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OFFICE OF MANAGEMENT AND BUDGET
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CLEARANCE PACKAGE

SUPPORTING STATEMENT-PART A

REVISIONS TO THE IRF-PAI (V4.3) FOR THE COLLECTION OF DATA PERTAINING TO INPATIENT REHABILITATION FACILITY (IRF) PROSPECTIVE PAYMENT SYSTEM (PPS) & QUALITY REPORTING PROGRAM (QRP)

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SUPPORTING STATEMENT-PART A

IRF-PAI
FOR THE COLLECTION OF DATA PERTAINING TO
THE IRF PPS and QRP

TABLE OF CONTENTS

Supporting Statement PART A

IRF-PAI for the collection of data pertaining to the Inpatient Rehabilitation Facility Prospective Payment System and Quality Reporting Program

A. BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) is requesting approval of revisions to the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI) Version 4.3 that will be effective on October 1, 2026.

On August 6, 2024 the Centers for Medicare & Medicaid Services (CMS) published the IRF Prospective Payment System (PPS) for Federal FY 2024 and Updates to the IRF Quality Reporting Program final rule (89 FR 64276) which proposes modifications to the collection of quality reporting data in the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP). Specifically, CMS is finalizing the collection of four new items as standardized patient assessment data elements, the modification of one item collected as a standardized patient assessment data element, and the removal of one item from the IRF-PAI. Per the Final Rule, CMS will require IRFs to start collecting these new and modified assessment data using the IRF-PAI Version 4.3 for IRF patients beginning October 1, 2026. Per the Final Rule, CMS will remove one item from the IRF-PAI effective October 1, 2026. However, IRFs will no longer be required to collect and submit data on this item beginning with patients admitted on October 1, 2024. The IRF PPS Final Rule is available here: https://www.federalregister.gov/documents/2024/08/06/2024-16911/medicare-program-inpatient-rehabilitation-facility-prospective-payment-system-for-federal-fiscal.

CMS is asking for approval of the IRF-PAI Version 4.3, which will have an October 1, 2026 implementation date. The IRF-PAI Version 4.2 will have a runoff period through September 30, 2026 and sunset when the IRF-PAI Version 4.3 takes effect on October 1, 2026.

B. JUSTIFICATION

1. Need and Legal Basis

This instrument with its supporting manual is needed to permit the Secretary of Health and Human Services, and CMS, to implement Section 1886(j) of the Social Security Act, 42 U.S.C. 1395ww(j), as enacted by §4421 of the Balanced Budget Act of 1997 (BBA), Pub. L. No. 105-33. The statute requires the Secretary to develop a prospective payment system for inpatient rehabilitation facility services for the Medicare program. This payment system is to cover both operating and capital costs for inpatient rehabilitation facility services. It applies to inpatient rehabilitation hospitals as well as rehabilitation units of acute care hospitals, both of which are exempt from the current PPS for inpatient hospital services. CMS implemented the inpatient rehabilitation facility prospective payment system for cost reporting periods beginning on or after January 1, 2002.

The statute requires that the prospective payment system for each Medicare rehabilitation facility be based on patient case mix groups and directs the Secretary to “establish classes of patients of rehabilitation facilities based on such factors as the Secretary deems appropriate, which may include impairment, age, related prior hospitalization, comorbidities, and functional capability of the patient, as well as a method of classifying specific patients in rehabilitation facilities within these groups.” In addition, for each case mix group the Secretary shall assign an appropriate weighting which reflects the relative facility resources used with respect to patients classified within that group compared to patients classified within other groups. The statute gives the Secretary authority to require inpatient rehabilitation facilities to submit data as the Secretary deems necessary to establish and administer the prospective payment system. Thus, a comprehensive, reliable system for collecting standardized

patient assessment data is necessary for: 1) the objective assignment of Medicare beneficiaries to appropriate Case Mix Groups (CMGs); 2) the development of a system to monitor the effects of an inpatient rehabilitation facility prospective payment system on patient care and outcomes; 3) the determination of whether future adjustments to the CMGs are warranted; and 4) the development of an integrated system for post-acute care in the future.

Since October 1, 2012, the IRF-PAI has also been used to collect quality measure data, using data items in the Quality Indicator section, as required by Section 1886(j)(7) of the Social Security Act added by section 3004 of the Patient Protection and Affordable Care Act[1]. The statute requires the Secretary to establish a quality reporting program for inpatient rehabilitation facilities (IRFs), which was established in the FY 2012 IRF PPS final rule (76 FR 47873 through 47883)[2]. Further, section 1886(j)(7)(A)(i) of the Act requires the Secretary to reduce the increase factor with respect to a fiscal year by 2 percentage points for any IRFs that do not submit data to the Secretary in accordance with requirements established by the Secretary for that fiscal year, beginning in fiscal year 2014.

Section 2(a) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113-185, enacted on Oct. 6, 2014), requires that the Secretary specify not later than the applicable specified application date, as defined in section 1899B(a)(2)(E), quality measures on which IRF providers are required to submit standardized patient assessment data described in section 1899B(b)(1) and other necessary data specified by the Secretary. Section 1899B(c)(2)(A) requires, to the extent possible, the submission of the such quality measure data through the use of a post-acute care (PAC) assessment instrument and the modification of such instrument as necessary to enable such use; for IRFs, this requirement refers to the Inpatient Rehabilitation Facility – Patient Assessment Instrument (IRF-PAI).

2. Information Users

The IRF-PAI is required by the CMS as part of the Inpatient Rehabilitation Facility Prospective Payment System (IRF PPS). CMS uses the data to determine the payment for each Medicare Part A fee-for-service patient admitted to an inpatient rehabilitation unit or hospital.

The IRF-PAI is also used to gather data for the IRF Quality Reporting Program (IRF QRP). Section 3004(b) of the Affordable Care Act requires the Secretary to establish the IRF QRP. Beginning with the FY 2014 IRF QRP, the Secretary is required to reduce any annual update to the standard federal rate for discharges occurring during such fiscal year by 2 percentage points for any IRF that does not comply with the requirements established by the Secretary. The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) enacted new data reporting requirements for IRFs. All of the data that must be reported in accordance with section 1899B(a)(1)(A) must be standardized and interoperable so as to allow for the exchange of the information among PAC providers and other providers and the use of such data in order to enable access to longitudinal information and to facilitate coordinated care. The FY 2023 IRF PPS final rule (87 FR 47038) finalized the collection of IRF-PAI assessment data on each patient receiving care in an IRF, regardless of payer. IRFs will be required to report these data with respect to admission and discharge of all patients, regardless of payer, discharged beginning October 1, 2024.

In addition, the public/consumer is a data user, as CMS is required to make IRF QRP data available to the public after ensuring that an IRF has the opportunity to review its data prior to public display. Measure data is currently displayed on the Inpatient Rehabilitation Facility Compare Web site, at https://www.medicare.gov/inpatientrehabilitationfacilitycompare/.

[1] Patient Protection and Affordable Care Act. Pub. L. 111-148. Stat. 124-119. 23 March 2010. Web. http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf.

[2] Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2012, Federal Register/Vol 76, No. 151, Friday, August 5, 2011. https://www.gpo.gov/fdsys/pkg/FR-2011-08-05/pdf/2011-19516.pdf

3. Use of Information Technology

CMS uses information technology to decrease the burden associated with data collection of the IRF-PAI. This is accomplished through strategies that (1) streamline information and submission processes, (2) minimize costly documentation requirements, and (3) utilize information technology for improving communication.

First, CMS creates data collection specifications for IRF electronic health record (EHR) software with 'skip' patterns to ensure the IRF-PAI is limited to the minimum data required to meet quality reporting requirements and to calculate IRF payment. These specifications are available free of charge to all IRFs and their technology partners. Further, these minimum requirements are standardized for all users of the IRF-PAI assessment forms. CMS also provides flexibility to IRFs by giving them the option of recording the required data on a printed form and later transferring the data to electronic format or they can choose to directly enter the required data electronically to the CMS designated submission system, which is currently used by Inpatient Rehabilitation Facilities (IRFs), Skilled Nursing Facilities (SNFs), Long-Term Care Hospitals (LTCHs), and Home Health Agencies (HHAs).

Second, CMS has minimized costly documentation requirements by allowing IRFs to electronically self-attest to the accuracy of the data in the IRF-PAI prior to transmitting the IRF-PAI, eliminating the need for supportive documentation to be submitted with the IRF-PAI. CMS has also developed customized software that allows IRFs to encode, store and transmit the IRF-PAI data. The software is available free of charge on the CMS Website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/index.html?redirect=/InpatientRehabFacPPS/06_Software.asp. Additionally, the software delivers real-time warnings to the IRF when the data is incomplete. IRFs receive warnings when the data is accepted by the system but may be incomplete for purposes of quality reporting submission. IRFs receive fatal warnings when the data collection form is not accepted by the system for any reason.

Third, we provide customer support for software and transmission problems encountered by the providers. IRFs have the ability to self-select their preferred method of communication. For example, we have dedicated help desks to respond to questions about issues IRFs may encounter with the software. We also offer IRFs the ability to sign up for listservs that send out timely and important new information, reminders, and alerts via electronic mail related to the software. CMS has also established a website to assist providers with questions regarding the IRF-PAI, at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html. This website publishes new information related to the IRF-PAI, houses archived versions of the tool, and is available at all times to IRFs.

4. Duplication of Efforts

The data required for reimbursement and monitoring the effects of an inpatient rehabilitation facility prospective payment system on patient care and outcomes are not available from any other source. This data collection for the QRP does not duplicate any other effort and the standardized data cannot be obtained from any other source. There are no other data sets that will provide comparable information on patients admitted to IRFs.

5. Small Businesses

As part of our PRA analysis for an update of our existing approval, we again considered whether the change impacts a significant number of small entities. Out of a total of 1,160 IRFs, only 144 or 12% are rural IRFs, 13% of which are government-owned.[3] The average number of assessments completed annually is 492 per IRF, and is the same across all respondents based on the number of actual assessments completed by IRFs in fiscal year 2023.

[3] FY 2025 IRF PPS Final Rule; 89 FR 64334.

CMS requests authorization for IRFs to use the updated IRF-PAI 4.3 for the submission of quality measure information finalized in the FY 2025 IRF PPS final rule. Provider participation in the submission of quality data is mandated by Section 3004 of the Affordable Care Act and Section 1899B(c)(2)(A) of the IMPACT Act. Small business providers viewing the data collection as a burden can elect not to participate. However, if an IRF does not submit the required quality data, this provider shall be subject to a 2% reduction in their payment update for the standard Federal rate for discharges from that IRF during that rate year.

6. Less Frequent Collection

We need to collect the data on the IRF-PAI at the required frequency (that is, at admission and at discharge from the IRF) in order to calculate payment and any possible payment penalty under the IRF PPS. This data frequency is also required for the purposes of measures calculation.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

The FY 2025 IRF PPS Notice of Proposed Rulemaking (NPRM) (89 FR 22246) was published on March 29, 2024. In response to the NPRM, CMS received four comments related to the proposed burden estimate. Three commenters urged CMS to update its estimate of the change in burden resulting from these new IRF QRP changes to account for the costs associated with training and education, time required to administer and reconcile patient assessments, and costs associated with software development and other required technical updates. One commenter asked CMS to recognize that administrative requirements are already overburdening the IRF workforce and incorporating these new standardized patient assessment data elements would further decrease resources from patient care. CMS responded to those comments in the FY 2025 PPS Final Rule that was displayed on July 31, 2024.

The FY 2025 IRF PPS Final Rule (89 FR 64276) was published on August 6, 2024, and can be found here: https://www.federalregister.gov/documents/2024/08/06/2024-16911/medicare-program-inpatient-rehabilitation-facility-prospective-payment-system-for-federal-fiscal.

CMS informed the provider community on July 31, 2024. A reference to the announcement can be found on the IRF QRP webpage found here https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/irf-quality-reporting/spotlights-announcements.

a) Consideration of Burden of Information Collection Requests

CMS continually looks for opportunities to minimize burden associated with collection of the IRF-PAI for information users through strategies that (1) simplify collection and submission requirements, (2) improve IRF-PAI comprehension, and (3) enhance communication, navigation, and outreach, (4) minimize learning costs, and (5) provide flexible time frames for data submission.

First, interviews are conducted with information users before new items are introduced. The interviews provide valuable evidence in order to ensure the item(s) are precise and result in meaningful information.

Second, improving IRF-PAI comprehension is a priority. A number of strategies are used, including standardizing the collection instructions across all IRFs, ensuring that all instructions and notices are written in plain language, and by providing step-by-step examples for completing the IRF-PAI. Human-centered design best practices are used, such as prioritizing key communication in headings, text boxes, and bold text. Close attention is paid to the amount of information required in the forms so that only the necessary data is collected on the IRF-PAI.

Third, CMS looks for opportunities to improve communication with users and conducts outreach. CMS provides a dedicated help desk to support users and respond to questions about the data collection. Additionally, a dedicated IRF QRP webpage houses multiple modes of tools, such as instructional videos, case studies, user manuals, and frequently asked questions which support understanding of the IRF-PAI, and can be used by current and assist new users of the IRF-PAI. CMS utilizes a listserv to facilitate outreach to users, such as communicating timely and important new material(s), as well as reminders and alerts related to the IRF-PAI completion. Finally, CMS provides a free internet-based system through which users can access on-demand reports for feedback on the collection of the IRF-PAI associated with their facility.

Fourth, CMS is aware of the learning costs that IRFs may incur when new data collection is required. CMS provides multiple free training resources and opportunities for IRFs to use, reducing the burden to IRFs in creating their own training resources. These training resources include live training, online learning modules, tip sheets, and/or recorded webinars and videos. Having the materials online and on-demand gives IRFs the flexibility to use the materials in a group setting or on an individual basis at times that work for them.

Fifth, CMS allows up to 4.5 months for IRFs to submit all data required in this information collection, providing ample time for data submission. CMS acknowledges that some small providers may experience difficulties complying with data collection requirements, and having additional time may reduce the stress and anxiety IRF providers may experience.

9. Payment/Gifts to Respondents

There will be no payments/gifts to respondents for the use of the IRF-PAI. However, per § 412.604, IRFs must complete the IRF-PAI as a condition for payment under the IRF PPS. If an IRF fails to comply fully, CMS may withhold (in full or in part) or reduce Medicare payment to the IRF.

10. Confidentiality

The system of records (SOR) establishes privacy stringent requirements. The IRF-PAI SORN (09-70-0521) was published in the Federal Register on November 9, 2001 (66 FR 56681-56687). A SOR modification notice was published in the Federal Register on November 20, 2006 (71 FR 67143).

CMS has also provided, as part of the current Manual, a section that addresses in writing statements of confidentiality consistent with the Privacy Act of 1974. All patient-level data is protected from public dissemination in accordance with the Privacy Act of 1974, as amended. The data collected is protected and held confidential in accordance with 20 CFR 401.3. Data will be treated in a confidential manner, unless otherwise compelled by law.

11. Sensitive Questions

There are no sensitive questions on the IRF-PAI.

12. Burden Estimates (Hours & Wages)

The burden associated with the IRF QRP is the time and effort required for complying with the IRF QRP. The estimated burden for completing the IRF-PAI was established in the FY 2002 IRF PPS Final Rule. Since the establishment of the IRF PAI, CMS has calculated programmatic burden accounting for the time and cost it takes an IRF to encode the IRF PAI, prepare the data for electronic submission, and transmit the data to CMS. Our estimates of time to complete new items is based on past IRF burden calculations, and our assumptions for staff type are based on the categories generally necessary to collect this data, and subsequently encode it.[4] However, individual providers determine

[4] FY 2002 Final Rule (66 FR 41316), FY 2015 Final Rule (79 FR 45872), FY 2016 Final Rule (80 FR 47036), FY 2020 Final Rule (84 FR 39054), FY 2023 Final Rule (87 FR 47038), FY 2024 Final Rule (88 FR 50956)

their own processes to collect the information and the staffing resources necessary to collect it. We acknowledge that some IRFs will incur a higher cost than was estimated, while some IRFs will incur a lower cost.

a) Assessing Burden of Information Collection

When adding a new assessment item to the IRF PAI, CMS takes several considerations, assessing the need for collection and burden associated with complying with the IRF QRP. These considerations include a functional description of the item, evaluating the need for the collection, and providing a specific, objectively supported estimate of the burden we anticipate these new collections will impose on IRFs. We have outlined these considerations in the FY2025 IRF PPS final rule and in this section under assessment item proposals that we anticipate will add burden when completing the IRF-PAI 4.3.

In the FY 2025 IRF PPS final rule, we finalized the removal of one item from the IRF-PAI 4.2, which we estimate will decrease burden. Overall, we estimate an increase in the total burden incurred for the FY 2028 IRF QRP as a result of these proposals becoming final.

b) Collection of Four New Items as Standardized Patient Assessment Data Elements and Modification of One Item Collected as a Standardized Patient Assessment Data Element Beginning with the FY 2028 IRF QRP

In the FY 2025 IRF PPS Final Rule (89 FR 64310 to 64323), CMS finalized a requirement for IRFs to report the following four new items to be collected as standardized patient assessment data elements in the IRF-PAI under the Social Determinants of Health (SDOH) category under the IRF QRP: one item for Living Situation; two items for Food; and one item for Utilities. CMS also finalized the modification of one of the current items collected as standardized patient assessment data under the SDOH category. IRFs will be required to report these data with respect to admission of all patients, regardless of payer, discharged beginning October 1, 2026. As a result, the estimated burden and cost for IRFs for complying with requirements of the FY 2028 IRF QRP will increase. Specifically, we believe there will be 0.015 hour increase in clinical staff time to report data per patient stay.

Functional Description of the items: The new items and modified item are collected at admission to the IRF. The Living Situation item asks "What is your living situation today?" The response options are: (1) I have a steady place to live; (2) I have a place to live today, but I am worried about losing it in the future; (3) I do not have a steady place to live; (7) Patient declines to respond; and (8) Patient unable to respond. The first Food item states, "Within the past 12 months, you worried that your food would run out before you got money to buy more." The second Food item states, "Within the past 12 months, the food you bought just didn't last and you didn't have money to get more." We finalized the same response options for both items: (1) Often true; (2) Sometimes true; (3) Never True; (7) Patient declines to respond; and (8) Patient unable to respond. The Utilities item asks, "In the past 12 months, has the electric, gas, oil, or water company threatened to shut off services in your home?" The response options are: (1) Yes; (2) No; (3) Already shut off; (7) Patient declines to respond; and (8) Patient unable to respond. The Transportation item asks, "In the past 12 months, has a lack of reliable transportation kept you from medical appointments, meetings, work or from getting things needed for daily living?" The response options are: (0) Yes; (1) No; (7) Patient declines to respond; and (8) Patient unable to respond. A draft of what the new and modified items will look like can be found in the Downloads section of the IRF-PAI and IRF-PAI Manual webpage and readers can view it at *https://www.cms.gov/medicare/quality/inpatient-rehabilitation-facility/irf-pai-and-irf-qrp-manual*. The final IRF-PAI 4.3, which includes these items, can be found in the Downloads section of the IRF-PAI and IRF-PAI Manual webpage and readers can view it at *https://www.cms.gov/medicare/quality/inpatient-rehabilitation-facility/irf-pai-and-irf-qrp-manual.*

Evaluation of the need for the items: Section 1899B(b)(1)(B)(vi) of the Act authorizes the Secretary to collect standardized patient assessment data elements with respect to other categories deemed necessary and appropriate. Accordingly, we finalized the creation of the SDOH category of standardized patient assessment data elements in the FY 2020 IRF PPS final rule (84 FR 39149pr through 39161), and defined SDOH as the socioeconomic, cultural, and environmental circumstances in which individuals live that impact their health.[5] According to the World Health Organization, research shows that the SDOH can be more important than health care or lifestyle choices in influencing health, accounting for between 30-55% of health outcomes.[6] This is a part of a growing body of research that highlights the importance of SDOH on health outcomes. Access to standardized data relating to SDOH on a national level permits us to conduct periodic analyses, and to assess their appropriateness as risk adjustors or in future quality measures. Our ability to perform these analyses and to make adjustments relies on existing data collection of SDOH items from PAC settings. The SDOH items we are finalizing as standardized patient assessment data elements under the SDOH category in this final rule were also identified in the 2016 NASEM report[7] or the 2020 NASEM report[8] as impacting care use, cost, and outcomes for Medicare beneficiaries. The items have the capacity to take into account treatment preferences and care goals of patients and their caregivers, to inform our understanding of patient complexity and SDOH that may affect care outcomes, and ensure that IRFs are in a position to impact through the provision of services and supports, such as connecting patients and their caregivers with identified needs with social support programs.

Estimate of the Burden: Using data from fiscal year 2023, we estimated 571,151 admission assessments from 1,160 IRFs annually and 492 admission assessments per IRF. This equates to an increase of 8,859.64 hours in burden for all IRFs [(0.020 hour x 571,151 admissions) minus (0.005 x 512,677 planned discharges)]. We believe the IRF-PAI items affected by the proposal to collect four new items and modify one item are completed by Registered Nurses (RN) and Licensed Practical and Licensed Vocational Nurses (LVN). Therefore, we averaged the national median for these labor types and established a composite cost estimate of $65.31. This composite estimate was calculated by weighting each salary based on the following breakdown regarding provider types most likely to collect this data: RN 50 percent and LVN 50 percent. For the purposes of calculating the costs associated with the collection of information requirements, we obtained median hourly wages for these staff from the U.S. Bureau of Labor Statistics' (BLS) May 2022 National Occupational Employment and Wage Estimates.[9] To account for overhead and fringe benefits, we have doubled the hourly wage. These amounts are detailed in Table 1.

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[5] Office of the Assistant Secretary for Planning and Evaluation (ASPE). Second Report to Congress on Social Risk and Medicare's Value-Based Purchasing Programs. June 28, 2020. Available at: *https://aspe.hhs.gov/reports/second-report-congress-social-risk-medicares-value-based-purchasing-programs*.

[6] World Health Organization. Social determinants of health. Available at: *https://www.who.int/health-topics/social-determinants-of-health#tab=tab_1*.

[7] Social Determinants of Health. Healthy People 2020. *https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health*. (February 2019).

[8] National Academies of Sciences, Engineering, and Medicine. 2020. Leading Health Indicators 2030: Advancing Health, Equity, and Well-Being. Washington, DC: The National Academies Press. https://doi.org/10.17226/25682.

[9] https://www.bls.gov/oes/current/oes_nat.htm.

Table 1. U.S. Bureau of Labor and Statistics' May 2022 National Occupational Employment and Wage Estimates.

Occupation title	Occupation code	Median Hourly Wage ($/hr)	Overhead and Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Registered Nurse (RN)	29-1141	$39.05	$39.05	$78.10
Licensed Vocational Nurse (LVN)	29-2061	$26.26	$26.26	$52.52

We estimated that the total cost will increase by $578,622.76 for all IRFs annually [($78.10 x (8,859.64 hours)/2)] + [($52.52 x (8,859.64 hours)/2)], or $498.81 per IRF annually ($578,622.76 total reduction/1,160 IRFs) based on the finalization of the requirement for IRFs to report four new items to be collected as standardized patient assessment data elements in the IRF-PAI and the modification of one of the current items collected as standardized patient assessment data under the SDOH category.

Burden Hours and Cost Calculation for IRF-PAI V4.3 for the FY 2028 IRF QRP:

Average number of IRFs in U.S. in 2023[10]	1,160
Average number of IRF-PAI admission reports submitted per each IRF for the FY 2026 IRF QRP	492
Average number of IRF-PAI admission reports submitted for all IRFs for the FY 2026 IRF QRP	571,151
Minutes to complete each IRF-PAI	106.6
Increase in minutes to complete each IRF-PAI	0.9
Increase in Hours for each IRF annually	7.64
Increase in Hours for all IRFs annually	8,859.64
Previous Cost Burden for all IRFs per year	$82,529,360.56
New Cost Burden for all IRFs beginning with the FY 2028 IRF QRP	$83,107,983.32

c) Removal of the Admission Class Item From the IRF-PAI Beginning October 1, 2026

In the FY 2025 IRF PPS Final Rule (89 FR 64328 and 64329), CMS is finalizing the removal of Item 14 entirely from the IRF-PAI, beginning October 1, 2026. However, IRFs will no longer be required to collect and submit data on Item 14 beginning with patients admitted on October 1, 2024. As a result, the estimated burden and cost for IRFs for complying with requirements of the IRF-PAI collection and submission will decrease. Specifically, we believe there will be a decrease of 0.005 hours of clinical staff time to report data per patient stay.

Using data from fiscal year 2023, we estimate 571,151 admission assessments from 1,160 IRFs annually and 492 admission assessments per IRF. This equates to a decrease of 2,855.76 hours in burden for all IRFs (0.005 hour × 571,151 admissions). We believe the IRF-PAI item affected by the proposal to remove the Admission Class item from the IRF-PAI is completed by Registered Nurses (RN) and Licensed Practical and Licensed Vocational Nurses (LVN). Therefore, we averaged the national median for these labor types and established a composite cost estimate of $65.31. This composite estimate was calculated by weighting each salary based on the following breakdown regarding provider types most likely to collect this data: RN 50 percent and LVN 50 percent. For the purposes of calculating the costs associated with the collection of information requirements, we obtained median hourly wages for these staff from the U.S. Bureau of Labor Statistics' (BLS) May 2022 National Occupational Employment and Wage Estimates.[11] To account for overhead and fringe benefits, we have doubled the hourly wage. These amounts are detailed in Table 1.

[10] FY 2025 IRF PPS Final Rule; 89 FR 64335 and 64336.

We estimated that the total cost will decrease by $186,509.36 for all IRFs annually [($78.10 x (2,855.76 hours)/2)] + [($52.52 x (2,855.76 hours)/2)], or $160.78 per IRF annually ($186,509.36 total reduction/1,160 IRFs) based on the removal of the Admission Class item from the IRF-PAI.

Burden Hours and Cost Calculation for IRF-PAI V4.3 beginning with the FY 2028 IRF QRP:

Average number of IRFs in U.S. in 2023	1,160
Average number of IRF-PAI admission reports submitted per each IRF for the FY 2026 IRF QRP	492
Average number of IRF-PAI admission reports submitted for all IRFs for the FY 2026 IRF QRP	571,151
Minutes to complete each IRF-PAI	106.6
Decrease in minutes to complete each IRF-PAI	(0.3)
Decrease in Hours for each IRF annually	(2.46)
Decrease in Hours for all IRFs annually	(2,855.76)
Previous Cost Burden for all IRFs for the FY 2028 IRF QRP	$83,107,983.32
New Cost Burden for all IRFs beginning with the FY 2028 IRF QRP	$82,921,473.96

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

The Department of Health & Human Services (DHHS) will incur costs associated with the administration of the IRF QRP including costs associated with the IT system used to process IRF submissions to CMS and analysis of the data received.

CMS has engaged the services of an in-house CMS contractor to create and manage an online reporting/IT platform for the IRF-PAI. This contractor works with the CMS Center for Clinical Standards and Quality, Division of Post-Acute and Chronic Care (DCPAC) in order to support the IT needs of multiple quality reporting programs. When IRF providers transmit the data contained within the IRF-PAI to CMS it is received by this contractor. Upon receipt of all data sets for each quarter the contractor performs some basic analysis which helps to determine each provider's compliance with the reporting requirements of the IRF QRP. The findings are communicated to the IRF QRP lead in a report. Contractor costs include the development, testing, and roll-out of updates to data submission systems.

DCPAC had also retained the services of a separate contractor for the purpose of performing a more in-depth analysis of the IRF quality data, as well as the calculation of the quality measures, and future public reporting of the IRF quality data. Said contractor will be responsible for obtaining the IRF quality reporting data from the in-house CMS contractor. They will perform statistical analysis on this data and prepare reports of their findings, which will be submitted to the IRF QRP lead.

DCPAC has retained the services of a third contractor to assist us with provider training and support services related to the IRF QRP.

In addition to the contractor costs, the total includes the cost of the following Federal employees:

- GS-13 (locality pay area of Washington-Baltimore-Northern Virginia) at 100% effort for 3 years, or $353,886.
- GS-14 (locality pay area of Washington-Baltimore-Northern Virginia) at 33% effort for 3 years, or $139,395.

[11] https://www.bls.gov/oes/current/oes_nat.htm.

The estimated cost to the federal government for the contractor is as follows:

CMS in-house contractor – Maintenance and support of IT platform that supports the IRF-PAI	$750,000
Data analysis contractor	$1,000,000
Provider training & helpdesk contractor	$1,000,000
GS-13 Step 1 Federal Employee (100% X 3 years at $117,962 annually)	$353,886
GS-14 Step 1 Federal Employee (33% X 3 years at $46,465 annually)	$139,395
Total cost to Federal Government:	**$3,243,281**

15. Changes to Burden

Since the IRF PAI 4.2 was approved, new information demonstrates a change in both the number of IRFs and the number of IRF-PAI assessments completed per IRF. The number of IRFs has increased from 1,133 to 1,160.

We estimated an increase in the amount of time it will take to complete a single IRF PAI 4.3 as compared to the IRF PAI 4.2. As finalized, the burden will increase from 106 minutes to 106.6 minutes and 1,188,810 hours across all IRFs to 1,194,814 hours across all IRFs beginning October 1, 2026 [(1,188,810 + (1,160 IRFs x 7.64 hr increase/IRF for FY 2028 IRF QRP) = 1,197,670)]; [(1,197,669.64 - (1,160 IRFs x 2.46 hr decrease/IRF for FY 2028 IRF QRP) = 1,194,814)].

16. Publication/Tabulation Dates

For the final changes to the IRF-PAI Version 4.3 related to the IRF QRP, the final rule was published in the Federal Register on August 6, 2024 (89 FR 64276). The final IRF-PAI 4.3 item set can be found here: https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/irf-quality-reporting/irf-pai-and-irf-pai-manual. The IRF-PAI Version 4.2 will have a runoff period through September 30, 2026 and sunset when the IRF-PAI Version 4.3 takes effect on October 1, 2026

17. Expiration Date

The OMB expiration date will be displayed on all disseminated data collection materials.

18. Certification Statement

There are no exceptions to the certifications statement.

APPENDIX A: FINAL IRF-PAI VERSION 4.3

See attached PDF.