

**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 V2.00.0
FOR THE COLLECTION OF DATA
PERTAINING TO THE
HOSPICE QUALITY REPORTING PROGRAM

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Exhibit A

FY 2017 Hospice PRA Burden Estimate Calculation Worksheet

Supporting Statement A
For Paperwork Reduction Act Submissions

***Hospice Item Set for the Collection of Data Pertaining to the
Hospice Quality Reporting Program
(CMS-10390 - OMB Control Number – 0938-1153)***

A. Background

On July 1, 2014, hospices began using a newly created data collection instrument, titled the “Hospice Item Set” (HIS) V1.00.0. The HIS is used for the collection of quality measure data related to the Hospice Quality Reporting Program (HQRP), and the HIS V1.00.0 specified the collection of data items that supported seven National Quality Forum (NQF) endorsed Quality Measures (QMs) for hospice. On April 1, 2017, hospices began using an updated HIS V2.00.0, which includes the same items from the HIS V1.00.0 along with the addition of several new items for use in new measures, measure refinement, patient record matching, and future public reporting. Data collected from the HIS are used to calculate the seven NQF-endorsed QMs, the NQF-endorsed Hospice and Palliative Care Composite Process Measure – Comprehensive Assessment at Admission QM, and the Hospice Visits when Death is Imminent measure pair. This Paperwork Reduction Act submission is a request for an extension of the currently approved data collection for HIS V2.00.0. No further changes have been made to the HIS V2.00.0.

The HIS V2.00.0 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
- Visits when Death is Imminent

The HIS was developed specifically for use by hospices, and contains data elements that can be used by the Center for Medicare & Medicaid Services (CMS), to collect patient-level data to calculate eight NQF-endorsed quality measures and an additional measure pair that is not yet NQF-endorsed under the HQRP (see Table 1).

Table 1. 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
NQF #3235	Hospice and Palliative Care Composite Process Measure – Comprehensive Assessment at Admission
(not yet NQF-endorsed)	Visits when Death is Imminent Measure Pair

B. Justification

1. Circumstances Making the Collection of Information Necessary

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.¹ 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 HQRP in the FY 2012 Hospice Wage Index Final Rule (76 FR 47318 through 47324, and 47325 through 47326).² In this rule, CMS set forth the initial framework for the HQRP and established that the first reporting period would take place from October 1, 2012 through December 31, 2012. During this first reporting period, hospice providers were required to report their data gathered from January 1, 2012 and April 1, 2012. The data that hospices gathered for this first reporting period pertained 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 NQF-endorsed #0209 pain measure.

In the CY 2013 HH PPS final rule (77 FR 67132 through 67136),³ CMS retained the two measures that had previously been adopted in the FY 2012 rule. Hospices continued to collect data for these measures until December 31, 2013. CMS retired these two measures in the FY 2014 final rule (78 FR 48256 through 48257).

In the FY 2014 Hospice Wage Index final rule (78 FR 48257),⁴ CMS finalized the specific collection of data items that support seven NQF-endorsed measures for hospice. Data for the seven measures were collected via the HIS V1.00.0.

In the FY 2017 Hospice Wage Index final rule, CMS retained the seven measures that were previously adopted in the FY 2014 rule, and adopted two new quality measures: the Hospice and Palliative Care Composite Process Measure – Comprehensive Assessment at Admission, and the Hospice Visits when Death is Imminent Measure Pair. Data for each of these measures is collected using the HIS V2.00.0, which is the data collection instrument currently approved and in use.

The HIS V2.00.0 allows for the collection of standardized, patient-level data for quality reporting purposes. The use of the HIS V2.00.0 is necessary to enable CMS to collect quality data from hospices in compliance with Section 3004 of the ACA.

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>

³ Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2013, Hospice Quality Reporting Requirements, and Survey and Enforcement Requirements for Home Health Agencies; Final Rule, Federal Register/Vol. 77, No. 217 November 8, 2012. <https://www.gpo.gov/fdsys/pkg/FR-2012-11-08/pdf/2012-26904.pdf>

⁴ Medicare Program; FY 2014 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements; and Updates on Payment Reform; Final Rule, Federal Register/Vol. 78, No. 152 August 7, 2013. <https://www.gpo.gov/fdsys/pkg/FR-2013-08-07/pdf/2013-18838.pdf>

Furthermore, Section 3004 of the ACA 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.

The currently implemented HIS V2.00.0 fulfills both of these requirements. Firstly, the item set allows for standardized, patient-level data collection of data elements required to calculate the aforementioned quality measures. Secondly, data collection through HIS V2.00.0 has resulted in standardized data, which is 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 to collect patient-level quality data from hospices that would fulfill the requirements of publicly reporting quality measures, set forth in the ACA.

2. Purpose and Use of the Information Collection

All hospices providers must submit the specified type and amount quality data for participation in the HQRP to avoid a 2 percentage point reduction in the market basket update for FY 2014 and beyond.

There are two primary users of the HQRP data. The first user is CMS, which collects 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 uses the hospice quality data collected for the purpose of calculation of quality measures, for determining provider compliance with the data reporting requirements of the HQRP, and for public reporting.

The second primary group of data users is the public, who have had access to this data since public reporting of the HQRP data began the summer of 2017.

3. Use of Improved Information Technology and Burden Reduction

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

CMS requires that the collected data be transmitted to CMS electronically. This manner is similar to the process also used by HHAs for the Outcome and Assessment Information Set, Version C (OASIS-C), SNFs for the Minimum Data Set (MDS 3.0), IRFs for Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI), and LTCHs for the LTCH Care Data Set. Hospices are required to attest to the accuracy of the data collected for the HIS. However, if electronic signatures were to be required at a future date, CMS could accommodate this as well.

4. Efforts to Identify Duplication and Use of Similar Information

This information collection does not duplicate any other efforts, and the standardized data elements in the HIS V2.00.0 to collect data on pain, respiratory status, medications, patient preferences, beliefs/values, and visits when death is imminent, 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.

5. Impact on Small Businesses or Other Small Entities

To minimize the burden on hospices that qualify as small business entities, CMS is using a web-based data submission process so that hospices can submit the specified data electronically. This minimizes the burden that this Information Collection Requests (ICRs) places on the provider. CMS is asking hospices to collect and submit data elements that can be used to calculate eight NQF-endorsed quality measures and an additional measure pair that is not yet NQF-endorsed. When the HIS was under development, results from the data collection pilot testing 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 HIS. 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. Consequences of Collecting the Information Less Frequently

The HIS V2.00.0 will be used in hospices to collect quality data specific to the eight NQF-endorsed quality measures and additional measure pair that is not yet NQF-endorsed. Data collection is required for every patient admission and discharge. Hospices are 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 shall reduce the market basket update by 2 percentage points for any hospice that does not submit quality data submission for a fiscal year. CMS began collection of HQRP data on October 1, 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 Relating to the Guidelines of 5 CFR 1320.5

No special circumstances apply to these collections.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A 60-day Notice published in the Federal Register on January 19, 2017 (83 FR 2785). No comments were received. A 30-day Notice will be published in the Federal Register on March 27, 2018 (83 FR 13129).

No additional outside consultation was sought.

9. Explanation of Any Payment or Gift to Respondents

Respondents will not receive any payments or gifts as a condition of complying with this information collection request.

10. Assurance of Confidentiality Provided to Respondents

The patient-level data collected using the HIS V2.00.0 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 their 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. Justification for 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 = 4,259⁵

Total number of admissions to all hospices per year = 1,248,419⁶

Total number of admissions to all hospices over three years = 3,745,257

Estimated average number of admissions to each hospice:

- **per year:** 1,248,419 admissions to all hospices / 4,259 hospices = 293 admissions per hospice per year
- **per month:** 1,248,419 admissions to all hospices / 4,259 hospices / 12 months per year = 24 per month
- **over 3 years:** 3,745,257 admissions to all hospices over 3 years / 4,259 hospices = 879 per 3 years

Estimated average number of Hospice Item Set records submitted by all hospices

- **per year:** 1,248,419 admissions to all hospices per year x 2 Hospice Item Set records (1 Admission Record and 1 Discharge Record) per patient = 2,496,838 records per year
- **per month:** 2,496,838 Hospice Item Set records per all hospices per year / 12 months per year = 208,070 per month
- **over 3 years:** 2,496,838 Hospice Item Set records per all hospices per year x 3 years = 7,490,514 per 3 years

⁵ Quality Improvement and Evaluation System (QIES) List of Hospice Providers, January 2016

⁶ The discharge number was calculated using the number of HIS discharge assessments submitted October 1, 2014 – September 30, 2015.

Estimated average number of Hospice Item Set records submitted by each hospice

- **per year: 2,496,838** Hospice Item Set records per all hospices / **4,259** hospices = **586** records per hospice per year
- **per month: 208,070** Hospice Item Set records per all hospices per month / **4,259** hospices = **49** per month
- **over 3 years: 7,490,514** Hospice Item Set records per all hospices per 3 years / **4,259** hospices = **1,759** per 3 years

PART 2. Cost/Wage Calculation

Note that this worksheet presents rounded inputs for each calculation. The actual calculations were performed using unrounded inputs, so the outputs of each equation below may vary slightly from what would be expected from the rounded inputs.

Time required to complete each Hospice Item Set record

14 minutes nursing/clinical staff time to abstract data for Admission Record – paid @ **\$67.10/hr.**⁷

9 minutes nursing/clinical staff time to abstract data for Discharge Record – paid @ **\$67.10/hr.**

5 minutes administrative/clerical staff time to upload Assessment Record data – paid @ **\$32.24/hr.**⁸

5 minutes administrative/clerical staff time to upload Discharge Record data – paid @ **\$32.24/hr.**

Nursing Time:

- **23** minutes x **293** Hospice Item Sets per each hospice per year / **60** minutes per hour = **112.36** nursing hours per each hospice per year
- **112.36** hours per year x **\$67.10** per hour = **\$7,539.66** nursing wages per each hospice per year
- **\$7,539.66** per each hospice per year x **4,259** hospice providers = **\$32,111,417.38** nursing wages per all hospices per year
- **\$7,539.66** per each hospice per year x **3** years = **\$22,618.98** nursing wages per each hospice over 3 years
- **\$32,111,417.38** per all hospices per year x **3** years = **\$96,334,252.13** nursing wages for all hospices over 3 years

Administrative Assistant Time:

- **10** minutes x **293** Hospice Item Sets per each hospice per year / **60** minutes per hour = **48.85** administrative/clerical hours per each hospice year
- **48.85** hours per year x **\$32.24** per hour = **\$1,575.06** administrative/clerical wages per each hospice per year

⁷ The adjusted hourly wage of \$67.10 per hour for a Registered Nurse was obtained using the mean hourly wage from the May 2016 U.S. Bureau of Labor Statistics, \$33.55. This mean hourly wage is adjusted by a factor of 100 percent to include fringe benefits. See <http://www.bls.gov/oes/current/oes291141.htm>

⁸ The adjusted hourly wage of \$32.24 per hour for a Medical Secretary was obtained using the mean hourly wage from the May 2016 U.S. Bureau of Labor Statistics, \$16.12. This mean hourly wage is adjusted by a factor of 100 percent to include fringe benefits. See <http://www.bls.gov/oes/current/oes436013.htm>

- **\$1,575.06** per each hospice per year x **4,259** hospice providers = **\$6,708,171.43** administrative/clerical wages per all hospices per year
- **\$1,575.06** per each hospice per year x **3** years = **\$4,725.17** administrative/clerical wages per each hospice over 3 years
- **\$6,708,171.43** per all hospices per year x **3** years = **\$20,124,514.28** administrative/clerical wages per each hospice over 3 years

Total annualized cost to each hospice provider:

\$7,539.66	Nursing wages per each hospice per year
\$1,575.06	Administrative assistant wages per each hospice per year
\$9,114.72	Total

Total annualized cost to all hospice providers:

\$32,111,417	Nursing wages per all hospice providers per year
\$6,708,171	Administrative assistant wages per all hospice providers per year
\$38,819,589	Total

Total 3-year cost to each hospice provider:

\$22,618.98	Nursing wages per each hospice over 3 years
\$4,725.17	Administrative assistant wages per each hospice over 3 years
\$27,344.16	Total

Total 3-year cost to all hospice providers:

\$96,334,252	Nursing wages per all hospice providers over 3 years
\$20,124,514	Administrative assistant wages per all hospice providers over 3 years
\$116,458,766	Total

PART 3. Additional Calculations

Average monthly cost to each individual hospice provider:

\$38,819,589 for all Hospices per year / **4,259** hospices / **12** months per year = **\$759.56**

Cost to provider per each individual hospice patient:

\$38,819,589 for all hospices per year / **1,248,419** Hospice Item Sets per year = **\$31.10**

Table 2 – Summary of Burden Hours and Costs

Regulation Section(s)	OMB Control No.	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting (\$)	Total Cost (\$)
Hospice Item Set Admission Assessment (CMS-10390)	0938-1153	4,259	1,248,419 per year	0.233 clinician hours; 0.083 clerical hours	395,333 hours	Clinician at \$67.10 per hour; Clerical staff at \$32.24 per hour	\$22,900,166
Hospice Item Set Discharge Assessment (CMS-10390)	0938-1153	4,259	1,248,419 per year	0.150 clinician hours; 0.083 clerical hours	291,298 hours	Clinician at \$67.10 per hour; Clerical staff at \$32.24 per hour	\$15,919,423
3-year total		4,259	7,490,514	0.55 hours	2,059,891 hours	Clinician at \$67.10 per hour; Clerical staff at \$32.24 per hour	\$116,458,766

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

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

14. Annualized Cost to the Federal Government

The federal government will incur costs related to the HIS V2.00.0 for provider training, preparation of HIS V2.00.0 manuals and materials, receipt and storage of data, data analysis, and upkeep of data submission software.

There are costs associated with the maintenance and upkeep of a CMS-sponsored web-based program that hospice providers will use to submit their HIS V2.00.0 data. The work to 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 HQRP. In addition, the federal government will also incur costs for help-desk support that must be provided to assist hospices with the data submission process.

After hospice providers submit HQRP data to CMS, this data is transmitted to a CMS contractor for processing and analysis. Thereafter, the data is 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 HIS V2.00.0 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 HIS Manuals and Materials	\$ 25,000
Contractor Costs for Receipt and Storage of HIS Data	\$ 550,000
Cost for Aggregation & Data Analysis	\$ 500,000
Costs for Upkeep & Maintenance of HIS Data Submission	
Software by CMS/DQSAS	\$ 500,000

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

15. Explanation for Program Changes or Adjustments

This Paperwork Reduction Act submission is a request for an extension of the currently approved data collection for HIS V2.00.0. No changes have been made to the HIS V2.00.0.

16. Plans for Tabulation and Publication and Project Time Schedule

As required by ACA 3004(c)(5)(E), CMS launched the Hospice Compare web site⁹ in summer 2017 to publicly report hospice quality measurement data, including seven quality measures calculated from HIS data.

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

CMS has no objection to displaying the expiration date. The expiration date appears in the top right corner of the first page of each instrument.

⁹ Hospice Compare web site: <https://data.medicare.gov/data/hospice-compare>