

Supporting Statement – Part A
Hospices Voluntary Quality Reporting Program
which is related to
Section 3004 of the Affordable Care Act for Hospice Programs
CMS-10390, OMB 0938-New

A. Background

We are requesting an initial approval for a data collection instrument that hospice providers may voluntarily elect to use upon which to submit quality measures data to CMS during a voluntary reporting period which shall take place from 10/01/2011 through 12/31/2011. At the close of this voluntary reporting period, Hospice providers will have until 01/31/2012 to file reports of the voluntary quality measures data collected, should they elect to do so.

To meet the voluntary quality reporting requirements for hospices, we request that hospices report quality data pertaining to one structural measure. Structural measures assess the characteristics and capacity of the provider to deliver quality health care. The structural measure is: Participation in a Quality Assessment and Performance Improvement (QAPI) Program that Includes at Least Three Quality Indicators Related to Patient Care. We believe that participation in QAPI programs that address at least three indicators related to patient care reflects a commitment not only to assessing the quality of care provided to patients but also to identifying opportunities for improvement that pertain to the care of patients. Examples of domains of indicators related to patient care include providing care in accordance with documented patient and family goals, effective and timely symptom management, care coordination, and patient safety.

It is important to note that a mandatory quality data reporting period will begin on 10/01/2012, in which hospice providers will be required to report two quality measures: (1) the structural measure known as “Participation in a Quality Assessment and Performance Improvement (QAPI) Program that Includes at Least Three Quality Indicators Related to Patient Care”; and (2) NQF #0209: The percentage of patients who were uncomfortable because of pain on admission to hospice whose pain was brought to a comfortable level within 48 hours.

B. Justification and Legal Basis

1. Need and Legal Basis

Section 1814(i)(5) of the Act added by section 3004 of Patient Protection and Affordable Care Act, Pub. L. 111-148, enacted on March 23, 2010 (Affordable Care Act), authorizes the Secretary to establish a quality reporting program for Hospices. Section 1814(i)(5)(A)(i) of the Social Security Act requires that the Secretary, beginning with FY 2014, 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.

To meet the quality reporting requirements for hospices, which are set forth in the final Hospice Wage Index for Fiscal Year 2012 rule, we stated that there shall be a first **voluntary** Hospice

quality reporting cycle which will consist of data collected from October 1, 2011 through December 31, 2011. This data shall be reported to CMS by no later than January 31, 2012. There shall be a second **mandatory** Hospice quality reporting cycle which will consist of data collected from October 1, 2012 through December 31, 2012. This data shall be reported to CMS by no later than April 1, 2013. Thereafter, it was finalized that all subsequent Hospice quality reporting cycles would be based on the calendar-year basis (that is, January 1, 2013 through December 31, 2013 for determination of the Hospice market basket increase factor for each Hospice in FY 2015, etc.).

The voluntary data collection instrument, which is the subject of this PRA request, is needed to meet the voluntary quality reporting requirements for hospices set forth in the Hospice Wage Index for Fiscal Year 2012 final rule. In said final rule, CMS finalized a voluntary quality reporting cycle for hospices that precedes, but is related to, the required quality reporting requirements mandated for the FY 2014 payment determination as set forth in Section 1814(i)(5) of the Act. For the voluntary reporting, hospices shall report one structural measure collected for the period **October 1, 2011 through December 31, 2011**. Submission of data collected during this time frame will permit CMS to analyze the data and learn what the important patient care quality issues are for hospices as we enhance the quality reporting program design to require more standardized and specific quality measures to be reported by hospices in subsequent years.

The following operational details have been formulated about how the voluntary quality data reporting will work:

Each hospice will be given the option to complete the voluntary data submission form which will be provided by CMS. If a hospice provider chooses to participate during the voluntary reporting period, said provider should report whether or not (yes/no) they have a QAPI program that includes at least three quality indicators related to patient care for the voluntary reporting period **October 1, 2011 through December 31, 2011**.

If a hospice provider chooses to participate in the voluntary reporting period, said provider should list the number of patient-care related indicators that are included in their hospice's QAPI program.

If a hospice provider chooses to participate in the voluntary reporting period, said hospice should provide further information about their QAPI program, **if it includes at least one patient care related quality indicator**. The provider is asked to do the following:

- Select, from drop-down menus, up to 20 topical descriptions of their patient-care focused quality indicators, which were collected as a result of their QAPI program during the voluntary reporting period **October 1, 2011 through December 31, 2011**;
- For each indicator topic selection, provide an indicator name;
- For each indicator topic selection, provide a brief description;
- For each indicator topic selection, select a data source description from a drop-down menu.

If a hospice provider chooses to participate in the voluntary reporting period, said provider will be requested to provide a summary of the amount of time required to complete the voluntary data submission form, by selecting from one of six pre-defined time period categories.

If a hospice provider does elect to participate in the voluntary data reporting program, then the data collected by the provider for the voluntary time period of **October 1, 2011 through December 31, 2011** should be reported to CMS by no later than **January 31, 2012**.

The reporting period **10/01/2011 to 12/31/2011** is voluntary. Responses from hospice programs reporting the structural measure data with specific quality indicators related to patient care will allow CMS to learn what hospices consider to be important patient care quality issues. However, a mandatory reporting period will begin effective **10/01/2012**. Further details regarding the mandatory hospice quality reporting program will be announced at the CMS website; however the date for this announcement has not yet been determined.

CMS has prepared a quality data submission spreadsheet. CMS will announce operational details with respect to the data submission methods for the voluntary reporting cycle using this CMS Web site <http://www.cms.gov/LTCH-IRF-Hospice-Quality-Reporting> by no later than December 31, 2011.

Structural measures assess the characteristics and capacity of the provider to deliver quality health care. The structural measure hospices shall report is: **Participation in a Quality Assessment and Performance Improvement (QAPI) Program that Includes at Least Three Quality Indicators Related to Patient Care**. We believe that participation in QAPI programs that address at least three indicators related to patient care reflects a commitment not only to assessing the quality of care provided to patients but also to identifying opportunities for improvement that pertain to the care of patients. Examples of domains of indicators related to patient care include, but are not limited to, providing: (1) care in accordance with documented patient and family goals; (2) effective and timely symptom management; (3) care coordination; and (4) patient safety.

Since the development, implementation and maintenance of an effective, ongoing, hospice-wide data driven quality assessment and performance improvement program have been requirements in the Medicare CoPs since 2008, we do not believe that the collection of the structural measure on QAPI indicators would be considered new work.

This quality data submission shall permit the Secretary of Health and Human Services, and CMS, to learn what the important patient care quality issues are for hospices. This voluntary data collection instrument shall also serve to provide useful information in the future design and structure of the hospice quality reporting program. Our intent is to require additional standardized and specific quality measures to be reported by hospices in subsequent years.

Heretofore, hospices have not been required to report quality data directly to CMS. However, the development, implementation and maintenance of an effective, ongoing, hospice-wide data driven quality assessment and performance improvement program have been requirements in the Medicare Conditions of Participation (CoPs) since 2008. In reviewing and considering the Hospice Conditions of Participation at CFR 418.58, it was noted that Hospices are required to develop, implement, and maintain an effective, ongoing, hospice-wide data-driven quality assessment and performance improvement program. Furthermore, to meet the CoP's, each hospice must maintain documentary evidence of its quality assessment and performance improvement program and be able to demonstrate its operation to CMS. Therefore, we do not believe that the collection of the structural measure on QAPI indicators would be considered new work.

2. Information Users

- Data Submitters – All Hospice providers may participate in the Hospice Voluntary Reporting program. However, participation in the Hospice Voluntary Reporting program is not required. Based on the number of Hospice providers that have registered to participate in this program so far, it is expected that approximately 25-50% of all Medicare certified Hospices will participate in the Hospice Voluntary Reporting program.
- Data Users:
 - CMS - as required under Section 1886(j)(7) of the Social Security Act added by section 3004 of Patient Protection and Affordable Care Act
- Public - these data will be made available for public use on CMS' website to provide the public with information about the performance of each Hospice Provider with regards to quality improvement efforts and pain management.

3. Improved Information Technology

CMS has developed a web-based form for the voluntary quality reporting submission. Hospices will be able to enter and submit the voluntary information via this web-based form, accessed through a link that is available on the CMS website. For hospices that cannot use the web-based form, CMS will provide an alternative method for data submission.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

In order to minimize burden, CMS is utilizing a web based process for Hospice Providers to submit the requisite information electronically.

6. Less Frequent Collection

a. Structural Quality Improvement Measure:

CMS is only offering hospice providers the opportunity to participate in a voluntary quality

reporting program which shall take place from 10/01/2011 through 12/31/2011. At the close of this voluntary reporting period, Hospice providers will have until 01/31/2012 to file reports of the voluntary quality measures data collected, should they elect to do so. If hospice providers elect to participate in this voluntary reporting program, a one-time data submission from each participating provider is estimated to take approximately **15 minutes** at a cost of approximately **\$5.14** to each provider. While this data submission is not mandatory, any data voluntarily submitted by hospice providers, shall permit the Secretary of Health and Human Services, and CMS, to learn what the important patient care quality issues are for hospices. This voluntary data collection instrument shall also serve to provide useful information in the future design and structure of the hospice quality reporting program.

7. Special Circumstances
NOT APPLICABLE

8. Federal Register/Outside Consultation
The 60-day Federal Register notice published on September 2, 2011 (76 FR 54776). No comments were received.

9. Payments/Gifts to Respondents
No payments or gifts will be provided to respondents.

10. Confidentiality
Quality reporting data will be submitted by hospice providers to CMS using a secure web-based form available on the CMS website at <http://www.cms.gov/LTCH-IRF-Hospice-Quality-Reporting> prior to the voluntary reporting period deadline of January 31, 2012. . The data that is being requested at this time does not contain any sensitive or protected patient information.

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

12. Burden Estimates (Hours & Wages)
CMS feels that the level of burden to Hospice providers will be minimal. CMS requests that Hospice providers voluntarily submit quality data on one measure. CMS estimates the burden associated with the reporting of this quality measures data to be as follows:

Burden Associated with Structural Measures Submissions:

Total Number of Hospice Providers = **3,531** estimated 50% participation or 1,766

Average Number of Submissions/each Hospice/Year = **1**

Average Time per submission / Provider = **15 minutes***

(15 minutes attributed to administrative assistant or clerical data entry time)

Estimated Annual Hour Burden per each Hospice = **0.25 hours**

Estimated Annual Hour Burden all Hospices = **442**
(0.25 hr x 1,766 Hospice providers = 442 hours/all hospices /year)

Average Annual Cost /Each Hospice = **\$5.14**
(0.25 hours per year x \$20.57 per hour)

Average Annual Cost / All Hospice = **\$9,092**
(442 hr per year x \$20.57 per hour)

Average Cost per Submission = **\$5.14**
(\$9,092 / 1,766 submissions)

CMS retrieved the average national salary from the U.S. Bureau of Labor for a Medical Billing Clerks (**\$20.57/hour**).

***Re: Average time per submission:** We have estimated that it will take only 15 minutes or less for each hospice provider to complete this ICR because it does not require the Hospice provider to aggregate data. This ICR simply requires that the provider give information about the type of QAPI programs that they have in place. No patient level data is required for this ICR. Therefore, no aggregation of data is necessary. There are 4 questions on the ICR are as follows:

Q1. Does your hospice have a QAPI program that includes *three or more* quality patient care?

(Check answer that applies to your program in box to left

Q2. How many patient care-related indicators are included in your hospice's QAPI program? Please check the appropriate box below. Refer to the instructions sheet for definition and examples of patient care-related quality indicators

Q3. If your hospice's QAPI program includes at least one patient care-related quality indicator, list each indicator (up to 20 indicators) using the form provided below. Select a topic from the dropdown menu, and then provide details about your indicator and data source. Refer to the examples and to the instructions sheet for additional information.

Q4. How much time did it take you to complete this voluntary data submission?

The first question asks if the Hospice has a QAPI program that includes *three or more* quality patient care. This requires the provider to check one of two boxes. The time required to answer this question should be no longer than 1 minute.

The second question asks the Hospice provider to state how many patient care-related indicators are included in their hospice's QAPI program? This question simply requires the hospice provider to check one out of 3 boxes. The time required to answer this question should be no more than 1 minute.

The third question asks the hospice provider to give information about each of the patient care-related quality indicators which are used in their QAPI program. The provider merely has to select from a drop-down menu of patient care-related quality indicator. The time required to answer this question should be no more than 10-12 minutes.

The fourth question merely asks the provider to state how much time it took the hospice provider to complete the voluntary submission form. The time required to answer this question should be no more than 1 minute. As the provider is completing this ICR via an online transmission, once the provider has answered the 4

questions, they merely have to hit the “submit” button. This would take only a matter of seconds to do.

13. Capital Costs

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

14. Cost to Federal Government

HHS will incur costs associated with the collection and handling of this data. It is anticipated that this data will be transmitted to a contractor who is already under contract to work with the CMS Office of Clinical Standards and Quality, Division of Post Acute and Chronic Care.

Said contractor will be responsible for the receipt the Hospice quality reporting data, the performance of statistical analysis on same, and the reporting of the results of said statistical analysis to CMS. The estimated cost to the federal government to execute this contract will be \$123,300. This estimate was derives by the following calculations:

1,766 hospices x 30 minutes per hospice to download data from mailboxes and import into data base = 833 hours

833 hours x \$100 per hour ***\$88,300***

A. Overhead which consists of:

- ***Setting up mailboxes***
- ***Project lead***
- ***Miscellaneous tasks*** ***\$ 10,000***
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B. Organizing Data/Reporting to CMS **\$ 25,000**
\$123,300

15. Changes to Burden

This is a new collection.

16. Publication/Tabulation Dates

Under section 1814(i)(5)(E) of the Act, the Secretary is required to establish procedures for making any quality data submitted by Hospices available to the public.

As we interpret the statute, these procedures will ensure that a Hospice will have the opportunity to review the data regarding the Hospice’s respective program before it is made public. Also, under section 1814(i)(5)(E) of the Act, the Secretary is authorized to report quality measures that relate to services furnished by a Hospice on the CMS internet Web site. At the time of the publication of the final rule, no date has been set for public reporting of data.

17. Expiration Date

The voluntary reporting period shall take place from 10/01/2011 through 12/31/2011. At the close of this voluntary reporting period, hospice providers will have until 01/31/2012 to file reports of the voluntary quality measures data collected, should they elect to do so.

18. Certification Statement

CMS does not request any exception to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submissions," of OMB Form 83-I.