

Supporting Statement for the Paperwork Reduction Act Submission, Medicare and Medicaid Programs: Conditions of Participation for Hospices

A. Background

The purpose of this package is to request Office of Management and Budget (OMB) re-approval of the collection of information requirements for the existing conditions of participation (CoPs), eligibility requirements, and reimbursement standards and procedures that hospices must meet to participate in the Medicare program. Portions of the collection of information requirements for the existing conditions of participation (CoPs) were previously accounted for in OMB control number 0938-0302. We have merged these requirements into this package in order to consolidate all hospice PRA burdens into a single request.

CMS published the conditions of participation for hospice on June 5, 2008. 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.

CMS published additional hospice certification requirements in the Home Health Prospective Payment System Rate Update for Calendar Year 2011; Changes in Certification Requirements for Home Health Agencies and Hospices final rule on November 17, 2010. This rule implemented a provision of the Affordable Care Act. The Affordable Care Act requires that on and after January 1, 2011, a hospice physician or hospice nurse practitioner (NP) must have a face-to-face encounter with longer-stay hospice patients prior to the 180th-day recertification, and prior to every recertification thereafter, to determine continued eligibility for the Medicare hospice benefit. The Affordable Care Act also requires that the physician or NP who had the face-to-face encounter attest that such visit took place. To implement this provision of the Affordable Care Act, CMS requires that the attestation either be a separate section of the certification or an addendum, and that the attestation state that the physician or NP who signed and dated it had a face-to-face encounter with the patient, and include the patient's name and the date of the visit. We also require that when completing the certification or recertification, the physician must sign and date the document, and include the benefit period dates on the form. With the new statutory requirements for a face-to-face encounter prior to the 180th-day recertification, and for every recertification thereafter, it is important for hospices to easily identify which benefit periods require a recertification visit.

CMS also published an additional hospice certification requirement in the FY 2012 Hospice Wage Index Final Rule related to the hospice face-to-face encounter attestation. The FY 2012 Hospice Wage Index Final Rule required that the attestation of a nurse practitioner or of a non-certifying hospice physician shall state that the clinical findings of that visit were provided to the certifying

physician for use in determining continued eligibility for hospice care.

This document represents all hospice CoPs and the physician certification and recertification requirements, including the face-to-face encounter requirements.

B. Justification

1. Need and Legal Basis

The information collection requirements described herein are needed to implement the Medicare CoPs for Medicare-participating hospices. Additionally, they are needed to implement the certification of terminal illness requirements. 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. In addition, these requirements help ensure that Medicare hospice eligibility requirements are being met.

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, Subparts C and D. 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 1814(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, Subpart B. 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 CoPs. Specifically, the Balanced Budget Act of 1997 (BBA, Pub. L. 105–33) 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).

Section 3132 of the Affordable Care Act amended section 1814(a)(7) of the Social Security Act to require that a hospice physician or nurse practitioner (NP) must have a face-to-face encounter with the patient prior to the 180th-day recertification, and prior to all subsequent recertifications, to determine continued eligibility for the hospice benefit. The Affordable Care Act also requires that the physician or NP who had the encounter attest that such a visit took place.

2. Information Users

The primary users of this information will be Federal and State agency surveyors for determining whether a hospice qualifies for approval or re-approval under Medicare, CMS and its contractors for 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, and hospices for assuring their own compliance with all requirements.

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

There is no duplication of information.

5. Small Business Impact

This information collection affects small businesses. However, the requirements are sufficiently flexible for providers to meet them in a way consistent with their existing operations.

6. Less Frequent Collection

CMS does not collect information directly from hospices on a scheduled basis. Rather, hospices are expected to maintain their own records in a timely fashion. With less frequent collection, CMS would not be able to ensure compliance with hospice CoPs and eligibility requirements.

7. Special Circumstances Leading to Information Collection

There are no special circumstances for collecting this information.

8. Federal Register Notice/Outside Consultation

The 60-day Federal Register notice published on November 29, 2013. No public comments were received.

9. Payments or Gift to Respondents

There are no payments or gifts to respondents.

10. Confidentiality

We do not pledge confidentiality of aggregate data. We pledge confidentiality of patient-specific data in accordance with the Privacy Act of 1974 (5 U.S.C. 552a).

11. Sensitive Questions

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

12. Burden Estimates (Hours and Wages)

The information collection requirements are shown below with an estimate of the annual reporting and record keeping burdens. Included in the estimates is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

ASSUMPTIONS AND ESTIMATES USED THROUGHOUT

# of Medicare-participating hospices nationwide, CY 2012	3,897
# of hospice patients nationwide, CY 2012	1,535,919
# of patients per average hospice	394
# of new Medicare-participating hospices per year	110
# of Medicare-billing hospices, from CY 2012 claims	3,727
# of Medicare hospice patients, from CY2012 claims	1,274,076

# of Medicare patients per hospice	342
# of new Medicare-billing hospices per year	95
# of annual certifications & recertifications, from CY 2012 Medicare Enrollment Database (EDB)	2,021,745
# of initial certifications, CY 2012 EDB	988,630
# of recertifications for benefit period 2, CY 2012 EDB	262,806
# of annual recertifications at 180+, from CY 2012 claims, CY 2012 EDB	770,309
# of elections, from CY 2012 claims	1,048,044
Revocations/beneficiary, based on Jul – Dec 2012 claims	.061
Hourly rate of registered nurse	\$41
Hourly rate of office employee	\$17
Hourly rate of administrator	\$63
Hourly rate of hospice aide	\$13
Hourly rate of MSW	\$33
Hourly rate of pharmacist	\$69
Hourly rate of clinical manager	\$55
Hourly rate of QAPI coordinator	\$41
Hourly rate of medical director	\$107
Hourly rate of nurse practitioner	\$51

Note: All salary information is from the Bureau of Labor Statistics (BLS) website at http://www.bls.gov/oes/current/naics4_621600.htm and includes a fringe benefits package worth 30% of the base salary. Hourly rates are based on May 2012 BLS data for each discipline, for those providing “home health care services.” CY = Calendar Year

418.22 Certification of terminal illness

(b) Content of the Certification

Hospices develop their own form for certifications and recertifications, provided the form conforms to the requirements in 418.22(b), including requirements related to the physician narrative and to the face-to-face encounter. All forms would include a statement which specifies that the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course, and would be signed, dated, and include the benefit period dates to which the certification or recertification applies. Additionally, the forms would include space for the physician’s narrative and narrative attestation or a separate narrative addendum, and the physician or nurse practitioner’s face-to-face encounter attestation. The burden associated with certification and recertification requirements is 1) the time for hospices to develop their own forms; 2) the time for the physician to complete the narrative and its attestation, 3) the time for physician or nurse practitioner to complete the face-to-face attestation; and 4) the time for the physician to sign and date the form, and the physician or nurse to include the benefit period dates.

Because all of these requirements have been in place since 2011, the one-time cost of form

development only falls on new hospices that begin filing Medicare claims. The average change in the number of hospices that filed Medicare claims from CY 2007 to CY 2012 is an increase of 95 hospices per year. We estimate that a hospice administrator could develop a certification or recertification form within 45 minutes. Estimating 45 minutes (0.75 hours) per hospice to develop the form, the estimated total time burden is $(0.75 \times 95) = 71.25$ hours. At \$63 per hour for the administrator's time, the cost per hospice would be $(\$63.00 \times 0.75) = \47.25 . Assuming the same growth rate in the number of hospices, the total estimated cost burden for all new hospices $(\$63.00 \times 0.75 \times 95) = \$4,489$.

We also estimate that it would take a clerical staff person 15 minutes (0.25 hours) to prepare the certification or recertification form at \$17.00 per hour, for an estimated clerical burden of \$4.25 per new hospice $(\$17.00 \times 0.25)$. For all new hospices each year, we estimate a total burden of $(0.25 \times 95) = 23.75$ hours, and $(\$17.00 \times 0.25 \times 95) = \404 .

In total, the estimated annual burden for certification/recertification form development is \$51.50 per new hospice, and \$4,893 for all new hospices.

(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 directly above 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 narrative associated with the 3rd benefit period recertification and every subsequent recertification must include an explanation of why the clinical findings of the face-to-face encounter support a life expectancy of 6 months or less.

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. The Medicare Enrollment Database showed that in CY 2012 there were 988,630 initial certifications, 262,806 recertifications of beneficiaries entering the second benefit period, and 770,309 recertifications for beneficiaries entering the 3rd or later benefit periods. A narrative would be required on each of these certifications or recertifications, for a total of 2,021,745 narratives. At 5 minutes per narrative, the total annual burden hours for the hospice are estimated to be 168,479 hours ($[2,021,745 \times 5 \text{ minutes}] / 60$). At \$107 per hour for a Medical Director, the total annual cost burden is estimated to be \$4,837 per hospice ($168,479 \times \$107 / 3,727$), and \$18,027,253 for all hospices ($168,479 \times \$107$).

(b)(4)Content of the Certification

The physician or nurse practitioner who performs the face-to-face encounter with the patient must attest in writing that he or she had a face-to-face encounter with the patient, including the name of the patient and the date of that visit. The attestation of a nurse practitioner or a non-certifying hospice physician shall state that the clinical findings of that visit were provided to the certifying physician, for use in determining whether the patient continues to have a life expectancy of 6 months or less, should the illness run its normal course. The attestation, its accompanying signature, and the date signed, must be a separate and distinct section of, or an addendum to, the recertification form, and must be clearly titled.

The burden associated with these requirements also includes the time for a physician or nurse practitioner to complete the attestation, include his or her signature and the date signed, and include the name of the patient and the date visited. We estimate that half of the attestations would be completed by physicians, and half by nurse practitioners. We also estimate that it would take a physician or nurse practitioner 30 seconds to complete the attestation form. Based on CY 2012 Medicare Enrollment Database data, there were 770,309 recertifications for patients with lengths of stay of 180 days or longer, which would require an attestation statement. At \$107 per hour for 30 seconds of time for Medical Directors to complete 385,155 attestations (half the attestations), we estimate a burden of \$92.15 per hospice ($[\$107 \times 0.0083333 \times 385,155] / 3,727$). For all hospices, we estimate a burden of 3,210 hours ($0.0083333 \times 385,155$) at a cost of \$343,429 ($\$107 \times 0.0083333 \times 385,155$). Similarly, at \$51.00 per hour for 30 seconds of time for nurse practitioners to complete 385,154 attestations (half the attestations), we estimate a burden of \$43.92 per hospice ($[\$51.00 \times 0.0083333 \times 385,154] / 3,727$). For all hospices, we estimate a burden of 3,210 hours ($0.0083333 \times 385,154$) at a cost of \$163,690 for all hospices ($\$51.00 \times 0.0083333 \times 385,154$). Therefore we estimate a total burden of \$136.07 per hospice, and 6,420 hours at a cost of \$507,119 for all hospices to complete the attestation form.

(b)(5)Content of the Certification

All certifications and recertifications must be signed and dated by the physician. It has been longstanding policy for hospices to have physicians sign and date the certification, so we do not believe that making this requirement explicit in the regulatory text creates any burden for

hospices. We also required that the certification or recertification include the benefit period dates to which it applies, but the physician does not have to be the person to record that information on the certification. We estimate that it would take a physician or nurse no longer than 30 seconds, on average, to write in the benefit period dates to which a certification or recertification applies. Based on 2012 claims data, we estimate that there are 2,021,745 certifications or recertifications completed in a year, with half the benefit period dates written in by physicians, and half by a nurse. At 30 seconds per certification or recertification, and using a Medical Director's hourly rate of \$107, we estimate a total burden of \$241.85 per hospice ($[1,010,873 \times 0.0083333 \times \$107] / 3,727$), and a total burden of 8,424 hours ($1,010,873 \times 0.0083333$) at a cost of \$901,358 for half of all certifications and recertifications ($1,010,873 \times 0.0083333 \times \107). Likewise, at 30 seconds per certification or recertification, and using a nurse's hourly rate of \$41, we estimate a total burden of \$92.67 per hospice ($[1,010,872 \times 0.0083333 \times \$41] / 3,727$), and a total burden of 8,424 hours ($1,010,873 \times 0.0083333$) at a cost of \$345,380 for the remaining certifications and recertifications ($1,010,872 \times 0.0083333 \times \41). Therefore, in total, the estimated burden of recording period dates on certifications and recertifications is \$334.52 per hospice, and 16,848 hours at a cost of \$1,246,738 for all hospices.

§418.24 Election of Hospice Care

The individual who elects hospice care must file an election statement with the hospice. The election statement must include the following:

- (a) Identification of the particular hospice that will provide care to the individual.
- (b) The individual's or representative's acknowledgment that he or she has been given a full understanding of the palliative rather than curative nature of hospice care, as it relates to the individual's terminal illness.
- (c) Acknowledgment that coverage of certain Medicare services is waived by the election.
- (d) The effective date of the election.
- (e) The signature of the individual or representative.

Section 1812(d) of the Act requires that an individual make an election for the period with respect to a particular hospice program and that the individual shall then be deemed to have waived this right to payment for certain other Medicare services.

Hospices would bear the one-time cost of developing an election form, and the time to explain the election form to beneficiaries who are choosing to elect hospice care. Because these election requirements have been in place since 2005 or prior, election form development would only apply to new hospices. We expect that each hospice would design its own election form, which will require a one-time effort of about 1 hour by the hospice administrator. We estimate that it will take 15 minutes for the hospice nurse to explain the election form to beneficiaries, and to ensure that they understand what they're signing.

For form development, the total hours for the estimated 95 new hospices per year would be (1.0×95) or 95 hours. At \$63 per hour for the administrator's time, the cost per hospice

would be $(1.0 \times \$63) = \63 , and the cost for all new hospices would be $(\$63 \times 95) = \$5,985$.

For explaining the form to beneficiaries, we estimate 15 minutes (0.25 hours) of time per election. We estimate that there would be 1,048,044 elections, for a total time burden per hospice of $(0.25 \times 1,048,044) = 262,011$ hours. With 3,727 hospices, there would be $(262,011 / 3,727) = 70$ hours per hospice. At \$41 per hour for a registered nurse, we estimate a cost per hospice of $(70 \times \$41) = \$2,870$, and a total cost for all hospices of $(0.25 \times \$41 \times 1,048,044) = \$10,742,541$.

§418.28 Revoking the Election of Hospice Care

Election of hospice may be revoked at any time during an election period. To revoke the election the beneficiary must complete a statement that includes the following information:

1. A signed statement that the individual or representative revokes the individual's election for Medicare coverage of hospice care for the remainder of the period.
2. The date that the revocation is to be effective.

The revocation provision is found in section 1812(d) of the Act. The revocation waives the right of the individual to receive Medicare hospice care benefits made in his behalf for the remaining time in the period. Each hospice is free to design its own form or statement. Because these requirements have been in place since 1983, the cost to hospices would be the one-time cost for new hospices to develop a revocation form, and the cost to explain the form to any beneficiary who revokes hospice care.

We estimate that this would require about 15 minutes (.25 hours) of the hospice administrator's time at \$63 per hour to develop a form. With 95 new hospices per year, the one-time hours burden to hospices would be $95 \times .25 = 23.75$ hours, and the one-time cost per new hospice would be $(0.25 \times \$63) = \15.75 . The total one-time cost for all new hospices would be $(23.75 \times \$63) = \$1,496$.

We also estimate that it would take about 5 minutes (0.083333 hours) of the hospice nurse's time at \$41 per hour to explain the form to the beneficiary. With .061 revocations per beneficiary and 1,274,076 beneficiaries, we estimate that there would be 77,719 revocations in a year. At 5 minutes per revocation, we estimate there would be a total of $(77,719 \times 0.083333) = 6,477$ hours for all hospices, and $(6,477 / 3,727) = 1.74$ hours per hospice to explain the form to the beneficiaries who revoke. The cost associated with explaining the revocation form to revoking beneficiaries would be \$41 per hour for a nurse's time, for 5 minutes per revocation, or $(\$41 \times 0.083333 \times 77,719) = \$265,539$, and the cost per hospice would be $(\$265,539 / 3,727) = \71.25 .

418.52 Patient 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. 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 newly participating hospice to develop the form. From 2008-2013 551 new hospices began participating in the Medicare program, for an average of 110 new Medicare-participating hospices per year. The total one time burden for the industry is 880 hours (8 hours x 110 new hospices per year). At the average hourly rate of \$63 for an administrator, it will cost a hospice \$504 to meet this requirement. The total one time burden cost for the industry is \$55,440 a year (\$63 x 880 hours).

We estimate that it will take a registered nurse approximately five minutes per patient to describe the patient rights information to each patient. We estimate that on average, each hospice will provide 394 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 33 hours $([5 \text{ minutes} \times 394 \text{ patients}] / 60)$. The total annual burden for the industry would be 127,993 hours $([5 \text{ minutes} \times 1,535,919 \text{ patients}] / 60)$. At an average hourly rate of \$41 for a registered nurse, it will cost a hospice \$3.42 per patient annually to meet this requirement; the annual burden cost for a hospice is \$1,347 $(\$3.42 \times 394 \text{ patients})$. The total annual burden cost for the industry is \$5,252,843 $(\$3.42 \times 1,535,919 \text{ patients})$.

(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% (20) of its patients and each session would take 1 hour to complete. The total annual burden hours per hospice would be 20 and the total annual

burden hours for the industry are 77,940 (20 hours x 3,897 hospices) At an average hourly rate of \$63 for an administrator, the annual burden cost for a hospice to perform the investigations is \$1,260 (\$63 x 20 hours) and the total annual burden cost for the industry would be \$4,910,220 (\$1,260 x 3,897 hospices).

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). We estimate the time associated for a nurse to educate and train the patient and caregivers is 30 minutes per patient and 197 hours per hospice ([30 minutes x 394patients] /60), at a cost of \$8,077 (\$41 x 197). The total annual burden hours for the industry are 767,709 (197 x 3,897 hospices), and the total annual burden cost for the industry would be \$31,476,069 (\$41 x 767,709).

(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 as frequently as the patient's condition warrants, but no less than every 15 days. Based on a 19 day median length of service, patients would likely receive one update to their plans of care. The burden associated with these requirements is the time and effort associated with documenting the plan of care. We estimate the average time for the plan of care updates is 10 minutes per patient every 15 days, for a total of 65.67 hours per hospice ($[10\text{minutes} \times 394 \text{ patients}] / 60$), at a cost of \$2,692 ($\$41 \times 65.67$). The total annual burden hours for the industry are 255,916 ($65.67 \times 3,897 \text{ hospices}$), at a cost of \$10,492,556 ($\$41 \times 255,916$).

(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. We estimate the burden of this requirement in three phases that 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 policies 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 to perform these functions. 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, and develop policies and procedures. Hospices that already participate in Medicare have already completed this phase, and are therefore excluded from our analysis. The total burden for the industry is 1,320 hours (12 hours x 110 new hospices per year). At an average hourly rate of \$41, \$63, and \$55 respectively for these committee members, the total annual cost for an average hospice to identify the domains and measures is \$636 ($[\$41 + \$63 + \$55] \times 4$ hours). The total annual burden cost for the industry is \$69,960 ($\636×110 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 for each hospice is 53 hours ($[4 \text{ minutes per patient assessment} \times 2 \text{ assessments per patient} \times 394 \text{ patients}] / 60$); the total annual burden hours for the industry is 204,789 hours ($[4 \text{ minutes per patient assessment} \times 2 \text{ assessments per patient} \times 1,535,919 \text{ patients}] / 60$). At an average hourly rate of \$41 for a registered nurse, the annual burden cost for a hospice will be \$2,173 ($\41×53 hours) and the annual cost for all hospices will be \$8,396,349 ($\$41 \times 204,789$ hours).

Once the data are gathered, a hospice must aggregate and organize the data regularly. We assume that a hospice will use an office employee to perform the data aggregation and organization, and that this activity will require four hours per month for a total of 48 hours a year ($4 \text{ hours} \times 12 \text{ months}$); the annual burden hours for the industry would be 187,056 hours ($48 \text{ hours} \times 3,897 \text{ hospices}$). At an average hourly rate of \$17 for an office employee, the cost burden for a hospice will be \$816 ($\17×48 hours) and the cost for all hospices will be \$3,179,952 ($\$17 \times 187,056$).

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 ($3 \text{ members} \times 4 \text{ hours}$) and for an annual cost burden of \$ 636 ($[\$41 \times 4] + [\$63 \times 4] + [\$55 \times 4] = \636). The total annual burden for the industry to comply with this requirement would be 46,764 hours ($12 \text{ hours} \times 3,897 \text{ hospices}$) and the total cost burden for the industry would be \$2,478,492 ($\$636 \times 3,897 \text{ hospices}$).

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 for the industry would be 11,691 hours (3 hours x 3,897 hospices). The associated cost burden will be \$159 (\$41 + \$63 + \$55). The total annual burden cost for the industry is \$619,623 (\$159 x 3,897 hospices).

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.

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 its 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 its 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 325 annual burden hours ([5 minutes x 3,879 hospices] / 60) for the hospice industry. At an hourly rate of \$17 for an office employee, the annual burden cost for a hospice is \$1.42 and the annual burden cost for the industry is \$5,534 (\$1.42 x 3,897).

(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 7,794 hours (2 hours x 3,897 hospices). At an hourly rate of \$17 for an office employee, the annual burden cost for a hospice is \$34 and the annual burden cost for the industry is \$132,498 (\$34 x 3,897).

(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 year per hospice (5 minutes x 6 times per year) per. The total annual burden associated with this requirement is 1,949 hours for the industry ($[30 \text{ minutes} \times 3,897 \text{ hospices}] / 60$). At an hourly rate of \$17 for an office employee, the annual burden cost for a hospice is \$8.50 and the annual burden cost for the industry is \$33,125 ($\$8.50 \times 3,897 \text{ hospices}$).

(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 11,691 hours for the industry (3 hours x 3,897 hospices). At an hourly rate of \$17 for an office employee, the annual burden cost for a hospice is \$51 and the annual burden cost for the industry is \$198,747 ($\$51 \times 3,897 \text{ hospices}$).

(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 11,691 annual burden hours for the industry (3 hours x 3,897 hospices). At an hourly rate of \$63 for an administrator, the annual burden cost for a hospice is \$189 and the annual burden cost for the industry is \$736,533 ($\$189 \times 3,897 \text{ hospices}$).

(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 year per hospice for a total annual burden of 187,056 hours for the industry (48 hours x 3,897 hospices). At an hourly rate of \$17 for an office employee, the annual burden cost for a hospice is \$816 and the annual burden cost for the industry is \$3,179,952 (\$816 x 3,897 hospices).

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 written agreement serves as a contract between the hospice and another individual or entity. The agreement protects the beneficiary, the hospice, and the other provider. This requirement assures accountability of the hospice and the other provider.

The agreement will list the responsibilities of the hospice and the inpatient provider, as well as the regulatory provisions. We estimate the development of the agreement will take the administrator approximately 80 hours. Although establishing a written agreement with a given entity is usually a one-time process, we believe that hospices change or add new contracting partners on a routine basis. The burden associated with this requirement is the time and effort necessary to develop, the written agreements. For purposes of this analysis, we assume that, on average, each hospice will establish one new written agreement per year, for a total of 311,760 hours for all hospices (80 hours x 3,897 hospices). At an hourly rate of \$63 for an administrator, the annual burden cost for a hospice is \$5,040 (\$63 x 80 hours) and the annual burden cost for the industry is \$19,640,880 (\$5040 x 3,897 hospices).

(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. The burden for certifying and recertifying a patient's life expectancy is already assessed in a previous section of this document.

(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 provision does not impose a burden upon a hospice.

418.104 Clinical records associated.

(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 from 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 to confer with an individual with education and training in drug management to ensure that drugs and biologicals meet patient 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.

The burden associated with this requirement is the time necessary to document the results of

this consultation in each patient's clinical record. For purposes of our analysis only, we assume that an average hospice will confer with a pharmacist, and that the pharmacist will document the results of his/her consultation. We estimate that it requires 5 minutes to document the initial review of a patient's drug and biologicals. Additionally, we estimate that it requires 5 minutes of the pharmacist's time to document a review of updates to the patient's drug profile. Based on a 19 day median length of service, patients would likely receive one update to their plans of care. At an average hourly rate of \$69 for a pharmacist, we estimate that it would cost a hospice \$12 per patient (\$69 x [5 minutes for initial + 5 minutes for 1 update]) and an annual cost of \$4,728 (\$12 x 394 patients). The total annual burden hours for all hospices are 255,987 hours ([1,535,919 patients x 10 minutes per patient] / 60), and the total annual burden cost for all hospices is \$18,431,028 (\$12 per patient x 1,535,919 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 \$3 for each patient (5 minutes/60 x \$41). The total annual burden hours for a hospice to meet this requirement would be 33 hours ([5 minutes x 394 patients] / 60) at a cost of \$1,353 (33 hours x \$41 per hour), and the total annual burden hours for the industry would be 127,993 ([5 minutes x 1,535,919 patients] / 60). The total annual burden cost for the industry is \$4,607,757 (\$3 per patient x 1,535,919 patients).

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 1,510 deficiencies issued by State surveyors 2012, only two were related to controlled drug discrepancies. Thus, we do not believe that investigating drug discrepancies and documenting the results of those investigations occurs on a regular basis. Therefore, 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.

(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.

(c)(1) The hospice must furnish a copy of the hospice plan of care to any inpatient provider that is furnishing inpatient hospice care under arrangements. The inpatient care must be furnished by a facility that meets the requirements in § 418.110(b) and (e).

This requirement is an important factor in assuring that the hospice maintain professional management responsibility for all services furnished to an individual, regardless of the location or facility in which such services are furnished (1861(dd)(2)(A)(ii)(I) of the Act). The plan of care is typically from two to five pages long. It is estimated that 23% of hospice patients receive one inpatient care stay for an average of 5.5 days per stay. The average number of hospice patients per hospice is $394 \times 23\% = 91$ patients per hospice require inpatient stays. This requirement may be met by providing a copy of this plan, thus the burden is the time taken to produce a copy of the plan. We estimate it will take the hospice office employee 10 minutes to copy and mail each plan, for a total of 15 hours per hospice annually ($[10 \text{ minutes} \times 91] / 60$) at an estimated cost of \$255 per hospice ($\$17 \times 15 \text{ hours}$). The total annual burden hours for the industry would be 58,455 hours for all hospices ($15 \text{ hours} \times 3,897 \text{ hospices}$) at an estimated cost of \$993,735 ($\$17 \times 58,455$).

(c)(3) Inpatient services and events (e.g., treatments, tests, consultations, evaluations, etc.) furnished by the inpatient provider, and a copy of the discharge summary, are entered in the hospice's medical record.

This requirement implements section 1861(dd)(2)(C) of the Act, which requires the hospice to maintain a complete clinical record. It is also designed to assure continuity of care and professional management responsibility. This requirement will be met by including a copy of the discharge summary prepared by the inpatient provider. We estimate that it will takes the hospice office staff 5 minutes to place the inpatient discharge summary into the hospice medical record, for a total of 8 hours per hospice annually ($[5 \text{ minutes} \times 91] / 60$) at an estimated burden of \$136 ($8 \text{ hours} \times \17). The total annual burden hours for the industry would be 31,176 ($8 \text{ hours} \times 3,897 \text{ hospices}$) at an estimated cost of \$529,992 ($\$136 \times 3,897 \text{ hospices}$).

The burden of acquiring this information is required under 418.108(c)(1), above. Retaining it is necessary to meet the clinical record requirement in 1861(dd)(2)(C) of the Act to assure continuity of care and professional management responsibility. The requirement that health care providers retain medical records is also a matter of State law.

418.110 Hospices that provide inpatient care directly.

(b) Twenty-four hour nursing services

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.

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 at a cost of \$31 ($[\$41/60] \times 45$). There are 1,018 hospices that operate their own inpatient facilities. Based on public comments related to the hospice CoP proposed rule and the results of hospice surveys, we believe 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 764 hours annually at a cost of \$23,684 ($\31×764).

(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.

The burden associated with this requirement is the time to develop a staff-wide training program and to document the required training completion information in each employee's personnel record. We estimate that developing a staff-wide training program will require 40 hours on a one-time basis for each affected hospice, at a cost of \$1,640 ($\41×40 hours) per newly opened hospice inpatient facility. In the past 5 years, 272 new inpatient facilities have been opened, for an average of 54 new inpatient facilities per year. All currently existing inpatient facilities have already incurred a burden develop a staff-wide training program, and should be excluded from this analysis. Therefore, we will only be assessing the burden imposed upon the 54 new inpatient facilities that are likely to open each year. As such, we estimate a total one-time cost of \$88,560 for the industry each year ($\$1,640 \times 54$). The total associated annual burden hours for the industry are 2,160 (40 hours per hospice \times 54).

A hospice is required to revise its training program annually as needed. We estimate that it will take 4 hours a year each hospice to complete this task, and the total annual burden hours for the industry are 4,072 hours (4 hours \times 1,018 hospices with inpatient units). At an average hourly rate of \$41 for a registered nurse, the annual burden cost for each hospice is \$164 ($\41×4 hours), and the total annual burden cost for the industry are \$166,952 ($\$164 \times 1,018$ hospices with inpatient units).

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

to document each participant's training record. For purposes of this analysis only, we assume that 16 hospice employees (12 nurses and 4 ordering physicians) will be trained and need documentation. We estimate that it will take an office employee 1.33 hours ([5 minutes x 16 trainees] / 60) at a cost of \$23 (\$17 x 1.33 hours) annually to meet this requirement. For the hospice industry, the total annual burden hours are 1,357 hours ([5 minutes x 16 employees x 1,018] / 60) and the total annual burden cost for the industry is \$23,069 (\$17 x 1,357 hours).

(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. Since the inception of this requirement, CMS has not received any reports, which confirms our understanding that such deaths are exceedingly rare. Therefore, 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. Validating Medicare eligibility for hospice services is already addressed in a previous section of this package; therefore we will not be re-estimating the burden here.

(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 a 2009 Office of the Inspector General report (<https://oig.hhs.gov/oei/reports/oei-02-10-00070.pdf>), 31 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 hospice 476,135 patients (1,535,919 patients x 31%) residing in those facilities. We also estimate that the average hospice will provide care to 122 patients residing in a SNF/NF or ICF/MR (476,135 patients nationwide / 3,897 hospices). We estimate that the total annual burden hours for each hospice to meet this requirement are 20 hours ([10 minutes x 122 patients] / 60), and the total burden hours for the industry are 79,356 hours ([10 minutes x 476,135 patients] / 60). At an average hourly rate of \$17 for an office employee, the cost burden cost for each hospice is \$340 (\$17 x 20 hours) and the total cost for the industry is \$1,349,052 (\$17 x 79,356 hours). The cost per patient for a hospice to fax the forms would be \$2.83 (\$1,349,052 / 476,135 patients).

(f) Standard: Orientation and training of staff

A hospice is required to ensure that SNF/NF and ICF/MR staffs 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. 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 existed from the inception of the hospice CoPs in 1983 until finalization of the new CoPs in 2008, all hospices in existence prior to 2008 qualified for an exemption of MSW supervision described above.

In 2009 7,992 MSWs were employed by hospices throughout the country (Hospice Facts and Statistics, Hospice Association of America, November 2010), indicating that most hospices employ at least one MSW. For purposes of this estimate only, we assume that 33 percent of hospices or 1,286 (3,897 x .33) hospices also use BSWs to provide social work services to patients, and are therefore required to document MSW supervision of a BSW. Furthermore, we estimate that a hospice MSW would spend 4 hours per month documenting supervision activities. As such, at an average hourly rate of \$33 for a MSW, we estimate that an affected hospice would spend \$1,584 annually (4 hours x 12 months x \$33). Therefore, for all 1,286

hospices to comply with this requirement would require a total of 61,728 annual burden hours (4 hours x 12 months x 1,286 hospices) and an estimated total cost of \$2,037,024 (\$1,584 x 1,286 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. We estimate that compliance with this provision requires 10 minutes of clerical time per background check to process the paper work, at a cost of \$3 per check. According to National Association for Home Care 2010 Hospice Facts and Statistics, there are 150,629 hospice employees in 50 states. This is an average of 3,013 employees per state (150,629 /50 states). According to a report by the National Conference of State Legislatures titled “Safe at Home? Developing Effective Criminal Background Checks and Other Screening Policies for Home Care Workers: State Summaries”, 47 states required criminal background checks for at least some types of hospice employees. For purposes of our analysis, we estimate that a hospice will replace 20% of its staff in a given year. We also estimate that half of the replacement staff would receive a criminal background check in accordance with State requirements in the absence of this Federal rule. Therefore, only 10 percent of the hospice workforce in those 47 states in a given year receives a criminal background check due to this regulation, or 301 individuals per state (3,013 employees per state x 10 percent). Based on an estimated 20 percent turnover rate in the 3 remaining states that do not have any criminal background check requirements, we estimate that 603 individuals per state will receive a criminal background check in accordance with this rule in a given year (3,013 employees per state x 20 percent). We estimate a total of 15,956 individuals will receive a criminal background check as a result of this requirement ([301 individuals in states that have criminal background check requirements x 47 states] + [603 individuals in states that do not have criminal background check requirements x 3 states]), requiring 2,659 hours ([15,956 x 10 minutes] / 60) at a cost of \$47,868 (15,956 x \$3 per check).

The average hospice has 39 employees (150,629 employees/3,897 hospices). Assuming a 20% turnover rate, and assuming that half of all new employees will have a criminal background check completed due to State-imposed requirements, we estimate that hospices in the 47 states that require some background checks will complete checks on approximately 4 new employees per year, for a total burden of 40 minutes per hospice (4 employees x 10 minutes / 60) at a cost of \$12 (40 minutes per hospice x \$17 per hour). We estimate that hospices in the 3 states that do not require background checks will complete background checks on approximately 8 new employees per year, for a total burden of 1.33 hours per hospice (8 employees x 10 minutes / 60) at a cost of \$24 (1.33 hours per hospice x \$17 per hour).

In addition to those criminal background checks performed by existing hospice providers, such checks will also need to be performed by new hospices that are entering the Medicare program. From 2008-2013 551 new hospices began participating in the Medicare program,

for an average of 110 new hospices per year, or approximately 2 new hospices per state. As start-up businesses, we believe that these new hospices have significantly smaller staffs than existing hospices. For purposes of this analysis only, we assume that a new hospice has 15 staff members that will need criminal background checks. For new hospices in states with existing criminal background check requirements, we estimate that 1,410 background checks will be completed (15 staff members per new hospice x 2 new hospices per state x 47 states), and that this will require 235 hours ($[1,410 \times 10] / 60$). For new hospices in states without existing criminal background check requirements, we estimate that 120 background checks will be completed (20 staff members per new hospice x 2 new hospices per state x 3 states), and that this will require 20 hours ($[120 \times 10] / 60$). In total, we estimate that 1,530 background checks will be completed for new hospices, requiring 255 hours at a cost of \$4,590 (1,530 x \$3). On an individual hospice level, we estimate that it will require 1.66 hours for each new hospice in a state with existing criminal background check requirements to complete the documentation associated with a criminal background check (10 employees x 10 minutes per check / 60) at a cost of \$28 (1.66 hours x \$17). For new hospices in states without existing criminal background check requirements, we estimate that it will require 3.33 hours for each new hospice to complete the documentation associated with a criminal background check (20 employees x 10 minutes per check / 60) at a cost of \$57 (3.33 hours x \$17).

On an annual basis, we estimate that all hospices, both new and existing, will complete 17,486 background checks (1,530 new + 15,956 existing), requiring 2,914 hours (255 new + 2,659 existing) at a cost of \$52,458 (\$4,590 new + \$47,868 existing).

Total burden hours requested = 3,300,735 hours

Total hours previously approved = 1,393,111.5 hours

Increase of hours = 1,907,624 hours

13. Capital Costs

There are no capital costs associated with this information collection.

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. The changes to coverage and payment requirements associated with the face-to-face requirement, which were implemented in the CY 2011 home health final rule, do not create additional federal level costs; payment contractors use the data collected as part of their usual and customary claims processing and review activities.

15. Changes to Burden

The total annual hourly burden for the information collection requirements is estimated to be 3,300,735 hours. The 1,907,624 hour increase is due to three main factors. First, the number of Medicare-certified hospices has increased by 36 percent, from 2,872 to 3,897. Second, the number of patients receiving hospice services has increased by 77 percent, from 869,201 to 1,535,919. Third, the burden hours previously accounted for in OMB control number 0938-0302 have been updated and moved into this package in order to consolidate all hospice PRA burdens into a single package. However, the increase for some of the requirements is moderated by the fact that the original burden estimates included substantial initial compliance burdens as hospices adjusted their practices from those required by the previous CoPs to those required by the new CoPs. Now that most hospices have completed the more time-intensive initial phase of compliance, and have moved to the less time intensive maintenance phase of compliance, the annual burdens have leveled-off to an extent.

The total annual cost burden has also increased due to these same factors. Additionally, we have increased salary estimates to reflect recent Bureau of Labor Statistics wage data. We believe that this adjustment more accurately reflects the impact of these requirements.

16. Publication and Tabulation Dates

There are no publication or tabulation dates.

17. Expiration Date

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