

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES**

**OFFICE OF MANAGEMENT AND BUDGET  
PAPERWORK REDUCTION ACT  
CLEARANCE PACKAGE**

**REVISED SUPPORTING STATEMENT-PART A**

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

**REVISED SUPPORTING STATEMENT-PART A**  
HOSPICE ITEM SET V1.0  
FOR THE COLLECTION OF DATA  
PERTAINING TO THE  
HOSPICE QUALITY REPORTING PROGRAM

**TABLE OF CONTENTS**

1. Background & Justification.....	2
2. Information Users.....	3
3. Use of Information Technology.....	3
4. Duplication of Efforts.....	4
5. Small Businesses.....	4
6. Less Frequent Collection.....	5
7. Special Circumstances.....	5
8. Federal Register/Outside Consultation.....	5
9. Payment/Gifts to Respondents.....	5
10. Confidentiality.....	5
11. Sensitive Questions.....	6
12. Estimates of Annualized Burden Hours and Costs.....	5
13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers.....	8
14. Annualized Cost to the Federal Government.....	8
15. Explanation for Program Changes or Adjustments.....	9
16. Plans for Tabulation and Publication and Project Time Schedule.....	10
17. Reason(s) Display of OMB Expiration Date is Inappropriate.....	10
18. Certification Statement.....	10

Exhibit A

FY 2014 Hospice PRA Burden Estimate Calculation Worksheet

Exhibit B

Burden Calculation from 2013 Hospice Rule PRA Package

**Revised Supporting Statement A**  
**For Paperwork Reduction Act Submissions**

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

**1. Background & Justification**

Section 3004(c) of the Affordable Care Act (ACA) (which added section 1814(i)(5)(A)(i) to the Social Security Act (The Act) authorized the establishment of a new quality reporting program for hospices.<sup>1</sup> Section 3004(c)(5)(C) of the ACA requires that hospices must submit quality data in a form, manner, and time specified by the Secretary. Section 3004(c)(5)(A)(i) further provides that, beginning with FY 2014, the Secretary shall apply a reduction in the amount of two (2%) percentage points to the market basket percentage increase for any hospice that fails to submit data to the Secretary in accordance with requirements established by the Secretary for that fiscal year.

CMS established the Hospice Quality Reporting Program (HQRP) in the FY 2012 Hospice Wage Index Final Rule (76 FR 47318 through 47324, and 47325 through 47326)<sup>2</sup>. In this rule, CMS set forth the initial framework for the HQRP and established that the first “mandatory” reporting period would take place from October 1, 2012 through December 31, 2012. During the first “mandatory” reporting period, hospices were required to gather data pertaining to two quality measures: (1) a structural measure titled “Participation in a Quality Assessment and Performance Improvement (QAPI) Program that Includes at Least Three Quality Indicators Related to Patient Care” and; (2) the National Quality Forum (NQF)-endorsed #0209 pain measure. Hospice providers were then required to report their data between 01/01/2012 and 04/01/2012.

In the CY 2013 HH PPS final rule (77 FR 67132 through 67136), CMS retained the two measures that had previously been adopted in the FY 2012 rule. Hospices will continue to collect data for these measures until December 31, 2013, using the current data collection instrument.

Beginning on July 1, 2014, hospices will begin using a newly created data collection instrument, titled the “Hospice Item Set” (HIS). This item set will be used for the collection of quality measure data related to the Hospice Quality Reporting Program (HQRP), .

The HIS consists of data elements that are designed 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 six National Quality Forum (NQF)

---

<sup>1</sup> 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>.

<sup>2</sup> 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>

endorsed quality measures and a modification of one NQF-endorsed measure 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 (modified)	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.

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.

There will be two primary users of the Hospice QRP data. The first user is CMS, collect this data as required by Section 3004(c)(5)(A)(i) of the ACA (which added section 1814(i)(5)(A)(i) to the Social Security Act. CMS will use the hospice quality data collected for the purpose of 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. Who will have access to this data, after it 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), Long Term Care Hospitals (LTCHs), and Home Health Agencies (HHAs).

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 six NQF-endorsed quality measures and a modification of one NQF-endorsed measure. 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 six NQF-endorsed quality measures and a modification of one NQF-endorsed measure. 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**

The 60 day PRA notice was given in the Hospice Wage Index Rule Notice of Proposed Rule, which went on display on the Federal Register website on Monday, April 29, 2013. This proposed rule was also published in the Federal Register on Thursday, May 10, 2013 (78 FR 27847 - 27848).

The 60 day public comment period began on Monday, April 29, 2013 and continued until Thursday, June 27, 2013. Public comments were received during that time. Included, with this PRA package, is a written summary of the public comments which were received during the 60 day comment period as well as our responses to these comments.

## **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 = 1,089,719<sup>3</sup>

#### 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

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.<sup>4</sup>

---

<sup>3</sup> 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.

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

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.<sup>5</sup>  
 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

\$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
<b>\$3,818.26</b>	<b>Total</b>

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
<b>\$14,287,929</b>	<b>Total</b>

**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**

<sup>5</sup> 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>



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 Quality Systems for Assessment & Surveys (DQSAS) or groups under contract with DQSAS to perform this work. DQSAS 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 (i)(5)(A)(i) of the 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 for any given fiscal year.

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/DQSAS	\$ 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 the new Hospice Item Set. 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 a previous PRA package, which was published in the Federal Register on August 13, 2012,<sup>6</sup> we estimated that the total annualized burden to each hospice for the reporting of hospice quality measure data would be \$3,038 and the annualized burden across all hospices in the U.S. would be \$11,034,016. (See Exhibit B).

We have noted that there will be some increase in burden associated with the use of the 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 data collection instrument (ICR) which contained a significantly different format. Also, the previous PRA package burden estimate was based on the collection of data for two relatively simple quality measures. These quality measures required data submission only once for each measure per reporting cycle. In contrast, 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 of data per patient as opposed to 2 submissions of aggregated data 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 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(c) 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

---

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

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, CMS is making plans for the public reporting of Hospice quality measure data as required by ACA 3004(c)(5)(E). This public reporting is tentatively planned to begin in 2017.

#### **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.

#### **18. Certification Statement**

There are no exceptions to the certifications statement.