**CMS Response to Public Comments Received for CMS-10036: IRF-PAI for the collection of data pertaining to the Inpatient Rehabilitation Facility Prospective Payment System and Quality Reporting Program**

We received comments from two stakeholders on the Centers for Medicare & Medicaid Services (CMS) request to extend the currently approved collection for the IRF-PAI V4.0 that will be effective on October 1, 2022. We believe these comments to be related to policies previously finalized for the Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP) and therefore are outside the scope of the comment request in this notice. Commenters previously raised these concerns, and CMS formally responded to them when these items were originally finalized in the Fiscal Year (FY) 2020 IRF Prospective Payment System (PPS) Final Rule (84 FR 39054 through 39165) and again in the FY 2022 HH PPS Final Rule (86 FR 62381 through 62386) when the revised compliance date was finalized. However, CMS has summarized the comments of these two stakeholder below and provided comment responses.

**Staffing shortages**

Comment: Both commenters urged CMS to delay the implementation of the IRF-PAI 4.0 until there is measurable evidence that the IRF workforce challenges have improved, indicating that it is unrealistic for CMS to expect them to pull staff from direct patient care for training and education on new IRF-PAI data elements. One commenter pointed to the ongoing trauma of dealing with a pandemic that has exacerbated workforce shortages, and another commenter stated they believe the factors compelling the initial IRF-PAI V.4.0 delay are in some ways even more severe than they were at the start of the pandemic, and therefore the delay in compliance should remain in place until there is consensus across the IRF field that staffing levels have returned to an adequate level to allow for implementation.

Response:

We interpret the commenter’s concern to be associating the nursing shortage with the COVID-19 pandemic. According to the Centers for Disease Control and Prevention’s (CDC) COVID Data Tracker Weekly review on March 30, 2022,[[1]](#footnote-1) the current 7-day moving average of daily cases has continued to decrease compared to the previous 7-day moving average and is currently at a level not seen since July 2021. Additionally, new hospital admissions due to COVID-19 cases have been steadily declining. Despite this progress, the impacts of the COVID-19 Public Health Emergency (PHE) on the healthcare system, including staffing shortages, make it especially important now to monitor quality of care,[[2]](#footnote-2) and the IRF-PAI 4.0 will support these efforts.

Still, we are mindful of burden that may occur from the collection and reporting of our measures. As stated in the Fiscal Year (FY) 2020 IRF Prospective Payment System (PPS) Final rule (84 FR 39054 through 39173) when the items for the IRF-PAI 4.0 were finalized, we convened a Technical Expert Panel (TEP)[[3]](#footnote-3) and conducted a pilot test.[[4]](#footnote-4) Both the TEP feedback and the pilot participants found the burden of reporting not to be significant.

Additionally, as stated in section IX.A. 2 of the Calendar Year (CY) 2022 Home Health (HH) PPS proposed rule (86 FR 35983 through 35984), CMS has provided IRFs a number of flexibilities to accommodate the COVID-19 PHE, including delaying the adoption of the updated version of the IRF-PAI 4.0 with which IRFs would have used to report the Transfer of Health Information (TOH) measures and standardized patient assessment data elements (85 FR 27595 through 27596). We also waived the IRF QRP reporting requirements for Q1 (January 1, 2020 through March 31, 2020) and Q2 (April 1, 2020 through June 30, 2020) and modified the required face-to-face visits in IRF such that they could be completed by telehealth [42 CFR 412.622(a)(3)(iv) and 412.29(e)] during the PHE for COVID-19. Additionally, we also made the waiver on the post-admission physician evaluation requirement permanent beginning October 1, 2021 in the FY 2021 IRF PPS final rule (85 FR 48445 through 48447). We believe we have provided a number of flexibilities to provide relief to IRFs throughout the PHE. We have also previously provided IRFs with the necessary tools they would need to implement the new IRF PAI 4.0, including release of the item set in 2019 and draft data specifications in early 2020.

CMS has effectively granted a two-year delay to the originally planned release of the IRF-PAI 4.0, a delay we granted due to the PHE. We believe that there has been a sufficient timeframe for IRFs to adjust to the change in care patterns associated with the PHE.

**Increase burden of collection**

Comment: One commenter stated the new requirements “nearly double the length” from current requirements and the additional time and resources would be significant enough as to have a “ripple-effect throughout IRFs”. This commenter raised concern that CMS’ burden estimate was not representative of the true administrative burden IRFs would face.

Response: We believe the commenter is referring to the estimate of time to complete each IRF-PAI used in the information collection request. However, since the commenter did not provide any alternative information to support their belief that the IRF PAI 4.0 would ‘double the length’ of the current assessment tool, CMS cannot respond specifically to their concern.

However, we do maintain that the estimate of time set forth in the information collection request was the same estimate of time set forth in the FY 2020 IRF PPS final rule. At that time, CMS estimated that the collection of the TOH data elements would add an additional 1.2 minutes in clinical staff time to report data per patient stay. For the standardized patient assessment data elements, CMS estimated an addition of 7.8 minutes on admission and 10.95 minutes on discharge, for a total of 18.8 minutes of additional clinical staff time to report data per patient stay. We received no comments at that time, and no alternative information to suggest these times were in error when the IRF-PAI 4.0 was finalized for FY 2020.

The time-to-complete estimates are based on the National Beta Test, and were calculated using the data from Facility/Agency Staff only, and not Research Nurses, who completed more training and conducted more assessments overall than the Facility/Agency staff. This decision to calculate time-to-complete estimates from Facility/Agency Staff only supports our claim that the time-to-complete estimates are accurate reflections of the time the standardized patient assessment data elements will require when implemented by IRFs in day-to-day operations.

More information on the methods, analysis plan, and results for the National Beta Test are available in the document titled, “Development and Evaluation of Candidate Standardized Patient Assessment Data Elements: Findings from the National Beta Test (Volume 2),” available at [*https://www.cms.gov/​Medicare/​Quality-Initiatives-Patient-Assessment-Instruments/​Post-Acute-Care-Quality-Initiatives/​IMPACT-Act-of-2014/​IMPACT-Act-Downloads-and-Videos.html*](https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html).

**Time for training**

Comment: Both commenters stated they do not believe IRFs are prepared to undergo the necessary training and implementation steps to begin using the IRF-PAI 4.0, and do not believe CMS has provided the necessary training materials in a timely enough manner to sufficiently train their staff. One commenter pointed to the fact that CMS stated training materials would be released in “early 2022” and at the time of their comment letter (dated March 9, 2022), the IRF-PAI manual for the IRF-PAI 4.0 had not be released, and they asserted it would be inappropriate to now require IRFs to implement the IRF-PAI 4.0. One commenter suggested that the IRF-PAI 4.0 documentation and data collection processes would need to be implemented well in advance of October 1, 2022 since some patients have a longer length of stay.

Response: We acknowledge the additional burden that the standardized patient assessment data elements will impose on providers and patients. Our development and selection process for the standardized patient assessment data elements prioritized data elements that are essential to comprehensive patient care. We maintain that there will be significant benefit associated with each of the standardized patient assessment data elements to providers and patients, in that they are clinically useful (for example, for care planning), they support patient-centered care, and they will promote interoperability and data exchange between providers. During the standardized patient assessment data element development process, we were cognizant of the changes that providers will need to make to implement these additions to the IRF-PAI.

We understand provider’s concerns about training their staff for the TOH-Patient measure and TOH-Provider measure items and the standardized patient assessment data elements. As we stated in the FY 2022 HH PPS final rule, we have provided training resources for IRFs to take advantage of, and we will continue to release online learning modules, tip sheets, questions and answers documents and recorded webinars and videos. Specifically, CMS re-released the IRF-PAI Version 4.0 item set on February 25, 2022 and item set change table. On April 1, 2022, both the CMS IRF-PAI Manual Version 4.0 and an accompanying guidance manual change table was released. The change tables will allow IRF providers to easily see what guidance has been added or removed. Both of these resources can be found on the IRF-PAI and IRF QRP Manual webpage at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-PAI-and-IRF-PAI-Manual>. Additionally, CMS will soon be announcing both on-demand and live training opportunities for IRFs on the new items and measures. Finally, the IRF QRP Help Desk is always available to IRFs to answer any questions related to the IRF QRP measures and the Quality Indicators. In fact, the IRF QRP Help Desk has been fielding questions about the new IRF-PAI 4.0 items since last November, shortly after the CY 2022 HH PPS final rule was released.

**Additional feedback on 4.0**

Comment: One commenter stated that CMS should delay the implementation of the IRF-PAI V4.0 so that CMS could gather additional stakeholder feedback on the IRF-PAI 4.0 and refine the IRF-PAI to reduce burden. This commenter suggested using the FY 2023 PPS proposed rule as a vehicle for soliciting stakeholder comments on the IRF-PAI 4.0.

Response: CMS has provided ample opportunity for IRFs to provide feedback on the IRF-PAI 4.0. The clinical standardized patient assessment data elements included in the IRF-PAI 4.0 were the result of an extensive consensus vetting process in which experts and stakeholders were engaged through TEPs, Special Open Door Forums, notice-and-comment rulemaking, and posting of interim reports and other documents on the CMS website. Results of these activities provide evidence that experts and providers believe that the finalized standardized patient assessment data elements have the potential for measuring quality, for describing case mix, and improving care. We refer the commenter to the Improving Medicare Post-Acute Care Transformations (IMPACT) Act of 2014 Data Standardization and Cross Setting Measures webpage where all of the TEP meeting summaries, draft and final specifications, and public comment summary reports are housed at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos>.

The new standardized patient assessment data element items in the IRF-PAI 4.0 are also reflective of patient characteristics that providers are likely already gathering in order to meet hospital conditions of participation, such as patients’ preferred language, race, ethnicity, hearing, vision, health literacy, pain, high-risk drug classes and cognitive function.

**Information systems**

Comment: Both commenters also stated that IRF Information System (IS) Departments have not had adequate time to update their systems to include the IRF-PAI 4.0. They also stated that IRFs’ IS departments are still significantly backlogged as a result of implementing mandatory and time-sensitive COVID-19-related tracking platforms, as well as 2020 and 2021 maintenance releases that were delayed due to the pandemic. Both commenters pointed to the fact that IS departments are likewise burdened with staff shortages, and implementing the IRF-PAI 4.0 would pull them away from other work impacting patient care. One commenter stated that Electronic Health Record (EHR) vendors are not assisting with updating to the IRF-PAI 4.0, and instead tasking local hospital staff with building the appropriate platform, while smaller rehabilitation units may take lower priority in IS updates compared to their acute-care hospital partners.

Response: For over eight years, CMS has been transparent about its intentions and goals to implement standardized patient assessment data elements across post-acute care facilities pursuant to the IMPACT Act of 2014. CMS provided information in the FY 2018 and FY 2019 IRF PPS final rules ([82 FR 36287](https://www.federalregister.gov/citation/82-FR-36287) through [36289](https://www.federalregister.gov/citation/82-FR-36289), [83 FR 38555](https://www.federalregister.gov/citation/83-FR-38555)) about goals, scope, and timeline for implementing standardized patient assessment data elements, as well as updated IRFs about ongoing development and testing of data elements through other public forums. We believe that IRFs have had an opportunity to familiarize themselves with other new reporting requirements that we have adopted under the IMPACT Act and prepare for these changes.

While we acknowledge there will be some updates required of information technology (IT) vendors and systems, we believe a significant portion of the work has already been completed. For example, we posted a change table in November 2019 illustrating the changes that would occur to the IRF-PAI with the transition from the IRF-PAI 3.0 to 4.0. In March 2020, we posted the IRF-PAI Draft Technical Data Submission Specifications. The IRF-PAI 4.0 was not postponed due to the PHE until June 17, 2020, fewer than 4 months before it was to be implemented October 1, 2020. Therefore, we believe that most IRFs would have already made the necessary enhancements to their electronic medical records and flowsheets in preparation for the transition.

**Time points for SDOH collection**

Comment: We received two comments requesting CMS change the requirements for when the social determinants of health (SDOH) standardized patient assessment data elements would be collected. One commenter requested the items not be required at discharge since they believe the data elements are unlikely to change throughout the course of the stay. Specifically, they suggested removing the requirement to collect the Transportation, Health Literacy, the Brief Interview of Mental Status (BIMS), Confusion Assessment Method (CAM), Patient Health Questionnaire (PHQ), Special Treatments, Procedures, and Programs at discharge. One commenter also raised concerns about CMS requiring the same data collection for a patient in an IRF and a long-term care patient living in a skilled nursing facility, calling it ‘redundant’.

Response: We disagree with the commenters that the information is redundant. To support data exchange between settings, and to support quality measurement, section 1899B(b)(1)(A) of the Act requires that the standardized patient assessment data elements be collected with respect to both admission and discharge. For example, we note that a patient's ability to hear or ability to see are more likely to change between admission and discharge. The hearing and vision standardized patient assessment data elements are also different from the other standardized patient assessment data elements (that is, Race, Ethnicity, Preferred Language, and Interpreter Services) because evaluation of sensory status is a fundamental part of the ongoing nursing assessment conducted for IRF patients. Therefore, clinically significant changes that occur in a patient's hearing or vision status during the IRF stay would be captured as part of the clinical record and communicated to the next setting of care, as well as taken into account during discharge planning as a part of standard best practice.

**Flexibility in collection**

Comment: One commenter recommended CMS provide IRFs flexibility in standardized patient assessment data element collection to reduce reporting burden and regulatory duplication. They stated that CMS’ “blanket approach to data collection” across post-acute care (PAC) settings means an IRF is either over-assessing or under-assessing a patient. They do not find this approach to be patient-centered or efficient, and instead believe it increases the cost of care. They suggested that CMS allow providers flexibility to apply measures relevant to a patient’s individual care. Another commenter echoed the theme of flexibility, suggesting that CMS revise the requirements for the SDOH standardized patient assessment data elements to be collected at “some point” during the IRF stay.

Response: We appreciate the commenters' recommendations. However, the COVID-19 PHE has illustrated the important need for these TOH Information measures and standardized patient assessment data elements for all patients under the IRF QRP. The PHE’s disproportionate impact among Black, Latino, and American Indian and Alaska Native (AI/AN) persons[[5]](#footnote-5),[[6]](#footnote-6) demonstrates the importance of analyzing this impact in order to improve quality of care within IRFs especially during a crisis. As stated in section VII.F of the FY 2022 IRF PPS proposed rule (86 FR 19110 through 19112), one important strategy for addressing these important inequities is by improving data collection to allow for better measurement and reporting on equity across PAC programs and policies, and the data collected will support future activities under Executive Order 13985, entitled “Advancing Racial Equity and Support for Underserved Communities Throughout the Federal Government,” issued January 20, 2021 (<https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government>). Allowing IRFs flexibility to collect the information when they determine it necessary would not facilitate the goal of achieving health equity. As always, we will monitor and conduct analysis on the standardized patient assessment data elements as they are submitted in order to identify any problems and to identify any unnecessary burden or duplication

**Increased resource use related to the information**

Comment: One commenter raised concerns that CMS has not addressed reimbursement policies that fail to account for increased resource use related to the IRF-PAI 4.0. The commenter provided an example that if a patient responded yes to the question of whether a “lack of transportation” has kept them “from medical appointments, meetings, work, or from getting things needed for daily living”, then the IRF would be likely to devote resources to address the transportation difficulties. However, they point out that non-emergent transportation is not included in the Medicare fee-for-service benefit.

Response: Transportation barriers commonly affect access to necessary health care, causing missed appointments, delayed care, and unfilled prescriptions, all of which can have a negative impact on health outcomes.[[7]](#footnote-7) Access to transportation for ongoing health care and medication access needs, particularly for those with chronic diseases, is essential to successful chronic disease management. Adopting a data element to collect and analyze information regarding transportation needs across PAC settings will facilitate the connection to programs that can address identified needs.

We believe that this is an important nuance for informing IRF discharge planning to a community setting, as transportation needs for non-medical activities may differ than for medical activities and should be taken into account.[[8]](#footnote-8) We believe that use of this data element will provide sufficient information about transportation barriers to medical and non-medical care for IRF patients so that IRFs can determine the most appropriate methods to facilitate appropriate discharge planning and care coordination.

**Special services, treatments and interventions from claims**

Comment: One commenter suggested that the information IRFs would be required to collect on special services, treatments, and interventions could be obtained by CMS through other methods, such as claims and billing information. They believe CMS should already have access to this information without burdening direct patient care staff with duplicating the information on the IRF-PAI.

Response: We believe that assessment of various special services, treatments, and interventions received by patients in the IRF setting will provide important information for care planning and resource use in IRFs. The assessments of the special services, treatments, and interventions with multiple responses are formatted as a “check all that apply” format. Therefore, when treatments do not apply, the assessor need only check one row for “None of the Above.” Obtaining the information only from claims would also limit the clinical utility of the information. We believe it is clinically appropriate and important to the ultimate usefulness of these standardized patient assessment data elements that they are collected with respect to both admission and discharge.

**No benefit to quality of care**

Comment: One commenter questioned how the new information on the IRF-PAI 4.0 would improve quality of care in IRFs. They believe there will be unintended consequences to a “check-the-box” provision of care that is likely to take time away from more individualized care needs, and believe these requirements would be meaningless for the patient and their needs. This commenter also questioned whether the information would be used to establish a payment methodology or provide an opportunity for marked improvement in care.

Response: CMS believes IRFs must maintain its commitment to the quality of care for all patients, and we continue to believe that the collection of the standardized patient assessment data elements and TOH Information measures will contribute to this effort. That includes staying committed to achieving health equity by improving data collection to better measure and analyze disparities across programs and policies[[9]](#footnote-9),[[10]](#footnote-10),[[11]](#footnote-11),[[12]](#footnote-12),[[13]](#footnote-13),[[14]](#footnote-14) and improving the quality of care in IRFs through a reduction in preventable adverse events. Health information, such as medication information, that is incomplete or missing increases the likelihood of a patient safety risk, and is often life-threatening.[[15]](#footnote-15),[[16]](#footnote-16),[[17]](#footnote-17),[[18]](#footnote-18),[[19]](#footnote-19),[[20]](#footnote-20)  Poor communication and coordination across health care settings contributes to patient complications, hospital readmissions, emergency department visits, and medication errors.[[21]](#footnote-21),[[22]](#footnote-22),[[23]](#footnote-23),[[24]](#footnote-24),[[25]](#footnote-25),[[26]](#footnote-26),[[27]](#footnote-27),[[28]](#footnote-28),[[29]](#footnote-29),[[30]](#footnote-30)  We do not believe that further delaying the data collection is an actionable solution to these concerns.

We also believe that as the healthcare community continues to learn about the enormous impact that SDOH and social risk factors (SRFs) have on patient health and health outcomes,[[31]](#footnote-31) it becomes more critical to collect this in order to better understand the impact of the PHE on our healthcare system, as well as how to improve the inequities that the PHE has made so visible.

**Lower the data completeness threshold**

Comment: One commenter urged CMS to reduce the data completeness threshold for IRFs to be in alignment with other PAC QRPs. At a minimum, they requested CMS lower the data completeness threshold for the first year of reporting the new standardized patient assessment data elements.

Response: We did not propose any changes to the compliance threshold, which has been codified at § 412.634(f). While these comments were out of scope for this notice, we will take these comments under consideration.

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