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 (V3.0)
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
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

We are requesting an approval for a revision to the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI). The current PRA approval expiration date is October 31, 2020. Revisions to the IRF-PAI are needed for the following reasons: 1) to administer the payment rate methodology under the IRF PPS described in 42 CFR 412 Subpart P, and 2) to permit the Secretary of Health and Human Services, and CMS, to collect quality measure data.

Regarding the IRF Quality Reporting Program (IRF QRP), **Table 1-1** lists the quality measures, collected via the IRF-PAI, included as of the 2014 extension approval. Subsequent tables will highlight the quality measures that are proposed for removal since the last PRA approval.

Table 1-1.
Quality Measures Currently Collected via the IRF-PAI

NQF Number	Measure Name	Data Collection Start Date
NQF #0678	Percent of Residents or Patients with Pressure Ulcers That are New or Worsened (Short-Stay)*	October 1, 2012
NQF #0680	Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay)	October 1, 2014
NQF #0678	Percent of Residents or Patients with Pressure Ulcers That are New or Worsened (Short-Stay)	October 1, 2016
NQF #0674	an application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)	October 1, 2016
NQF #2631	an application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function	October 1, 2016
NQF #2633	IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients	October 1, 2016
NQF #2634	IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients	October 1, 2016
NQF #2635	IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients	October 1, 2016
NQF #2636	IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients	October 1, 2016
Not endorsed	Drug Regimen Review Conducted With Follow-Up for Identified Issues- Post Acute Care (PAC) Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP)	October 1, 2018
Not endorsed	Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury	October 1, 2018

*Note: this measure will be removed effective October 1, 2018 and replaced with Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury. This burden change was finalized in the previous PRA update.

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

---

[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

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 removal of the FIM™ instrument and associated Function Modifiers from the IRF PAI

In the FY 2019 IRF PPS Proposed Rule (83 FR 20988 through 20995) we are proposing to remove the FIM™ instrument and associated Function Modifiers from the IRF-PAI beginning with FY 2020, that is, for all IRF discharges beginning on or after October 1, 2019. The proposed removal of the FIM™ instrument and associated Function Modifiers from the IRF PAI would result in the removal of 11 data items. As a result, we estimate the burden and costs associated with the collection of this data will be reduced for IRFs.

Specifically, we estimate the proposed removal of the FIM™ instrument and the associated Function Modifiers will save 25 minutes of nursing/clinical staff time used to report data on both admission and discharge which was the estimated time needed to complete these items when the FIM™ instrument was added to the IRF-PAI in the FY 2002 IRF PPS Final Rule (66 FR 41375). We believe that the FIM™ items we are proposing to remove may be completed by social service assistants, Licensed Practical Nurses (LPN), recreational therapists, social workers, dietitians and nutritionists, Nurses (RN), Occupational Therapists (OT), Speech Language Pathologists (SLP) and audiologists, and or Physical Therapists (PT), depending on the item. To estimate the burden associated with the collection of these data items, we obtained mean hourly wages for these staff from the U.S. Bureau of Labor Statistics' May 2016 National Occupational Employment and Wage Estimates (https://www.bls.gov/oes/2016/may/oes_nat.htm) and doubled them to account for overhead and fringe benefits. We estimate IRF-PAI preparation and coding costs using a social worker hourly wage rate of $48.76, a social work assistant's hourly wage rate of $32.82, an RN hourly wage rate of $69.40, an LPN hourly wage rate of $43.12, a recreation therapist hourly wage rate of $46.34, a dietitian/nutritionist hourly wage rate of $57.38, a speech-language pathologist hourly wage rate of $75.20, an audiologist hourly wage rate of $76.24, an occupational therapist hourly wage rate of $80.50, and a physical therapist hourly wage rate of $83.86. Using the mean hourly wages (doubled to account for overhead and fringe benefits) for the staffing categories above, we calculate an average rate of $61.36. The $61.36 rate is a blend of all of these categories, and reflects the fact that IRF providers have historically used all of these clinicians for preparation and coding for the IRF-PAI. To estimate the burden reduction associated with this proposal, we estimate that there are approximately 401,760 discharges from 1,124 IRFs in FY 2017 resulting in an approximate average of 357 discharges per IRF annually. This equates to a reduction of 167,400 hours for all IRFs ((discharges x 25 minutes)/60 minutes). This is 149 hours (167,400 hours/1,124 IRFs) per IRF annually.

We estimate the total cost savings per IRF will be approximately $9,100 (149 hours x $61.36) annually. We estimate that the total cost savings for all IRF providers will be approximately $10.2 million (1,124 IRFs x $9,100) annually.

b) <u>Proposed removal of quality measure (NQF #0680) Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay)</u>

In the FY 2019 IRF PPS Proposed Rule (83 FR 21001 through 21002) we are proposing to remove the measure, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680), beginning with the FY 2021 IRF QRP. IRFs will no longer be required to submit data on this measure beginning with patients discharged on October 1, 2018, and the items will be removed from the IRF-PAI V3.0, effective October 1, 2019. As a result, the estimated burden and cost for IRFs for complying with requirements of the FY 2021 IRF QRP will be reduced. Specifically, we believe that there will be a 4.8 minute reduction in clinical staff time to report data per patient stay. We estimate 401,760 discharges from 1,124 IRFs annually. This equates to a decrease of 32,141 hours in burden for all IRFs (0.08 hours per assessment × 401,760 discharges).

Given 4.8 minutes of RN time at $69.40 per hour completing an average of 357 sets of IRF-PAI assessments per provider per year, we estimate that the total cost will be reduced by $1,982 per IRF annually, or $2,227,768 for all IRFs annually.

See **Appendix A** for the IRF-PAI Version 3.0 (effective October 1, 2019).

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 1,124 IRFs, only 148 or 13% are rural IRFs, 14% of which are government-owned. The average number of assessments completed yearly is 357, and is the same across all respondents based on the number of actual assessments completed by IRFs in fiscal year 2017.

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

For changes related to the IRF-PAI V3.0, we published a 60-day Federal Register notice on May 8, 2018 (83 FR 20972) for this information collection.

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)

a) Current Burden Calculation for IRF-PAI V2.0

Time Burden Calculation for current IRF-PAI V2.0:

- Average number of IRFs in U.S. = 1,124
- Average number of IRF-PAI assessment per IRF per year = 357
- Average number of IRF PAI reports submitted per each IRF per year = 401,760
- Minutes to complete each IRF-PAI = 115.8 (1.67 hours)
- Hours for each IRF annually = 1.67 hours x 357 = 597 hours
- Hours for all IRFs annually: = 670,118

In this section, we provide burden estimates, provided in the IRF PPS FY 2019 proposed rule, associated with items removed from the IRF-PAI Version 3.0. The burden estimates provided are included on the **Part I Worksheet**.

b) Removal of the FIM™ instrument and associated Function Modifiers - Proposed IRF-PAI V3.0

Time Burden Calculation for IRF-PAI V3.0:

- Average number of IRFs in U.S. = 1,124
- Average number of IRF-PAI assessment per IRF per year = 357
- Average number of IRF PAI reports submitted per each IRF per year = 401,760
- Average Time Spent per FIM™ instrument and associated Function Modifiers = 25 minutes

Estimated Annual Hour Burden Reduction per each IRF= 149 hours
- 357 IRF-PAI assessments per IRF per year x 25 min/assessment = 8,925 minutes per IRF per year
- 8,925 minutes per IRF per year / 60 minutes/hour = 149 hours per IRF per year

Estimated Hour Burden Reduction for All IRFs per year = 167,400 hours
149 hours per IRF per year x 1,124 IRFs = 167,400 hours per all IRFs per year

Estimated Costs Associated with the IRF-PAI V3.0:

Estimated Annual Cost Burden Reduction per each IRF = $9,142.64
149 hours per IRF per year x $61.36 average clinician rate = $9,142.64

Estimated Cost Burden Reduction for All IRFs per year = $10,276,327.36
1,124 IRFs x $9,142.64 per IRF per year = $10,276,327.36

c) <u>Removal of Patient Flu items – Proposed IRF-PAI V3.0</u>

<u>Time Burden Calculation for IRF-PAI V3.0:</u>

- Average number of IRFs in U.S. = 1,124
- Average number of IRF PAI reports submitted per each IRF per year = 401,760
- Average Time Spent per Patient flu measure items = 4.8 minutes

<u>Estimated Annual Hour Burden Reduction per each IRF = 29 hours</u>
- 357 IRF-PAI assessments per IRF per year x 4.8 min/assessment = 1714 minutes per IRF per year
- 1714 minutes per IRF per year / 60 minutes/hour = 29 hours per IRF per year

<u>Estimated Hour Burden Reduction for All IRFs per year = 32,141 hours</u>
29 hours per IRF per year x 1,124 IRFs = 32,141 hours per all IRFs per year

<u>Estimated Costs Associated with the IRF-PAI V3.0:</u>

<u>Estimated Annual Cost Burden Reduction per each IRF = $1,982</u>
29 hours per IRF per year x $69.40 average clinician rate = $1,982

<u>Estimated Cost Burden Reduction for All IRFs per year = $2,227,768</u>
1,124 IRFs x $1,982 per IRF per year = $2,227,768

d) <u>Summary of burden reduction for IRF-PAI V3.0</u>

<u>Time Burden Calculation for IRF-PAI V3.0:</u>

<u>Estimated Annual Hour Burden Reduction per each IRF = 178 hours</u>
- FIM removal = 149 hours per IRF
- Patient flu removal = 29 hours per IRF
- Total = 178 hours per IRF per year

<u>Estimated Hour Burden Reduction for All IRFs per year = 200,072 hours</u>
178 hours per IRF per year x 1,124 IRFs = 200,072 hours per all IRFs per year

- ❖ Previous annual hour burden (not exempt from PRA) = 227,151 hours

- ❖ New annual hour burden for all IRFs = 27,079 hours for all IRFs per year

<u>Estimated Costs Associated with the IRF-PAI V3.0:</u>

<u>Estimated Annual Cost Burden Reduction per each IRF = $11,124.64</u>
- FIM removal = $9,142.64 per IRF
- Patient flu removal = $1,982 per IRF
- Total = $11,124.64 per IRF per year

<u>Estimated Cost Burden Reduction for All IRFs per year = $12,504,095</u>
1,124 IRFs x $11,124.64 per all IRFs per year = $12,504,095

- ❖ Previous cost burden for all IRFs per year = $38,831,781.04

- ❖ New cost burden for all IRFs per year = $26,327,686.04

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

Since the Information Collection Requirements (ICR) approval, the number of IRFs has decreased from 1,137 to 1,124. We estimate that changes to the IRF-PAI Version 3.0 will decrease the amount of time required to complete the IRF-PAI by about 178 hours per year per IRF. Therefore, the overall burden hours decreased from 227,151 to 27,079.

16. Publication/Tabulation Dates

For changes to the IRF-PAI Version 3.0, the proposed rule went on display in the Federal Register on May 8, 2018.

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 3.0 (EFFECTIVE OCTOBER 1, 2018) AND ASSOCIATED CHANGE TABLE

See attached PDF