

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES**

**OFFICE OF MANAGEMENT AND BUDGET
PAPERWORK REDUCTION ACT
CLEARANCE PACKAGE**

SUPPORTING STATEMENT-PART A

REVISIONS TO THE IRF-PAI (V4.2)
FOR THE COLLECTION OF DATA
PERTAINING TO
INPATIENT REHABILITATION FACILITY (IRF) PROSPECTIVE PAYMENT SYSTEM (PPS) &
QUALITY REPORTING PROGRAM (QRP)

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.....1

A. Background.....3

B. Justification.....3

1. Need and Legal Basis.....3

2. Information Users.....4

3. Use of Information Technology.....5

4. Duplication of Efforts.....6

5. Small Businesses.....6

6. Less Frequent Collection.....6

7. Special Circumstances.....6

8. Federal Register/Outside Consultation.....6

9. Payment/Gifts to Respondents.....8

10. Confidentiality.....8

11. Sensitive Questions.....9

12. Burden Estimates (Hours & Wages).....9

b) Proposal to Remove the IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients Measure, and the IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients Measure Beginning with the FY 2025 IRF QRP.....9

c) Proposal to Remove the Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function Measure Beginning with the FY 2025 IRF QRP.....9

d) Proposed Adoption of the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date Measure Beginning with the FY 2026 IRF QRP.....10

13. Capital Costs.....11

14. Cost to Federal Government.....11

15. Changes to Burden.....12

16. Publication/Tabulation Dates.....12

17. Expiration Date.....13

18. Certification Statement.....13

APPENDIX A: draft IRF-PAI Version 4.2.....13

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 4.2 that will be effective on October 1, 2024.

On August 2, 2023 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 (88 FR 50956) which finalizes modifications to the collection of quality reporting data in the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP). Specifically, CMS adopted two new measures and removed three measures from the IRF QRP. Per the Final Rule, CMS will require IRFs to start collecting assessment data using the IRF-PAI Version 4.2 for IRF patients beginning October 1, 2024. The IRF PPS Final Rule is available here: <https://www.federalregister.gov/documents/2023/08/02/2023-16050/medicare-program-inpatient-rehabilitation-facility-prospective-payment-system-for-federal-fiscal#citation-47-p51001fiscal>.

CMS is asking for approval of the IRF-PAI Version 4.2, which would have an October 1, 2024 implementation date.

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 Act¹. 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 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 and Medicare Part C (Medicare Advantage) 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.

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/>.

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.

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>

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.

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 (her) 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), Long-Term Care Hospitals (LTCHs), and Home Health Agencies (HHAs), and will be used by Skilled Nursing Facilities (SNFs) beginning in calendar year 2023.

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](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/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 1,133 IRFs, only 147 or 13% are rural IRFs, 14% of which are government-owned. The average number of assessments completed annually is 454 per IRF, and is the same across all respondents based on the number of actual assessments completed by IRFs in calendar year 2022.

CMS requests authorization for IRFs to use the updated IRF-PAI 4.2 for the submission of quality measure information finalized in the FY 2024 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 2024 IRF PPS Notice of Proposed Rulemaking (88 FR 20950) was published on April 7, 2023. In response to the NPRM, CMS received five comments related to the proposed burden estimate. The comments were primarily about the burden associated with the IRF QRP requirements

in the wake of the COVID-19 pandemic. Commenters said that although CMS was removing three measures from the IRF QRP, there was still a net increase in burden associated with the two new measures proposed (and adopted) for the FY 2024 IRF PPS rule. Commenters specifically pointed to the DC Function Score measure proposed (and adopted) for the FY 2025 IRF QRP, and noted that IRF software systems would require updates to accommodate the implementation and monitoring of the measure's calculations. Additionally, two commenters stated the time allocated for the collection of the Patient/Resident COVID-19 Vaccine measure was underestimated. CMS responded to those comments in the FY 2024 PPS Final Rule that was published on August 2, 2023. Please see the response to comments document.

The FY 2024 IRF PPS Final Rule (88 FR 50956) was published on August 2, 2023. The two, new measures (see B.1.a. and B.1.b.) and three measure removals (see B.1.c. and B.1.d.) were finalized. As a result, IRFs will collect IRF-PAI data using the IRF PAI 4.2 beginning with patients discharged October 1, 2024. This final rule can be found here:

<https://www.federalregister.gov/documents/2023/08/02/2023-16050/medicare-program-inpatient-rehabilitation-facility-prospective-payment-system-for-federal-fiscal#citation-47-p51001>.

CMS informed the provider community on July 27, 2023. 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>.

9. Payment/Gifts to Respondents

There will be no payments/gifts to respondents for the use of the IRF-PAI.

10. Confidentiality

The system of records (SOR) establishes privacy stringent requirements. The IRF-PAI SOR 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)

In this section, we provide burden estimates, provided in the IRF PPS FY 2024 final rule, associated with the collection of new information requirements for the IRF QRP using the IRF-PAI 4.2.

We note that the burden associated with the measures and data elements related to the IMPACT Act of 2014 have been exempt from the PRA. Section 1899B(m) and the sections referenced in section 1899B(a)(2)(B) of the Act exempt modifications that are intended to achieve the standardization of patient assessment data.

a) Adoption of the Discharge Function Score Measure Beginning with the FY 2025 IRF QRP

In the FY 2024 IRF PPS Final Rule (88 FR 51009 to 51023), CMS adopted the Discharge Function Score measure beginning with the FY 2025 IRF QRP. This new measure will be calculated with

existing data elements reported by IRFs for other payment and quality reporting purposes. As a result, the adoption of this measure has no effect on burden and costs for IRFs.

- b) Removal of the IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients Measure and the IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients Measure Beginning with the FY 2025 IRF QRP

In the FY 2024 IRF PPS Final Rule (88 FR 51024 to 51026), CMS finalized the removal of the IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients measure and the IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients measure beginning with the FY 2025 IRF QRP. IRFs are no longer required to submit data on these measures beginning with patients discharged on October 1, 2023. Although these two measures are removed from the IRF QRP, the data elements used to calculate the measures will still be reported by IRFs for other payment and quality reporting purposes. As a result, the removal of these measures has no effect on burden and costs for IRFs.

- c) Removal of the Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function Measure Beginning with the FY 2025 IRF QRP

In the FY 2024 IRF PPS Final Rule (88 FR 51023 to 51024), CMS finalized the removal of the Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function Measure beginning with the FY 2025 IRF QRP. IRFs are no longer be required to submit data on this measure beginning with patients discharged on October 1, 2023. Although this measure is removed from the IRF QRP, some of the data elements used to calculate the measure will still be reported by IRFs for other payment and quality reporting purposes. As a result, the estimated burden and cost for IRFs for complying with requirements of the FY 2025 IRF QRP will decrease. Specifically, we believe there will be 0.005 hour reduction in clinical staff time to report data per patient stay.

Using data from calendar year 2021, we estimate 511,938 admission assessments from 1,133 IRFs annually and 454 admission assessments per IRF. This equates to a decrease of 2,560 hours in burden for all IRFs ($0.005 \text{ hour} \times 511,938 \text{ admissions}$) and 2.26 hours burden reduction for each IRF ($2,560 \text{ total hours} / 1,133 \text{ IRFs}$). We believe the IRF-PAI item affected by the proposed removal of the Application of Functional Assessment/Care Plan measure is completed by Occupational Therapists (OT), Physical Therapists (PT), Registered Nurses (RN), Licensed Practical and Licensed Vocational Nurses (LVN), and/or Speech-Language Pathologists (SLP) depending on the functional goal selected. Therefore, we averaged the national average for these labor types and established a composite cost estimate of \$86.21. This composite estimate was calculated by weighting each salary based on the following breakdown regarding provider types most likely to collect this data: OT 45 percent; PT 45 percent; RN 5 percent; LVN 2.5 percent; SLP 2.5 percent. For the purposes of calculating the costs associated with the collection of information requirements, we obtained mean hourly wages for these staff from the U.S. Bureau of Labor Statistics' (BLS) May 2021 National Occupational Employment and Wage Estimates.³ To account for overhead and fringe benefits, we have doubled the hourly wage. These amounts are detailed in Table 1.

³ https://www.bls.gov/oes/current/oes_nat.htm.

Table 1. U.S. Bureau of Labor and Statistics’ May 2021 National Occupational Employment and Wage Estimates.

Occupation title	Occupation code	Mean Hourly Wage (\$/hr)	Overhead and Fringe Benefit (\$/hr)	Adjusted Hourly Wage (\$/hr)
Registered Nurse (RN)	29-1141	\$39.78	\$39.78	\$79.56
Licensed Vocational Nurse (LVN)	29-2061	\$24.93	\$24.93	\$49.86
Speech Language Pathologist (SLP)	29-1127	\$41.26	\$41.26	\$82.52
Physical Therapist (PT)	29-1123	\$44.67	\$44.67	\$89.34
Occupational Therapist (OT)	29-1122	\$43.02	\$43.02	\$86.04

We estimate that the total cost would be reduced by \$220,697.60 for all IRFs annually (\$86.21 composite hourly rate x 2,560 hours), or \$194.79 per IRF annually (\$220,697.60 total reduction/1,133 IRFs) based on the proposed removal of the Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function measure.

Burden Hours and Cost Calculation for IRF-PAI V4.0 for the FY 2025 IRF QRP:

Average number of IRFs in U.S. in 2022	1,133
Average number of IRF-PAI admission reports submitted per each IRF for the FY 2025 IRF QRP	454
Average number of IRF-PAI admission reports submitted for all IRFs for the FY 2025 IRF QRP	511,938
Minutes to complete each IRF-PAI	106
Decrease in Hours for each IRF annually	(2.26)
Decrease in Hours for all IRFs annually	(2,560)
Previous Cost Burden for all IRFs per year	\$82,497,948.00
New Cost Burden for all IRFs for the FY 2025 IRF QRP	\$82,277,250.40

d) Adoption of the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date Measure Beginning with the FY 2026 IRF QRP

In the FY 2024 IRF PPS Final Rule (88 FR 51026 to 51036), CMS adopted the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure beginning with the FY 2026 IRF QRP. As a result, the estimated burden and cost for IRFs for complying with requirements of the FY 2026 IRF QRP will increase. Specifically, we believe there will be an additional 0.005 hours of clinical staff time to report data at discharge per patient stay.

Using data from calendar year 2021, we estimate 779,448 discharge assessments on all patients regardless of payer from 1,133 IRFs annually and 691 discharge assessments per IRF. This equates to an increase of 3,896 hours in burden for all IRFs (0.005 hour × 779,448 discharges) and 3.44 hours additional burden for each IRF (3,896 total hours / 1,133 IRFs. We believe the IRF-PAI item affected by the proposed COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure is completed by Registered Nurses (RN) and Licensed Practical and Licensed Vocational Nurses (LVN). Therefore, we averaged the national average for these labor types and established a composite cost estimate of \$64.71. 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 data collection requirements, we used the mean hourly wages for these staff, accounting for overhead and fringe benefits. These amounts are detailed in Table 1. We estimate that the total cost will increase by \$252,110.16 for all IRFs annually (3,896 hours x \$64.71) or \$222.52 per IRF annually (\$252,110.16 total increase/1,133 IRFs) based on the adoption of the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure.

We have included the full IRF-PAI burden in this PRA package.

Burden Hours and Cost Calculation for IRF-PAI V4.2 beginning with the FY 2026 IRF QRP:

Average number of IRFs in U.S. in 2022	1,133
Average number of IRF-PAI admission reports submitted per each IRF for the FY 2026 IRF QRP	691
Average number of IRF-PAI admission reports submitted for all IRFs for the FY 2026 IRF QRP	779,448
Minutes to complete each IRF-PAI	106
Increase in Hours for each IRF annually	3.44
Increase in Hours for all IRFs annually	3,896
Previous Cost Burden for all IRFs for the FY 2025 IRF QRP	\$82,277,250.40
New Cost Burden for all IRFs beginning with the FY 2026 IRF QRP	\$82,529,360.56

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 quality reporting program 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, roll-out, and maintenance of the Inpatient Rehabilitation Validation and Entry System (jIRVEN) software that is made available to IRF providers free of charge providing a means by which IRFs can submit the required quality measure data to CMS.

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 \$336,315.
- GS-14 (locality pay area of Washington-Baltimore-Northern Virginia) at 33% effort for 3 years, or \$132,368.

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 \$112,105 annually)	\$336,315
GS-14 Step 1 Federal Employee (33% X 3 years at \$132,368 annually)	\$132,368
Total cost to Federal Government:	\$3,218,683

15. Changes to Burden

Since the IRF PAI 4.1 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 1,115 to 1,133, and the average number of IRF-PAI assessments completed annually by each IRF has increased from 366 to 454 annually under current requirements to report data on Medicare fee-for-service and Medicare Advantage patients receiving IRF services. Beginning with the FY 2026 IRF QRP, IRFs will report data on all patients regardless of payer, and the number of IRF-PAI assessments completed by each IRF is estimated to increase from 454 to 691 assessments per year.

Although we estimate no change in the amount of time it would take to complete a single IRF PAI 4.2 as compared to the IRF PAI 4.1, the changes in total IRFs and total IRF-PAI assessments will change the burden associated with the IRF-PAI 4.2. As finalized, the burden will increase from 1,187,475 hours across all IRFs to 1,188,810 hours across all IRFs beginning October 1, 2024 [(1,187,475 – (1,133 IRFs x 2.26 hr decrease/IRF for FY 2025 IRF QRP) = 1,184,914)]; [(1,184,914 + (1,133 IRFs x 3.44 hr increase/IRF for FY 2026 IRF QRP) = 1,188,810)].

16. Publication/Tabulation Dates

For the changes to the IRF-PAI Version 4.2 related to the IRF QRP, the final rule was published on the Federal Register on August 2, 2023 (88 FR 50956). The IRF-PAI 4.2 can be found here: <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/irf-quality-reporting/irf-pai-and-irf-pai-manual>.

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: DRAFT IRF-PAI VERSION 4.2

See attached PDF