

Supporting Statement A for Paperwork Reduction Act Submissions

A. Background

OMB approved the IRF-PAI form and data collection on January 31, 2003. OMB approved an extension with change on May 29, 2009 and again on February 28, 2012. The OMB control number is 0938-0842. The current PRA approval expiration date is February 28, 2015.

We are requesting an approval for a revision to the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI). The IRF-PAI is the assessment instrument that inpatient rehabilitation facilities (IRFs) are required to submit in the manner necessary to administer the payment rate methodology under the IRF PPS described in 42 CFR 412 Subpart P. Since October 1, 2012, the IRF-PAI has been used to collect quality measure data, using data items in the Quality Indicator section.

The burden associated with this requirement is staff time required to complete and encode the data from the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI). The burden associated with transmitting the IRF-PAI is not being included in this revision, since the

requirement for IRFs to transmit the data is unaffected by the proposed revision to the assessment instrument (IRF-PAI) data

assessment
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B. Justification

1. Revisions to the IRF-PAI are needed to permit the Secretary of Health and Human Services, and CMS, to collect quality measure data as required by Section 1886(j)(7) of the Social Security Act added by section 3004 of the Patient Protection and Affordable Care Act. The statute requires the Secretary to establish a quality reporting program for inpatient rehabilitation facilities (IRFs). Specifically, section 1886(j)(7)(C) of the Act requires that each IRF submit data to the Secretary on quality measures specified by the Secretary. The data must be submitted in a form and manner, and at a time, specified by the Secretary. 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.

Under section 1886(j)(7)(E) of the Act, the Secretary is required to establish procedures for making data submitted by IRFs under the IRF quality reporting program available to the public. In accordance with this provision, we ultimately seek to adopt a comprehensive set of quality measures to be available for widespread use for informed decision making and quality improvement. However, we are not yet proposing a plan for making these data publicly available.

We propose to modify the current IRF-PAI instrument by making the following changes:

- a. We plan to renumber the Quality Indicator section of the IRF PAI using a flexible numbering scheme similar to that used in other CMS assessment item sets such as the LTCH CARE Data Set, and the MDS. Currently, the IRF-PAI assessment uses a “consecutive numbering scheme” for numbering assessment items. The Quality Indicator section items begin with the number 48A and end with 50C.

Problems arise with the use of a consecutive numbering scheme in two cases: (1) removal of an item; and (2) insertion of an item. When using a consecutive numbering scheme with the IRF-PAI (or any other document), and it is determined that an item must be removed,

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then all of the remaining items must be renumbered. For example, if item 10 is removed, then all subsequent items must be renumbered to maintain the consecutive numbering scheme. Item 11 must be renumbered to 10; item 12 must be renumbered to 11; etc.

Likewise, if a new item is added to the current version of the IRF-PAI, the new item receives the number after the item preceding it, and all subsequent items are renumbered. For example, when a new item is inserted between items 9 and 10, the new item is assigned the number 10 and all subsequent items must be renumbered (i.e. - item 10 is renumbered to 11; item 11 is renumbered to 12; etc.). Such re-numbering of items on the IRF-PAI will result a scenario in which a given item number will have very different meanings on different versions of the IRF-PAI item set.

To avoid such problems, other CMS assessment item sets (Hospice, LTCH, and Nursing Home MDS) have all adopted the MDS style item numbering scheme that allows greater flexibility for item removal and insertion. MDS style item numbering has advantages over the IRF-PAI consecutive number scheme because, when items are inserted or removed, renumbering of other items is not required; item numbers have consistent meanings over time, and item numbers can be harmonized across settings.

We believe that adopting this flexible numbering scheme for the Quality Indicator section of the IRF-PAI will allow for greater flexibility in the adding of new data items as the IRF Quality Reporting Program is expanded. The adoption of a numbering system similar to

that used in other CMS assessment instruments will allow Harmonization among the assessment items sets. This harmonization has the benefit of allowing clinicians to work across settings and also can assist analysts comparing patient characteristics and conditions across settings.

- b. We propose to remove the current pressure ulcer data items (Items #48A to 50C) and replace them with a more comprehensive set of pressure ulcer data items. The proposed new pressure ulcer items are similar to those collected through the Minimum Data Set 3.0 (MDS 3.0), which is a reporting instrument that is used in nursing homes. The current MDS 3.0 pressure ulcer items evolved as an outgrowth of CMS' work to develop a standardized patient assessment instrument, now referred to as the CARE (Continuity Assessment Records & Evaluation). CARE was developed and tested in the post-acute care payment reform demonstration as required by section 5008 of the 2005 Deficit Reduction Act (DRA) (Pub. L. 109-171, enacted February 8, 2006). The MDS data

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elements are supported by the National Pressure Ulcer Advisory Panel (NPUAP). We believe that modifying the current IRF-PAI pressure ulcer items to be consistent with the standardized data elements now used in the MDS 3.0, will drive uniformity across settings that will lead to better quality of care in IRFs and ultimately, across the continuum of care settings.

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- c. We have proposed to add a new measure, "Percent of Patients/Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine" (NQF #0680) to the IRF quality reporting program beginning on October 1, 2014. We propose to add a set of data elements necessary to collect the data for this new measure. These data items are similar to those collected through the Minimum Data Set 3.0 (MDS 3.0).
- d. We proposed to make changes to the main section of the IRF-PAI. These changes include the following:
 - 1) The "Identification Information" and "Admission Information" sections are consolidated into one section titled "Identification Information";
 - 2) The "Medical Information" and "Medical Needs" sections are consolidated into one section titled "Medical Information" ;

- 3) Response selections to questions # 15, 16 & 20 have been updated to be more relevant and accurate;
- 4) Items #15 & 16 were re-numbered to 15A and 16A;
- 5) Items #18 & 19, 25, 26, & 28 have been deleted;
- 6) In question #24, the number of available spaces for insertion of ICD- codes for co-morbid condition has been increased from 10 to 25;
- 7) Height & weight have been added as #25A and 26A respectively

2. Information Users

CMS uses the IRF-PAI data to reimburse IRFs for services furnished to Medicare beneficiaries. CMS will review the data for completeness to assess whether to reduce the increase factor with respect to a fiscal year by 2 percentage points for any IRFs that do not submit data in accordance with requirements established by the Secretary for that fiscal year, beginning in FY 2014. Ultimately, CMS intends to make quality measures based on the pressure ulcer assessment data available for public use to inform decision making and promote quality improvement.

3. Use of Information Technology

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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 Web site at http://www.cms.gov/InpatientRehabFacPPS/06_Software.asp#TopOfPage. Further, CMS provides customer support free of charge for software and transmission problems encountered by the providers through a CMS Help Desk. Contact information for the CMS Help Desk, including phone numbers and an email address, are posted on the CMS Web site at http://www.cms.gov/InpatientRehabFacPPS/10_Hotlines.asp#TopOfPage.

4. Duplication of Efforts

We are seeking approval of revision to the Quality indicator section of the IRF-PAI. These revisions include updates to the existing pressure ulcer data items, and the addition on items for new measure that are being added to the IRF quality reporting program. The data required does not duplicate any other effort and the information cannot be obtained from any other source.

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. In this filing we utilized the instructions that pertain to the I-83, Part II to determine the number of small entities. Out of a total of 1,161

IRFs, only 194 or 17% are small rural IRFs, 6% percent of which are small government-owned. The average number of assessments completed yearly is 309, and is the same across all respondents based on the number of actual assessments completed by IRFs in calendar year 2010. We estimate that removal of existing pressure ulcer items from the IRF-PAI reduces the amount of time required to complete the IRF-PAI by about 10 minutes, but the addition of new pressure ulcer, and patient influenza vaccination items adds about 20 minutes of time for the admission assessment and 20 minutes of time for the discharge assessment to complete the IRF-PAI, so the net change in the amount of time required to complete the IRF-PAI is 30 minutes. Although we have not fully analyzed data reported during the first reporting period, we estimate that about 98 percent of IRFs completing the Quality Indicator items on the IRF-PAI during that reporting period. The burden estimates for the purposes of this IRF-PAI PRA submission are based on 100 percent IRF participation.

6. Less Frequent Collection

We need to collect the IRF-PAI data 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.

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The information must be collected at admission and at discharge, and is used to calculate the IRF's payment rate. Therefore, IRFs complete only two assessments per patient, although some assessment may need to be revised under specific circumstances.

8. Federal Register/Outside Consultation

The 60-day Federal Register was included in the proposed rule which published on May 8, 2013 (78 FR 26880).

9. Payments/Gifts to Respondents

There were no gifts or payments to respondents.

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.

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimates (Total Hours & Wages)

CMS estimates the burden to IRF facilities to be calculated as follows:

Burden Estimate for IRF QRP Proposed Measure #1:

Percent of Patients or Residents with Pressure Ulcers That Are New or Worsened Measure (NQF #0678) – (NQF Endorsed Version)

A. Time Burden Calculation:

Average number of IRFs in U.S. = 1161

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Average Number of IRF-PAI reports Submitted Per All IRFs Per Year = 359,000¹
Average Number of IRF-PAI reports Submitted Per Each IRF Per Year = 309

Average Number of IRF-PAI reports Submitted Per Each IRF Per Month = 25.75

(359,000 IRF-PAI reports per all IRFs per year / 1161 IRFs in U.S. = 309 IRF-PAI reports per each IRF per year)

(309 IRF-PAI reports per IRF per year / 12 months per year = 26 IRF-PAI reports per each IRF per year)

Average Time Spent per Each IRF-PAI Quality Indicator Section Assessment = 28 minutes

10 minutes clinical time to obtain Quality Indicator data for admission assessment

15 minutes clinical time to obtain Quality Indicator data for discharge assessment

3 minutes administrative time to enter data into CMS system or JIRVEN program

Estimated Annual Hour Burden per each IRFs = 144 hours

25.75 IRF-PAI assessments per IRF per month x 28 min/assessment = 721 minutes per IRF per month

721 min per IRF per month / 60 minutes/ hour = 12 hours per IRF per month

12 hours per IRF per month x 12 months/year = 144 hours per each IRF per year

Estimated Annual Hour Burden All IRFs per year = 167,184 hours

¹ MedPAC, A Data Book: Health Care Spending and the Medicare Program (June 2012), <http://www.medpac.gov/chapters/Jun12DataBookSec8.pdf>

144 hours per IRF per month x 1161 IRFs = 167,184 hours per all IRFs per year

B. Cost/Wage Calculation:

Nursing Time:

25 minutes x 309 IRF-PAI assessments per each IRF per year = 7,725 minutes per each IRF per year

7,725 minutes per each IRF per year / 60 minutes per hour = 128.75 hours per each IRF per year

128.75 hours per year x \$33.23² per hour = **\$4,278.36** nursing wages per each IRF per year
\$4,278.36 x 1161 IRF providers = **\$4,967,176** per all IRFs per year

Administrative Assistant Time:

3 minutes x 309 IRF-PAI assessments per each IRF per year = **927** minutes per each IRF yearly
927 minutes per IRF per year / 60 minutes per hour = **15.45** hours per each IRF per year

15.45 hours per year x \$15.55 per hour = **\$240.25** administrative/clerical wages per each IRF yearly
\$240.25 x 1161 IRFs = \$278,930 per all IRFs yearly

Total Annualized Cost To Each IRF Provider:

\$4,278.36 Nursing wages per each hospice per year

\$ 240.25 Administrative assistant wages per each hospice per year

\$4,518.61 Total

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Total Annualized Cost Across All IRF Providers:

\$4,967,176 Nursing wages per each hospice per year

\$ 278,930 Administrative assistant wages per each hospice per year

\$5,246,106 Total

C. Additional Calculations:

Average Yearly Cost to Each IRF Provider :

\$5,246,106 – cost for all IRFs per year / 1161 IRFS = **\$4,518.61**

Average Monthly costs to EACH INDIVIDUAL IRF Providers:

\$5,246,106 -cost for all IRFs per year / 12 months per year / 1161 IRFS = **\$376.55**

Cost To Provider Per Each Individual Quality Indicator Section Assessment:

\$5,246,106 –cost for all IRFs per year / 359,000 IRF-PAI assessments per year = **\$14.61**

2 According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Registered Nurse is \$33.23. See <http://www.bls.gov/oes/current/oes291111.htm> .

Burden Estimate for IRF QRP Proposed Measure #2:
Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) Measure (NQF #0680)

A. Time Burden Calculation

Average number of IRFs in U.S. = 1161

Average Number of IRF-PAI reports Submitted Per All IRFs Per Year = 359,000³

Average Number of IRF-PAI reports Submitted Per All IRF Per Year = 309

Average Number of IRF-PAI reports Submitted Per Each IRF Per Month = 25.75

(359,000 IRF-PAI reports per all IRFs per year / 1161 IRFs in U.S. = 309 IRF-PAI reports per each IRF per year)

(309 IRF-PAI reports per IRF per year / 12 months per year = 25.75 IRF-PAI reports per each IRF per year)

Average Time Spent Per Each IRF-PAI Quality Indicator Section Assessment = 5 minutes

Estimated Annual Hour Burden per each IRFs = 25.75 hours

25.75 IRF-PAI assessments per IRF per month x 5 min/assessment = 128.75 min. per IRF per month

128.75 min per IRF per month / 60 minutes/ hour = 2.14 hours per IRF per month

2.14 hours per IRF per month x 12 months/year = 25.75 hours per each IRF per year

Estimated Annual Hour Burden All IRFs per year = 29,895.75 hours

25.75 hours per IRF per month x 1161 IRFs = 29,895.75 hours per all IRFs per year

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B. Cost/Wage Calculation

Average Time per Each Patient Influenza Assessment = 5 minutes

5 minutes nursing time to collect clinical data for admission assessment @ \$33.23 per hour = \$2.80

5 minutes x 309 IRF-PAI assessments per each IRF per year = 1545 minutes per each IRF per year

1545 minutes per each IRF per year / 60 minutes per hour = 25.75 hours per each IRF per year

25.75 hours per year x \$33.23 per hour = **\$855.67** nursing wages per each IRF per year

\$855.67 x 1161 IRF providers = **\$993,433** per all IRFs per year

³ MedPAC, **A Data Book: Health Care Spending and the Medicare Program (June 2012)**, <http://www.medpac.gov/chapters/Jun12DataBookSec8.pdf>

C. Additional Calculations

Average Yearly Cost to Each IRF Provider :

\$993,433 – cost for all IRFs per year / 1161 IRFS = **\$855.67**

Average Monthly costs to EACH INDIVIDUAL IRF Providers:

\$993,433 - cost for all IRFs per year / 12 months per year / 1161 IRFS = **\$71.30**

Cost To Provider Per Each Individual Quality Indicator Section Assessment:

\$993,433– cost for all IRFs per year / 359,000 IRF-PAI assessments per year = **\$2.78**

Summary of Estimated Burden to Providers

Measure Title NQF #	Annualized cost to each individual IRF	Annualized cost across all IRF
Percent of Patients or Residents with Pressure Ulcers That Are New or Worsened Measure (NQF #0678) (NQF Endorsed Version)	\$4,518.61	\$5,246,106
Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) Measure (NQF #0680)	\$855.67	\$993,433
TOTAL	\$5,374.28	\$6,399,539

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13. Capital Costs

By now, all IRFs have the computer hardware capability and the related software to be able to handle the computerization and data transmission requirements associated with the IRF-PAI. Therefore, we estimate that IRF-PAI capital cost maintenance is largely a part of normal computer operations at IRFs that cannot be identified as a separate cost borne by the IRF to comply with program requirements.

In addition, because CMS supplies the IRFs with the software that performs the electronic functions associated with the IRF-PAI free of charge, there are no costs incurred by IRFs to purchase the software. This software allows users to computerize the assessment data and transmit the data in a standard format specified by us to the CMS patient data system. IRFs that use our IRF-PAI software need to have Internet access in order to be able to download and install our software into their computer system. We believe that all IRFs currently have the capability to

access the Internet. Therefore, the cost of internet services is largely a part of normal IRF operations and cannot be identified as a separate cost borne by the IRF to comply with the existing requirements for submission of the IRF-PAI or IRF quality data, or any proposed new requirements.

14. Cost to Federal Government

We have projected on-going IRF-PAI-related costs at approximately \$2,000,000 per year. We do not anticipate that our proposed changes to the IRF-PAI will cause any increases in the cost that the Federal government incurs for the administration and handling of the IRF-PAI.

15. Changes to Burden

We estimate that changes to the Quality Indicator Section of the IRF-PAI, as noted in Section B1 above, will increase the amount of time required to complete the IRF-PAI by about 25 hours per each IRF and 29,025 hours per year across all IRFs.

We do not anticipate any changes in burden as a result of the changes made to non-quality related items of the IRF-PAI. We are proposing to revise several items on the IRF-PAI to provide greater IRF-PAI data providers. The proposed changes include updating several items regarding the response options available to providers. Additionally, we are proposing to remove several items that we believe are unnecessary for providers to continue documenting on the IRF-PAI since those items are already being documented in the patients' medical record. We are also proposing to add several items, such as a signature page, to fulfill providers' request to have an organized way to document who has assessed the patient and when that assessment took place. We do not estimate any additional burden for IRFs to complete this section of the IRF-PAI as a result of these proposals. We estimate the time that will be needed to complete the new non-quality related proposed items, equals the time that was needed to complete the previous non-quality related items. When the original burden estimates were completed for the IRF-PAI, we estimated that the proposed deletion of the non-quality related items would take approximately 3 minutes to complete. Thus, removing these items the IRF-PAI would decrease the total estimated burden of completing the non-quality related portions of the IRF-PAI by 3 minutes. However, we estimate that it will take about 3 minutes to complete the new non-quality related items that we are proposing to add. Therefore, we estimate no net change in the amount of time associated with completing the non-quality related portions of the IRF-PAI and that the burden for completing these portions of the IRF-PAI will not change.

16. Publication/Tabulation Dates

The proposed regulation is scheduled to go on display in the Federal Register on or about April 29, 2013 and be published on or about May ____, 2013.

17. Expiration Date

With respect to the OMB approval, CMS does not object to the displaying of the expiration date.

18. Certification Statement

There are no exceptions.