

**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

HOSPICE ITEM SET V1.0
FOR THE COLLECTION OF DATA
PERTAINING TO THE
HOSPICE QUALITY REPORTING PROGRAM

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Exhibit A

FY 2014 Hospice PRA Burden Estimate Calculation Worksheet

Exhibit B

Burden Calculation from 2013 Hospice Rule PRA Package

Supporting Statement for Paperwork Reduction Act Submissions
PART A

Hospice Item Set For the Collection of Data Pertaining to the Hospice Quality Reporting Program

1. Background & Justification

Section 3004 of The Affordable Care Act authorizes the establishment of a new quality reporting program for hospices.¹ Pursuant to Section 3004 of The Affordable Care Act, the Hospice Quality Reporting Program (HQRP) was implemented in the Hospice Wage Index for Fiscal Year (FY) 2012 Final Rule (76 FR 47318 through 47324).² Implementation of the HQRP established that beginning in FY 2014, and for each subsequent FY, the Secretary shall reduce the market basket update by 2 percentage points for any hospice that does not comply with the quality data submission requirements with respect to that fiscal year.

For the FY 2016 data submission requirements, the Centers for Medicare & Medicaid Services (CMS) is proposing that beginning July 1, 2014, each hospice collect data using a newly created data collection instrument, the Hospice Item Set, as part of the HQRP. The item set consists of data elements to collect standardized, patient-level data for the following domains of care:

- Pain
- Respiratory Status
- Medications
- Patient Preferences
- Beliefs & Values

The Hospice Item Set was developed specifically for use by hospices and contains data elements that could be used by CMS to collect patient-level data to calculate seven National Quality Forum (NQF) endorsed quality measures under the HQRP (see Table 1).

Table 1. NQF-Endorsed Measures Corresponding to the Hospice Item Set

NQF Number	Measure Name
NQF #1634	Hospice and Palliative Care – Pain Screening
NQF #1637	Hospice and Palliative Care – Pain Assessment
NQF #1639	Hospice and Palliative Care – Dyspnea Screening
NQF #1638	Hospice and Palliative Care – Dyspnea Treatment
NQF #1617	Patients Treated With an Opioid who are Given a Bowel Regimen
NQF #1641	Hospice and Palliative Care – Treatment Preferences
NQF #1647	Beliefs/values addressed

Use of the Hospice Item Set will allow standardized, patient-level data collection for quality reporting purposes as part of the HQRP. The use of this Hospice Item Set is necessary in order to allow CMS to collect quality data from hospices in compliance with Section 3004 of the Affordable Care Act.

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 Medicare Program; Hospice Wage Index for Fiscal Year 2012; Final Rule, Federal Register/Vol. 76, NO. 150, August 4, 2011. <http://www.gpo.gov/fdsys/pkg/FR-2011-08-04/pdf/2011-19488.pdf>

Section 3004 of the Affordable Care Act requires that the Secretary establish procedures for making the data submitted for the HQRP available to the public. In general, any measures selected for the HQRP be endorsed by the consensus-based entity which holds a contract regarding performance measurement with the Secretary. This contract is currently held by NQF.

Implementation of the Hospice Item Set fulfills both of these requirements – the item set allows for standardized, patient-level data collection of data elements required to calculate the aforementioned quality measures currently NQF-endorsed for palliative and end of life care. Secondly, data collection through the Hospice Item Set will result in standardized data which can be used to calculate the aforementioned quality measures in a manner consistent with the scientific methods required to create a publicly reported quality measure under the HQRP. There are no other reasonable or currently available alternatives for CMS to use for the collection of patient-level quality data from hospices that would fulfill the requirements of publicly reporting quality measures, set forth in the Affordable Care Act.

2. Information Users

All hospices providers must submit the specified type and amount quality data for participation in the Hospice Quality Reporting program in order not to be subjected to a 2 percentage point reduction in the market basket update for FY 2014 and beyond. This data will be used by 2 primary sources.

The estimate that there will be two primary users of the Hospice QRP data. The first is CMS is required to collect this data by Section 1814(j)(7) of the Social Security Act (as added by section 3004 of Patient Protection and Affordable Care Act). CMS will use the data collected for the calculation of quality measures, for determining provider compliance with the data reporting requirements of the Hospice QRP and at a later date for public reporting .

The second primary group of data users is the public, after this after is made available by posting on the CMS website. However, no date has been set for public reporting of the Hospice Quality Reporting Program data.

- CMS - as required under Section 3004 of the Affordable Care Act
- Public - the measure calculated from the data obtained will be made available at a later date for public use on CMS’ website.

3. Use of Information Technology

Hospices 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. Hospices will use the Quality Improvement Evaluation System (QIES) Assessment Submission and Processing (ASAP) system for data submission, which is currently used by Inpatient Rehabilitation Facilities (IRFs), Skilled Nursing Facilities (SNFs), and Long Term Care Hospitals (LTCHs).

CMS will require that the collected data be transmitted to CMS electronically, in a manner similar to the process that is currently used by HHAs for the Outcome and Assessment Information Set, Version C (OASIS-C), SNFs for the Minimum Data Set (MDS 3.0), and IRFs for Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI), and LTCHs for the LTCH Care Data Set. Hospices

will be required to attest to the accuracy of the data collected for the Hospice Item Set. However, if electronic signatures were to be required at a future date, CMS could accommodate this as well.

Data specifications will be made available for hospices to submit the specified data items in a manner for meeting the 2014 reporting requirements for 2016 payment update determination.

4. Duplication of Efforts

This information collection does not duplicate any other effort, and the standardized, data elements in the Hospice Item Set to collect data on pain, respiratory status, medications, patient preferences, and beliefs/values cannot be currently obtained from any other existing data source. There are no other data sets that will provide comparable and standardized information on patients receiving hospice care. This information collection request will replace the current data collection instrument that is being used for the HQRP.

5. Small Businesses

In order to minimize burden to hospices that qualify as small business entities, CMS is utilizing a web-based data submission process, so that hospices can submit the specified data electronically. This will minimize the burden that this ICR places on the provider. CMS is asking hospices to collect and submit data elements that can be used to calculate seven endorsed quality measures. A pilot test of the data collection showed that hospices of varying sizes (including several very small hospices) were able to find the required data elements in their medical record systems and complete the Hospice Item Set. There was minimal difference between the burden of finding and recording the required data experienced by small versus medium or large sized hospices. The amount and type of quality data specified for participation in the HQRP is already currently collected by hospices as part of their patient care processes.

6. Less Frequent Collection

The Hospice Item Set will be used in hospices to collect quality data about physical and psychosocial symptoms, specific to the seven NQF-endorsed measures. Data collection will be required upon admission and discharge for every patient. Hospices will be required to submit this data to CMS on a periodic basis.

Section 3004 (C) (which added 1814(i)(5)(A)(i) to the “Act”) required the Secretary to establish a quality reporting program for hospices. This statute further required that, beginning with FY 2014, the Secretary, reduce the market basket update by 2 percentage points for any hospice that does not submit quality data submission for a fiscal year. CMS did begin collection hospice QRP data on 10/01/2012. To remain in compliance with the ACA Section 3004 and 1814(i)(5)(A) of the Act, we must continue to collect Hospice quality measure data and add new measures as appropriate.

7. Special Circumstances

None.

8. Federal Register/Outside Consultation

OSORA will fill in

9. Payment/Gifts to Respondents

There will be no payments/gifts to respondents for the use of the Hospice Item Set.

10. Confidentiality

The data collected using the Hospice Item Set will be kept confidential by CMS. Data will be stored in a secure format meeting all federal privacy guidelines. Data will be collected using a secure platform for electronic data entry and secure data transmission. The electronic system will be password protected with access limited to CMS and project staff. To protect patient confidentiality, the patient's name will not be linked to his/her individual data. For identification purposes, a unique identifier will be assigned to each sample member.

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. A System of Records will be established for this ICR prior to the time that it is implemented.

11. Sensitive Questions

This data collection does not incorporate any questions that would be considered sensitive in nature.

12. Estimates of Annualized Burden Hours and Costs

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

PART 1. Time Burden

Estimated number of hospice admissions and Hospice Item Set record submissions

Total number of Medicare-participating hospices = 3,742

Total number of admissions to all hospices per year = 1,089,719³

Estimated number of admissions to each hospice per year

1,089,719 admissions to all hospices / 3,742 hospices = 291

Estimated number of admissions to each hospice per month

1,089,719 admissions to all hospices / 3,742 hospices / 12 months per year = 24

Estimated number of Hospice Item Set records submitted by all hospices per year

³ The admissions number, 1,089,719, was calculated using 2011 Medicare hospice claims data. MedPAC listed the number of beneficiaries in hospice as 1,159,000 in their 2012 "Data Book." However, MedPAC's numbers are not restricted to admissions and are based on 2010 claims data.

1,089,719 admissions to all hospices per year x 2 Hospice Item Set records (1 Admission Record and 1 Discharge Record) per patient = 2,179,438

Estimated number of Hospice Item Set records submitted by each hospice per year
2,179,438 Hospice Item Set records per all hospices / 3,742 hospices = 582

Estimated average number of Hospice Item Set records submitted by each hospice per month
2,179,438 Hospice Item Set records per all hospices / 3,742 hospices / 12 months per year = 49

Estimated average number of Hospice Item Set records submitted by all hospices per month
2,179,438 Hospice Item Set records per all hospices per year / 12 months per year = 181,620

PART 2. Cost/Wage Calculation

Time required to complete each Hospice Item Set record:

14 minutes nursing/clinical staff time to abstract data for Admission Record – paid @ \$33.23/hr.⁴
5 minutes nursing/clinical staff time to abstract data for Discharge Record – paid @ \$33.23/hr.
5 minutes administrative/clerical staff time to upload Assessment Record data – paid @ \$15.59/hr.⁵
5 minutes administrative/clerical staff time to upload Discharge Record data – paid @ \$15.59/hr.

Nursing Time:

19 minutes x 291 Hospice Item Sets per each hospice per year = **5,529** minutes per each hospice per year

5,529 minutes per each hospice per year / 60 minutes per hour = 92.15 hours per each hospice per year

92.15 hours per each hospice per year x 3732 Hospices = 344,825 hours across all Hospices

92.15 hours per year x \$33.23 per hour = **\$3,062.14** nursing wages per each hospice per year
\$3,062.14 x 3,742 hospice providers = \$11,458,528 per all hospices per year

Administrative Assistant Time:

10 minutes x 291 Hospice Item Sets per each hospice per year = **2,910** minutes per hospice per year
2,910 minutes per provider per year / 60 minutes per hour = **48.50** hours per each hospice year
48.5 hours per each hospice year x 3732 Hospices = 181,002 hours across all Hospices

48.50 hours per year x \$15.59 per hour = **\$756.12** administrative/clerical wages per each hospice per year

⁴ The mean hourly wage of \$33.23 per hour for a Registered Nurse was obtained from the U.S. Bureau of Labor Statistics. See

<http://www.bls.gov/oes/current/oes291111.htm>

⁵ The mean hourly wage of \$15.59 per hour for a Medical Secretary was obtained from the U.S. Bureau of Labor Statistics. See <http://www.bls.gov/oes/current/oes436013.htm>

\$756.12 x 3,742 hospice providers = **\$2,829,401** per all hospices per year

Total annualized cost to each hospice provider:

\$3,062.14	Nursing wages per each hospice per year
\$ 756.12	Administrative assistant wages per each hospice per year
\$3,818.26	Total

Total annualized cost to all hospice providers:

\$11,458,528	Nursing wages per all hospice providers per year
\$ 2,829,401	Administrative assistant wages per all hospice providers per year
\$14,287,929	Total

PART 3. Additional Calculations:

Average yearly cost to each individual hospice provider:

\$14,287,929 – cost for all hospices per year / 3,742 hospices = **\$3,818.26**

Average monthly cost to each individual hospice provider:

\$14,287,929 – cost for all Hospices per year / 3,742 hospices / 12 months per year = **\$318.19**

Cost to provider per each individual hospice patient:

\$14,287,929 – cost for all hospices per year / 1,089,719 Hospice Item Sets per year = **\$13.11**

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

No anticipated capital costs since a web based interface will be available to all providers to submit the requisite information.

14. Annualized Cost to the Federal Government

The federal government will incur costs associated with the development maintenance and upkeep of a CMS-sponsored web-based program that hospice providers will use to submit their Hospice Item Set. The work to create and maintain this web-based data submission platform will be performed by a CMS IT group known as the Division of National Systems (DNS) or groups under contract with DNS to perform this work. DNS will use approximately 0.5 FTE's at a grade 13 or higher to manage the technology aspect of the Hospice Quality Reporting Program. In addition, the federal government will also incur costs for help-desk support that must be provided to assist Hospice the data submission process.

After Hospice providers have submitted their HQRP data to CMS, this data will then transmitted to a CMS contractor for processing and analysis. Thereafter, the data will be stored by another CMS contractor for future use. There are costs associated with the transmission, analysis, processing and storage of the Hospice data by these CMS contractors.

Also, pursuant to §1814 (b)(3)(B)(v)(I) of the Social Security Act, Hospices that do not submit the required data will receive a 2 percentage point reduction of their annual market basket increase. The federal government will incur additional costs associated with aggregation and analysis of the data necessary to determine provider compliance with the reporting requirements mandated by §1814 (b)(3)(B)(v)(I) of the SSA.

CMS began incurring costs associated with the HQRP, since it the program began on October 1, 2012. The total annual cost to the federal government for the implementation and ongoing management of Hospice Item Set data is estimated to be \$1,583,500. These costs are itemized below:

ESTIMATED ANNUAL COSTS TO FEDERAL GOVERNMENT:

• Create and Conduct Provider Web-based Training	\$ 8,500
• Prepare and update Hospice Item Set Manuals and Materials	\$ 25,000
• Contractor Costs for Receipt and Storage of Hospice Item Set Data	\$ 550,000
• Cost for Aggregation & Data Analysis	\$ 500,000
• Costs for Upkeep & Maintenance of Hospice Item Set Data Submission Software by CMS/DNS	\$ 500,000

TOTAL COST TO FEDERAL GOVERNMENT: \$1,583,500

15. Explanation for Program Changes or Adjustments

The attached Burden Estimate Calculation Worksheet (Exhibit A) provides a detailed explanation of the burden we estimate hospice providers will experience as a result of reporting hospice quality measure data using this proposed new ICR format. We estimate the annualized yearly burden per each hospice to be \$3,818 and the annualized burden across all hospices to be \$14,287,929. In the previous PRA package, which was published in the Federal Register on August 13, 2012,⁶ we estimated that the total annualized burden to each hospice would be \$3,038 and the annualized burden across all hospices in the U.S. to be \$11,034,016. (See Exhibit B).

We have noted that there will be some increase in burden associated with the change to the new Hospice Item Set. We estimate that the increase to each individual hospice will be approximately \$780 and the total increase in burden across all 3,742 hospices will be approximately \$3,253,913. (See Exhibit A & Appendix 4). We believe that this increase in burden can be attributed to several factors. First, the burden calculation used in the previous PRA package was based on the use of a different ICR format and the collection of data for only 2 relatively simple quality measures. These measures only required data submission only twice per reporting cycle. The burden calculation for the Hospice Item Set is structured differently. This calculation is based on the assumption that each hospice will be making 2 submissions per patient as opposed to 2 submissions per reporting cycle.

Other changes that have been made to the Hospice ICR and the HQRP in general that account for this increased burden include the following:

- Replacement of the structural measure and the NQF #0209 pain measure with the

⁶ <https://www.federalregister.gov/articles/2012/08/13/2012-19689/agency-information-collection-activities-submission-for-omb-review-comment-request>

Hospice Item Set. The Hospice Item Set contains more data elements for hospices to report, which increases the burden. However, some of this increase in burden is offset by the fact that hospices will now be reporting patient-level data. The structural measure and NQF #0290 pain measure required hospices to submit facility-level data. To do this for the NQF #0209 pain measure, hospices had to aggregate their patient level data to calculate and submit data.

- Updated information from the Center for Medicare regarding the current number of Medicare-participating hospices in the U.S. We use this information to inform our burden calculations. This figure has increased since the previous PRA submission and thus has increased the burden calculation included in this package.

This quality reporting program was mandated by Section 3004(c) of the Affordable Care Act, (1814(i)(5) (A)(i) of the Social Security Act) and therefore, this burden is statutorily mandated:

- In order for CMS to meet the requirements set forth in section added by section 3004 of the Patient Protection and Affordable Care Act) which states that the Secretary of the Department of Health and Human Services should establish a quality reporting program for hospices by Fiscal Year 2014.
- In order for each hospice to comply with the reporting requirements of ACA Section 3004(c).
- In order for each hospice to be entitled to receive their annual market basket for update beginning in Fiscal Year 2014.

16. Plans for Tabulation and Publication and Project Time Schedule

At this time, there are no plans for publication of the data that will be obtained from the Hospice Quality Reporting Program.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

CMS requests an exemption from displaying the expiration date of this PRA package approval, as these forms are to be used on a continuing basis for hospices' compliance with the requirements of the HQRP.