Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1748-P  
P.O. Box 8016  
Baltimore, Maryland 21244-8016  

June 7, 2021  

SUBMITTED VIA REGULATIONS.GOV  


Dear Administrator Brooks-LaSure:  

Congratulations on your recent confirmation as the Administrator for the Centers for Medicare and Medicaid Services (“CMS”). On behalf of the Arizona Hospital and Healthcare Association and our more than 80 hospital, healthcare and affiliated health system members, we are pleased to present CMS with the following comments on the Fiscal Year 2022 Inpatient Rehabilitation Facility (“IRF”) Prospective Payment System Proposed Rule (86 Fed. Reg. 19,086) (April 12, 2021) (referred to herein as the “Proposed Rule”).  

A. Proposed Update to the Case-Mix Group (CMG) Relative Weights and Average Length of Stay Values for FY 2022  

CMS has proposed updates to CMG relative weights and average length of stay values using FY 2020 IRF claims and 2019 IRF cost reporting data. Based on discussion included in the Proposed Rule, it appears that CMS considered using FY 2019 claims data due to the effects of the Public Health Emergency (“PHE”) on FY 2020 claims. The agency ultimately decided to propose to use FY 2020 claims data as “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.  

While we support CMS’ proposal to use the FY 2020 claims data, we note that CMS has not provided a comprehensive analysis regarding the impacts the PHE has had on the IRF sector and the underlying data used to develop the proposed changes to update the IRF PPS update for FY 2022, including the CMG relative weights. We note that in the FY 2022 inpatient acute care hospital (“IPPS”) Proposed Rule (CMS-1752-P), CMS provided such an analysis as part of the appendix to that rule. We respectfully request that CMS provide this type of in-depth analysis and discussion of the PHE and its effects on the IRF sector in the IRF PPS Final Rule, including the impact COVID-19 has had on the relative weights and their development, case-mix changes, impacts on IRF expenditures (e.g.,...
personal protective equipment ("PPE"), temporary labor, supplies, etc.) and the impact of CMS waivers and flexibilities. Understanding these and other issues will help inform CMS in making updates to the IRF PPS in FY 2022 and beyond.

AzHHA member Encompass Health’s rehabilitation hospitals have treated over 12,000 patients diagnosed with COVID-19. The PHE has led to significant changes and disruptions at Encompass Health’s hospitals, including patient admission restrictions at certain hospitals due to COVID outbreaks; intensified micromanagement of infection control practices; prohibitions and restrictions on visitors in Encompass Health’s hospitals and referring general acute care hospitals; significant numbers of staff being quarantined; altered provision of care practices due to general social distancing or isolation of COVID-19 patients; new costs for personal protective equipment ("PPE") and supplies; and increased use of contract clinical staffing, among other impacts.

While the effects of these disruptions may have impacted and in many instances will continue to impact inpatient rehabilitation facilities’ clinical practices and general operations, we agree with the proposal to use FY 2020 claims data to develop the FY 2022 IRF PPS. We concur with CMS that the IRF PPS update must be based on the changes to CMG definitions and data used to classify IRFs into CMGs implemented on October 1, 2019. Applying FIM-based FY 2019 claims data in FY 2022 will not reflect the effects of numerous changes that occurred during the PHE. Further, IRFs will continue to treat patients recovering from COVID-19 in FY 2022 and beyond, especially when considering that the effects of "Long COVID" are not fully understood. While the numbers of COVID cases may decline, the underlying case-mix and costs to treat these patients should be embedded into the relative weights and average length of stay values.

Last, the use of FY 2020 data does not result in a significant difference than the values using FY 2019 claims. The relative weight budget neutrality factor would be 1.0000 using FY 2020 claims in comparison to 0.9998 using FY 2019 claims. For all of these reasons, we respectfully request that CMS update the CMG relative weights and average length of stay values using FY 2020 claims and FY 2019 cost report data in the IRF PPS Final Rule using the latest available data.

B. Proposed Measure: COVID-19 Vaccination Coverage among Healthcare Personnel ("HCP")

This measure would calculate the percentage of HCP eligible to work in the facility for at least one day during the reporting period who received a complete vaccination course. The measure would exclude persons with medical contraindications to the COVID-19 vaccination as described by the Centers for Disease Control and Prevention (CDC), but otherwise all facility personnel — including licensed independent practitioners affiliated with but not directly employed by the facility and students, trainees and volunteers — are included in the denominator, regardless of clinical responsibility or patient contact. The measure would be reported using CDC’s National Healthcare Safety Network (“NHSN”) Healthcare Personnel Safety Component submission framework.

AzHHA strongly supports COVID-19 vaccinations of both HCPs and the communities they serve. We have encouraged vaccination to help protect both patients and our health care workforce from this crippling disease. Health care facilities have made remarkable progress in vaccinating large proportions of their teams in a short timeframe, and are working hard to close any remaining gaps. Notwithstanding the remarkable scientific achievement of having three available and highly effective COVID-19 vaccines, we are barely six months into deploying them. The underlying scientific evidence about how to implement the vaccines continues to evolve, and there remain important unanswered questions that would affect both the design and feasibility of any HCP vaccination measure. To list just a few, for how long do the vaccines confer immunity? How frequently might booster shots be required? Should one receive the same type of booster shot as the original shot? Will vaccine supply
remain sufficient across the nation to ensure all HCP can receive it?

None of these questions detract from the importance of encouraging COVID-19 vaccinations. However, the answers to all of these questions are of foundational importance to building a meaningful, accurate and fair performance measure whose results would be shared publicly. AzHHA is concerned that a premature mandate to report this measure would lead to unpredictable shifts in reporting requirements that would prove disruptive to hospitals, and result in data that are unhelpful to policymakers, the public and health care providers.

Due to the unique nature of the COVID-19 pandemic and the limited experience the nation has with the vaccine products currently available, we do not recommend implementing this measure for mandatory reporting this year, as its use could have negative unintended consequences and might not be the most useful tool to promote vaccination. Instead, AzHHA recommends that CMS either delay adoption of the measure for at least one year (i.e., until Oct. 1, 2022), or adopt the measure for voluntary reporting for at least the first year to allow time for the issue described below to be addressed. Any voluntarily reported data should not be publicly reported.

In its rationale and explanation of the measure’s design, CMS relies heavily on the specifications and experience with the Influenza Vaccination among Healthcare Personnel measure (NQF #0431). However, the circumstances around use of the COVID-19 vaccine are not entirely comparable to those of the influenza vaccine, as COVID-19 and the vaccines have had a short and at times, unpredictable implementation. The three vaccine products on the market — from Moderna, Pfizer, and Johnson and Johnson — are currently only available under the Food and Drug Administration (FDA)’s emergency use authorization. While we are confident in the safety and efficacy of these products and at least one is likely to receive full FDA approval imminently, we find it to be incongruous to adopt a measure into federal quality reporting programs that assesses the use of a product that has not yet received full federal approval.

Another important distinction between the measure proposed in this rule and the influenza measure already in use is that the COVID-19 vaccination measure has not gone through the rigorous testing and NQF endorsement review process to which other measures adopted in CMS quality reporting programs are subject. The measure was presented to the NQF’s Measure Applications Partnership (“MAP”) as a concept rather than as a measure ready for implementation; CMS leadership explained during the MAP meetings that the agency was bringing forward a measure that wasn’t “fully fleshed out” in anticipation of incorporating it into rule-writing in 2022 at the earliest.

While the measure is designed nearly identically to the flu vaccine measure in terms of its calculation and reporting structures, many questions about the specifics of the COVID-19 measure remain (questions that might be answered during the testing and NQF endorsement processes). For example, what are the long-term plans for use of this measure in terms of its reporting period? The flu vaccine measure assesses vaccinations during “flu season,” which is defined as October through March; will there be a similar “COVID-19 season,” and how will reporting interact with that of the flu measure? Is this measure in alignment with other COVID-19 vaccination measures under consideration, such as the Merit-based Incentive Payment System measure that was reviewed by the MAP which assessed patients who received at least one dose (as opposed to a complete course)?

Considering the magnitude of changes in the circumstances regarding COVID-19 vaccinations in 2021 alone, additional questions concerning the logistics of this measure may arise. The availability of doses played a major role in vaccination status earlier this year; for example, safety violations at a single plant resulted in millions of unusable doses of the Johnson and Johnson vaccine. If the supply chain were disrupted again, health care facilities could be unable to ensure the vaccination status of
their employees through no fault of their own. The nation has not yet completed the first wave of complete vaccinations — as of this writing, less than 40% of Americans were fully vaccinated — and thus we have not yet begun to address needs or logistics for “booster” shots. Because of the rapidly changing circumstances in which the COVID-19 vaccines are being deployed, we believe it is unwise to permanently adopt this measure into federal quality reporting programs at this time.

In addition to these logistical concerns, CMS also should consider the potential unintended consequences of the use of this measure. The reporting burden associated with this measure may be high depending on how it interacts with other COVID-19 data reporting requirements. Certain health care settings (including skilled nursing facilities as well as inpatient psychiatric facilities) do not currently use the National Healthcare Safety Network to report data for quality reporting programs, so the introduction of this measure would require adjustments in workflow for which CMS would need to provide significant technical support. In addition, use of this measure may cause providers to amend other employee-facing policies, which take time to implement.

Moreover, while the measure does not directly compel facilities to ensure that their employees are vaccinated, publicly reporting performance on this measure might incent facilities to adopt mandatory vaccination policies for their personnel. Clearly, a vaccination mandate could be beneficial to measure performance. Yet, the decision about whether to implement a mandate is complex, and in some cases, the decision may be beyond the control of health care facilities. Already, multiple states have introduced or passed legislation prohibiting discrimination based on COVID-19 vaccination status; other existing state laws might also run afoul of mandatory vaccine policies. In practical terms, this could mean that facilities that are unable to mandate the vaccine could be at a systematic performance disadvantage on the measure. We also urge CMS to be mindful of other complex issues that could shape any mandatory vaccination approach. For example, the measure only excludes patients who do not get the vaccine due to medical contraindications. According to the Equal Employment Opportunity Commission, employers must provide a reasonable accommodation if an employee’s sincerely held religious belief, practice or observance prevents them from receiving the vaccination; this policy seems to conflict with the specifications of the proposed measure. A mandatory vaccine policy — with suitable exceptions and employee protections — might be appropriate, but until we have more than eight months of data on the vaccine’s safety and side effects, we are unsure whether indirectly encouraging through the mandatory public reporting of COVID-19 vaccination rates is judicious.

The COVID-19 pandemic is not the last public health emergency this nation is likely to face, but our national response will have long-lasting effects on policy. AzHHA is concerned about the precedent of adopting a measure assessing COVID-19 vaccination of HCP under these circumstances, and would thus recommend that CMS reconsider adopting the measure during this rulemaking cycle. Instead, CMS should either delay adoption of the measure for at least one year or adopt the measure for voluntary reporting only — without publicly reporting performance — for at least the first quarter of the measure’s use (beginning Oct. 1 of this year) to allow for time to answer the questions raised above regarding feasibility, validity, and the incidence of any unintended consequences.

C. Future Measure and Measure Concepts Under Consideration for the IRF Quality Reporting Program

CMS seeks comment on the “importance, relevance, appropriateness, and applicability of measures and concepts under consideration” for future IRF QRPs, including the topics discussed below.
1. **Frailty**

A frailty measure would not be applicable for all IRF patients. Frailty measures are used in acute care settings such as for ICU patients, and in primary care to monitor for risk of adverse events, rehospitalization, death, and indicate if functional dependence may occur. Frailty is a syndrome or state typically used to describe the geriatric population. There are numerous tools that have been used to describe a multidimensional loss of reserve that describes these patients, however, this would not be applicable for all IRF patients, many of whom were relatively young and high functioning prior to their hospitalization. Therefore, we recommend that a frailty measure not be included in the IRF QRP.

2. **Opioid Use and Frequency**

In the IRF PPS Proposed Rules for FYs 2015, 2016, 2017, and 2018, CMS indicated the possibility of adopting an application of Percent of Residents Who Self-Report Moderate to Severe Pain (Short-Stay) (NQF #0676). If CMS pursues opioid use and frequency, we recommend a measure using morphine equivalent dosing rather than number of pills prescribed. We also recommend a measure around the use of non-opioid pain reduction modalities.

3. **Patient Reported Outcomes ("PROs")**

We recommend the use of PROs, and note that many of the SPADE elements finalized for the IRF-PAI version 4.0, effective October 1, 2020 but delayed due to the public health emergency are PROs, including Ethnicity, Race, Language, Transportation, Health Literacy, Social Isolation, Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day activities.

4. **Shared Decision Making Process**

Since shared decision making, or informed decision making, is an important part of patient/caregiver involvement in the inpatient rehabilitation stay and already part of the CMS Conditions of Participation (“CoP”), this would likely not add any value to providers or patients. IRFs are expected to involve patients from goal setting at admission to planning and preparation for discharge. A measure intended to track shared decision making would likely be a process measure and we generally do not support adding more process measures to the IRF QRP.

5. **Appropriate Pain Assessment and Pain Management Processes**

It is unclear how this measure/measure concept would relate to the finalized SPADE items, Pain Effect on Sleep (J0510), Pain Interference with Therapy Activities (J0520), and pain Interference with Day-to-Day Activities (J0530). Moreover, in the IRF PPS Proposed Rules for FYs 2015, 2016, 2017, and 2018, CMS indicated the possibility of adopting an application of Percent of Residents Who Self-Report Moderate to Severe Pain (Short-Stay) (NQF #0676). IRF patients are more likely to experience pain than patients in other PAC settings, by virtue of their intense therapy regimen. IRF patients must need, be expected to benefit from, and receive intense rehabilitative therapy treatment. Such treatment is designed to encourage patients to meet their functional and mobility goals, and can sometimes include instances of pain or discomfort. Typically, such pain or discomfort is a healthy byproduct of an effective therapy regime.

For example, an IRF patient recovering from a recent hip replacement procedure may feel some pain.

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2 Id.
after an intensive early mobility therapy exercise. Invasive procedures like hip replacements may naturally cause some residual pain in a patient during the IRF stay. However, this pain is not necessarily a negative quality indicator, and part of a successful rehabilitation hospital stay often includes helping patients manage pain as part of their recovery process. Encompass Health rehabilitation hospitals’ clinical practices require that nurses assess patient pain on a daily basis, including before and after each therapy session. Because pain is often an inherent part of intensive rehabilitation therapy, and frequent pain assessment is an integral part of a medical rehabilitation program, it is not an appropriate quality reporting measure for the IRF QRP.

A more meaningful pain measure in the IRF setting would be designed to assess whether staff are responsive to and help manage patients’ pain, not whether pain existed or pain was assessed. We support CMS’ proposal for this measure to rely on patient-reported data. This measure could feasibly be collected as a patient report outcome (“PRO”). A PRO measure would be significantly more meaningful for quality measurement than a process measure collecting the existence of pain and could be collected directly from the patient without additional measure collection burden to an IRF.

6. Consideration of Retiring Existing IRF QRP Measures

We respectfully request CMS to equally consider retiring or removing measures from the IRF QRP when considering whether to add measures and measure concepts. In the FY 2015 IPPS/LTCH Final Rule, CMS finalized the standards by which quality measures in the Hospital Inpatient Quality Reporting Program (“IQR”) would be eligible for removal on the grounds of “topping out.”3 In order to determine “topped out” status under CMS’ IQR definition, a measure must meet two criteria:

(1) Statistically indistinguishable performance at the 75th and 90th percentiles; and
(2) Truncated coefficient of variation ≤ 0.10.

Accompanying these technical standards, CMS offered a rationale on why measures that meet these standards should be removed. CMS specifically stated:

A measure is “topped-out” when measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made. We do not believe that measuring hospital performance on “topped-out” measures provides meaningful information on the quality of care provided by hospitals. We further believe that quality measures, once “topped-out,” represent care standards that have been widely adopted by hospitals. We believe such measures should be considered for removal from the Hospital IQR Program because their associated reporting burden may outweigh the value of the quality information they provide.4

Because IRFs follow acute care hospital Conditions of Participation and provide an acute level of care, a similar “topped out” standard and rationale should apply to IRF QRP measures. Under CMS’ rationale for removing topped-out measures, we have identified the following two IRF QRP measures that would qualify for removal based on being “statistically indistinguishable”:

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4 Id.
(1) Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674); and,

(2) 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)

The second measure, NQF #2631, also has a truncated coefficient of variation of 0.002, meeting the additional technical standard for IQR measure removal. The following analysis of reporting data for these two measures indicates that both of them should be removed from the IRF QRP based on being “topped out.” Accordingly, we recommend that CMS remove these measures from the QRP as soon as practicable.

<table>
<thead>
<tr>
<th>Measure</th>
<th>N size</th>
<th>75th/25th Percentile</th>
<th>90th/10th Percentile</th>
<th>Truncated coefficient of variation</th>
<th>Statistically Indistinguishable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Falls w/ Injury</td>
<td>1057</td>
<td>0.0</td>
<td>0.0</td>
<td>1.65</td>
<td>Yes</td>
</tr>
<tr>
<td>Functional Assessment/Goals</td>
<td>1057</td>
<td>100%</td>
<td>100%</td>
<td>0.002</td>
<td>Yes</td>
</tr>
</tbody>
</table>

While IRFs generally support the IRF QRP, it is important to evaluate the burden of newly proposed IRF QRP measures in light of the program’s intended benefits, namely improved care and information transparency for IRF patients and their families, healthcare providers, payors, and other stakeholders affected by IRFs’ quality of care and outcomes. In the initial IRF QRP rule (FY 2012 IRF-PPS Final Rule), CMS expressed its goals as follows:

> In implementing the IRF Quality Reporting Program, we seek to collect data on measures that will provide information on the full spectrum of the quality of care being furnished by IRFs while imposing as little burden as possible on IRFs. We seek to collect data on valid, reliable, and relevant quality measures and to make that data available to the public in accordance with applicable law.5

Despite CMS’s stated intentions to implement a program that imposes as little burden as possible on IRFs, the Proposed Rule continues to add burden to the IRF QRP at an overwhelmingly aggressive pace, ignoring the reality of implementing the proper operational, clinical, and administrative techniques for effective and comprehensive IRF QRP reporting. By CMS’ own estimates, since its inception the IRF QRP will have cost the IRF industry over $120 million dollars and more than 2.2 million hours of time by October 1, 2019. For each IRF, this has cost an average of $110,000 and around 2,000 hours since 2012. These measures and items have significant cost and time estimates and the effect accumulates over time as more and more are added to the program. It is now more critical than ever to assure each measure or item added to the QRP follows the CMS’s comprehensive “Meaningful Measures” initiative. For these reasons, we have significant concerns with the current SPADE proposal.

Given the immense expansion of the IRF PAI and other PAC patient assessment instruments, we do not support additional measures or measure concepts without a focus on burden reduction as a leading priority. The burden associated with continuing to add measures to the IRF QRP is far too high.

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In conclusion, AzHHA appreciates the opportunity to comment on this Proposed Rule and CMS's careful consideration of the issues raised in this letter. We sincerely appreciate the steps that CMS has taken in the Proposed Rule and other rules to deliver on its promise to ease regulatory barriers that allow hospitals and health systems to function more efficiently while continuing to provide high-quality patient care.

If you or your staff wish to discuss this letter, please feel free to contact me at 602-445-4304 or djohnston@azhha.org.

Sincerely,

Debbie Johnston
Executive Vice President