Revised Supporting Statement – Part A Revised Supporting Statement for the Hospices Quality Reporting Program Which is Related to Section 3004 of the Affordable Care Act for Hospice Programs

A. Background

We are requesting approval, under the Paperwork Reduction Act of 1995, of a revised internet based, data submission form that hospice providers will use to submit quality measures data to CMS for the Hospice Quality Reporting Program (Hospice QRP). Use of this revised internet data submission form shall begin during the Hospice QRP reporting period which takes place from 10/01/2012 through 12/31/2012. Thereafter, hospice quality data collection shall commence on January 1st and end on December 31st each year.

To meet the quality reporting requirements which were set forth in the Hospice Wage Index Final Rule (76 F.R. Vol. 76, No. 150, August 4, 2011), hospices are to report quality 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 NQF endorsed #0209 pain measure which is further described as: the percentage of patients who report being uncomfortable because of pain at the initial assessment (after admission to hospice services) who report pain was brought to a comfortable level within 48 hours.

Hospice Quality Measure #1 - Structural Measure - "Participation in a Quality Assessment and Performance Improvement (QAPI) Program that Includes at Least Three Quality Indicators Related to Patient Care."

Structural measures assess the characteristics and capacity of the provider to deliver quality health care. The structural measure that will be used in this quality reporting program can further be described as "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.

From 10/01/11 to 12/31/11, Hospice providers were invited to participate in the Hospice Quality Reporting Program submit data about the QAPI structural measure to CMS for the purpose of assessing CMS in program development and design. This early data submission was well received by hospice providers. Over 900 hospices participated during this time and submitted a wealth of useful information about their QAPI programs.

Hospice Quality Measure #2 - NQF #0209 pain measure: The percentage of patients who report being uncomfortable because of pain at the initial assessment (after admission to hospice services) who report pain was brought to a comfortable level within 48 hours

The NQF #0209 pain measure is added to the hospice quality reporting program requirements that will impact the FY2014 annual payment update (APU). The data collection period impacting FY 2014 is from 10/01/2012 through 12/31/2012. The NQF #0209 pain measure is an important and appropriate measure for the hospice quality reporting program because a primary goal of hospice care is to enable patients to be comfortable and free of pain so that they may live each day as fully as possible.

The data for this measure are collected at the patient level, but are reported in the aggregate for all patients cared for within the reporting period. The patient's definition of "comfort" is used in this measure; there is no set numeric value on a standardized assessment that's used to quantify "comfort." The measure is not limited to asking the patient about one specific pain site; rather it is a reflection of the patient's overall experience of pain. There is no assumption that every patient's pain will be managed to a "comfortable" level within 48 hours. This measure was tested in two studies during its initial development, and it has been collected on a voluntary basis by hospices for many years.

B. Justification and Legal Basis

1. Need and Legal Basis

Section 1814(i)(5) of the Social Security Act (the Act) added by section 3004 of the 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 Act requires that the Secretary, beginning with FY 2014, reduce the market basket update by 2 percentage points for any hospice that does not submit quality data that fiscal year.

Hospices were invited to submit information on their QAPI structural measure for the time period of October 1, 2011 through December 31, 2011, with a data submission deadline of no later than January 31, 2012.

Many hospice providers chose to submit QAPI data to CMS during this time period. The data that was submitted has been very informative. This data has helped CMS revise the data submission form that has been submitted with this PRA package that will be used for the subsequent reporting periods. The information submitted during this time period was for the purpose of assessing CMS in program development and design. No impact to payment was associated with this data submission period.

The FY 2012 Hospice Wage Index Final Rule also provided that there shall be subsequent hospice quality reporting periods, which will affect the annual payment update (APU) for any hospice provider that fails to submit the specified quality data. The reporting period which shall be subject to the 2 percentage point payment penalty for failure to report the specified quality data, shall consist of data collected from October 1, 2012 through December 31, 2012. The data for this reporting period must be reported to CMS by no later than January 31, 2013 for the QAPI measure and April 1, 2013 for the NQF #0209 pain measure. Thereafter, all subsequent hospice data collection periods will be based on a calendar-year¹.

The Hospice Quality Data Submission Form, which is the subject of this PRA request, was created for hospice providers to collect specified quality data, and submit that data to CMS, for the data collection period starting October 1, 2012 through December 31, 2012 and continuing on a calendar year thereafter. Webinar training on data collection and data submission has been and will continue to be provided by CMS. A User Guide will also be provided on the cms.gov site.

Use of the Hospice Quality Data Submission Form is necessary in order for Hospices to submit the quality data specified for the Hospice Quality Reporting Program. CMS believes that the web-based data entry is the best method to use for the collection of the Hospice Quality Reporting Program quality data.

2. Information Users

- Data Submitters:
 - Hospice providers must submit the quality data specified 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.
 - Data collection for this reporting period will begin on 10/01/12 and end on 12/31/12.
- Data Users:
 - o CMS as required under Section 1886(j)(7) of the Social Security Act added by section 3004 of Patient Protection and Affordable Care Act
 - O Public Data obtained from the Hospice Quality Reporting Program will be made available to the public on the CMS website. However, no date has been set for public reporting of the Hospice Quality Reporting Program data.

¹ e.g. – Reporting cycle of 01/01/2013-12/31/2013 affects the market basket update determination for FY 2015; reporting cycle of 01/01/2014-12/31/2014 affects the market basket update determination for FY 2016, etc.).

3. **Improved Information Technology**

CMS has developed a web-based form for the submission of hospice quality measures data. Hospices will be able to enter and submit their data via the internet based program which can be 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 to hospice providers that qualify as small business entities, CMS is utilizing a web-based data submission process, so that Hospice Providers can submit the specified quality data electronically. This will minimize the burden that this Information Collection Request (ICR) places on the provider. In addition burden to small business Hospices should be limited for several reasons. First, CMS is asking Hospice providers to collect and submit data on only 2 quality measures. The amount and type of quality data specified for participation in the quality reporting program (QRP) is straightforward, easily collected and easily reported. Secondly, to successfully participate in the hospice QRP hospices submit data for each measure only once per year.

6. Less Frequent Collection

This quality reporting program specifies submission of data only once per reporting period. However, as each of the two quality measures has separate submission deadlines, providers may elect to submit their data for each measure separately.

7. **Special Circumstances**

NOT APPLICABLE

8. Federal Register/Outside Consultation

The 60 day Federal Register notice was published on Monday, June 4, 2012 (FR Vol.77, No. 107). The 60 day public comment period began on Monday, June 4, 2012 and continued until Friday, August 3, 2012. Two (2) 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. Payments/Gifts to Respondents

No payments or gifts will be provided to respondents.

10. **Confidentiality**

Quality measure data will be submitted by hospice providers to CMS using a secure webbased data submission form which will be available on the CMS website.

The data that is being requested at this time does not contain any sensitive or protected patient information.

The data submission portion of the website will become available to Hospice providers to for submission of data as follows:

- For the structural measure: beginning on January 1, 2013 until January 31, 2013
- For the NQF #0209 pain measure: beginning on January 1, 2013 until April 1, 2013.

11. Sensitive Questions

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

12. Burden Estimates (Hours & Wages)

CMS estimates that the time and financial burden to Hospice providers will be as follows:

Burden Associated with Structural Measures Submissions:

Total Number of Hospice Providers = **3,632**

Average Number of Submissions/each Hospice/Year = 1-2 times per reporting period (Submission of QAPI data on or after 01/01 to 01/31)

(Submission of #0209 pain measure on or after 01/01 to 03/31)

CALCULATION OF ESTIMATED ANNUAL HOUR BURDEN:

STRUCTURAL MEASURE

- **150** minutes per each Hospice per year for submission of Structural Measure data x **3632** Hospices in U.S. = **544,800** minutes per ALL Hospice/year for Structural Measure data submission
- **544,800** minutes per ALL Hospices per year for Structural Measure divided by **60** minutes/hour = **9080** hours for ALL Hospices per year for each Structural Measure data submission.

NQF #0209 PAIN MEASURE

- **10,710** minutes per each Hospice per year for submission of NQF# 0209 Measure data x **3632** Hospices in U.S. = **38,898,720** minutes per ALL Hospice/year for NQF #0209 Measure data submission
- **38,898,720** minutes per ALL Hospices per year for submission of NQF# 0209 Measure data divided by 60 minutes/hour = **648,312** hours for ALL Hospices per year for each NQF #0209 Pain Measure data submission.

BOTH MEASURES:

9080 hours for ALL Hospices per year for each Structural Measure data submission.
 648,312 hours for ALL Hospices per year for each NQF #0209 Pain Measure data submission.
 657,392 hours for ALL Hospices per year for submission of ALL Quality
 Measure data

Cost/Wage Calculation:

Estimate of the average time spent by each Hospice provider per year for submission of Hospice Quality Reporting Program data = 181 hours. The cost burden for the submission of quality data is itemized as follows: (further itemization is provided in Exhibits A & B).

Job Description	Measure	Time Spent per year	Average Hourly Rate of Pay	Cost/Wage Calculation
Administrative Assistant	NQF#0209	10,710 min	\$16.66	\$2,973.81
	QAPI measure	70 min	\$16.66	\$ 19.43
Registered Nurse	QAPI measure	80 min	\$33.23	\$ 44.30
TOTAL		181 hours		\$3,037.54
		(10,860 min)		Per year

\$3,038*- Total Annualized Cost To Each Hospice Providers

\$11,034,016* - *Total Annualized Cost To ALL Hospice Providers* \$3,038* per Hospice per year x 3632 Hospices in the U.S. = **\$11,034,016***

Estimated Average Annual Cost / Provider = **\$3,038*** (**\$11,034,016***/ 3632 Hospices)

Estimated Average Yearly Cost per submission of all QRP data for each Hospice = **\$1,519*** (**\$11,034,016***/ **7,264** submissions)_

Estimated Actual Yearly Cost per Hospice for Submission of Structural Measure Data: \$63.73*

Estimated Actual Yearly Cost per Hospice for Submission of NQF #0209 Measure Data: **\$2,973.81***

*NOTE: For purposes of total annualized cost calculations, all numerical figures have been rounded up or down to the nearest whole number.

12A. Explanation of Increased in Burden Estimate

<u>Explanation of Increased in Burden Estimate or the NQF #0209 Pain Measure</u> We have estimated that it will take each Hospice approximately 178.5 hours per year to collect and report the data for the NQF #0209 pain measure.

The 178.5 hour burden estimate that we used for the new measure (#0209 pain measure) breaks down to approximately 15 hours per month for each Hospice. The 15 hours per Hospice provider includes the time needed for collection of data for each Hospice patients over a 12 month period and the time that it takes to gather, aggregate, upload and submit this data to CMS. We have based our burden estimate on the time that we believe that it would take a larger sized Hospice to complete this task. However, it is likely that smaller sized Hospices would incur less burden because they would have fewer patients from which to collect the NQF #0209 pain measure data. Roughly half of the Hospices in the U.S. are smaller in size.

Explanation of Increased in Burden Estimate for the Structural Measure

The burden estimate that we made for the voluntary reporting period was 15 minutes per provider per year. In the current PRA package, we increased our burden estimate for the structural measure to 2.5 hours per provider per year.

At the time that we prepared the PRA package for the voluntary reporting period, we did not have any data which could be used to make an accurate burden estimate because the ACA 3004 Hospice Quality Reporting Program is a new quality reporting program. By necessity, we made an educated guess as to how much time it would take for Hospice providers to collect and submit the structural measure data.

In order to obtain data regarding the burden related to the structural measure, we added a question to the voluntary data collection tool which asked providers to tell us how "How much time did it take you to complete this voluntary data submission?" Over 800 Hospice providers participated in the voluntary reporting program.

After reviewing that data that was obtained from the voluntary data reporting forms, we realized that we had underestimated the burden. We revised the burden estimate for the structural measure in accordance with the data that we received on the voluntary reporting forms. We believe that our revised burden estimate now reflects a more accurate representation of the burden associated

with the structural measure.

Our revised burden estimate of 2.5 hours per Hospice per year takes into consideration the time necessary for the recording of QAPI data throughout the year, gathering and preparing the data for submission each year at the yearly deadline, and the actual work of uploading the data into the computer and transmitting it to CMS once per year. We believe that 2.5 hours for that amount of work is a modest time estimate and not overly burdensome to Hospices.

General Factors That Affect the Burden Estimates for Both Hospice Quality Measures

Also, several other factors had changed since the time of the filing of the voluntary reporting period PRA package and the current PRA package that had led to an increase in the total burden costs for both measures. These changes include:

The total number of hospices has increased by 100 Increase in % of hospices expected to participate from 50% to 100% Increase in number of submissions per year from 1 to 2

13. Capital Costs

There are no anticipated capital costs.

14. Cost to Federal Government

HHS/CMS will incur costs associated with the collection and handling of the data that is collected through the Hospice Quality Reporting Program. It is anticipated that this data will be transmitted by the Hospices to the CMS data processing unit of CMS known as the Division of National Systems (DNS). Included in the cost to the federal government are the cost necessary to create and maintain the IT platform that will be used to capture and process the hospice quality data. 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.

The estimated annual cost to the federal government for the handling of this quality measures data is estimated to be **\$250,000**.

15. Changes to Burden

Change to existing burden to hospice providers includes:

- Transition from the 10/01/11 to 12/31/11 reporting period which had no payment penalty associated with it to subsequent reporting periods that will be subject to a 2 percentage point reduction in the APU for failure to report the specified quality data to CMS beginning with FY 2014.
- The addition of a 2nd measure NQF#0209 pain measure
- Time and wage burdens (as stated above).

The burden that Hospice providers will incur as a result of reporting quality data to CMS is

required for 2 reasons:

- o in order for CMS to meet the requirements set forth in section 1886(i)(5)(A)(i) of the Social Security Act (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 hospice providers by Fiscal Year 2014.
- O In order for each Hospice provider to comply with the reporting requirements of ACA Section 3004(c).
- O In order the each Hospice to be entitled to receive their annual market basket update beginning in 07/01/2014

16. Publication/Tabulation Dates

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

17. Expiration Date

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.