Supporting Statement For Paperwork Reduction Act Submissions

A. Background

This information collection package is a request for new information collection requirements. With this submission, we are creating a new PRA package for hospices.

The information collection requirements in the regulation establish eligibility requirements, reimbursement standards and procedures, and delineate the revised conditions a hospice must meet to be Medicare approved.

The hospice conditions of participation (CoPs) were originally published on December 16, 1983 and were amended on December 11, 1990 largely to implement provisions of section 6005(b) of the Omnibus Budget Reconciliation Act of 1989. However, many CoPs remained unchanged since their inception. To take advantage of the continuing advances in the health care delivery field, incorporate changes made to the Act, and incorporate recommendations made by various government agencies, we revised the Medicare hospice CoPs, which are also used by Medicaid.

CMS published revised conditions of participation for hospice on June 5, 2008. The revised CoPs focus on a patient-centered, outcome-oriented, and transparent process that promotes quality patient care. The final rule contained both new provisions and provisions that were carried over from the previous hospice regulations.

CMS also published a FY 2010 Hospice Wage Index Final Rule on August 6, 2009. This final rule promulgated a change in the physician certification and recertification requirements, which requires physicians to include a brief narrative on or with the certification or recertification, of terminal illness, and which synthesizes the clinical information that supports the patient's having a life expectancy of 6 months or less. This change was originally suggested by the Medicare Payment Advisory Commission, based on recommendations from a panel of hospice experts; the change is intended to increase physician engagement in the certification and recertification process and ensure that those Medicare beneficiaries who are receiving hospice care are eligible for the benefit.

The information collection captures information necessary to support the implementation of the Medicare CoPs for 2,872 hospices. Salary data is based on the salary website at http://www.bls.gov/oes/current/oes_nat.htm#b29-0000, salary estimates contained in this package are based on the following personnel:

"Administrator" refers to the http://www.bls.gov/oes/current/oes_nat.htm#b29-0000 for an administrator. The estimated median annual salary of $101,920 for all administrators at http://www.bls.gov/oes/current/oes_nat.htm#b29-0000 used to calculate an estimated hourly rate of $49.00 per hour (i.e., $101,920 divided by 52 weeks per year divided by 40 hour per week).

"Registered nurse" refers to the nurse who runs the day to day operation of a hospice who, according to http://www.bls.gov/oes/current/oes_nat.htm#b29-0000 has a median annual income of $72,800. Thus, the hourly rate used in this report is $35.00 (i.e., $72,800 divided by 52 weeks per year divided by 40 hours per week).

"Quality assessment and performance improvement (QAPI) coordinator" refers to an individual designated by a hospice's governing body who coordinates the hospice QAPI program. For purposes of our analysis, we assume that a hospice would appoint a registered nurse, who, according to http://www.bls.gov/oes/current/oes_nat.htm#b29-0000, has a median salary of $72,800. Thus, the hourly rate used in this report is $35.00 (i.e., $72,800 divided by 52 weeks per year divided by 40 hours per week).

"Clinical manager" salary is based on the median hourly wage of the clinical manager who manages the clinical aspects of a hospice and who, according to http://www.bls.gov/oes/current/oes_nat.htm#b29-0000, has a median annual salary of $74,880. Thus, the hourly rate used in this report is $36.00 (i.e., $74,880 divided by 52 weeks per year divided by 40 hours per week).

"Office employee" refers to the employee who provides clerical support in a hospice and who, according to http://www.bls.gov/oes/current/oes_nat.htm#b29-0000 has median annual salary of $29,120. Thus, the hourly rate used in this report is $14.00 per hour (i.e., $29,120 divided by 52 weeks per year divided by 40 hours per week).

"Home health aide" refers to the employee who helps a registered nurse to provide home health care to hospice patients and who, according to http://www.bls.gov/oes/current/oes_nat.htm#b29-0000 has a median annual salary of $39,520. Thus, the hourly rate used in this report is $19.00 per hour (i.e., $39,520 divided by 52 weeks per year divided by 40 hours per week).

"Medical director" refers to the http://www.bls.gov/oes/current/oes_nat.htm#b29-0000 median salary for a medical director. The estimated median annual salary of $237,120 for all medical directors at http://www.bls.gov/oes/current/oes_nat.htm#b29-0000 was used to calculate an estimated hourly rate of $114.00 per hour (i.e., $237,120 divided by 52 weeks per year divided by 40 hour per week).

"Pharmacist" refers to the http://www.bls.gov/oes/current/oes_nat.htm#b29-0000 median salary for a clinical pharmacist. The estimated median annual salary of $116,480 for all pharmacists at http://www.bls.gov/oes/current/oes_nat.htm#b29-0000 was used to calculate an estimated hourly rate of $56.00 per hour (i.e., $116,480 divided by 52 weeks per year divided by 40 hour per week).

"Social worker" refers to the http://www.bls.gov/oes/current/oes_nat.htm#b29-0000 median salary for a social worker with a master degree (MSW). The estimated median annual salary

of $52,000 for all pharmacists at http://www.bls.gov/oes/current/oes_nat.htm#b29-0000 was used to calculate an estimated hourly rate of $25.00 per hour (i.e., $52,000 divided by 52 weeks per year divided by 40 hour per week).

This document represents all hospice CoPs currently effective and the new physician certification and recertification requirements which will become effective October 1, 2009.

B. Justification

1 . Need and Legal Basis

Section 122 of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), Pub. L. 97–248, added section 1861(dd) to the Social Security Act (the Act) to provide coverage for hospice care to terminally ill Medicare beneficiaries who elect to receive care from a Medicare-participating hospice. Under the authority of section 1861(dd) of the Act, the Secretary has established the Conditions of Participation (CoPs) that a hospice must meet to participate in Medicare and/or Medicaid, and these conditions are set forth at 42 CFR part 418. The CoPs apply to a hospice as an entity as well as to the services furnished to each individual under hospice care. Under section 1861(dd) of the Act, the Secretary is responsible for ensuring that the CoPs, and their enforcement, are adequate to protect the health and safety of individuals under hospice care. To implement this requirement, State survey agencies conduct surveys of hospices to assess their compliance with the CoPs.

Section 122(c) of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), Pub. L. 97–248, also added section 1814(a)(7) to the Social Security Act (the Act) to outline coverage requirements for hospice care to terminally ill Medicare beneficiaries who elect to receive care from a Medicare-participating hospice. Under the authority of section 1861(a)(7)(A)-(C) of the Act, the Secretary has established eligibility requirements that a hospice must meet for Medicare hospice services to be covered and paid by Medicare, and these requirements are set forth at 42 CFR part 418. Under section 1814(a)(7)(A) of the Act, hospices are required to have a certification of terminal illness for their services to be covered and paid. To implement this requirement, CMS or its contractors may conduct reviews of claims to assess compliance with coverage requirements.

There are several statutory changes that are incorporated in the hospice CoP final rule. The Balanced Budget Act of 1997 (Pub. L. 105–33) made changes to the hospice statute that must now be incorporated into the CoPs. Specifically, the Balanced Budget Act of 1997 (BBA) permitted hospices to provide physician services, including those of a medical director, under contract (§418.64 and §418.102 of the final rule). It also allowed hospices located in non-urbanized areas to receive a waiver of the requirement that physical therapy, occupational therapy, speech-language pathology , and dietary counseling be available on a 24-hour as needed basis (§418.74 of the final rule). Additionally, the legislation allowed hospices located in non-urbanized areas to receive a waiver of the requirement that dietary

therapy be provided by hospice employees (§418.74 of the final rule). Furthermore, section 946 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) amended section 1861(dd) of the Act, to permit a hospice to enter into an arrangement with another hospice to provide core hospice services or to provide the highly specialized services of a registered professional nurse, in certain circumstances (§418.64 of the final rule).

The information collection requirements described herein are needed to implement the Medicare CoPs for 2,872 Medicare-approved hospices, and an estimated 50 hospices that apply for approval every year. Additionally, they are needed to implement the change to the certification of terminal illness requirements which were finalized in the August 6, 2009 hospice wage index final rule. We believe many of the requirements applied to these hospices will impose no burden since a prudent institution would self-impose them in the course of doing business. Regardless, we have made an attempt to estimate the associated burden for a hospice to engage in these standard industry practices. Statutory requirements and our responsibility to assure an adequate level of patient health and safety in participating hospices require the inclusion of these requirements in standards for care provided in hospices.

2. Information Users

The CoPs and accompanying requirements specified in the regulations are used by Federal or State surveyors as a basis for determining whether a hospice qualifies for approval or re-approval under Medicare**.** The certification of terminal illness requirements specified in the regulations at 42 CFR 418.22 are used by contractors and by CMS when reviewing claims as a basis for determining whether the patient is eligible for the Medicare hospice benefit and whether the claim meets criteria for coverage and Medicare payment. CMS and the healthcare industry believe that the availability to the hospice of the type of records and general content of records, which this regulation specifies, is standard medical practice, and is necessary in order to ensure the well-being and safety of patients and professional treatment accountability.

3. Use of Information Technology

Hospices may use various information technologies to store and manage patient medical records as long as they are consistent with the existing confidentiality in record-keeping regulations at 42 CFR 485.638. This regulation in no way prescribes how the hospice should prepare or maintain these records. Hospices are free to take advantage of any technological advances that they find appropriate for their needs.

4. Duplication of Efforts

These requirements are specified in ways that do not require a hospice to duplicate its efforts. If a hospice already maintains these general records, regardless of format, they are in

compliance with this requirement. The general nature of these requirements makes variations in the substance and format of these records from one hospice to another acceptable.

5. Small Businesses

These requirements will not have a significant impact on most hospices and other providers that are small entities because the cost of meeting the requirements in this rule is less than 1 percent of total hospice Medicare revenue. Further, most of the requirements in this rule are part of hospices' standard practices. We understand that there are different sizes of hospices and that the burden for hospices of different sizes will vary. A portion of the time and cost burden for providers is directly related to patient care and the staff necessary to provide care. A consistently smaller patient census leads to reduced burden because the smaller hospices have less staff, complete less data collection and less patient rights orientation, etc. Additionally, it is very uncommon for a hospice with a small annual patient census to operate its own inpatient facility. Therefore a large portion of the burden in the final rule would not apply because it is associated only with those hospices that choose to operate their own inpatient unit.

6. Less Frequent Collection

CMS does not collect information directly from hospices. In most cases, the rule does not prescribe the manner, timing, or frequency of the records or information that must be available. Hospice records are reviewed at the time of a survey for initial or continued participation in the Medicare program; certifications or recertifications of terminal illness are reviewed when claims processing edits identify a potential issue or when problem areas are identified as a significant risk to the Medicare program as a result of inappropriate payments. Less frequent information collection would impede efforts to establish compliance with the Medicare CoPs or Medicare coverage requirements.

7. Special Circumstances

Absent a legislative amendment, we are unable to anticipate any circumstances that would change the requirements of this package.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on March 13, 2009.

9. Payments/Gifts to Respondents

There will be no payments/gifts to respondents.

10. Confidentiality

Normal medical confidentiality practices are observed.

11. Sensitive Questions

There are no questions of a sensitive nature associated with this information collection.

12. Burden Estimates (Hours & Wages)

Assumptions and estimates used throughout the Impact Analysis section

# of Medicare hospices nationwide	2,872
# of hospice patients nationwide	869,201
# of patients per average hospice	303
Hourly rate of registered nurse	$35
Hourly rate of office employee	$14
Hourly rate of administrator	$49
Hourly rate of home health aide	$19
Hourly rate of MSW	$25
Hourly rate of pharmacist	$56
Hourly rate of clinical manager	$36
Hourly rate of QAPI coordinator	$35
Hourly rate of medical director	$114

Note: All salary information is from the Bureau of Labor Statistics website at http://www.bls.gov/oes/current/oes_nat.htm#b29-0000 and it include benefits package worth 30% of the fringe base salary.

418.22 Certification of terminal illness.
(b)(3)Content of Certification
The physician must include a brief narrative explanation of the clinical findings that supports a life expectancy of 6 months or less as part of the certification and recertification forms, or as an addendum to the certification and recertification forms. If the narrative is part of the certification or recertification form, then the narrative must be located immediately prior to the physician's signature. If the narrative exists as an addendum to the certification or recertification form, in addition to the physician's signature on the certification or recertification form, the physician must also sign immediately following the narrative in the addendum. The narrative shall include a statement under the physician signature attesting that by signing, the physician confirms that he/she composed the narrative based on his/her review of the patient's medical record or, if applicable, his or her examination of the patient. The narrative must reflect the patient's individual clinical circumstances and cannot contain check boxes or standard language used for all patients. The burden associated with these requirements is the time for the physician to compose a brief narrative which synthesizes the clinical information supporting the prognosis of a life expectancy of 6 months or less, and to write, type, or dictate that narrative so that it is on or attached to the certification or recertification of terminal illness. If the physician chooses to put the narrative on an

attachment, he or she must also sign that attachment, in addition to signing the certification or recertification form itself.

Because the physician has always been required to review the clinical information needed for deciding whether or not to certify or recertify the terminal illness, the time required to review that information is not included as part of the burden estimate. We estimate it will take the physician 5 minutes to compose the narrative; write, type, or dictate it; and sign any attachment. We estimate that, based on the number of Medicare hospice beneficiaries, there would be 869,201 initial certifications. We estimate that 21% of hospice beneficiaries would still be on the benefit at 90 days, requiring a second certification, or 869,201 x 0.21 = 182,532 additional certifications. We estimate that an additional 10% of hospice patients would have a 3rd certification, or 869,201 x 0.10 = 86,920 additional certifications. A narrative would be required on each of these certifications or recertifications, for a total of 1,138,653 narratives. At 5 minutes per narrative, the total annual burden hours for the hospice are estimated to be 1,138,653 x 5 minutes / 60 minutes per hour = 94,888 hours. At $114 per hour for a Medical Director, the total annual cost burden is estimated to be $10,817,232.

PHYSICIAN NARRATIVE BURDEN ASSESSMENT

	Number of certifica-tions or recertifica-tions	Time per narrative (minutes)	Total narrative time (hours)	Time per hospice (hours)	Cost per average hospice @ $114/hour	Total cost
Initial certification	869,201	5	72,434	25.22	$2,875	$8,257,476
1st recertification	182,532	5	15,211	5.30	$604	$1,734,054
2nd recertification	86,920	5	7,243	2.52	$287	$825,702
Totals	1,138,653	5	94,888	33.04	$3,766	$10,817,232

418.52 Patients rights.

(a) Standard: Notice of rights and responsibilities

A hospice must provide patients or their representatives with written and verbal notice of the patient's rights and responsibilities, during the initial assessment visit. The notification must be presented in a manner and language consistent with the patient's ability to comprehend the information. A hospice must also inform and distribute written information to the patient regarding its policies on advance directives. A hospice must obtain the patient or representative's signature to confirm his or her receipt of a copy of the notice of rights and responsibilities. The burden associated with this notification requirements is the time and effort necessary for a hospice to: develop the notification form; provide, both verbally and in writing, the patient or the patient's representative with a notice of patient's rights; inform and

distribute information pertaining to its policies on advance directives and applicable State laws; and obtain signatures from either the patient or representative confirming receipt of a copy of the notice of rights. There are 2,872 hospices that must comply with the aforementioned requirements. We estimate that a hospice will utilize an administrator to develop the patient right form. We estimate that it will take eight hours on a one-time basis for a hospice to develop the form. The total one time burden hours for the industry are 22,976 (8 hours x 2,872 hospices). At the average hourly rate of $49 for an administrator, it will cost a hospice $392 to meet this requirement. The total one time burden cost for the industry is $1,125,824.

We estimate that it will take a registered nurse approximately five minutes per patient to incorporate the patient rights information into the existing informed consent process. We estimate that on average, each hospice will provide 303 notifications per year and the annual burden hours for a hospice to notify all its patients of their rights as part of the informed consent process would be 25.25 hours (5 minutes/60 x 303 patients). The total annual burden hours for the industry would be 72,433 (5 minutes/60 x 869,201 patients). We assume a registered nurse would incorporate the information into the existing informed consent process. At an average hourly rate of $35 for a registered nurse, it will cost a hospice $2.92 per patient annually to meet this requirement; the annual burden cost for a hospice is $885 ($2.92 x 303 patients = $885). The total annual burden cost for the industry is $2,538,130 ($2.92 x 303 patients x 2,872 = $2,538,130).

(b) Standard: Exercise of rights and respect for property and person

As an exercise of patient rights and respect for property and person, a hospice is required to investigate and document all allegations of abuse, unexplained injuries, and misappropriations of patient property involving hospice employees and contractors. Hospice employees and contractors must report alleged patient rights violations to the hospice administrator, and must report verified violations to appropriate State and local bodies having jurisdiction. A hospice must also take action to correct problems once they are identified. The burden associated with the recordkeeping and reporting requirements described in §418.52(b) is the time and effort necessary to report all alleged violations to the hospice administrator, to conduct and document an investigation and to maintain record of the documented investigation. We expect that a hospice administrator will investigate alleged patient rights violations. We estimate that, in a one year period, a hospice would need to conduct investigational sessions for alleged violations involving about 5% (15) of its patients and each session would take 1 hour to complete. The total annual burden hours per hospice would be 15 and the total annual burden hours for the industry are 43,080 (15 hours x 2,872 hospices) At an average hourly rate of $49 for an administrator, the annual burden cost for a hospice to perform the investigations is $735 ($49 x 15 hours = $735) and the total annual burden cost for the industry would be $2,110,920 ($735 x 2,872 hospices).

(c) Standard: Rights of the patient

Standard	Time per patient (minutes)	Time per hospice (hours)	Total time (hours)	Cost per patient	Cost per average hospice	Total cost
Develop form (1st year)	N/A	8	22,976	N/A	$392	$1,125,824
Notice of rights (annual)	5	25.25	72,433	$3	$885	$2,538,130
Exercise of rights (annual)	N/A	15	43,080	N/A	$735	$2,110,920
Totals	5	48.25	138,489	$3	$2,012	$4,649,379

418.54 Initial and comprehensive assessments of the patient.
(a) Standard: Initial assessment; (b) Standard: Timeframe for completion of the comprehensive assessment; (c) Standards: Content of the comprehensive assessment; (d) Standard: Update of the comprehensive assessment

The interdisciplinary group (IDG) of a hospice must conduct, document and update, within a defined timeframe, a patient-specific comprehensive assessment that identifies the patient's need for hospice care and services, and the patient's need for physical, psychosocial, emotional and spiritual care. While these requirements are subject to the PRA, the associated burden is as defined in both 5 CFR 1320.3(b)(2) as the burden imposed by these requirements are considered to be usual and customary business practice. In addition, the burden imposed by this requirement would exist even in the absence of Federal requirements.

418.54(e) Standard: Patient outcome measures

A hospice is required to include pre-determined data elements in the comprehensive assessment for patient care outcome measure purposes. There are no data reporting requirements. We believe this standard will pose a burden on the hospice provider. However, the burden of collecting information related to these outcome measures is calculated as part of a hospice's quality assessment and performance improvement program (418.58).

418.56 Interdisciplinary group (IDG), care planning and coordination of services.
(a) Standard: Approach to service delivery

A hospice is required to designate an interdisciplinary group with qualified professionals to establish policies governing the day-to-day provision of hospice care and services. The burden associated with this requirement is the time and effort necessary to draft, implement, and maintain the policies governing the day-to-day provision of hospice care services. While this requirement is subject to the PRA, the burden is considered to be usual and customary, and is exempt as stated under 5 CFR 1320.3(b)(2).

(b) Standard: Plan of care

A hospice is required to designate an interdisciplinary group with qualified professionals to develop a plan of care for each patient. In addition, a hospice must ensure that each patient and the primary caregiver(s) receive appropriate education and training. The burden associated with this requirement is the time and effort associated with educating and training the patient and patient caregiver(s). This requirement is currently approved under OMB control number 0938-0302. The expiration date for the approval is August 31, 2009.

(c) Standard: Content of the plan of care; (d) Standard: Review of the plan of care

A hospice is required to develop a written, individualized, and content-specific plan of care with for each patient. The IDG of a hospice is also required to review, revise and document the plan of care on a timely basis. The burden associated with these requirements is the time and effort associated with drafting, reviewing, revising, and maintaining the plan of care. This requirement is currently approved under OMB control number 0938-0302, with an expiration date of August 31, 2009.

(e) Standard: Coordination of services

A hospice must develop and maintain a system of communication and integration of patient care information. The burden associated with this requirement is the time and effort required to develop and maintain the system of communication in accordance with the hospice's policies and procedures. While this requirement is subject to the PRA, the associated burden is considered to be usual and customary as stated in 5 CFR 1320.3(b)(2).

418.58 Quality assessment and performance improvement.

A hospice must develop, implement, and maintain an effective, ongoing, hospice-wide data-driven quality assessment and performance improvement (QAPI) program. In addition, the hospice must maintain documentary evidence of its quality assessment and performance improvement program. The QAPI program must be able to demonstrate measurable improvement in indicators related to improved palliative outcomes and hospice services. A hospice must use all relevant quality indicator data to design its QAPI program, monitor the effectiveness and safety of services and quality of care, identify, and prioritize improvement opportunities. A hospice must track adverse patient events, analyze their causes, and implement preventative actions and mechanisms that include feedback and learning throughout the hospice. A hospice must measure its success and track performance in its performance improvement initiatives to ensure that the improvements are continuous**.**
A hospice is required to develop, justify, implement, and evaluate performance improvement projects.

The burden associated with the requirements contained in §418.58 is the time and effort necessary to develop, draft, and implement a QAPI program. As part of implementing the QAPI program, a hospice must record quality data for performance improvement initiatives. We estimate that for each hospice, 1 hour will be required to comply with the documentation of the domains and measures, 40.4 hours (4 minutes per patient assessment x 2 assessments per patient x 303 patients) will be required to collect and enter quality measure data, 50.5

hours (5 minutes per patient to document during IDG meeting x 2 IDG meetings per patient x 303 patients) will be required to document the data, and 48 hours (4 hours a month to gather and organize data x 12 months) will be required to aggregate and organize the data. This is a total annual burden of 140 hours per hospice to meet the requirements of this section. The estimated annual burden associated with these requirements is 402,080 hours ((1 hour + 40.4 hours + 50.5 hours + 48 hours) x 2,872 hospices).

These estimates are based on three phases that we believe an average hospice will go through in complying with the QAPI requirements. These phases are based on our experience in implementing the QAPI requirements of the proposed rule in the Rural Hospice Demonstration project required by section 409 of the MMA, and from discussions with hospice industry representatives who are active in implementing QAPI programs nationwide.

In phase one, we believe that a hospice will: 1) identify quality domains and measurements that reflect its organizational complexity, affect palliative outcomes, patient safety, and quality of care; focus on high risk, high volume, or problem-prone areas, and track adverse events; 2) develop polices and procedures to collect, document, retrieve, and analyze data; and 3) educate hospice employees and contractors about the QAPI program. We anticipate that a hospice will use a hospice QAPI committee which may include a QAPI coordinator, a hospice administrator, and a clinical manager. We estimate that the QAPI committee will hold four one-hour meetings for a total of 12 hours a year to identify quality domains and measures. The total burden hours for the industry are 34,464 (12 hours x 2,872 hospices). At an average hourly rate of $35, $49, and $36 respectively for these committee members, the total annual cost for an average hospice to identify the domains and measures is $480 ($35 + $49 + $36) x 4 hours). The total annual burden cost for the industry is $1,378,560 ($480 x 2,872 hospices).

In phase two, we believe a hospice will: 1) enter data into patient records and aggregate data from different sources; 2) analyze aggregate data to identify patterns, outliers and areas for improvement; and 3) develop, implement, and evaluate performance improvement projects based on data analysis. We anticipate that a hospice will use a registered nurse to collect and enter patient-level quality data at the time of each assessment. We estimate that it will take the nurse 4 minutes per patient per assessment to comply with this requirement. The annual burden hours for each hospice are 40.4 hours (4 minutes per patient assessment x 2 assessments per patient x 303 patients = 40.4 hours); the total annual burden hours for the industry would be 116,028. At an average hourly rate of $35 for a registered nurse, the annual burden cost for a hospice will be $1,414 ($35 x 40.4 hours = $1,414). We believe that a hospice will assign a registered nurse to coordinate the plan of care and it will take him or her 5 minutes to document such during the IDG meeting. The annual burden hours for each hospice would be 50.5 hours (5 minutes/60 x 2 IDG meetings x 303 patient = 50.5 hours); the total annual burden hours for the industry would be 145,036 (50.5 hours x 2,872). The annual cost burden for each hospice would be $35 x 50.5 hours = $1,768).

Once the data are gathered, a hospice must aggregate and organize the data regularly. We

estimate that a hospice will use an office employee to perform the data aggregation and organization four hours per month for a total of 48 hours a year (4 hours x 12 months = 48 hours); the annual burden hours for the industry would be 137,856 (48 hours x 2,872). At an average hourly rate of $14 for an office employee, the cost burden for a hospice will be $672 ($14 x 48 hours = $672). A hospice must analyze data to identify trends, patterns and outliers, areas of strength and concerns. To meet these requirements, we believe the data analysis will be performed by the QAPI committee described previously. We assume the committee will meet one hour each quarter. The annual burden hours for each hospice would be 12 hours (3 members x 4 hours = 12 hours) and for an annual cost burden of $480 ($35 x 4 + $49 x 4 + $36 x 4 = $480). The total annual burden hours for the industry to comply with this requirement would be 34,464 hours (12 hours x 2,876 = 34,464) and the total cost burden for the industry would be $1,378,560 ($480 x 2,872 = $1,378,560).

In phase three, we estimate that the QAPI committee of a hospice will spend three hours a year to identify and update new domains and quality measures. The associated annual burden hours for a hospice will be 3 hours and the total annual burden hours for the industry would be 8,616 (3 hours x 2,872). The associated cost burden will be $120 ($35 + $49 + $36). The total annual burden cost for the industry is $344,640 ($120 x 2,872 = $344,640).

A hospice must designate an individual to be responsible for its QAPI program. We estimate that the QAPI coordinator will spend 1.5 hours per week to oversee the program. The associated total annual burden hours for a hospice are 78 hours (1.5 hours x 52 weeks). The total annual burden hours for the industry would be 224,016 (78 hours x 2,872). At an average hourly rate of $35 for a QAPI coordinator, the associated annual burden cost for a hospice is $2,730 (78 hours x $35 = $2,730) and the annual burden cost for the industry is $7,840,560 ($2730 x 2,872 = $7,840,560).

A hospice is required to conduct projects to improve its performance in areas where a weakness is identified. However, we believe that conducting performance improvement projects is standard practice within the hospice industry. Therefore, there is no additional burden associated with this provision.

QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT BURDEN ASSESSMENT

Standard	Time per hospice (hours)	Total time (hours)	Cost per hospice	Total cost
Identify domains and measures (1st year)	12	34,464	$480	$1,378,560
Enter data (1st year and annual)	91	261,352	$3,182	$9,138,704
Aggregate data (1st year and annual)	48	137,856	$672	$1,929,984

Data analysis (1st year and annual)	12	34,464	$480	$1,378,560
QAPI coordinator (1st year and annual)	78	224,016	$2,730	$7,840,560
Update domains and measures (annual)	3	8,616	$120	$344,640
Total 1st year	241	692,152*	$7,544	$21,666,368*
Total annually	232	666,304*	$7,184	$20,632,448*

* Note: The overall national estimates are based on the assumption that every hospice will begin to develop and implement a QAPI program upon the effective date of this final rule. Anecdotal evidence suggests that many hospices began developing and implementing QAPI programs upon publication of the proposed hospice rule, and therefore will not be impacted to the same extent as we have estimated above. Thus, we expect that the actual impact of this final requirement will be less than estimated in this section.

418.60 Infection control.

A hospice must maintain and document an effective infection control program that protects patients, families, visitors, and hospice personnel by preventing and controlling infections and communicable diseases. We believe that the burden associated with this requirement is exempt from the PRA as defined in 5 CFR 1320.3(b)(2). As stated in 5 CFR 1320.3(b)(2), the burden imposed by this requirement is considered to be usual, customary and long-standing clinical practices in the hospice care industry. In addition, the burden imposed by this requirement would exist even in the absence of the Federal requirement.

418.64 Core services.

A hospice is allowed to contract out core services in certain extraordinary or other non-routine circumstances. We believe that negotiating, documenting and signing a business contract is standard business practice and does not pose a burden and is exempt from the PRA as defined in 5 CFR 1320.3(b)(2).

A hospice is also required to offer bereavement services to appropriate residents of a SNF/NF or ICF/MR. Residents of a facility often act as a patient's family, support, and companionship throughout the terminal illness. Since offering and subsequently providing bereavement services to a patient's family is standard practice, we do not believe that extending such services to those who act as a patient's family in a SNF/NF or ICF/MR imposes an additional burden upon a hospice.

418.66 Nursing services – Waiver of requirements that substantially all nursing services be routinely provided directly by a hospice.

CMS can waive the requirement in §418.64(b) to allow a hospice to provide nursing services directly, if the hospice is located in a non-urbanized area. To obtain a waiver, the hospice must provide evidence to CMS that it made good faith efforts to hire a sufficient number of nurses to provide services. To obtain an extension for a currently approved waiver, a hospice must submit its request to CMS prior to the expiration of the waiver period and certify that the conditions under which the hospice originally requested the waiver have not changed.

The burden associated with this requirement is the time and effort associated with a hospice demonstrating good faith efforts for it staffing process and submitting a certified extension request to CMS stating that the circumstances that caused the original waiver request have not changed. We believe this requirement and the associated burden is exempt from the PRA under 5 CFR 1320.3(c)(4). We believe the requirement will affect less than 10 entities on an annual basis.

418.70 Furnishing of non-core services.
A hospice must ensure that the required non-core services are provided directly by the hospice or under arrangements. These services must be provided in manner consistent with current standard of practice. We believe that provision of these services is standard industry practice, and therefore, the burden is not subject to the PRA as stipulated in 5 CFR 1320.3(b)(2).

418.72 Physical therapy, occupational therapy, occupational therapy, speech-language pathology.

A hospice is required to have physical therapy services, occupational therapy services, and speech-language pathology services available, and when provided, they must be offered in a manner consistent with accepted standards of practice. We believe that provision of these services is standard industry practice, and therefore, the burden is not subject to the PRA as stipulated in 5 CFR 1320.3(b)(2).

418.74 Waiver of requirement – Physical therapy, occupational therapy, speech-language pathology, and dietary counseling.

CMS can waive the requirement for providing physical therapy, occupational therapy, speech-language pathology, and dietary counseling services (as needed) on a 24-hour basis for hospices located in non-urbanized areas. To obtain a waiver, a hospice must provide evidence to CMS that it made good faith efforts to meet the requirements for the aforementioned services prior to submitting a waiver request. To obtain an extension for a currently approved waiver, a hospice must submit its request to CMS prior to the expiration of the waiver period and certify that the conditions under which the hospice originally requested the waiver have not changed. The burden associated with this requirement is the time and effort associated with a hospice demonstrating good faith efforts for it staffing process and submitting a certified extension request to CMS stating that the circumstances that caused the original waiver request have not changed. We believe this requirement and the associated burden is exempt from the PRA under 5 CFR 1320.3(c)(4). We believe the requirement will affect less than 10 entities on an annual basis.

418.76 Hospice aide and homemaker services.
(a) Standard: Hospice aide qualifications.
(b) Standard: Content and duration of hospice aide classroom and supervised practical training.

(c) Standard: Competency evaluation.

All hospice aide services must be provided by individuals who meet the personnel requirements and training criteria as specified. A hospice is required to maintain documentation that each hospice aide meets these qualifications. The burden associated with these standards is the time to complete the required documentation. We estimate that it will take five minutes a year to document the information and that an office employee will complete this task. In addition, based on an employee turnover rate of 30% as indicated in the 2002 NHPCO National Data Set Summary Report, we assume that the average hospice would replace 30% of its hospice aides in a given year, or roughly one hospice aide a year based on the employment of 5 hospice aides. We estimate that there will be 239 annual burden hours (5 minutes/60 x 2,872 hospices) for the hospice industry. At an hourly rate of $14 for an office employee, the annual burden cost for a hospice is $1.17 and the annual burden cost for the industry is $3,360 ($1.17 x 2,872 = $3,360).

(d) Standard: In-service training

A hospice is required to maintain documentation that all hospice aides have received at least 12 hours of in-service training during each 12-month period. The burden associated with this requirement is the time and effort necessary to document and maintain record of the required in-service training. We estimate it will take each hospice 2 hours annually to meet this requirement. The estimate total annual burden for this requirement is 5,744 hours (2 hours x 2,872 hospices). At an hourly rate of $14 for an office employee, the annual burden cost for a hospice is $28 and the annual burden cost for the industry is $80,416 ($28 x 2,872 = $80,416).

HOSPICE AIDE AND HOMEMAKER SERVICES BURDEN ASSESSMENT

Standard	Time per aide	Time per hospice	Total time (hours)	Cost per aide	Cost per average hospice	Total cost
Documentation (based on 1 new hospice aide per year)	5 minutes	5 minutes	239	$1.17	$1.17	$3,360
In-service training	N/A	2 hours	5,744	N/A	$28	$80,416
Total	5 minutes	2 hours 5 minutes	5,983	$1.17	$29.17	$83,776

(g) Standard: Hospice aide assignment and duties

A hospice aide is assigned to a patient by a registered nurse who is a member of that patient's IDG. Additionally, a hospice aide receives written patient care instructions prepared by the registered nurse who is responsible for supervising the hospice aide. The burden associated with this requirement is the time and effort necessary for a registered nurse responsible for supervising a hospice aide to draft written patient care instructions for the hospice aide. We

believe that preparing patient care instructions is a usual and customary business practice, and is hereby exempt from the PRA under 5 CFR 1320.3(b)(2).

(h) Standard: Supervision of hospice aides

A hospice is required to have a registered nurse perform a periodic on-site evaluation of a hospice aide and evaluate the sufficiency of services ordered by the IDG. The burden associated with this requirement is the time and effort necessary for a nurse to conduct an onsite evaluation of aide services in the patient's home, to document the quality of care provided by the hospice care aide, and to evaluate the services ordered by the IDG to ensure that they are consistent with the patient's needs. We believe this is a usual and customary business practice, and is thereby exempt from the PRA under 5 CFR 1320.3(b)(2).

(i) Standard: Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit

Prior to furnishing personal care services, an individual must demonstrate competency in the services they are required to furnish. The burden associated with this requirement is the time and effort necessary to demonstrate competency. While this requirement is subject to the PRA, we believe the associated burden is exempt stated in 5 CFR 1320.3(b)(2). We believe this is a usual and customary business practice.

(j) Standard: Homemaker qualifications

(k) Standard: Homemaker supervision and duties

A hospice homemaker is required to complete a hospice orientation program addressing the needs and concerns of patients and families. A member of the interdisciplinary group is required to provide written instructions to the homemaker. Since all hospices usually train, instruct, and supervise all of their employees, including homemakers, we do not believe this standard would impose any additional regulatory burden.

Homemakers are also required to report all concerns about the patient or family to the member of the IDG who is coordinating the homemaker's services. The burden associated with this requirement is the time and effort needed for the homemaker to report all concerns. We believe the burden is exempt as stated in 5 CFR 1320.3(b)(2); this is a usual and customary business practice.

418.78 Volunteers.

(a) Standard: Training

A hospice must document, maintain, and provide volunteer orientation and training that is consistent with hospice industry standards. We estimate on average that a hospice would provide orientation and training six times per year; we estimate that it will take no longer than five minutes to document each orientation section for a total of 30 minutes (5 minutes x 6 times/year) per year per hospice. The total annual burden associated with this requirement is 1,436 hours (30 minutes/60 x 2,872 hospices) for the industry. At an hourly rate of $14 for an office employee, the annual burden cost for a hospice is $7 and the annual burden cost for the industry is $20,104 ($7 x 2,872 = $20,104).

(c) Standard: Recruiting and retaining

A hospice is required to document and demonstrate viable and ongoing efforts to recruit and retain volunteers. The burden associated with this requirement is the time and effort necessary to document and demonstrate the recruitment and retention efforts. We estimate that it will take each hospice 3 hours to document and demonstrate its recruitment and retention efforts, for a total annual burden of 8,616 hours (3 hours x 2,872 hospices) for the industry. At an hourly rate of $14 for an office employee, the annual burden cost for a hospice is $42 and the annual burden cost for the industry is $120,624 ($42 x 2,872 = $120,624).

(d) Standard: Cost saving

A hospice is required to document the cost savings achieved through the use of volunteers. We estimate that complying with this requirement will take 3 hours per hospice per year, or 8,616 annual burden hours (3 hours x 2,872 hospices) for the industry. At an hourly rate of $49 for an administrator, the annual burden cost for a hospice is $147 and the annual burden cost for the industry is $422,184 ($147 x 2,872 = $422,184).

(e) Standard: Level of activity

A hospice is required to document and maintain records on the use of volunteers for patient care and administrative services, including the type of services and time worked in a minimum amount that equals 5% of the total patient care hours of all paid employees and contract staff. The burden associated with this requirement is the time and effort necessary to document and maintain the volunteer records. We estimate that recording these examples would take approximately 48 hours per hospice for a total annual burden of 137,856 hours (48 hours x 2,872 hospices) for the industry. At an hourly rate of $14 for an office employee, the annual burden cost for a hospice is $672 and the annual burden cost for the industry is $1,929,984 ($672 x 2,872 = $1,929,984).

VOLUNTEERS BURDEN ASSESSMENT

Standard	Time per hospice (hours)	Total time	Cost per hospice	Total cost
Training	0.5	1,436	$7	$20,104
Recruiting and retaining	3	8,616	$42	$120,624
Cost savings	3	8,616	$147	$422,184
Level of activity	48	137,856	$672	$1,929,984
Total	54.5	156,524	$868	$2,492,896

418.100 Organization and administration of services.

(e) Standard: Professional management responsibility

A hospice that has a written agreement with another agency, individual, or organization to

furnish any services under arrangements, must retain administrative and financial management, and oversight of staff and services for all arranged services, to ensure the provision of quality care. The burden associated with this requirement is the time and effort necessary to develop, draft, execute and maintain the written agreements. We believe these written agreements are part of the usual and customary business practices of hospices, and are thereby exempt from the PRA under 5 CFR 1320.3(b)(2).

(f) Standard: Hospice multiple locations

A hospice must continually monitor and manage all services provided at all of its locations. The burden associated with this requirement is the time and effort necessary to monitor and manage all of the services provided at all of its locations. The burdens associated with this requirement is considered to be usual and customary as stated in 5 CFR 1320.3(b)(2), and is thereby exempt from the PRA.

(g) Standard: Training

A hospice is required to provide an initial orientation for each employee that addresses the employee's specific job duties. In addition, a hospice must have written policies and procedures describing its method(s) of assessment of competency. Also, the hospice must maintain a written description of the in-service training provided during the previous 12 months. The burden associated with the requirements of this section is considered to be usual and customary under 5 CFR 1320.3(b)(2); usual and customary burdens are exempt from the PRA.

418.102 Medical director.

A hospice is required to designate an alternative physician as the medical director to assume the role and responsibilities of the medical director in the absence of the latter. All hospices routinely meet the medical needs of their patients 24 hours a day with the availability of more than one physician. We do not believe this requirement would pose a burden to a hospice.

(a) Medical director contract

We added a provision permitting the medical director to work under a contractual arrangement, reducing the program and hiring burden on the hospice. If a hospice chooses to secure medical director services through a contract, this rule requires the contract to specify the physician who will serve as the medical director. Identifying a single individual to serve as the hospice medical director is standard practice in the hospice industry and does not present a burden.

(b) Standard: Initial certification of terminal illness

(c) Standard: Recertification of the terminal illness

Hospice medical directors or physician designees are required to review the clinical information for each hospice patient and provide written certification that it is anticipated that the patient's life expectancy is 6 months or less if the illness runs its normal course. Certifying and recertifying a patient's life expectancy is standard practice for the hospice medical director in the hospice industry and does not present a burden.

(d) Standard: Medical director responsibility

This standard re-codifies the requirement that the medical director or designee has responsibility for the medical component of the hospice's patient care program. It is standard practice for the hospice medical director to lead, and thus bear responsibility for, the medical component of the hospice's patient care services. Therefore, this re-codified provision does not impose a burden upon a hospice.

418.104 Clinical records.

(a) Standard: Content

(b) Standard: Authentication

(c) Standard: Protection of information

A hospice is required to maintain a clinical record for each patient. The clinical records must contain specific information and must be authenticated in accordance with hospice policy. The burden associated with the requirement is the time and effort necessary to document and maintain the information. The maintenance of clinical records is a usual and customary business practice; the burden associated with maintaining a clinical record is exempt form the PRA under 5 CFR 1320.3(b)(2). Furthermore, a hospice is required to protect and retain the information contained in the clinical record in accordance with the Department's rules regarding personal health information at 45 CFR parts 160 and 164. All of these requirements reflect standard hospice practices and do not pose a burden.

(d) Standard: Retention of records

A hospice is required to retain patients' clinical records for 6 years after the death or discharge of the patient, unless State law stipulates a longer period of time. If the hospice discontinues operation, hospice policies must provide for retention and storage of clinical records. The burden associated with these requirements is the time and effort necessary to maintain records for 6 years after the death or discharge of the patient, and to draft, implement, and maintain the record retention policy in the event that the hospice discontinues operation. While this requirement is subject to the PRA, we believe the associated burden is exempt as stated in 5 CFR 1320.3(b)(2). The development and maintenance of a record retention policy is a usual and customary business practice.

(e) Standard: Discharge or transfer of care

A hospice is required to prepare and send a comprehensive discharge summary for all patients that are discharged alive. The discharge summary must include a summary of the patient's stay, the patient's current plan of care, the most recent physician orders, and any other documentation to aid in post-discharge care of the patient. These are standard elements for discharge summaries in the health care industry, including the hospice industry. This rule also requires a hospice to send a copy of the patient's clinical record to the provider assuming care of the patient, upon request of the provider. A comprehensive discharge summary should remove any reason for the provider assuming care to request a copy of the patient's clinical record. We believe that these discharge requirements reflect standard industry practice and add no burden to a hospice.

(f) Standard: Retrieval of clinical records

A hospice must make clinical records, whether in hard copy or electronic form, readily available on request by an appropriate authority. The burden associated with this requirement is the time and effort required to disclose a clinical record to an appropriate authority. While this requirement is subject to the PRA, we believe the associated burden is exempt as stated in 5 CFR 1320.3(b)(2). Making clinical records available to the appropriate authority is part of the survey and certification process, and imposes no additional burden as a usual and customary business practice.

418.106 Drugs and biologicals, medical supplies, and durable medical equipment.

(a) Standard: Managing drugs and biologicals

A hospice must require its interdisciplinary group confers with an individual with education and training in drug management to ensure that drugs and biologicals meet patients needs. A hospice may meet this requirement by hiring or contracting with a pharmacist(s), or contracting with a pharmacy benefit management company, or hiring or contracting with a physician or other clinician with the necessary education and training in drug management, or by ensuring the appropriate education and training of one or more existing hospice employees.

For purposes of our analysis only, we are estimating the impact of this provision based on the assumption that an average hospice will choose to use a pharmacist to meet this requirement. We believe that a hospice will most likely contract with a pharmacy benefit management company to provide all drugs and biologicals for its patients at an industry average price for patients, without increasing a hospice's expenditures. The benefit of a pharmacy benefit management company is that it allows a hospice IDG to speak with a pharmacist on a 24-hour basis to gather information, input, and advice from the pharmacist regarding an individual patient's drug and biological profile. For a hospice that opts not to use a pharmacy benefit management company, it may also choose to employ or contract with a pharmacist(s) for pharmacist advisement services. In this case, the hospice retains the responsibility and flexibility of managing the purchase of drugs and biologicals. We estimate that it requires 30 minutes for an individual such as a pharmacist to initially review a patient's drug and biologicals profile and advise the IDG during the time of the patient's comprehensive assessment and development of the plan of care. Additionally, we estimate that it requires 15 minutes of the pharmacist's time to review updates to the patient's drug profile and advise the IDG about updates to the patient's plan of care. Based on a 26 day median length of stay, patients would likely receive two updates to their plans of care. At an average hourly rate of $56 for a pharmacist, we estimate that it would cost a hospice $56 per patient ($56 x (30 minutes + 15 minutes + 15 minutes)) and an annual cost of $16,968 ($56 x 303 patients) to secure pharmacist advisement services. The total annual burden hours for all hospices are 869,201 hours (869,201 patients x 1 hour), and the total annual burden cost for all hospices are $48,675,256 ($56 x 869,201 patients).

(b) Standard: Ordering of drugs

Under the hospice final rule, the individual receiving a drug order must record and sign it immediately and have the prescribing person sign it in accordance with State and Federal regulations. The burden associated with this requirement is the time and effort necessary for the recipient of the order record and sign the order and to have the prescribing person sign the prescription. The burden associated with this requirement is exempt under both 5 CFR 1320.3(b)(2) and 5 CFR 1320.3(b)(3). As defined in 5 CFR 1320.3(b)(2), this process is a usual and customary business practice. As defined in 5 CFR 1320.3(b)(3), a State requirement would exist even in the absence of the Federal requirement. The associated burden is thereby exempt from the PRA.

(c) Standard: Dispensing of drugs and biologicals

A hospice that provides inpatient care directly in its own facility must have a written policy in place that promotes dispensing accuracy. Additionally, a hospice that provides inpatient care directly must maintain current and accurate records of the receipt and disposition of all controlled drugs. The burden associated with this requirement is the time and effort necessary to develop, draft, implement, and maintain a written policy that promotes dispensing accuracy and to maintain controlled drug records. The existence of this type of policy and these records are usual and customary business practices. The burden associated with this section is exempt from the PRA under 5 CFR 1320.3(b)(2).

(e) Standard: Labeling, disposing and storing of drugs and biologicals

A hospice must have a written policy for the management and disposal of controlled drugs in a patient's home. A hospice must educate the patient or his/her representative and family in the safe use and disposal of controlled drugs when a controlled is first ordered. A hospice must document in a patient's clinical record that the written policy for managing controlled drugs was provided and discussed. A hospice must maintain current and accurate records of the receipt and disposition of all controlled drugs. The burden associated with these requirements is the time and effort necessary to document a written copy of the policy on the management and disposal of controlled drugs in the patient's home was given to the patient representative and family. We estimate that it will take a registered nurse five minutes to complete the patient education documentation at a cost of $2.92 (5 minutes/60 x $35) for each patient. The total annual burden hours for a hospice to meet this requirement would be 25.25 hours (5 minutes/60 x 303 patients), and the total annual burden hours for the industry would be 72,518 (25.25 x 2,872). The total annual burden cost for the industry is $2,541,031 ($2.92 x 303 patients x 2,872 hospices).

Furthermore, the pharmacist and the administrator of a hospice program that provides inpatient care directly in its own facility must investigate discrepancies involving controlled drugs and to document an account of the investigation. Of the 2,533 deficiencies issued by State surveyors in 1,161 surveys in 2006, two were potentially related to controlled drug discrepancies. The 1,161 surveys in 2006 represent approximately 30 percent of all hospices. Therefore, we can expect that if all hospices were surveyed, six deficiencies would be issued that are potentially related controlled drug discrepancies. Hence, our estimate is based on six investigations per year for the hospice industry. We estimate that a thorough investigation,

including an examination of the records of incoming and outgoing drugs and biologicals, and report would require one hour per incident. We estimate the associated annual burden for the industry to fulfill this requirement is six hours (1 hour x 6 investigations). At an average hourly rate of $56 for a pharmacist and $49 for an administrator, the burden cost for each investigation is $105 ($56 + $49 x 1 hour) and the total associated cost is $630 ($56 + $49 x 1 hour x 6 investigations).

DRUGS, MEDICAL SUPPLIES AND DURABLE MEDIAL EQUIPMENT BURDEN ASSESSMENT

Standard	Time per patient (minutes)	Time per average hospice (hours)	Total industry time (hours)	Cost per patient	Cost per average hospice	Total industry cost
Drug Policy Education	5	25.25	72,518	$2.92	$884.76	$2,541,031
Drug Discrepancy Investigation	N/A	N/A	6	N/A	N/A	$624
Totals	5	25.25	72,524	$2.92	$884.76	$2,541,031

(f) Standard: Use and maintenance of equipment and supplies

A hospice must ensure that manufacturer recommendations for routine and preventive maintenance of equipment are followed. A hospice must ensure that repair and routine maintenance policies are developed in situations when a manufacturer's recommendation for a piece of equipment is nonexistent. The burden associated with this requirement is the time and effort necessary to develop, draft, implement, and maintain repair and routine maintenance policies. However, proper maintenance of equipment is standard practice.

A hospice is required to contract only with a durable medical equipment supplier that meets the Medicare DMEPOS Supplier Standards at 42 CFR 424.57. The vast majority of hospices provide durable medical equipment and supplies under contract with one or more vendors. All vendors with Medicare supplier numbers must meet the DMEPOS Standards, per separate CMS rulemaking. Since all Medicare-participating suppliers must already meet the standards, we do not believe that this requirement will compromise a hospice's ability to secure a contract or impose a burden.

In addition, a hospice must ensure that the patient, family, and other caregivers receive instruction in the safe use of durable medical equipment and supplies. After providing instruction, the patient, family, and/or caregiver must be able to demonstrate the appropriate use of durable medical equipment. As defined in 5 CFR 1320.3(b)(2), providing proper instruction on the use of durable medical equipment to patient, family members, and caregivers is a usual and customary business.

418.108 Short term inpatient care.
(c) Standard: Inpatient care provided under arrangement
A hospice is required to include specific provisions in a written agreement if it has an arrangement with a facility to provide short-term inpatient care. The burden associated with this requirement is the time and effort necessary to develop, draft, execute, and maintain the written agreement. While this requirement is subject to the PRA, the burden is exempt under 5 CFR 1320.2(b)(2). The use of the written agreements between providers is a usual and customary business practice.

418.110 Hospices that provide inpatient care directly.
(b) Twenty-four hour nursing services
This requirement is adopted from the existing hospice rule. This requirement for a hospice that provides general inpatient care directly to have a registered nurse on each shift to provide direct patient care has been in place since the inception of the Medicare hospice Conditions of Participation. As such, it is standard practice and does not pose a burden.

(c) Standard: Physical environment.
A hospice must have a written disaster preparedness plan in effect to manage emergencies that might compromise the hospice's ability to provide care. Additionally, the plan must be periodically reviewed. The burden associated with this requirement is the time and effort necessary to develop, draft, implement, maintain, and periodically review the disaster preparedness plan. A hospice is required to develop procedures for managing physical plant issues. The burden associated with the requirement is the time and effort necessary to draft, implement, maintain, and review the facility's disaster preparedness plans and procedures to address physical plant issues. While these requirements are subject to the PRA, we believe the associated burden is exempt as stated in 5 CFR 1320.3(b)(2).

(d) Standard: Fire protection
(e) Standard: Patient areas
(f) Standard: Patient rooms
(g) Standard: Toilet and bathing
(h) Standard: Plumbing facilities
(i) Standard: Infection control
(j) Standard: Sanitary environment
(k) Standard: Linen
(l) Standard: Meal service and menu planning
A hospice is required to comply with applicable fire safety requirements, provide a home-like atmosphere with sufficient space and amenities, maintain an adequate infection control program, provide clean linens and properly handle soiled ones and serve meals to meet patient needs. These requirements are standard practice in hospice-operated inpatient facilities and pose no additional burden.

(m) Standard: Restraint or seclusion

A hospice shall implement restraint and seclusion in accordance with safe and appropriate restraint and seclusion techniques as determined by hospice policy in accordance with State law and the written plan of care shall be modified. The burden associated with this requirement is the time and effort necessary to modify the plan of care in writing to include the physician order for restraint and seclusion.

A hospice shall use restraint or seclusion in accordance with a physician's orders per hospice policy in accordance with State law. There is a burden associated with creating a physician's order. However, we believe the burden associated with the aforementioned requirements is exempt from the PRA under 5 CFR 1320.3(b)(2), as they are part of the usual and customary business practice for hospices.

Under the final rule, prior to writing a new order for the use of restraint or seclusion, a physician must see and assess the patient. The burden associated with this requirement is the time and effort necessary for the ordering physician to see and assess the patient. Further, when restraint or seclusion is used, a hospice patient's clinical record must contain the specified documentation. The burden associated with this requirement is the time and effort necessary to compile the specified documentation in the patient's clinical record. We estimate the collective burden associated with the above requirements to be 45 minutes per event. There are 906 hospices (31.54 percent of all hospices, according to the March 2006 Hospice Facts & Statistics Report from the Hospice Association of America) that operate their own inpatient facilities and are thus subject to these seclusion and restraint requirements. We have not previously tracked the use of seclusion and restraint techniques in hospice-operated inpatient facilities. However, public comments on the hospice proposed rule indicated that the use of seclusion and restraint techniques is very rare. For purposes of this analysis, we assume that each hospice-operated inpatient facility will need to use a seclusion or restraint technique for one patient in a given year. Therefore, we estimate the collective burden associated with the above requirements to be 679.5 hours annually.

(n) Standard: Restraint or seclusion staff training requirements

Patient care staff working in the hospice inpatient facility and who are involved in the application of restraint or seclusion must be trained in accordance to specific requirements, and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment and providing care for a patient in restraint or seclusion. A hospice must document in the personnel records that each employee successfully completed the restraint and seclusion training and demonstrated competency.

We believe that most hospices would opt for the train-the trainer approach. That is, we believe hospices would send the trainers (most likely registered nurses) to attend one-time training from an outside organization. These trained individuals would in turn function as program developers and trainers of the appropriate hospice staff.

For analysis purposes, we assume that hospice staff will attend the four day instructor certification program given by the Crisis Prevention Institute (CPI, INC.) that costs $1,200 in

tuition plus travel, lodging, and participant salary. The burden hours for a hospice to train a nurse would be 32 hours (4 days x 8 hours) and the total burden hours for the industry would be 28,992 hours (32 hours per hospice x 906 hospices). We estimate, on average, that roundtrip travel (local or distant) for each nurse will cost approximately $400; lodging for each nurse will costs approximately $360 ($120 per night x 3 nights); and the meals and incidental expenses (M&IE) will be approximately $200 ($50 per day x 4 days) depending upon the location within the designated state. At an average hourly rate of $35 for a registered nurse, we estimate that the salary cost for that individual to attend the four-day training is $1,120 ($35 x 8 hours x 4 days). Thus, the total one-time cost for one hospice inpatient facility to train one nurse would be $3,280 ($1,200 + $400 + $360 + $200 + $1,120). The total industry cost would be $2,971,680 ($3,280 x 906).

We assume that the train-the-trainer program described above will provide hospices with the necessary personnel and materials to implement a staff-wide seclusion and restraint training program as part of their in-service training programs. We estimate that developing this staff-wide training program will require 40 hours of the trainer's time on a one-time basis for each affected hospice, at a cost of $1,400 ($35 x 40 hours) per hospice inpatient facility, and a total one-time cost of $1,268,400 for the industry . The total associated annual burden hours for the industry are 36,240 (40 hours per hospice x 906 hospices**).**

According to data from a March 2006 Hospice Association of America report, there were 116,148 total hospice employees and volunteers in 2005. Of these employees and volunteers, 32,412 employees and volunteers were nurses and physicians. Thus the average hospice operating its own inpatient facility has 11 nurse and physician employees and volunteers. Based on the assumption that one nurse trainer conducts an 8 hour training course for 11 hospice inpatient employees and volunteers, we estimate that it will take a hospice 96 hours ((1 trainer + 11 employees) x 8 hours) to comply with the training requirement and the burden hours for the industry are 86,976(96 hours per hospice x 906 hospices). At an average hourly rate of $35 for the trainer and the trainees, the associated cost for this requirement for each hospice is $3,360 (96 hours x $35) and the associated cost for the industry is $3,044,160 ($3,360 x 906 hospices)

A hospice is required to update and document staff's training annually. According to the National Association of Psychiatric Health Systems (NAPHS), it takes about 4 hours of staff and instructor time to update the training of each employee who has direct patient contact. We estimate that the burden hours for a hospice to meet this requirement would be 48 hours (4 hours x 12 employees) and a total of 43,499 hours for the industry. Based on our previous assumption that an average size hospice has 11 employees who must be trained in de-escalation techniques, we estimate that it will cost a hospice $1,680 ($35 x 4 + $35 x 4 hours x 11 employees) annually to update each of the above employee's training. The total cost associated with this requirement would be $1,522,080 ($1,680 x 906 hospices).

Additionally, a hospice is required to document in each trained individual's personnel record that he or she has successfully completed the training. We estimate that it will take 5 minutes for the trainer to document each participant's training record. Based on the assumption that

11 hospice employees and volunteers will be trained and need documentation, we estimate that it will take a hospice nurse 55 minutes (5 minutes x 11 trainees) at a cost of $32 ($35 x 55 minutes/60) annually to meet this requirement. For the hospice industry, the total annual burden hours are 830.5 hours (55 minutes/60 x 906 hospices) and the total annual burden cost fir the industry is $$29,068 ($35 x 830.5 hours).

Hospices that provide inpatient care directly burden assessment (one time).

Standard	Time per average hospice (hours)	Total time (hours)	Cost per average hospice	Total # of hospice inpatient facilities	Total cost
4 day trainer training	32	28,992	$3,280	906	$2,971,680
Staff training program development	40	36,240	$1,400	906	$1,268,400
Staff training	96	86,976	$3,360	906	$3,044,160
Staff training records	55 minutes	830.5	$32	906	$29,068
Totals 1st year	169	153,038.5	$8,072	906	$7,313,308

A hospice is required to revise its training program annually as needed. We estimate that it will take 4 hours a year for the trainer (most likely a nurse) in each hospice to complete this task, and the total annual burden hours for the industry are 3,624 hours (4 hours x 906 hospices). At an average hourly rate of $35 for a registered nurse, the annual burden cost for each hospice is $140 ($35 x 4 hours), and the total annual burden cost for the industry are $126,840 ($140 x 906 hospices).

Hospices that provide inpatient care directly burden assessment (annual).

Standard	Time per average hospice (hours)	Total time (hours)	Total # of hospice inpatient facilities	Cost per average hospice	Total cost
Staff training update	48	43,488	906	$1,680	$1,522,080
Staff training records	55 minutes	830.5	906	$32	$29,068
Staff training program update	4	3,624	906	$140	$126,840

Totals annually	53	47,943	906	$1,852	$1,677,988

(o) Standard: Death reporting requirements

A hospice must report deaths associated with the use of restraint or seclusion. The hospice staff must document in the decedents clinical record the date and time the death was reported to CMS by telephone. We cannot accurately estimate the number of deaths that would occur annually as a result of restraint or seclusion due to a lack of historical data. However, based on a lack of family complaints to State agencies or CMS, we believe such deaths to be a rare occurrence. We believe that the number of reports certainly should average less than one per hospice inpatient facility per year or less than 10 per year for the industry. Therefore, we believe that the impact associated with this provision (that is, making a telephone call and filling in a written report) is negligible. While this requirement is subject to the PRA, we believe the burden is exempt under 5 CFR §1320.3(c)(4), as it would affect less than 10 entities.

418.112 Hospices that provide hospice care to residents of a SNF/NF or ICF/MR.

(a) Standard: Resident eligibility

This standard requires that Medicare patients receiving hospice services and residing in a SNF, NF, or ICF/MR must be subject to the Medicare hospice eligibility criteria as delineated in the current hospice rule. The burden associated with this requirement is the time and efforts to validate patients' Medicare eligibility. We believe that validating Medicare eligibility for hospice services for patients residing in a SNF, NF, or ICF/MR is customary and standard practice, we do not believe it will pose a burden to a hospice.

(b) Standard: Professional management

A hospice must assume responsibility for professional management of the resident's hospice services provided, in accordance with the hospice plan of care and the hospice conditions of participation, and make any arrangements necessary for hospice-related inpatient care in a participating Medicare/Medicaid facility. The burden associated with this standard is the time and efforts needed to ensure these responsibilities are met. We believe that in fulfilling these requirements, a hospice will not incur any burden above and beyond its usual and customary business practice.

(c) Standard: Written agreement

A hospice and SNF/NF or ICF/MR must have a written agreement that specifies the provision of hospice services in the facility. The agreement must be signed by authorized representatives of the hospices and the SNF/NF or ICF/MR prior to the provision of hospice care services. This rule establishes the minimum content of the written agreement that a hospice provider must have with a SNF/NF or ICF/MR if the hospice is caring for a resident of the facility. The burden associated with this requirement is the time and effort necessary to develop, draft, sign, and maintain the written agreement. However, the use of this type of written agreement is a usual and customary business practice; the associated burden is exempt

from the PRA under 5 CFR §1320.3(b)(2).

(d) Standard: Hospice plan of care
A written plan of care must be established and maintained in consultation with SNF/NF or ICF/MR representatives. The burden associated with this requirement is discussed under our discussion of §418.56(c).

(e)(3) Standard: Coordination of services
In the coordination of services for residents of a SNF, NF, or ICF/MR, a hospice is required to designate an IDG member to coordinate a patient's care with facility representatives, including provision of specific information about the patient's care. The specific information includes the patient's hospice election form, advance directives, certification forms, physician orders, contact information for pertinent hospice personnel and hospice's 24-hour on-call system, patient's medication, and physician's orders.

With the exception of the election and advanced directives forms, certification forms, and physician orders, all of the specified information is routinely provided to a patient's caregiver(s). Since the facility is the caregiver, providing this information presents no burden to a hospice. We believe that a hospice would use an office employee to fax the required documents to the facility and it would take 10 minutes to complete this task for each patient.

According to the March 2006 report from the Hospice Association of America ("Hospice Facts & Statistics"), 27.19 percent of hospice patients nationwide resided in a SNF or other long term care facility. Therefore, we estimate that hospices will provide forms to SNFs/NFs and ICFs/MR for 236,336 hospice patients (869,201 patients x 27.19%) residing in those facilities. We also estimate that the average hospice will provide care to 82 patients residing in a SNF/NF or ICF/MR (236,336 patients nationwide / 2,872 hospices). We estimate that the total annual burden hours for each hospice to meet this requirement are 13.7 hours (10 minutes/60 x 82 patients), and the total burden hours for the industry are 39,389 hours (10 minutes/60 x 236,336 patients). At an average hourly rate of $14 for an office employee, the cost burden cost for each hospice is $192 ($14 x 13.7 hours) and the total cost for the industry is $551,446 ($14 x 39,389 hours). The cost for a hospice to fax the forms would be $2.33 ($551,446/236,336 patients) per patient.

HOSPICES THAT PROVIDE HOSPICE CARE TO RESIDENTS OF A SNF/NF OR ICF/MR BURDEN ASSESSMENT

Standard	Time per patient (minutes)	Time per average hospice(hours)	Total time (hours)	Cost per patient	Cost per average hospice	Total cost
Providing forms to facility	10	13.7	39,389	$2.33	$192	$551,446
Totals	10	13.7	39,389	$2.33	$192	$551,446

(f) Standard: Orientation and training of staff

A hospice is required to ensure that SNF/NF and ICF/MR staff receive orientation in caring for hospice patients. Staff orientation must address the following topics: hospice philosophy; hospice policies regarding patient comfort methods, pain control, and symptom management; principles about death and dying; individual responses to death; patient rights; appropriate forms; and record keeping requirements. We recognize that residents in a single facility may be served by several hospices, and many hospices will rely on the orientation already provided by another hospice. We do not know exactly how many hospices serve patients residing in a SNF/NF or ICF/MR, or how many of those facilities are served by multiple hospices. Therefore, we cannot estimate the number of hospices that will conduct orientation sessions for SNF/NF and ICF/MR staff. We believe that any burden associated with orienting SNF/NF and ICF/MR will be minimal because hospices already orient patients and families/caregivers about many of the topics covered in this standard (that is, hospice philosophy and principles about death and dying). Since the SNF/NF or ICF/MR staff act as the patient's care giver, orienting them would be very similar to orienting the patient's family/caregiver. Orientation to patient families/caregivers is usual and customary practice and does not incur burden for hospices.

418.114 Personnel qualifications.

(a) Standard: General qualifications

All hospice professionals, who furnish hospice services directly, under contract, or under arrangement with a hospice, must be legally authorized (licensed, certified or registered) in accordance with applicable Federal, State and local laws, and must act only within the scope of his or her State license, or State certification, or registration. All personnel qualifications must be kept current at all times.

As defined in 5 CFR 1320.3(b)(2), these requirements is a usual and customary business practice. As defined in 5 CFR 1320.3(b)(3), a State requirement would exist even in the absence of the federal requirement. The associated burden is thereby exempt from the PRA.

(b) Standard: Social worker

The social worker in a hospice program must either be a Social Worker with a master degree (MSW) from a school of social work accredited by the Council on Social Work Education and one year of experience in a health care setting; or a Social Worker with a baccalaureate degree (BSW) from a school of social work accredited by the Council on Social Work Education and one year of experience in a health care setting; or a Social Worker with a baccalaureate degree in psychology, sociology, or other field related to social work and at least one year of social work experience in a health care setting. If a hospice chooses to employ a social worker with a baccalaureate degree in social work, psychology, sociology, or other field related to social work, the services of the BSW must be provided under the supervision of a MSW. This supervision may occur in person, over the telephone, through electronic communication, or any combination thereof.

BSWs employed by the hospice before the effective date of this final rule are exempted from the MSW supervision requirement. If a hospice hires a new BSW and one year of experience in a health care setting, then the new BSW must be supervised by an MSW who has one year of experience in a health care setting. The burden associated with this social work qualification requirement is the time and cost to document BSW supervision by an MSW. By virtue of the personnel qualifications for social workers in hospice that have been in effect since 1983, all hospices are already required to have, at minimum, a BSW. Therefore, all hospices should qualify for the exemption for MSW supervision described above.

We are aware that many hospices already employ at least one MSW to provide direct patient care, although we do not know the precise number of hospices without an MSW. We believe that the number of hospices currently solely relying on BSWs is relatively small. For purposes of this estimate only, we assume that 33 percent of hospices or 948 (2,872 x 33) hospices rely solely on BSWs to provide social work services to patients. Of the 948 hospices without an MSW, we estimate that 25 percent of these hospices will hire a social worker after the effective date of this rule (based on a 25% social worker turnover rate described in the "Hospice Salary & Benefits Report 2006-2007" issued by the Hospital & Healthcare Compensation Service and the "2002 NHPCO National Data Set Summary Report"). Therefore, an estimated 237 hospices (944 x 25%) a year would be required to document MSW supervision of a BSW.

Furthermore, we estimate that a hospice MSW would spend 10 hour a week supervising and documenting supervision activities. As such, at an average hourly rate of $25 for a MSW, we estimate that an affected hospice would spend $13,000 (1 hours x 52 weeks x $25 = $1,300) annually. Therefore, for all 237 hospices to comply with this requirement would require a total of 12,324 annual burden hours (1 hours x 52 weeks x 237 hospices) and an estimated total cost of $308,100 ($1,300 x 237 hospices).

(d) Standard: Criminal background

A hospice must obtain a background check for each employee including contract employees, who have direct patient contact or access to patient records. According to National Association for Home Care 2005 Hospice Facts and Statistics, there are 116,148 hospice employees in 50 states. This is an average of 2,323 employees per state (116,148/50 states). In 2006, 40 states required criminal background checks for at least some types of hospice employees. For purposes of our analysis, we estimate that 50 percent (2,323 employees per state x 40 states/2 =46,460) of hospice employees in these states have already received a criminal background check, thus significantly reducing the overall potential burden. The remaining 46,460 hospice employees in those 40 states will require criminal background checks to comply with the requirements of this rule. Furthermore, we estimate that hospices in the 10 states that lack any criminal background check requirements have not previously performed background checks, accounting for approximately 23,230 (2,323 employees per state x 10 states) hospice employees. The average hospice has 40 employees (116,148 employees/2,872 hospices = 40). We estimate that hospices in the 40 states where criminal background checks are already required for some types of hospice employees will complete

criminal background checks on half (20) of their employees. We also estimate that hospices in the 10 states that lack any criminal background check requirements, hospices will complete checks for all 40 employees. Each background check request form will take 6 minutes to prepare and send, for a total burden of 2 hours (20 employees x 6 minutes/60) per hospice in states that already require some background checks, and 4 hours (40 employees x 6 minutes/60) per hospice in states where no background checks are required in the first year. The total initial burden hours for all 46,460 hospice employees in the 40 states requiring some checks and the 23,228 hospice employees in the 10 states requiring no checks are 6,969 ([46,460 employees x6/60 minutes] + [23,228 employees x 6/60 minutes]).

For each year thereafter, we estimate that hospices in the 40 states that require some background checks will complete checks on approximately 5 new employees per year, for a total burden of 30 minutes per hospice (5 employees x 6 minutes/60). We estimate that hospices in the 10 states that do not require background checks will complete background checks on approximately 10 new employees per year, for a total burden of 1 hour per hospice(10 employees x 6 minutes/60). There are approximately 2,298 hospices in the 40 states currently requiring some background checks and 574 hospices in the 10 states that do not require any background checks (2,872/50 states = 57.4 average number of hospices per state). We estimate the annual burden hours for the industry are 1,723 hours ([30 minutes x 2,298 hospices/60] + [1 hour x 574 hospices]).

Based on our research, the average cost for an individual background check is $17.00 plus $1 for 6 minutes of clerical time per background check to process the paper work. The first year criminal background cost for an average hospice with 40 employees located in a state that does not have any current criminal background check requirements is $720 ($18 per check x 40 employees requiring check). The first year criminal background cost for an average hospice with 40 employees located in a state that does have some current criminal background check requirements is $360 ($18 per check x 20 employees requiring check). In the first year, the burden cost for hospices in the 10 states that do not already require criminal background check is $418,140 ($18 per check x 23,230 employees). In the first year, the burden cost for hospices in the 40 states that already require criminal background check for some hospice employees is $836,280 ($18 per check x 46,460 employees). The total first year cost burden is $1,254,420. The subsequent annual cost burden for new employee criminal background check for each hospice in the 10 states that do not already require criminal background check is $180 ($18 x 10 new employees requiring checks). The subsequent annual cost burden for new employee criminal background check for each hospice in the 40 states that already require criminal background check for some hospice employees is $90 ($18 x 5 new employees). Therefore, we estimate the total annual cost for all hospices to comply with the criminal background check requirement in this section would be $310,140 ([$180 x 574 hospices] +[$90 x 2,298 hospices]).

PERSONNEL QUALIFICATIONS BURDEN ASSESSMENT

Standard	Time per average hospice (hours)	Total industry time (hours)	Total # of affected hospices	Total cost per average hospice	Total industry cost
MSW supervisor	52	12,324	237	$1,300	$308,100
Criminal background check	1st year- 2/4 annually- .5/1	1st year- 6,969 hours annually- 1,723	2,872	1st year-$360/720 annually-$90/180	1st year- $1,254,420 annually- $310,140
Totals	1st year- 54/56 annually- 52.5/53	1st year- 19,293 annually- 14,047	N/A	1st year- $1,660/2,020 annually- $1,390/1,480	1st year- $1,562,520 annually- $618,240

Based on information from the "Hospice Facts & Statistics 2006" report, the "Assuring the Sufficiency of Frontline Workforce: A National Study of Licensed Social Workers" report, and the "Licensed Social Workers in the United States, 2004" report, we estimate that the annual compensation for a full-time, supervisory, MSW working in the hospice industry is $52,811 ($25/hr).

13. Capital Costs

There are no additional capital costs.

14. Cost to Federal Government

There are minimal costs associated with these requirements that are accrued at the Federal level and especially at the regional office (RO) levels. For example, RO staff is responsible for acting on the information collections requirements discussed in this package as it relates to hospice compliance. Once state survey agencies have completed their surveys and if a final decision to terminate a hospice for noncompliance is to be made, such decisions are made by the Central Office and the RO.

15. Changes to Burden

The burden increase is due to program changes.

16. Publication/Tabulation Dates

We do not plan to publish any of the information collected.

17. Expiration Date

This collection does not lend itself to the displaying of an expiration date.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collections of Information Employing Statistical Methods

This section does not apply because statistical methods were not used in developing this collection.