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

EXTENSION OF THE IRF-PAI (V4.0)
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
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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 an extension of the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI) Version 4.0 that will be effective on October 1, 2022.

On November 2, 2021 the Centers for Medicare & Medicaid Services (CMS) issued a final rule (86FR 62240) which finalized proposed modifications to the effective date for the reporting of measures and certain standardized patient assessment data in the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP). Per the final rule CMS will require IRFs to start collecting assessment data using IRF-PAI Version 4.0 beginning October 1, 2022. The rule is available here: https://www.federalregister.gov/documents/2021/11/09/2021-23993/medicare-and-medicaid-programs-cy-2022-home-health-prospective-payment-system-rate-update-home

The information collection request for IRF PAI 4.0 was re-approved on 12/15/2021 with an October 1, 2022 implementation date. CMS is asking for an extension of the approved IRF-PAI Version 4.0, which expires on December 31, 2022.

The burden associated with this requirement is staff time required to complete and encode the data from the IRF-PAI. The burden associated with collecting and transmitting the data is unaffected by the proposed extension to the assessment instrument.

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 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).

a) Proposed adoption of Transfer of Health Measures for the IRF QRP

In the FY 2020 IRF PPS Final Rule (84 FR 39098 through 39165), we finalized the adoption of two new measures, (1) Transfer of Health Information to the Provider–Post-Acute Care (PAC); and (2) Transfer of Health Information to the Patient–Post-Acute Care (PAC), beginning with the FY 2022 IRF QRP. As a result, the estimated burden and cost for IRFs for complying with requirements of the FY 2022 IRF QRP will increase. Specifically, we believe that there will be a 1.2minute addition in clinical staff time to report data per patient stay. We estimate 411,622 discharges from 1,122 IRFs annually. This equates to an increase of 8,232 hours in burden for all IRFs (0.02 hours per assessment × 411,622 discharges). Given 0.7 minutes of RN time at $70.72 per hour and 0.5 minutes of LVN time at $43.96 per hour, we estimate that the total cost will be increased by $437 per IRF annually, or $490,314 for all IRFs annually.

b) Proposed adoption of Standardized Patient Assessment Data Elements for the IRF QRP

In addition, we are proposing to add the Standardized Patient Assessment Data Elements described in the FY 2020 IRF PPS final rule beginning with the FY 2022 IRF QRP. As a result, the estimated burden and cost for IRFs for complying with requirements of the FY 2022 IRF QRP will be increased. Specifically, we believe that there will be 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 estimate 411,622 discharges from 1,122 IRFs annually.

This equates to an increase of 122,995 hours in burden for all IRFs (0.3 hours per assessment × 409,982 discharges). Given 11.3 minutes of RN time at $70.72 per hour and 7.5 minutes of LVN time at $43.96 per hour, we estimate that the total cost will be increased by $6,902 per IRF annually, or $7,744,044 for all IRFs.

[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

c) Summary of additional burden proposed for the IRF QRP

In summary, the finalized IRF QRP quality measures and standardized patient assessment data elements will result in a burden addition of 19.8 minutes per IRF-PAI. This adds 121 hours per IRF, or 139,394 hours per all IRFs; and an added cost of $7,339 per IRF annually, and $8,234,450for all IRFs annually.

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/.

3. Use of Information Technology

IRFs will have 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. The IRFs will transmit the submission to the Quality Improvement Evaluation System (QIES) Assessment Submission and Processing (ASAP) system, which is currently used by Inpatient Rehabilitation Facilities (IRFs), Skilled Nursing Facilities (SNFs), and Home Health Agencies (HHAs).

CMS has 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. Further, CMS provides customer support for software and transmission problems encountered by the providers. CMS has established a website and a hotline to assist providers with questions regarding the IRF-PAI, at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html.

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 information collection for the QRP does not duplicate any other effort and the standardized information regarding 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 1,119 IRFs, only 147 or 13% are rural IRFs, 14% of which are government-owned. The average number of assessments completed yearly is 366, and is the same across all respondents based on the number of actual assessments completed by IRFs in fiscal year 2018.

CMS requests authorization for IRFs to use the updated IRF-PAI for the submission of quality measure information. 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 information 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 60-day Federal Register notice published February 3, 2022 (87 FR 6175). We received two comments on our request to extend the currently approved information collection. Both commenters urged CMS to delay the implementation of the IRF-PAI V4.0 for a variety of reasons. We thank the commenters for their time in responding however, we find these comments to be outside the scope of the information collection request.

The 30-day Federal Register notice published April 12, 2022 (87 FR 21661).

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 information 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 2020 proposed rule, associated with IRF QRP items being added to the IRF-PAI Version 4.0**.** Addition of quality measure and Standardized Patient Assessment Data Elements for the IRF QRP

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. The requirements and burden has been described in previous rules and submitted in prior PRA packages, but not included in the total burden hours. The proposals set forth in this proposed rule will achieve this standardization, so we have included the full IRF-PAI burden in this PRA package.

Time Burden Calculation for IRF-PAI V4.0:

- Average number of IRFs in U.S. = 1,122
- Average number of IRF PAI reports submitted per each IRF per year = 411,622
- Minutes to complete each IRF-PAI = 105.8 (1.76 hours)
- Hours for each IRF annually = 632 hours
- Hours for all IRFs annually: = 704,747

❖ Previous cost burden for all IRFs per year = $43,555,154

❖ New cost burden for all IRFs per year = $50,714,416

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 $239,592.
- GS-14 (locality pay area of Washington-Baltimore-Northern Virginia) at 33% effort for 3 years, or $111,102.

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 Federal Employee (100% X 3 years)	$293,59
GS-14 Federal Employee (33% X 3 years)	$111,102
Total cost to Federal Government:	**$3,154,694**

15. Changes to Burden

There is no change to the previously provided burden estimates of IRF PAI V4.0.

16. Publication/Tabulation Dates

For changes to the IRF-PAI Version 4.0 related to the IRF QRP, the final rule was published in the Federal Register on August 8, 2019 (84 FR 39054).

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: IRF-PAI VERSION 4.0

See attached PDF