Supporting Statement – Part A

Supporting Statement for Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI) data and Supporting Regulations in 42 CFR 412 Subpart P

Supporting Statement For Paperwork Reduction Act Submissions

A. Background

The IRF-PAI is an instrument for collecting standardized patient assessment data 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. The information provided on the IRF-PAI is used to establish reimbursement under the prospective payment system for inpatient rehabilitation facility services for the Medicare program.

We are requesting an approval for a revision to the existing assessment instrument to implement Section 1886(j)(7) of the Social Security Act (added by section 3004(b) of the Affordable Care Act), which requires the Secretary to develop a quality reporting program for inpatient rehabilitation facilities. Inpatient rehabilitation facilities are already required to submit in the assessment instrument data in a manner necessary to administer the payment rate methodolgy under the IRF PPS described in 42 CFR 412 Subpart P. The requested revision seeks to implement the statutory requirement of a quality reporting program for inpatient rehabilitation facilities by removing the voluntary "Quality Indicators" section at the end of the assessment instrument and replacing it with a required set of pressure ulcer items. The burden associated with the existing assessment instrument requirement is the staff time required to complete and encode the data from the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI), and the burden associated with transmitting the IRF-PAI. We estimate no net added burden as a result of the requested revisions to the IRF-PAI, since the requested revisions involve removing some items and replacing them with others.

B. Justification

1. The existing assessment 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 added by section 4421 of the Balanced Budget Act of 1997. 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 inpatient prospective payment system (IPPS) for inpatient acute care 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 patient 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.

The requested revision to the existing IRF-PAI is needed to permit the Secretary of Health and Human Services, and CMS, to implement 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.

CMS seeks to promote higher quality and more efficient health care for Medicare beneficiaries. Our efforts are, in part, effectuated by quality reporting programs coupled with the public reporting of data collected under those programs. Similar quality reporting programs exist for various settings such as hospital inpatient services (the Hospital Inpatient

Quality Reporting (Hospital IQR) Program), hospital outpatient services (the Hospital Outpatient Quality Data Reporting Program (HOP QDRP)), and for physicians and other eligible professionals the Physician Quality Reporting System (formerly called the Physician Quality Reporting Initiative, or PQRI). We have also implemented quality reporting programs for home health agencies and skilled nursing facilities that are based on conditions of participation, and an end-stage renal disease quality incentive program (ESRD QIP) that links payment to performance.

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.

Thus, we propose to modify the current IRF-PAI instrument by removing the current optional quality assessment items in the Quality Indicators section of the IRF-PAI (including the Respiratory Status, Pain, Pressure Ulcers, and Safety items) and adding revised pressure ulcer data elements to satisfy the statutory requirements described above and to further CMS's quality improvement goals across settings of care.

The new pressure ulcer data elements would be more comprehensive than the previous pressure ulcer assessment measurement in the optional Quality Indicators section of the IRF-PAI and 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 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.

OMB approved the existing IRF-PAI form and data collection on January 31, 2003. In addition, OMB approved an extension with change on May 29, 2009. The OMB number is 0938-0842, and the expiration date is May 31, 2012.

2. Information Users

CMS uses the existing IRF-PAI data to reimburse IRFs for services furnished to Medicare beneficiaries. Under the requested revision, CMS will also review the added quality 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

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 requesting a revision to the existing IRF-PAI to remove the voluntary Quality Indicators items that are currently on the instrument and replace them with mandatory pressure ulcer data elements, similar to items collected through the Minimum Data Set 3.0 (MDS 3.0). 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 1,146 IRFs, only 194 or 17% are small rural IRFs, 6% percent of which are small government-owned. The average number of assessments completed is 370, and is the same across all respondents based on the number of actual assessments competed by IRFs in calendar year 2010. We estimate that the existing IRF-PAI takes about 45 minutes to complete, at an estimated cost per IRF-PAI of $20.87, and about 6 minutes to transmit, at an estimated cost per IRF-PAI of $2.78, for a total of 51 minutes at an estimated cost per IRF-PAI of $23.65. We estimate that the requested removal of existing voluntary Quality Indicator items from the IRF-PAI reduces the amount of time required to complete the IRF-PAI by about 10 minutes, but the requested addition of new required pressure ulcer items in the place of the voluntary Quality Indicator items adds about 10 minutes to the time required

to complete the IRF-PAI, so the net change in the amount of time required to complete the IRF-PAI is 0. Although we estimate that about 20 percent of IRFs are currently completing the voluntary Quality Indicator items on the IRF-PAI, those voluntary Quality Indicator items were included in the 45 minute estimate for completing the existing IRF-PAI. Thus, the total time estimated to complete the IRF-PAI (45 minutes) likely remains unchanged, since removal of the existing Quality Indicators items decreases the time by 10 minutes but the addition of the new pressure ulcer items increases the time by 10 minutes.

6. Less Frequent Collection

We need to collect the existing IRF-PAI data at the required frequency (that is, at admission and at discharge from the IRF) in order to calculate payment under the inpatient rehabilitation facility prospective payment system. This requirement is not affected by the requested revision to the IRF-PAI.

7. Special Circumstances

The existing IRF-PAI 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. This requirement is not affected by the requested revision to the IRF-PAI.

8. Federal Register/Outside Consultation

The 60-day Federal Register proposed rule for this approval of an existing collection was published April 22, 2011. Please see the attached draft copy of the document.

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).

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:

Total number of Inpatient Rehabilitation Facilities**= 1,146**
Average Number of Pressure Ulcer Assessments Submitted/Provider/Month = **31**
Average Number of IRF-PAI Forms Submitted/Provider/Year = **370**
Average Number of IRF-PAI Assessments by all IRFs/Year = **424,020**
Average Time for Completing the Existing IRF-PAI/Per Assessment = 45 minutes
Average Time for Transmitting the Existing IRF-PAI/Per Assessment = 6 minutes
Average Time for Completing and Transmitting the Existing IRF-PAI/Per Assessment = 51 minutes
Average Time/Current Quality Indicators Items Removed from Instrument/Provider = **10 minutes**
Average Time /Pressure Ulcer Assessment / Provider = **10 minutes**
Clerical staff salary of $27.82 per hour

Estimated Hour Burden Associated with the Existing IRF-PAI
Estimated Annual Hour Burden per each IRF = 314. 5 hours
Estimated Annual Hour Burden for all IRFs/year **=** 360,417 hours
Estimated Annual Hour Burden per IRF/month**=** 26.35 hours

Estimated Cost Burden Associated with the Existing IRF-PAI
Average Cost per submission = $23.65
Average Annual Cost / IRF/month = $733.15
Average Annual Cost / IRF/year = $8750.50
Estimated Annual Cost for all IRFs/year = $10,028,073

Estimated Hour Burden Associated with Pressure Ulcer Assessment
Estimated Annual Hour Burden per each IRFs = **61.67 hours**
Estimated Annual Hour Burden for all IRFs/year **= 70,670** hour/year
Estimated Annual Hour Burden per IRF/month**= 5.17** hour/month

Estimated Cost Burden Associated with Pressure Ulcer Assessment
Average Cost per submission = **$4.64**
Average Annual Cost / IRF/month = **$143.84**
Average Annual Cost / IRF/year = **$1,716.80**
Estimated Annual Cost for all IRFs/year = **$1,967,453**

Estimated Net Hour Burden Associated with Pressure Ulcer Assessment (Net of Removal of the Quality Indicators Items)
Estimated Annual Hour Burden per each IRFs = **0**

Estimated Annual Hour Burden for all IRFs/year **= 0** hour/year
Estimated Annual Hour Burden per IRF/month**= 0** hour/month

Estimated Net Cost Burden Associated with Pressure Ulcer Assessment (Net of Removal of the Quality Indicators Items)
Average Cost per submission = **$0**
Average Annual Cost / IRF/month = **$0**
Average Annual Cost / IRF/year = **$0**
Estimated Annual Cost for all IRFs/year = **$0**

To estimate the total hour and cost burden of the pressure ulcer item, CMS did the following:

- Estimation of total hour burden:
  - Data source – Federal Register: October 13, 2010 (Volume 75, Number 197) - and IRF PAI Demonstration Project
  - Data Source – Original IRF-PAI PRA submission (OMB No. 0938-0842)

- Estimated time per pressure ulcer assessment:
  - **10** minutes of additional time per patient for pressure ulcer assessment to be added to the IRF-PAI instrument.
  - Estimated annual hour burden per provider for pressure ulcer assessment = **62** hours
  - Estimated annualized hour burden for all IRFs for pressure ulcer assessment = **71,052** hours

- Estimation of total cost burden:
  - CMS retrieved the average national salary from the U.S. Bureau of Labor which stated the average national salary of a Registered Nurse at **$41.59**/hour and an Administrative Assistant at **$20.57.** For work regarding the IRF-PAI data collection instrument, an average hourly wage rate of **$27.82**, which reflects a blend of the hourly wage rates for social workers, social work assistants, registered nurses, licensed practical nurses, recreational therapists, dietitians/nutritionists, speech-language pathologists, audiologists, occupational therapists, and physical therapists,

  - Based on the hour burden estimates, the cost per each IRF-PAI pressure ulcer submission = **$4.64** each

  - Based on the hour burden estimates, the estimated annualized cost per provider for the IRF-PAI pressure ulcer assessment = **$1,716.80**

  - Based on the hour burden estimates the estimated annualized cost for all IRFs for the IRF-PAI pressure ulcer assessment = **$1,967,453**

To estimate the total net hour and cost burden of the pressure ulcer item (net of removal of the Quality Indicators items), CMS did the following:

- Estimation of total net hour burden:
  - Data source – Federal Register: October 13, 2010 (Volume 75, Number 197) - and IRF PAI Demonstration Project
  - Data Source – Original IRF-PAI PRA submission (OMB No. 0938-0842)

- Estimated net time per assessment(net of removal of the Quality Indicators items):
  - **10** minutes of additional time per patient for pressure ulcer assessment to be added to the IRF-PAI instrument.

  - **10** minutes of reduced time per patient for Quality Indicators to be removed from the IRF-PAI instrument.

  - Estimated net annual hour burden per provider for pressure ulcer assessment (net of removal of the Quality Indicators items) = **0** hours

  - Estimated net annualized hour burden for all IRFs for pressure ulcer assessment (net of removal of the Quality Indicators items) = **0** hours

- Estimation of net total cost burden (net of removal of the Quality Indicators items):

  - Based on the net hour burden estimates, the net cost per each IRF-PAI pressure ulcer submission (net of removal of the Quality Indicators items)= **$0** each

  - Based on the net hour burden estimates, the estimated net annualized cost per provider for the IRF-PAI pressure ulcer assessment (net of removal of the Quality Indicators items) = **$0**

  - Based on the net hour burden estimates the estimated net annualized cost for all IRFs for the IRF-PAI pressure ulcer assessment (net of removal of the Quality Indicators items) = **$0**

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 program requirements.

14. Cost to Federal Government

We have projected on-going IRF-PAI-related costs at approximately $2,000,000 per year.

15. Changes to Burden

We estimate that the existing IRF-PAI takes about 45 minutes to complete, at an estimated cost per IRF-PAI of $20.87, and about 6 minutes to transmit, at an estimated cost per IRF-PAI of $2.78, for a total of 51 minutes at an estimated cost per IRF-PAI of $23.65. Removal of existing voluntary Quality Indicator 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 required pressure ulcer items in the place of the voluntary Quality Indicator items adds about 10 minutes to the time required to complete the IRF-PAI, so the net change in the amount of time required to complete the IRF-PAI is 0. Although we estimate that about 20 percent of IRFs are currently completing the voluntary Quality Indicator items on the IRF-PAI, the burden estimates for the initial IRF-PAI PRA submission were based on 100 percent IRF participation. Thus, the total time estimated to complete the IRF-PAI remains unchanged (see estimates in section 12 of this document). The addition of the required pressure ulcer items is necessary for CMS to meet the requirements set forth in Section 1886(j)(7) of the Social Security Act added by section 3004 of Patient Protection and Affordable Care Act.

16. Publication/Tabulation Dates

The final regulation was published August 1, 2011.

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.