**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 (V1.3, V1.4, V.1.5 and V2.0)

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

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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*

## 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 July 31, 2017. 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 and standardized data elements that have been added since the 2014 approval.

Table 1-1.  
Quality Measures for Collected via the IRF-PAI Effective October 1, 2014

|  |  |  |  |
| --- | --- | --- | --- |
| NQF Number | Measure Name | Fiscal Year Payment Determination | Data Collection Start Date |
| NQF #0678 | Percent of Residents or Patients with Pressure Ulcers That are New or Worsened (Short-Stay) | FY 2014 and subsequent | October 1 , 2012 |
| NQF #0680 | Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) | FY 2014 and subsequent | October 1 , 2014 |
| NQF #0431 | Influenza Vaccination Coverage among Healthcare Personnel | FY 2017 and subsequent | October 1 , 2014 |

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.

## 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]](#footnote-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]](#footnote-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).

Updates Associated with IRF-PAI Version 1.3 (Effective October 1, 2015)

We finalized the addition of an item (24A) to the IRF PAI to record arthritis conditions as part of our continued monitoring of the IRF benefit.

We also finalized the addition of items (O0401 and O0402) to the IRF PAI to record how much and what mode of therapy (i.e., individual, group, co-treatment) patients receive in each therapy discipline (i.e., physical therapy, occupational therapy, and speech-language pathology) as part of our continued monitoring and oversight of the IRF benefit, as well as to inform the necessity of any future policy making. See **Appendix A** for the IRF-PAI Version 1.3.

Updates Associated with IRF-PAI Version 1.4 (Effective October 1, 2016) – Exempt from PRA

In the IRF PPS Final Rule FY 2016[[3]](#footnote-3), several quality measures were finalized for the IRF QRP which require modification to the IRF-PAI Version 1.4, effective October 1, 2016. We note that the burden associated with the these measures is exempt from the PRA under the IMPACT Act of 2014. 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 requirement and burden will, however, be submitted to OMB for review and approval when the quality measures and the PAC assessment instruments are no longer used to achieve the standardization of patient assessment data.

We have included the list of measures in **Table 1-2**, along with a copy of the IRF-PAI Version 1.4 and a change table between V1.3 and V1.4 in **Appendix B.** We also included the burden estimates estimated in the FY 2016 IRF PPS Final Rule for IRF-PAI tracking purposes, but we note that they are currently exempt from the PRA.

**Table 1-2** lists the quality measures that were finalized in the IRF PPS FY 2016 Final Rule for addition to the IRF-PAI V1.4, effective October 1, 2016.

Table 1-2.  
Quality Measures Added to the IRF-PAI Version 1.4, Effective October 1, 2016

|  |  |  |
| --- | --- | --- |
| NQF Number | Measure Name | Fiscal Year Payment Determination |
| NQF #0678 | Percent of Residents or Patients with Pressure Ulcers That are New or Worsened (Short-Stay) | FY 2014 and subsequent |
| NQF #0674 | an application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) | FY 2018 and subsequent |
| NQF #2631 | an application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function | FY 2018 and subsequent |
| NQF #2633 | IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients | FY 2018 and subsequent |
| NQF #2634 | IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients | FY 2018 and subsequent |
| NQF #2635 | IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients | FY 2018 and subsequent |
| NQF #2636 | IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients | FY 2018 and subsequent |

Updates Associated with IRF-PAI Version 1.5 (Effective October 1, 2017)

We are proposing to remove an item (27) from the IRF PAI. This item is no longer needed, as new quality items have been added to Section K.

See **Appendix C** for the IRF-PAI Version 1.5 and change table from V1.4.

Updates Associated with IRF-PAI Version 2.0 (Effective October 1, 2018) – Exempt from PRA

In the FY 2017 IRF PPS final rule, we adopted 1 assessment-based measure to meet the requirements of the IMPACT Act. The Drug Regimen Review Conducted With Follow-Up for Identified Issues- Post Acute Care (PAC) Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP) measure was adopted for the FY 2020 and subsequent payment determinations.

In the FY 2018 IRF PPS proposed rule, we proposed to adopt 1 measure and remove 2 measures. The proposed measure for adoption is Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury. The proposed measures for removal are Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) and the All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Inpatient Rehabilitation Facilities (NQF #2502).

We also proposed adding standardized patient assessment data, including 23 items on admission and 24 items on discharge. Section 1886(j)(7)(F)(iii) of the Act requires that for fiscal years 2019 and each subsequent year, IRFs report standardized patient assessment data required under section 1899B9b)(1) of the Act, using the standard instrument in a time, form, and manner specified by the Secretary.

We note that the burden associated with these measures is exempt from the PRA under the IMPACT Act of 2014. 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 requirement and burden will, however, be submitted to OMB for review and approval when the quality measures and the PAC assessment instruments are no longer used to achieve the standardization of patient assessment data.

We have included the list of measures in **Table 1-3**, standardized data elements in **Table 1-4**, and a copy of the IRF-PAI Version 2.0 and a change table in **Appendix C.** We also included the burden estimates estimated in the FY 2018 IRF PPS Final Rule for IRF-PAI tracking purposes, but due to this exemption, we have ***not*** included the burden in our updated IRF-PAI estimates in Section 12.

Table 1-3.  
Quality Measures to be added to the IRF-PAI Version 2.0, Effective October 1, 2018

|  |  |  |
| --- | --- | --- |
| NQF Number | Measure Name | Fiscal Year Payment Determination |
| Not endorsed | Drug Regimen Review Conducted With Follow-Up for Identified Issues- Post Acute Care (PAC) Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP) | FY 2020 and subsequent |
| Not endorsed | Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury | FY 2020 and subsequent |

Table 1-4.  
Standardized Patient Assessment Data Elements to be added to the IRF-PAI Version 2.0, Effective October 1, 2018

|  |  |  |
| --- | --- | --- |
| Category | Data Element | Fiscal Year Payment Determination |
| Cognitive Function and Mental Status | Brief Interview for Mental Status (Admission only) | FY 2020 and subsequent |
| Signs and Symptoms of Delirium (from CAM©) | FY 2020 and subsequent |
| Behavioral Signs & Symptoms | FY 2020 and subsequent |
| Patient Health Questionnaire 2 (PHQ-2 ©) | FY 2020 and subsequent |
| Impairments | Ability to See (Admission only) | FY 2020 and subsequent |
| Ability to Hear (Admission only) | FY 2020 and subsequent |
| Special Services, Treatments, & Interventions | Chemotherapy and child items | FY 2020 and subsequent |
| Radiation | FY 2020 and subsequent |
| Oxygen Therapy | FY 2020 and subsequent |
| Suctioning | FY 2020 and subsequent |
| Tracheostomy Care | FY 2020 and subsequent |
| Invasive Mechanical Ventilator | FY 2020 and subsequent |
| Non-invasive mechanical ventilator | FY 2020 and subsequent |
| IV Medications | FY 2020 and subsequent |
| Transfusions | FY 2020 and subsequent |
| Dialysis | FY 2020 and subsequent |
| IV Access | FY 2020 and subsequent |
| Nutritional Approaches | Parenteral/IV feeding | FY 2020 and subsequent |
| Feeding tube | FY 2020 and subsequent |
| Mechanically altered diet | FY 2020 and subsequent |
| Therapeutic diet | FY 2020 and subsequent |

* 1. 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/>.

* 1. 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>.

* 1. 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.

* 1. 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 151 or 13% are small rural IRFs, 6% of which are small government-owned. The average number of assessments completed yearly is 354, and is the same across all respondents based on the number of actual assessments completed by IRFs in fiscal year 2013.

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.

* 1. 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.

* 1. Special Circumstances

There are no special circumstances.

* 1. Federal Register/Outside Consultation

For changes related to the IRF-PAI V1.4, the IRF PPS FY 2016 proposed rule was published in the Federal Register on April 27, 2015. We received several unique comments related to the burden estimates, which are summarized and responded to in the Final Rule, published to the Federal Register on August 2, 2015 and available at <https://www.gpo.gov/fdsys/pkg/FR-2015-08-06/pdf/2015-18973.pdf>.

For changes related to the IRF-PAI V1.5 and V2.0, the IRF PPS FY 2018 proposed rule published on May 3, 2017 (82 FR 22304).

The 60-day Federal Register notice is scheduled to publish on June 9, 2017.

* 1. Payment/Gifts to Respondents

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

* 1. 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.

* 1. Sensitive Questions

There are no sensitive questions on the IRF-PAI.

* 1. Burden Estimates (Hours & Wages)

In this section, we provide four burden estimates:

1. Burden associated with new items added to the IRF-PAI Version 1.3
2. Burden estimates, provided in the IRF PPS FY 2016 Final Rule, associated with items added to the IRF-PAI Version 1.4, exempt from PRA
3. Burden reduction associated IRF-PAI Version 1.5
4. Burden estimates, provided in the IRF PPS FY 2018 proposed rule, associated with items added to the IRF-PAI Version 2.0, exempt from PRA
5. Summary of burden associated with all IRF-PAI versions in this supporting statement

We note that the burden and cost estimates provided under (b) and (d) are currently exempt from PRA and are provided only for informational purposes. The burden estimates provided under (a) will be the burden associated with this request for revision and are included on the **Part I Worksheet**.

**Table 12-1** gives an overview of the minutes added or removed from each version.

Table 12-1.   
Summary of IRF-PAI burden and cost

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| IRF-PAI Version | Effective Date | Associated Rule | IRF-PAI Minutes Added  (Minutes Removed) | Net Change in Minutes per IRF-PAI | Hour burden for each IRF | Hour burden for all IRFs per year | Cost burden for All IRFs per year |
| 1.3 | October 1, 2015 | FY 2015 IRF PPS Final Rule | 5 | +5 | 29.5 | 33,424 | $2,155,741.48 |
| 1.4 | October 1, 2016 | FY 2016 IRF PPS Final Rule | 41.5 | +41.5 | 238.75 | 279,267 | $24,042,291.01 |
| 1.5 | October 1, 2017 | FY 2018 IRF PPS Proposed Rule | (0.5) | (0.5) | (2.95) | (3,353) | $8,630,421.62 |
| 2.0 | October 1, 2018 | FY 2017 & FY 2018 IRF PPS Proposed Rules | 24.4  (5) | +19.4 | 114.41 | 130,081 |
| **TOTAL Burden in this PRA package** | | | | **+65.4**  **Minutes** | **379.71**  **Hours** | **439,419**  **Hours** | **$34,828,454.11** |

### Burden Associated with new items added to IRF-PAI Version 1.3 (Effective October 1, 2015)

**Time Burden Calculation for IRF-PAI V1.3:**

* Average number of IRFs in U.S.= 1133
* Average number of IRF PAI reports submitted per each IRF per year = 354
* Average Time Spent per IRF-PAI Recording Arthritis Conditions = 1 minute
* Average Time Spent per IRF-PAI Regarding Therapy Data Collection = 4 minutes

Estimated Annual Hour Burden per each IRF= 29.5 hours

* 354 IRF-PAI assessments per IRF per year x 5 min/assessment = 1770 minutes per IRF per year
* 1770 minutes per IRF per year / 60 minutes/hour = 29.5 hours per IRF per year

Estimated Hour Burden for All IRFs per year = 33,424 hours

29.5 hours per IRF per year x 1133 IRFs = 33,424 hours per all IRFs per year

**Estimated Costs Associated with the IRF-PAI V1.3:**

To calculate burden, we obtained hourly wage rates for social worker assistants, LPNs, recreational therapists, social workers, dietitians and nutritionists, RNs, speech language pathologists and audiologists, occupational therapists, and physical therapists, all of whom may complete the IRF-PAI, from the Bureau of Labor Statistics (<https://www.bls.gov/oes/current/oes_nat.htm>) as of October 1, 2015 (when the IRF-PAI V1.3 went into effect). To account for overhead and fringe benefits (100% of the hourly wage), we have doubled the hourly wage.

IRF-PAI preparation and coding costs were estimated using social workers hourly wage rates of $22.07 (doubled to $44.14), social work assistants’ hourly wage of $14.82 (doubled to $29.64), RN hourly wage rates of $32.45 (doubled to $64.90), LPNs hourly wage rates of $20.76 (doubled to $41.52), recreational therapist hourly wage rates of $22.06 (doubled to $44.12), dietitian/nutritionist hourly wage rates of $27.84 (doubled to $55.68), speech-language pathologist hourly wage rates of $35.29 (doubled to $70.58), Audiologist hourly wage rates of $36.01 (doubled to $72.02), occupational therapist hourly wage rates of $38.54 (doubled to $77.08) and physical therapist hourly wage rates of $40.40 (doubled to $80.80). The $64.50 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.

Estimated Annual Cost Burden per each IRF = $1,902.68

29.5 hours per IRF per year x $64.50 average clinician rate = $1,902.68

Estimated Cost Burden for All IRFs per year = $2,155,741.48

1133 IRFs x $856.09 per IRF per year = $2,155,741.48

Burden Associated with new items added IRF-PAI Version 1.4 (Effective October 1, 2016) – Exempt from PRA until Standardization

In the FY 2016 IRF PPS Final Rule, we estimated the burden associated with the new quality measures that added items to the IRF-PAI V1.4, but noted that the burden associated with the these measures is exempt from the PRA under the IMPACT Act of 2014. 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.

**Time Burden Calculation for IRF-PAI V1.4**

*(As of the posting of the IRF PPS Final Rule FY 2016):*

* Total Number of IRFs in U.S. (as of February 1, 2015) = 1132
* Total Number of IRF Medicare (Part A and Part C) Discharges per year: 390,748
* Estimated Number of Discharges from each IRF per year = 345
* Estimated Number of Discharges from each IRF per month = 29
* Estimated Average Number of eligible IRF-PAI’s submitted per month = 32,526

**Time Required to Complete New Items added to IRF-PAI V1.4 = 41.5 minutes**

**25.5** minutes on Admission – nursing/clinical staff time to collect clinical data;

**16** minutes for Discharge assessment – nursing/clinical staff time to collect clinical data;

**0** additional minutes administrative data entry time to aggregate and submit data to CMS

**41.5 minutes**[[4]](#footnote-4) – Total time burden to complete new items on IRF-PAI V1.4 per patient

**Estimated Annual Time Burden per each IRF = 238.75 hrs/each IRF/year**

**Estimated Annual Time Burden all IRFs = 270,267hrs/all IRFs/year**

**Cost/Wage Calculation for Completion of the IRF-PAI V1.4:**

*From the FY 2016 IRF PPS Final Rule:*

We estimated that the additional elements for the 6 newly adopted measures (see Table 1-2) will take 25.5 minutes of nursing/clinical staff time to report data on admission and 16.0 minutes of nursing/clinical staff time to report data on discharge, for a total of 41.5 minutes. We believe that the additional IRF–PAI items we proposed will be completed by Registered Nurses (RN), Occupational Therapists (OT), Speech Language Pathologists (SLP) and/or Physical Therapists (PT), depending on the item. We identified the staff type per item based on past LTCH and IRF burden calculations in conjunction with expert opinion. Our assumptions for staff type were based on the categories generally necessary to perform assessment: RN, OT, SLP, and PT. Individual providers determine the staffing resources necessary; therefore, we averaged the national average for these labor types and established a composite cost estimate. This composite estimate was calculated by weighting each salary based on the following breakdown regarding provider types most likely to collect this data: RN 59 percent; OT 11 percent; PT 20 percent; SLP 1 percent. In accordance with OMB control number 0938–0842, we estimate 390,748 discharges from all IRFs annually, with an additional burden of 41.5 minutes. This would equate to 270,267total hours or 238.75 hours per IRF. We believe this work will be completed by RN, OT, PT, and SLP staff, depending on the item. We obtained mean hourly wages for these staff from the U.S. Bureau of Labor Statistics’ May 2013 National Occupational Employment and Wage Estimates (<http://www.bls.gov/oes/current/oes-nat.htm>), and to account for overhead and fringe benefits, we have doubled the mean hourly wage. Per the U.S. Bureau of Labor and Statistics, the mean hourly wage for a RN is $33.13. However, to account for overhead and fringe benefits, we have doubled the mean hourly wage, making it $66.26 for an RN. The mean hourly wage for an OT is $37.45, doubled to $74.90 to account for overhead and fringe benefits. The mean hourly wage for a PT is $39.51, doubled to $79.02 to account for overhead and fringe benefits. The mean hourly wage for a SLP is $35.56, doubled to $71.12 to account for overhead and fringe benefits. Given these wages and time estimates, the total cost related to the six newly proposed measures is estimated at $21,239.33 per IRF annually, $24,042,291.01 for all IRFs annually.

As noted above, we have included this burden estimate from the FY 2016 Final Rule for informational purposes, but since the burden associated with the these measures is exempt from the PRA under the IMPACT Act of 2014, we are not adding it to the burden associated with this request for approval. The requirement and burden will, however, be submitted to OMB for review and approval when the quality measures and the PAC assessment instruments are no longer used to achieve the standardization of patient assessment data.

Estimated Cost Burden for All IRFs per year = $24,042,291.01

IRFs x $21,239.33 per IRF per year = $24,042,291.01

Burden Associated with IRF-PAI Version 1.5 (Effective October 1, 2017)

*From the FY 2018 Proposed Rule:*

**Time Burden Calculation for IRF-PAI V1.5**

*(As of the posting of the IRF PPS FY 2018 Proposed Rule):*

* Total Number of IRFs in U.S (as of February 1, 2017). = 1137
* Total Number of IRF Medicare (Part A and Part C) Discharges per year: 402,311
* Estimated Number of Discharges from each IRF per year = 354
* Estimated Number of Discharges from each IRF per month = 29
* Estimated Average Number of eligible IRF-PAI’s submitted per month = 33,526

**Time Required to Complete Items removed from IRF-PAI V1.5 = 0.5 minutes**

**0.25** minutes reduced nursing/clinical **staff** time to collect clinical data on admission;

**0.25** minutes reduced nursing/clinical staff time to collect clinical data on discharge;

**0** additional minutes **administrative** data entry time to aggregate and submit data to CMS

**0.5 minutes** – Total time burden to complete items removed from on IRF-PAI V1.5 per patient

**Estimated REDUCED Annual Time Burden per each IRF = 2.95 hrs/each IRF/year**

**Estimated REDUCED Annual Time Burden all IRFs = 3,353 hrs/all IRFs/year**

**Cost/Wage Calculation for Completion of the IRF-PAI V1.5:**

*See below* – in the FY 2018 IRF PPS Proposed rule, we provide a cost accounting for both V1.5 and V2.0.

Burden Associated with new items added IRF-PAI Version 2.0 (Effective October 1, 2018) – Exempt from PRA until Standardization

In the FY 2017 and FY 2018 IRF PPS Proposed Rule, we estimated the burden associated with the new quality measures that added items to the IRF-PAI V2.0, but noted that the burden associated with the these measures is exempt from the PRA under the IMPACT Act of 2014. 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.

**Time Burden Calculation for IRF-PAI V2.0**

*(As of the posting of the IRF PPS FY 2018 Proposed Rule):*

* Total Number of IRFs in U.S (as of February 1, 2017). = 1137
* Total Number of IRF Medicare (Part A and Part C) Discharges per year: 402,311
* Estimated Number of Discharges from each IRF per year = 354
* Estimated Number of Discharges from each IRF per month = 29
* Estimated Average Number of eligible IRF-PAI’s submitted per month = 33,526

**Time Required to Complete New Items added to IRF-PAI V2.0 = minutes**

**13.2** minutes added – 5 minutes reduced = 8.2 minutes on Admission –clinical staff time to collect clinical data;

**11.2** minutes for Discharge assessment –clinical staff time to collect clinical data;

**0** additional minutes administrative data entry time to aggregate and submit data to CMS

**19.4 minutes (0.32 hours)** – Total time burden to complete new items on IRF-PAI V2.0 per patient

**Estimated Annual Time Burden per each IRF = 114.41 hrs/each IRF/year**

**Estimated Annual Time Burden all IRFs = 130,081 hrs/all IRFs/year**

**Cost/Wage Calculation for Completion of the IRF-PAI V2.0:**

*From the FY 2017 IRF PPS Proposed Rule:*

For the FY 2020 payment determination and subsequent years, we proposed one measure: Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP. Additionally, we proposed that data for this new measure will be collected and reported using the IRF-PAI (version effective October 1, 2018).

Our burden calculations take into account all “new” items required on the IRF-PAI (version effective October 1, 2018) to support data collection and reporting for this measure. The addition of the new items required to collect the newly proposed measure is for the purpose of achieving standardization of data elements.

We estimate the additional elements for the newly proposed Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP measure will take 6 minutes of nursing/clinical staff time to report data on admission and 4 minutes of nursing/clinical staff time to report data on discharge, for a total of 10 minutes. We estimate that the additional IRF-PAI items we proposed will be completed by Registered Nurses (RN) for approximately 75 percent of the time required, and Pharmacists for approximately 25 percent of the time required. Individual providers determine the staffing resources necessary. In accordance with OMB control number 0938-0842, we estimate 398,254 discharges from all IRFs annually, with an additional burden of 10 minutes. This will equate to 66,375.67 total hours or 58.69 hours per IRF. We believe this work will be completed by RNs (75 percent) and Pharmacists (25 percent). We obtained mean hourly wages for these staff from the U.S. Bureau of Labor Statistics’ May 2014 National Occupational Employment and Wage Estimates (<http://www.bls.gov/oes/current/oes_nat.htm>), and to account for overhead and fringe benefits, we have doubled the mean hourly wage. Per the U.S. Bureau of Labor and Statistics, the mean hourly wage for a RN is $33.55. However, to account for overhead and fringe benefits, we have doubled the mean hourly wage, making it $67.10 for an RN. Per the U.S. Bureau of Labor and Statistics, the mean hourly wage for a pharmacist is $56.98. However, to account for overhead and fringe benefits, we have doubled the mean hourly wage, making it $113.96 for a pharmacist. Given these wages and time estimates, the total cost related to the newly proposed measures is estimated at $4,625.46 per IRF annually, or $5,231,398.17 for all IRFs annually.

*From the FY 2018 IRF PPS Proposed Rule:*

We believe that the burden associated with the IRF QRP is the time and effort associated with data collection and reporting. As of February 1, 2017, there are approximately 1137 IRFs currently reporting quality data to CMS. 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' May 2016 National Occupational Employment and Wage Estimates (<http://www.bls.gov/oes/current/oes_nat.htm>). To account for overhead and fringe benefits, we have doubled the hourly wage. These amounts are detailed in Table 13.

Table 12-2.   
U.S. Bureau of Labor Statistics' May 2016 National   
Occupational Employment and Wage Estimates

| Occupation title | Occupation code | Mean Hourly Wage ($/hr) | Fringe Benefit ($/hr) | Adjusted Hourly Wage ($/hr) |
| --- | --- | --- | --- | --- |
| Registered Nurse (RN) | 29-1141 | $34.70 | $34.70 | $69.40 |
| Licensed Practical and Licensed Vocational Nurses (LVN) | 29-2061 | $21.56 | $21.56 | $43.12 |
| Respiratory Therapists (RT) | 29-1126 | $29.15 | $29.15 | $58.30 |
| Speech-Language Pathologists (SLP) | 29-1127 | $37.60 | $37.60 | $75.20 |
| Occupational Therapists (OT) | 29-1122 | $40.25 | $40.25 | $80.50 |
| Psychologist | 19-3030 | $38.77 | $38.77 | $77.54 |

In this proposed rule, we are proposing to adopt a new pressure ulcer measure to replace the current pressure ulcer measure beginning with the FY 2020 IRF QRP: (1) Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury. In addition, we propose that data for this new measure will be collected and reported using the IRF-PAI (version effective October 1, 2018). As noted in section VIII, we are also proposing to remove item 27 (Swallowing Status) from the IRF-PAI, on admission and discharge. We are also proposing to remove the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs (NQF #2502). This is a claims-based measure, and IRFs will still be required to submit the claims on which this measure is calculated. Therefore, we believe the IRF QRP burden estimate is unaffected by the proposed removal of this measure.

Adoption of the Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury measure would result in the removal of some data items related to pressure ulcer assessment that we believe are duplicative or no longer necessary. As a result, the estimated burden and cost for IRFs to report the updated version of the measure would be reduced from the burden and cost to report the current version of the measure. Specifically, we believe that there will be a 5 minute reduction in clinical staff time to report data, and we believe the items being removed would be completed by RNs. In addition, the removal of item 27 (Swallowing Status) on both admission and discharge will result in a 0.5 minute reduction in clinical staff time to report data. We believe that these swallowing items would be completed by RNs (approximately 75 percent of the time) and SLPs (approximately 25 percent of the time). We estimate 402,311 discharges from 1,137 IRFs annually. This equates to 36,878.51hours (0.0917 hours X 402,311 discharges) decrease in burden for all IRFs. Given 5.4 minutes of RN time and 0.1 minutes of SLP time, , completing an average of 354 IRF-PAIs per provider per year, and the wages listed in Table 13, we estimated the total cost would be reduced by $ $2,255.26 per IRF annually, or $2,564,229.74 for all IRFs annually.

In section XII.J. of this proposed rule, we are proposing requirements related to the reporting of standardized patient assessment data beginning with the FY 2019 IRF QRP. Some of these data elements are already included on the IRF-PAI assessment and are already included in current burden estimates. We are proposing, however, to require IRFs to report 24 new standardized patient assessment data elements on IRF admissions and 24 new standardized patient assessment data elements on IRF discharges We estimate that it will take an IRF’s clinical staff 7.2 minutes to report the data elements required on admission and 7.2 minutes to report the data elements required on discharge, for a total of 14.4 additional minutes. This equates to 96,554.64 additional burden hours per year (0.24 hours x 402,311 discharges).

We believe that the additional IRF-PAI items we are proposing would be completed by the following clinicians: RN (approximately 50 percent of the time), LVN (approximately 30 percent of the time), RT (approximately 7 percent of the time), SLP (approximately 6 percent of the time), and other therapists, including OT and psychologist (approximately 7 percent of the time). We estimate 402,311 discharges from 1,137 IRFs annually based on the numbers obtained February 1, 2017. To estimate the mean hourly wage for “other therapists,” we averaged the mean hourly wage of OTs and psychologists for a mean hourly rate of $39.51, doubled to $79.02 to account for overhead and fringe benefits. Individual providers determine the staffing resources necessary. Given the clinician times and wages in Table 13, completing an average of 354 IRF-PAIs per provider per year, the total cost related to the additional standardized patient assessment data elements is estimated at $5,244.73 per IRF annually, or $5,963,253.19 for all IRFs annually.

In summary, for the revisions to IRF-PAI V1.5 and V2.0 in the FY 2018 IRF PPS proposed rule, given the 5.5-minute reduction in burden for items being removed from the IRF-PAI, and the 14.4 additional minutes of burden for the proposed standardized patient assessment data elements, the overall cost associated with proposed changes to the IRF QRP is estimated at an additional $2,989.47 per IRF annually, or $3,399,023.45 for all IRFs annually.

While the reporting of data on quality measures and standardized patient assessment data elements involves collecting information, we believe that the burden associated with modifications to the IRF-PAI discussed in this proposed rule fall under the PRA exceptions provided in section 1899B(m) of the Act. Section 1899B(m) of the Act, which was added by the IMPACT Act, states that the PRA requirements do not apply to section 1899B of the Act. However, the PRA requirements and burden estimates will be submitted to OMB for review and approval when modifications to the IRF-PAI or other applicable PAC assessment instruments are not used to achieve standardized patient assessment data.

Estimated Cost Burden for All IRFs per year = $8,630,421.62

(FY 2017 rule) 1131 IRFs x $4,625.46 per IRF = $5,231,398.17

(FY 2018 rule) 1137 IRFs x $2,989.47 per IRF per year = $3,399,023.45

$5,231,398.17 + $3,399,023.45 = $8,630,421.62

Summary of burden for IRF-PAI Versions 1.3, 1.4, 1.5, and 2.0

Table 12-1 above summarizes the burden associated with each version of the IRF-PAI included in this application, and we have also included this information below:

* IRF-PAI V1.3 adds 29.5 hours of burden per IRF, or 33,424 hours for all IRFs per year
* IRF-PAI V1.4 adds 283.75 hours of burden per IRF, or 279,267 hours for all IRFs per year
* IRF-PAI V1.5 reduces burden by 2.95 hours per IRF, or 3,353 hours for all IRFs per year
* IRF-PAI V2.0 adds 114.41 hours of burden per IRF, or 130,081 hours for all IRFs per year

In summary, we add a total of 379.71 hours of burden per IRF, or 439,419 hours for all IRFs per year.

As noted above, the additions to IRF-PAI V1.4 and V2.0 are currently exempt from PRA under the IMPACT Act. However, we are providing the burden estimate for informational purposes. Taking into consideration only non-exempt revisions to the IRF-PAI, we add a total of 27 hours of burden per IRF, for a total of 30,071 hours for all IRFs annually.

* 1. Capital Costs

There are no capital costs.

* 1. 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) $293,592

GS-14 Federal Employee (33% X 3 years) $111,102

**Total cost to Federal Government: $3,154,694**

* 1. Changes to Burden

Since the ICR approval, the number of IRFs has decreased from 1,161 to 1,137. We estimate that changes to the IRF-PAI Version 1.3 will increase the amount of time required to complete the IRF-PAI by about 29.5 hours per year per IRF, and items removed in the V1.5 IRF-PAI will decrease the amount of time required to complete the IRF-PAI by about 2.95 hours per IRF, for a total increase of 30,071 burden hours annually for all IRFs. Therefore, the overall burden hours increased from 197,080 to 227, 151.

Items added to the IRF-PAI Versions 1.4 and 2.0 are currently exempt from PRA and are provided for informational purposes only.

* 1. Publication/Tabulation Dates

For changes to the IRF-PAI Version 1.3, there are no plans to publish or tabulate the information collected.

For changes to the IRF-PAI Version 1.4, the proposed rule went on display in the Federal Register on April 27, 2015 and was finalized on August 2, 2015. For changes to the IRF-PAI Versions 1.5 and 2.0, the proposed rule was published on May 3, 2017.

* 1. Expiration Date

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

* 1. Certification Statement

There are no exceptions to the certifications statement.

APPENDIX A

IRF-PAI Version 1.3 (Effective October 1, 2015)

APPENDIX B

Change Table from 1.3 to 1.4

IRF-PAI Version 1.4 (Effective October 1, 2016)

APPENDIX C

Change Table from 1.4 to 1.5 and Change Table from 1.5 to 2.0

IRF-PAI Version 1.5 (Effective October 1, 2017)

IRF-PAI Version 2.0 (Effective October 1, 2018)

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>. [↑](#footnote-ref-1)
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> [↑](#footnote-ref-2)
3. 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> [↑](#footnote-ref-3)
4. This time estimate includes the time required to complete both the required and voluntary questions on the IRF-PAI [↑](#footnote-ref-4)