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

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 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 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 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) 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.

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[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

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

In the IRF PPS Final Rule FY 2016[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 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

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

Effective October 1, 2017, we are finalizing the removal of 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.

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

Effective October 1, 2018, the IRF-PAI Version 2.0 will contain the following changes:

[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

- 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 final rule, we adopted 1 measure (Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury) and the removal of 2 measures: 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 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**, and a copy of the IRF-PAI Version 2.0 and a change table in **Appendix C.**

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

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 1,133 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.

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 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).

We published a 60-day Federal Register notice on June 9, 2017 (82 FR 26804) for this information collection.

The IRF PPS FY 2018 final rule displayed on July 31, 2017.

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 four burden estimates:

a) Burden associated with new items added to the IRF-PAI Version 1.3

b) 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

c) Burden reduction associated IRF-PAI Version 1.5

d) Burden estimates, provided in the IRF PPS FY 2018 final rule, associated with items added to the IRF-PAI Version 2.0, exempt from PRA

e) 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 Final Rule	(0.5)	(0.5)	(2.95)	(3,353)	($237,531.12)
2.0	October 1, 2018	FY 2017 & FY 2018 IRF PPS Final Rules	10 (5)	+5	29.20	32,850	$2,904,699.55
TOTAL Burden in this PRA package				**+51 Minutes**	**294.50 Hours**	**342,188 Hours**	**$28,865,200.92**

a) 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

b) 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] – 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 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 new 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

[4] This time estimate includes the time required to complete both the required and voluntary questions on the IRF-PAI

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

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

From the FY 2018 Final Rule:

Time Burden Calculation for IRF-PAI V1.5
(As of the posting of the IRF PPS FY 2018 Final 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 Final rule, we provide a cost accounting for both V1.5 and V2.0.

d) 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 Final 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 Final 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 = 5 minutes
10 minutes added – 5 minutes reduced = 5 minutes–clinical staff time to collect clinical data;
0 additional minutes administrative data entry time to aggregate and submit data to CMS
5 minutes (0.08 hours) – Total time burden to complete new items on IRF-PAI V2.0 per patient

Estimated Annual Time Burden per each IRF = 29.2 hrs/each IRF/year

Estimated Annual Time Burden all IRFs = 32,850 hrs/all IRFs/year

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

From the FY 2017 IRF PPS Final Rule:

For the FY 2020 payment determination and subsequent years, we adopted one measure: Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC IRF QRP. 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 new measure is for the purpose of achieving standardization of data elements.

We estimate the additional elements for the new 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 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 new 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 Final 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 the FY 2018 IRF PPS final rule, we adopted 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). We will also remove item 27 (Swallowing Status) from the IRF-PAI V1.5, on admission and discharge.

We also finalized the removal of 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 removal of this measure.

Adoption of the Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury measure results 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, there will be a 5 minute reduction in clinical staff time to report data, and 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.

While the reporting of data on quality measures involves collecting information, we believe that the burden associated with modifications to the IRF-PAI discussed in the FY 2018 IRF PPS final 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 = $2,904,699.55

IRF-PAI V1.5:
(FY 2018 rule) 1137 IRFs x reduction of $208.91 per IRF = $237,531.12 reduction for all IRFs
Total for IRF-PAI V1.5: Reduction of $237,531.12 per IRF

IRF-PAI V2.0:
(FY 2017 rule) 1131 IRFs x $4,625.46 per IRF = $5,231,398.17
(FY 2018 rule) 1137 IRFs x reduction of $2,255.26 per IRF = $2,564,229.74 reduction
Total for IRF-PAI V2.0: $5,231,398.17 - $2,564,229.74 = $2,904,699.55

e) 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 5 hours of burden per IRF, or 32,850 hours for all IRFs per year

In summary, we add a total of 294.50 hours of burden per IRF, or 342,188 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.

The burden hours for this package is 227,151.

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)	$293,592
GS-14 Federal Employee (33% X 3 years)	$111,102
Total cost to Federal Government:	**$3,154,694**

15. Changes to Burden

This supporting statement finalizes the burden related to IRF-PAI Versions 1.3, 1.4, 1.5 and 2.0. The changes to the IRF-PAI burden is unchanged for Versions 1.3, 1.4, and 1.5. However, we would like to note that through the FY 2018 IRF PPS final rule, we decided to delay the adoption of the standardized patient assessment data elements to fulfill the requirements of the IMPACT Act in the categories of cognitive function and mental status, special services, treatments, and interventions, and impairments and are no longer included in IRF-PAI Version 2.0. There was no change to the annual burden hours related to these data elements.

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

16. 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 and finalized on August 3, 2017.

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 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)