoid counting these patients in both TOH measures in the IRF QRP. This update will further improve the validity and usefulness of the measure and FAH appreciates CMS’s responsiveness to this issue.

Removal of Topped Out Measures

The FAH believes that two measures currently reported in the IRF QRP are topped out. These measures are:

- Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674); and,
- Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631)

Both measures demonstrate little to no variation across facilities and do not provide information that enables end users (e.g., facilities, patients, caregivers) to distinguish high quality of care. The FAH encourages CMS to propose these measures for removal to reduce data collection and reporting burdens for IRFs.

Request for Information (RFI) on IRF QRP Quality Measures Under Consideration for Future Years

CMS seeks comment on the importance, relevance, appropriateness and applicability on potential assessment-based quality measures and concepts under consideration for future addition to the IRF QRP.

- Frailty

The FAH does not recommend the inclusion of a frailty measure in the IRF QRP. Measures on frailty are most frequently used in acute care settings such as for intensive care unit patients or in primary care to monitor for risk of adverse events, re-hospitalization, death and indicate if functional dependence may occur. There are numerous tools that have been used to describe a multidimensional loss of reserve that describes these patients who are typically elderly; however, a frailty measure would not be applicable for all IRF patients, many of whom were relatively young and high functioning prior to their hospitalization..

- Opioid use and frequency

While the FAH and its members actively seek to prevent unintentional opioid overdose fatalities and advocate for evidence-based ways to address the opioid epidemic, we do not support measures that primarily focus on opioid use and frequency given the potential negative unintended consequences that may occur. The FAH continues to believe that CMS must implement a broader focus on pain management to provide a more comprehensive picture of the quality of care to patients rather than the current siloed view on opioid use alone. Specifically, the FAH does not believe that narrowly focused measures on opioids in the absence of understanding the root cause of the pain and pain management strategies will solve this public health concern nor will it provide information that will necessarily drive improvements for patients receiving care in the IRF setting. Because IRF patients are more likely to experience pain than patients in other post-acute care settings, by virtue of their intense therapy regimen,

they must need, be expected to benefit from, and receive intense rehabilitative therapy treatment. This treatment encourages patients to meet their functional and mobility goals, and can sometimes include instances of pain or discomfort and can be a healthy byproduct of an effective therapy regime. As a result, the FAH encourages CMS to explore the development of measures that examine pain and standardized pain assessments and alternative therapies in addition to understanding current opioid prescribing practices as this approach would prove more beneficial to IRFs and the patients they serve.

- Patient reported outcomes

The FAH supports the use of patient reported outcomes (PROs) but encourages CMS to allow IRFs adequate time and resources to ensure that the data collection and reporting of these types of measures are feasible and yields results that are reliable and valid. The FAH notes that reporting of many of the SPADE elements finalized for the IRF-PAI version 4.0, effective October 1, 2020, which could be potential data elements for PRO performance measures (PRO-PMs), were delayed due to the public health emergency and will likely affect the short-term feasibility of developing these types of measures. IRFs should also be provided with additional time to gain familiarity and experience with these data prior to the creation and implementation of any PRO.

- Shared decision making process

The FAH believes that it is critical that patients are informed and actively involved in decision making regarding the care that they receive but we encourage CMS to be thoughtful on how measures on shared decision making would be collected and reported, similar to our comments on PROs. It is also critical that any measure on shared decision making is complementary to but not duplicative of the goal setting at admission to planning and preparation for discharge that IRFs perform now. The FAH encourages CMS to balance the need for additional measures that address critical gaps in quality information along with the potential for additional reporting burden on IRFs.

- Appropriate pain assessment and pain management processes

The FAH encourages CMS to explore the development of measures in this area consistent with our comments under “opioid use and frequency.”

Form, Manner, and Timing of Data Submission: Policies Regarding Public Display of Measure Data for the IRF QRP

- COVID-19 Vaccination Coverage among Healthcare Personnel (HCP)

CMS proposes to add the new COVID-19 vaccination coverage measure to publicly reported IRF QRP data available in Care Compare and the Provider Data Catalog, beginning with the September 2022 Care Compare refresh based on data collected for Q4 2021. Each subsequent refresh would add one quarter of data until four quarters are reached, after which time display would continue using a rolling four quarters of data.

Given the FAH's concerns that the underlying evidence must become more stable and the need for reporting of the measure to occur for several years, we believe that it is premature to publicly report this measure at this time.

- Measures with Fewer Quarters Due to COVID-19 PHE Exemptions

CMS proposes temporary changes to the data collection quarters specified in prior rulemaking for IRF QRP measure results that are publicly displayed on Care Compare. These changes are intended to account for incomplete data reporting during the COVID-19 pandemic.

The FAH appreciates CMS's recognition of the impact that the COVID-19 pandemic has had on the data used for quality measures, particularly those used for IRF quality reporting. The FAH supports these initial efforts to address the potential for data that are not reliable and/or valid resulting in performance scores that may misrepresent IRF performance and/or unintentionally provide misleading information to patients and caregivers. CMS may want to include an "asterisk" or some type of notation that explains that temporary adjustments were made for the PHE. We encourage CMS to continue to monitor and explore the many causes of variation including the geographic and temporal differences in the spread of COVID-19 as well as variation in the acuity of COVID-19 impact across populations and COVID-19 influx."² The full extent of how this public health emergency may influence changes in care delivery and how IRFs perform on quality measures, which may be temporary or permanent, will require several more years of research and investigation. The FAH remains committed to work with CMS and others to better understand the full impact of this pandemic on quality reporting programs and care delivery.

The FAH appreciates the opportunity to comment on the Proposed Rule. If you have any questions regarding our comments, please do not hesitate to contact me or a member of my staff at (202) 624-1534.

Sincerely,



² Salzberg CA, Kahn C. COVID-19 will upend hospital reporting and value-based programs for years to come. Health Affairs Blog. May 24, 2021. DOI: [10.1377/hblog20210520.815024](https://doi.org/10.1377/hblog20210520.815024)